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Safety of machinery — Principles of risk assessment

Sécurité des machines — Principes pour l'appréciation du risque

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Contents

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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 3.

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.

International Standard ISO 14121 was prepared by the European Committee for Standardization (CEN) (as EN 1050:1996) and was adopted, under a special “fast-track procedure”, by Technical Committee ISO/TC 199, *Safety of machinery*, in parallel with its approval by the ISO member bodies.

Annexes A and B of this International Standard are for information only.

Introduction

This International Standard has been prepared to be a harmonized standard in the sense of the Machinery Directive of the European Union and associated regulations of the European Free Trade Association (EFTA).

The function of this Type A standard is to describe principles for a consistent systematic procedure for risk assessment as introduced in clause 6 of ISO/TR 12100-1:1992.

This International Standard gives guidance for decisions during the design of machinery (see 3.11 of ISO/TR 12100-1:1992) and will assist in the preparation of consistent and appropriate Type B and Type C standards in order to comply with the essential safety and health requirements (see annex A of EN 292-2:1991/A1:1995).

By itself this International Standard will not provide presumption of conformity to the essential safety and health requirements (see annex A of ISO/TR 12100-1:1992).

It is recommended that this International Standard be incorporated in training courses and manuals to give basic instruction on design methods.

Safety of machinery — Principles of risk assessment

1 Scope

This International Standard establishes general principles for the procedure known as risk assessment, by which the knowledge and experience of the design, use, incidents, accidents and harm related to machinery is brought together in order to assess the risks during all phases of the life of the machinery [see 3.11 a) of ISO/TR 12100-1:1992].

This International Standard gives guidance on the information required to allow risk assessment to be carried out. Procedures are described for identifying hazards and estimating and evaluating risk. The purpose of the International Standard is to provide advice for decisions to be made on the safety of machinery and the type of documentation required to verify the risk assessment carried out.

This International Standard is not intended to provide a detailed account of methods for analysing hazards and estimating risk, as this is dealt with elsewhere (e.g. text books and other reference documents). A summary of some of these methods is given for information only (see annex B).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO/TR 12100-1:1992, *Safety of machinery — Basic concepts, general principles for design — Part 1: Basic terminology, methodology.*

ISO/TR 12100-2:1992, *Safety of machinery — Basic concepts, general principles for design — Part 2: Technical principles and specifications.*

IEC 60204-1:1992, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements.*

EN 292-2:1991/A1:1995, *Safety of machinery — Basic concepts, general principles for design — Part 2: Technical principles and specifications*.

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO/TR 12100-1:1992 and the following apply.

3.1
harm
physical injury and/or damage to health or property

[ISO/IEC Guide 51:1990, 3.4]

3.2
hazardous event
event that can cause harm

3.3
safety measure
means that eliminates a hazard or reduces a risk

NOTE For additional information see clause 5 of ISO/TC 12100-1:1992.

3.4
residual risk
risk remaining after safety measures have been taken

4 General principles

4.1 Basic concept

Risk assessment is a series of logical steps to enable, in a systematic way, the examination of the hazards associated with machinery. Risk assessment is followed, whenever necessary, by risk reduction as described in clause 5 of ISO/TR 12100-1:1992. When this process is repeated it gives the iterative process for eliminating hazards as far as possible and for implementing safety measures.

Risk assessment includes (see Figure 1):

— 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);
— risk evaluation (see clause 8).

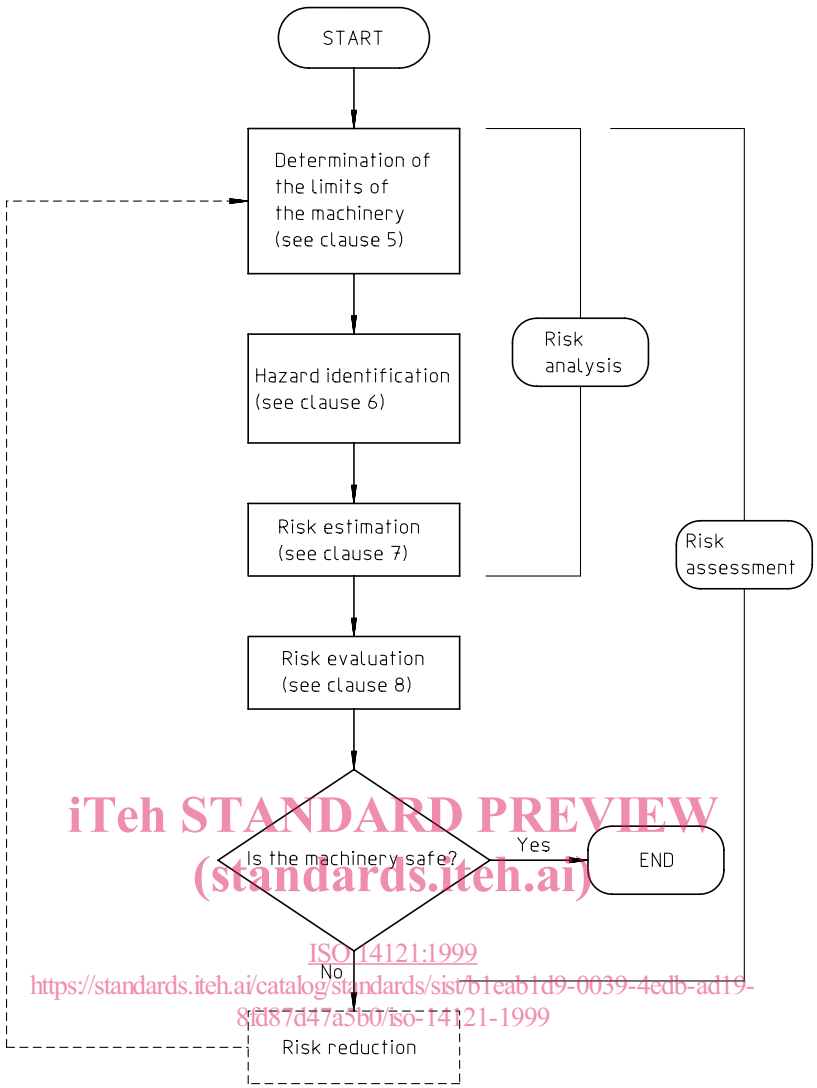
Risk analysis provides the information required for the risk evaluation, which in turn allows judgements to be made on the safety of machinery (see 3.4 of ISO/TR 12100-1:1992).

Risk assessment relies on judgemental decisions. These decisions shall be supported by qualitative methods complemented, as far as possible, by quantitative methods. Quantitative methods are particularly appropriate when the foreseeable severity and extent of harm are high.

Quantitative methods are useful to assess alternative safety measures and to determine which gives better protection.

NOTE The application of quantitative methods is restricted by the amount of useful data which is available, and in many applications only qualitative risk assessment will be possible.

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



NOTE Risk reduction and the selection of appropriate safety measures are not part of risk assessment. For further explanation, see clause 5 of ISO/TR 12100-1:1992 and ISO/TR 12100-2.

4.2 Information for risk assessment

The information for risk assessment and any qualitative and quantitative analysis shall include the following as appropriate:

— limits of the machinery (see clause 5);

— requirements for the life phases of the machinery [see 3.11 a) of ISO/TR 12100-1:1992];

— design drawings or other means of establishing the nature of the machinery;

— information concerning power supply;

— any accident and incident history;

— any information about damage to health.

The information shall be updated as the design develops and when modifications are required.

Comparisons between similar hazardous situations associated with different types of machinery are often possible, provided that sufficient information about hazards and accident circumstances in those situations is available.

The absence of an accident history, a small number of accidents or low severity of accidents shall not be taken as an automatic presumption of a low risk.

For quantitative analysis, data from databases, handbooks, laboratories and manufacturers' specifications may be used provided that there is confidence in the suitability of the data. Uncertaintly associated with this data shall be indicated in the documentation (see clause 9).

Data based on the consensus of expert opinion derived from experience (e.g. DELPHI Technique — see B.8) can be used to supplement qualitative data.

5 Determination of the limits of the machinery

Risk assessment shall take into account:

— the phases of machinery life (see 3.11a of ISO/TR 12100-1:1992);

— the limits of machinery (see 5.1 of ISO/TR 12100-1:1992) including the intended use (both the correct use and operation of the machinery as well as the consequences of reasonably foreseeable misuse or malfunction) in accordance with 3.12 of ISO/TR 12100-1:1992;

— the full range of foreseeable uses of the machinery (e.g. industrial, non-industrial and domestic) by persons identified by sex, age, dominant-hand usage, or limiting physical abilities (e.g. visual or hearing impairment, size, strength);

— the anticipated level of training, experience or ability of the foreseeable users such as:

1) operators (including maintenance personnel or technicians);

2) trainees and juniors;

3) general public;

— exposure of other persons to the hazards associated with the machinery, where it can be reasonably foreseen.

6 Hazard identification

All hazards, hazardous situations and hazardous events associated with the machinery shall be identified. Annex A gives examples to assist in this process (see clause 4 of ISO/TR 12100-1:1992, for further information on describing hazards generated by machinery).

Several methods are available for the systematic analysis of hazards. Examples are given in annex B.

7 Risk estimation

7.1 General

After hazard identification (see clause 6), risk estimation shall be carried out for each hazard by determining the elements of risk given in 7.2. When determining these elements, it is necessary to take into account the aspects given in 7.3.

7.2 Elements of risk

7.2.1 Combination of elements of risk

The risk associated with a particular situation or technical process is derived from a combination of the following elements:

— the severity of harm;

— the probability of occurrence of that harm, which is a function of:

1) the frequency and duration of the exposure of persons to the hazard;

2) the probability of occurence of a hazardous event;

3) the technical and human possibilities to avoid or limit the harm (e.g. reduced speed, emergency stop equipment, enabling device, awareness of risks).

The elements are shown in Figure 2 and additional details are given in 7.2.2 and 7.2.3

Several methods are available for the systematic analysis of these elements. Examples are given in annex B.

NOTE In many cases these elements cannot be exactly determined, but can only be estimated. This applies especially to the probability of occurrence of possible harm. The severity of possible harm cannot be easily established in some cases (e.g. in the case of damage to health due to toxic substances or stress).

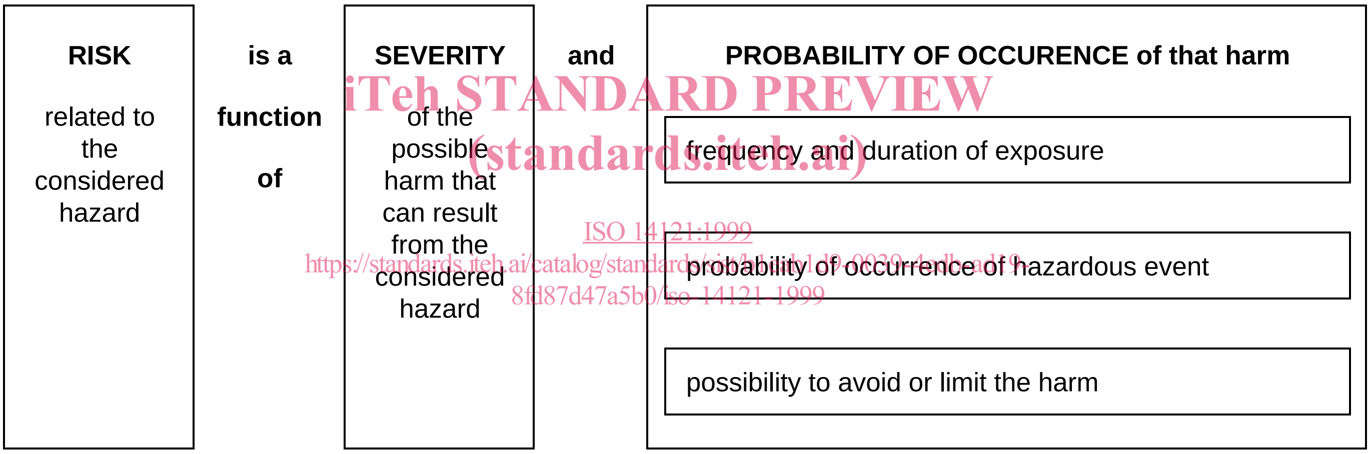


Figure 2 — Elements of risk

7.2.2 Severity (degree of possible harm)

The severity can be estimated by taking into account:

— the nature of what is to be protected:

1) persons;

2) property;

3) environment;

— the severity of injuries or damage to health:

1) slight (normally reversible);

2) serious (normally irreversible);

3) death;

— the extent of harm (for each machine):

1) one person;

2) several persons.

7.2.3 Probability of occurrence of harm

The probability of occurrence of harm can be estimated by taking into account 7.2.3.1 to 7.2.3.3.

7.2.3.1 Frequency and duration of exposure

— Need for access to the danger zone (e.g. for normal operation, maintenance or repair);

— nature of access (e.g. manual feed of materials);

— time spent in the danger zone;

— number of persons requiring access;

— frequency of access.

7.2.3.2 Probability of occurrence of a hazardous event

— Reliability and other statistical data;

— accident history;

— history of damage to health;

— risk comparison (see 8.3).

NOTE The occurrence of a hazardous event can be of technical or human origin.

7.2.3.3 Possibilities of avoiding or limiting harm

a) by whom the machinery is operated:
   1) by skilled persons;
   2) by unskilled persons;
   3) unmanned;
b) the speed of appearance of the hazardous event:
   1) suddenly;
   2) fast;
   3) slow;
c) any awareness of risk:
   1) by general information;
   2) by direct observation;
   3) through warning signs and indicating devices;
d) the human possibility of avoidance or limiting harm (e.g. reflex, agility, possibility of escape):
   1) possible;
   2) possible under certain conditions;
   3) impossible;
e) by practical experience and knowledge:
   1) of the machinery;
   2) of similar machinery;
   3) no experience.

7.3 Aspects to be considered when establishing elements of risk

7.3.1 Persons exposed

Risk estimation shall take into account all persons exposed to the hazards. This includes operators (see 3.21 of ISO/TR 12100-1:1992) and other persons for whom it is reasonably foreseeable that they could be affected by the machinery.

7.3.2 Type, frequency and duration of exposure

The estimation of the exposure to the hazard under consideration (including long-term damage to health) requires analysis of, and shall account for, all modes of operation of the machinery and methods of working. In particular this affects the need for access during setting, teaching, process changeover or correction, cleaning, fault-finding and maintenance (see 3.11 of ISO/TR 12100-1:1992).

The risk estimation shall account for situations when it is necessary to suspend safety functions (e.g. during maintenance).

7.3.3 Relationship between exposure and effects

The relationship between an exposure to a hazard and its effects shall be taken into account. The effects of accumulated exposure and synergistic effects shall also be considered. Risk estimation when considering these effects shall, as far as practicable, be based on appropriate recognized data.

NOTE Accident data may be available to indicate the probability and severity of injury associated with the use of a particular type of machinery with a particular type of safety measure.

7.3.4 Human factors

Human factors can affect risk and shall be taken into account in the risk estimation. This includes, for example:

— interaction of persons with the machinery;

— interaction between persons;

— psychological aspects;

— ergonomic effects;

— capacity of persons to be aware of risks in a given situation depending on their training, experience and ability.

The estimation of the ability of exposed persons shall take into account the following aspects:

— application of ergonomic principles in the design of the machinery;

— natural or developed ability to execute the required tasks;

— awareness of risks;

— level of confidence in carrying out the required tasks without intentional or unintentional deviation;

— temptations to deviate from prescribed and necessary safe working practices.

Training, experience and ability can affect the risk, but none of these factors shall be used as a substitute for hazard elimination, risk reduction by design or safeguarding where these safety measures can be implemented.

7.3.5 Reliability of safety functions

Risk estimation shall take account of the reliability of components and systems. It shall:

— identify the circumstances which can result in harm (e.g. component failure, power failure, electrical disturbances);