

AMERICAN NATIONAL ADOPTION
of an INTERNATIONAL STANDARD

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

Adopted by the U.S. TAG to ISO/TC199 through the ANSI B11 Accredited Standards Committee

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AMERICAN NATIONAL STANDARDS

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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.

National adoption of this International Standard as an American National Standard

ISO 12100 was published in 2010 as an editorial combination of three separate standards: ISO 12100-1:2003, 12100-2:2003 and ISO 14121-1:2007 plus related amendments. These three standards were very minimal revisions of EN 292:1991 / ISO/TR 12100:1992, and EN 1050 carried out by a special Working Group composed of experts from ISO, CEN, IEC and CENELEC.

To complete this combination of the three separate standards into a single ISO standard, ISO/TC 199 agreed that only editorial changes would be permitted – **no technical changes were considered**. As a result, ISO 12100:2010 contains language largely unchanged from the original publication in the early 1990s.

ANSI B11.GSR (2008) began by using the ISO 12100 and 14121 standards as a guide and then updating the ~20 year span by incorporating current knowledge and information on machinery safety. The B11 GSR document was further revised, updated and published in December 2010 as **ANSI B11.0-2010 Safety of Machinery – General Requirements and Risk Assessment**.

Readers interested in the most recent and current information on the general topic of *Safety of Machinery* should use ANSI B11.0 – 2010: Safety of Machines; General Requirements and Risk Assessment.

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.

This document is a part of the ISO 12100 series.

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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*

NFPA 79-2012, *Electrical Standard for Industrial Machinery* may be substituted for the North American market.

3 Terms and definitions

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

3.1 emergency operation: all actions and functions intended to end or avert an emergency situation.

3.2 emergency situation: hazardous situation needing to be urgently ended or averted.

NOTE: An emergency situation can arise:

- during normal operation of the machine (for example, due to human interaction, or as a result of external influences); or
- as a consequence of a malfunction or failure of any part of the machine.

3.3 emergency stop / emergency stop function: function which is intended to:

- avert arising or reduce existing hazards to persons, damage to machinery or to work in progress, and
- be initiated by a single human action.

NOTE: ISO 13850 gives detailed provisions.

3.4 emission value: numerical value quantifying an emission generated by a machine (for example, noise, vibration, hazardous substances, radiation)/

NOTE 1: Emission values are part of the information on the properties of a machine and are used as a basis for risk assessment.

NOTE 2: The term “emission value” ought not to be confused with “exposure value,” which quantifies the exposure of persons to emissions when the machine is in use. Exposure values can be estimated using the emission values.

NOTE 3: Emission values are preferably measured and their associated uncertainties determined by means of standardized methods (for example, to allow comparison between similar machines).

3.4.1 comparative emission data: set of emission values of similar machines collected for the purpose of comparison.

NOTE: For noise comparison, see ISO 11689.

3.5 failure: termination of the ability of an item to perform a required function.

NOTE 1: After failure, the item has a fault.

NOTE 2: “Failure” is an event, as distinguished from “fault”, which is a state.

NOTE 3: The concept as defined does not apply to items consisting of software only.

3.5.1 common cause failure: failure of different items, resulting from a single event, where these failures are not consequences of each other.

NOTE: Common cause failures should not be confused with common mode failures.

3.5.2 common mode failure: failure of items characterized by the same fault mode.

NOTE: Common mode failures should not be confused with common cause failures, as the common mode failures can result from different causes.

3.5.3 failure to danger: any malfunction in the machinery, or in its power supply, that increases the risk.

3.6 fault: state of an item characterized by inability to perform a required function, excluding the inability during preventive maintenance or other planned actions, or due to lack of external resources.

NOTE 1: A fault is often the result of a failure of the item itself, but can exist without prior failure.

NOTE 2: In practice, the terms “fault” and “failure” are often used synonymously.

3.7 guard: physical barrier, designed as part of the machine to provide protection.

NOTE 1: A guard may act 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: Depending on its construction, a guard may be described as, for example, casing, shield, cover, screen, door, enclosing guard.

NOTE 3: The terms for types of guards are defined in 3. 7.1 to 3.7.6. See also 6.3.3.2 and ISO 14120 for types of guards and their requirements.

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

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

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

- the hazardous machine functions “covered” by the guard cannot operate until the guard is closed;
- if the guard is opened while hazardous machine functions are operating, a stop command is given; and
- when the guard is closed, the hazardous machine functions “covered” by the guard can operate (the closure of the guard does not by itself start the hazardous machine functions)

NOTE: ISO 14119 gives detailed provisions.

3.7.4 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 “covered” by 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 “covered” by the guard has disappeared; and
- when the guard is closed and locked, the hazardous machine functions “covered” by the guard can operate (the closure and locking of the guard do not by themselves start the hazardous machine functions).

NOTE: ISO 14119 gives detailed provisions.

3.7.5 interlocking guard with a start function control guard: special form of interlocking guard which, once it has reached its closed position, gives a command to initiate the hazardous machine function(s) without the use of a separate start control.

NOTE: See 6.3.3.2.5 for detailed provisions on the conditions of use.

3.7.6 movable guard: guard which can be opened without the use of tools.

3.8 harm: physical injury or damage to health.

3.9 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).

3.9.1 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.

3.9.2 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.

3.10 hazard zone (danger zone): any space within and/or around machinery in which a person can be exposed to a hazard.

3.11 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.

3.12 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.

3.13 impeding device: any physical obstacle (low barrier, rail, etc.) which, without totally preventing access to a hazard zone, reduces the probability of access to this zone by offering an obstruction to free access.

3.14 inherently safe design measure: protective 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: See 6.2.

3.15 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.

3.16 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.

3.17 malfunction: failure of a machine to perform an intended function.

NOTE: See 5.4, item b) 2) for examples.

3.18 protective device: safeguard other than a guard.

NOTE: Examples of types of protective devices are 3.18.1 to 3.18.9.

3.18.1 active optoelectronic protective device (AOPD): device whose sensing function is performed by optoelectronic emitting and receiving elements detecting the interruption of optical radiation, generated within the device, by an opaque object present in the specified detection zone.

NOTE: IEC 61496 gives detailed provisions.

3.18.2 enabling device: additional manually operated device used in conjunction with a start control and which, when continuously actuated, allows a machine to function.

3.18.3 hold-to-run control device: control device which initiates and maintains machine functions only as long as the manual control (actuator) is actuated.

3.18.4 interlocking device (interlock): mechanical, electrical or other type of device, the purpose of which is to prevent the operation of hazardous machine functions under specified conditions (generally as long as a guard is not closed).

3.18.5 limiting device: device which prevents a machine or hazardous machine condition(s) from exceeding a designed limit (space limit, pressure limit, load moment limit, etc.).

3.18.6 limited movement control device: control device, a single actuation of which, together with the control system of the machine, permits only a limited amount of travel of a machine element.

3.18.7 mechanical restraint device: device which introduces into a mechanism a mechanical obstacle (for example, wedge, spindle, strut, scotch) which, by virtue of its own strength, can prevent any hazardous movement.

3.18.8 sensitive protective equipment (SPE): equipment for detecting persons or parts of persons which generates an appropriate signal to the control system to reduce risk to the persons detected.

NOTE: The signal can be generated when a person or part of a person goes beyond a predetermined limit — for example, enters a hazard zone — (tripping) or when a person is detected in a predetermined zone (presence sensing), or in both cases.

3.18.9 two-hand control device: control device which requires at least simultaneous actuation by both hands in order to initiate and to maintain hazardous machine functions, thus providing a protective measure only for the person who actuates it.

NOTE: ISO 13851 gives detailed provisions.

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.

3.20 reasonably foreseeable misuse: use of a machine in a way not intended by the designer, but which can result from readily predictable human behavior.

3.21 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.

3.22 residual risk: risk remaining after protective measures have been implemented.

NOTE 1: This American national adoption of an 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.

3.23 risk: combination of the probability of occurrence of harm and the severity of that harm.

3.23.1 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.

3.23.2 risk analysis: combination of the specification of the limits of the machine, hazard identification and risk estimation.

3.23.3 risk assessment: overall process comprising a risk analysis and a risk evaluation.

3.23.4 risk evaluation: judgment, on the basis of risk analysis, of whether the risk reduction objectives have been achieved.

3.23.5 risk estimation: defining likely severity of harm and probability of its occurrence.

3.24 safety function: function of a machine whose failure can result in an immediate increase of the risk(s).

3.25 safeguard: guard or protective device.

3.26 safeguarding: protective 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 measures.

NOTE: See 6.3.

3.27 task: specific activity performed by one or more persons on, or in the vicinity of, the machine during its life cycle.

3.28 unexpected start-up / unintended start-up: any start-up which, because of its unexpected nature, generates a risk to persons.

NOTE 1: This can be caused by, for example:

- a start command which is the result of a failure in, or an external influence on, the control system;
- a start command generated by inopportune action on a start control or other parts of the machine such as a sensor or a power control element;
- restoration of the power supply after an interruption;
- external/internal influences (gravity, wind, self-ignition in internal combustion engines, etc.) on parts of the machine.

NOTE 2: Machine start-up during normal sequence of an automatic cycle is not *unintended*, but can be considered as being *unexpected* from the point of view of the operator. Prevention of accidents in this case involves the use of safeguarding measures (see 6.3).

NOTE 3: Adapted from ISO 14118:2000, definition 3.2.

3.29 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.

3.29 information for use: protective measure consisting of communication links (for example, text, words, signs, signals, symbols, diagrams) used separately or in combination, to convey information to the user.

NOTE: See 6.4.

3.29 intended use: use of a machine in accordance with the information for use provided in the instructions.

4 Strategy for risk assessment and risk reduction

To implement risk assessment and risk reduction the designer shall take the following actions, in the order given (see Figure 1):

- a) determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof;
- b) identify the hazards and associated hazardous situations;

- c) estimate the risk for each identified hazard and hazardous situation;
- d) evaluate the risk and take decisions about the need for risk reduction;
- e) eliminate the hazard or reduce the risk associated with the hazard by means of protective measures.

Actions a) to d) are related to risk assessment and e) to risk reduction.

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. 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.

It is assumed that, when present on machinery, a hazard will sooner or later lead to harm if no protective measure or measures have been implemented. Examples of hazards are given in Annex B.

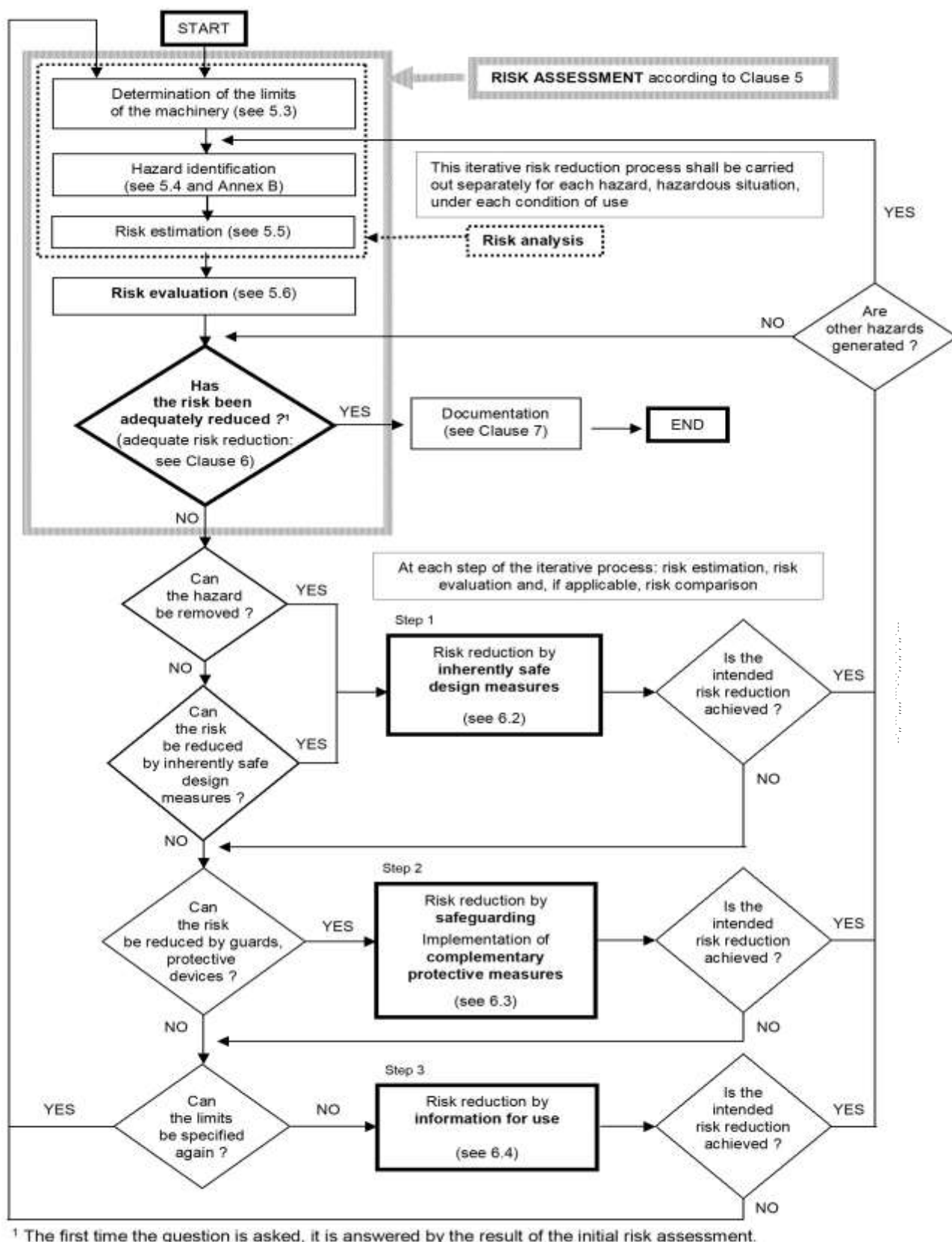
Protective measures are the combination of the measures implemented by the designer and the user in accordance with Figure 2. Measures which can be incorporated at the design stage are preferable to those implemented by the user and usually prove more effective.

The objective to be met is the greatest practicable risk reduction, taking into account the four below factors. The strategy defined in this clause is represented by the flowchart in Figure 1. The process itself is iterative and several successive applications can be necessary to reduce the risk, making the best use of available technology. In carrying out this process, it is necessary to take into account these four factors, in the following order of preference:

- the safety of the machine during all the phases of its life cycle;
- the ability of the machine to perform its function;
- the usability of the machine;
- the manufacturing, operational and dismantling costs of the machine.

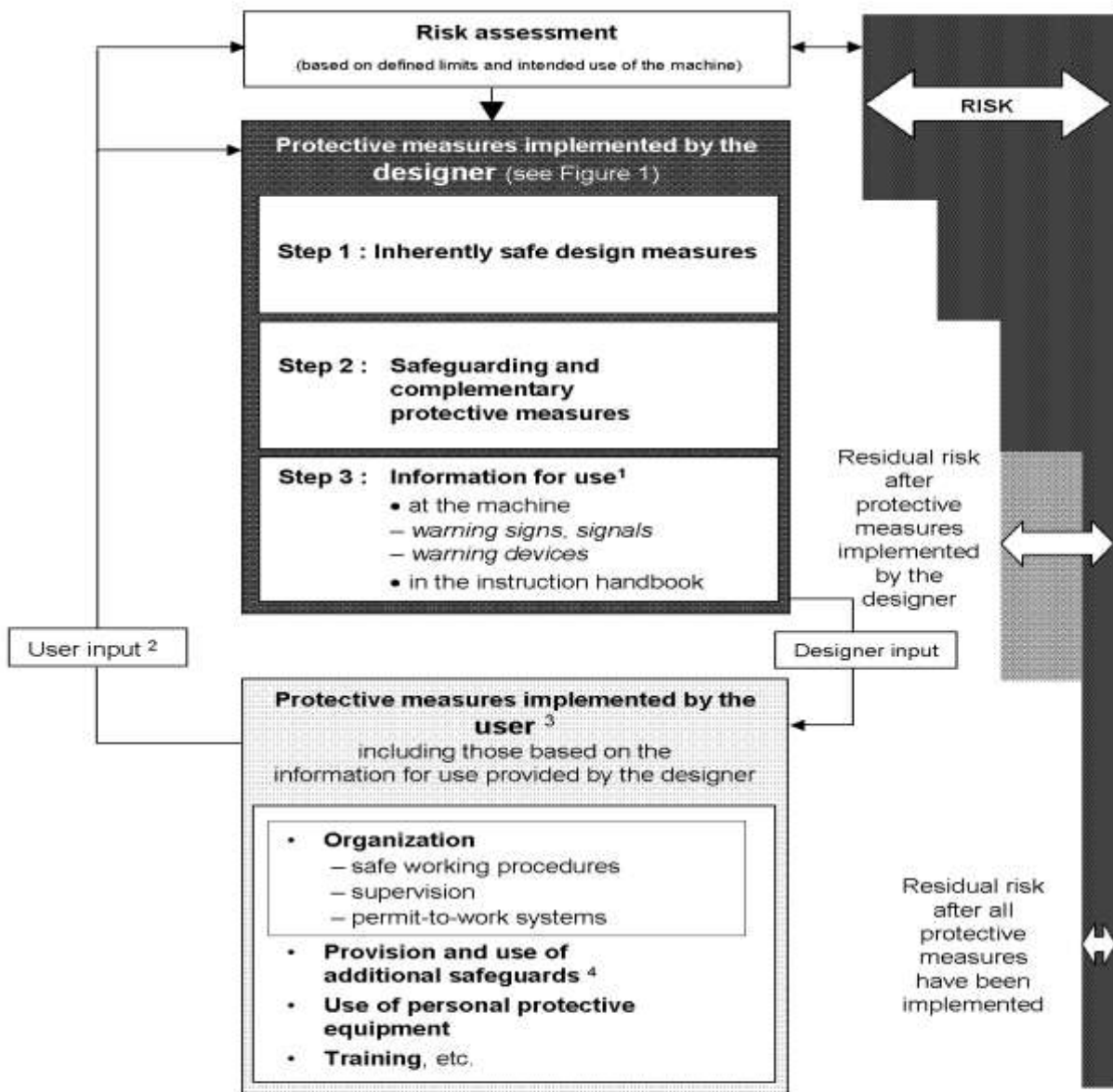
NOTE 1 The ideal application of these principles requires knowledge of the use of the machine, the accident history and health records, available risk reduction techniques, and the legal framework in which the machine is to be used.

NOTE 2 A machine design which is acceptable at a particular time could be no longer justifiable when technological development allows the design of an equivalent machine with lower risk.



^a The first time the question is asked, it is answered by the result of the initial risk assessment.

Figure 1 — Schematic representation of risk reduction process including iterative three-step method



- ¹ Providing proper information for use is part of the designer's contribution to risk reduction, but the protective measures concerned are only effective when implemented by the user.
- ² The user input is that information received by the designer from either the user community regarding the intended use of the machine in general or that which is received from a specific user.
- ³ There is no hierarchy between the various protective measures implemented by the user. These protective measures are outside the scope of this International Standard.
- ⁴ Those protective measures required due to specific process(es) not envisaged in the intended use of the machine or to specific conditions for installation that cannot be controlled by the designer.

- ^a Providing proper information for use is part of the designer's contribution to risk reduction, but the protective measures concerned are only effective when implemented by the user.
- ^b The user input is that information received by the designer from either the user community, regarding the intended use of the machine in general, or from a specific user.
- ^c There is no hierarchy between the various protective measures implemented by the user. These protective measures are outside the scope of this International Standard.
- ^d These are protective measures required due to a specific process or processes not envisaged in the intended use of the machine or to specific conditions for installation that cannot be controlled by the designer.

Figure 2 — Risk reduction process from point of view of designer

5 Risk assessment

5.1 General

Risk assessment comprises (see Figure 1)

- risk analysis, comprising
 - 1) determination of the limits of the machinery (see 5.3);
 - 2) hazard identification (5.4 and Annex B); and
 - 3) risk estimation (see 5.5); and
- risk evaluation (see 5.6).

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

These judgments shall be supported by a qualitative or, where appropriate, 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 documented according to Clause 7.

5.2 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) a 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;
- 3) documentation on previous designs of similar machinery, if relevant;
- 4) information for use of the machinery, as available.

b) Related to regulations, standards and other applicable documents:

- 1) applicable regulations;
- 2) relevant standards;
- 3) relevant technical specifications;
- 4) relevant safety data sheets.

c) **Related to experience of use:**

- 1) any accident, incident or malfunction history of the actual or similar machinery;
- 2) the history of damage to health resulting, for example, from emissions (noise, vibration, dust, fumes, etc.), chemicals used or materials processed by the machinery;
- 3) the experience of users of similar machines and, whenever practicable, an exchange of information with the potential users.

NOTE An incident that has occurred and resulted in harm can be referred to as an “accident”, whereas an incident that has occurred and that did not result in harm can be referred to as a “near miss” or “dangerous occurrence”.

d) **Relevant ergonomic principles.**

The information shall be updated as the design develops or when modifications to the machine 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.

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

For quantitative analysis, data from databases, handbooks, laboratories or manufacturers' specifications may be used, provided that there is confidence in the suitability of the data. Uncertainty associated with these data shall be indicated in the documentation (see Clause 7).

5.3 Determination of limits of machinery

5.3.1 General

Risk assessment begins with the determination of the limits of the machinery, taking into account all the phases of the machinery life. This means that the characteristics and performances of the machine or a series of machines in an integrated process, and the related people, environment and products, should be identified in terms of the limits of machinery as given in 5.3.2 to 5.3.5.

5.3.2 Use limits

Use limits include the intended use and the reasonably foreseeable misuse. Aspects to be taken into account include the following:

- a) the different machine operating modes and different intervention procedures for the users, including interventions required by malfunctions of the machine;
- b) the use of the machinery (for example, industrial, non-industrial and domestic) by persons identified by sex, age, dominant hand usage, or limiting physical abilities (visual or hearing impairment, size, strength, etc.);
- c) the anticipated levels of training, experience or ability of users including
 - 1) operators,
 - 2) maintenance personnel or technicians,
 - 3) trainees and apprentices, and
 - 4) the general public;

- d) exposure of other persons to the hazards associated with the machinery where it can be reasonably foreseen:
- 1) persons likely to have a good awareness of the specific hazards, such as operators of adjacent machinery;
 - 2) persons with little awareness of the specific hazards but likely to have a good awareness of site safety procedures, authorized routes, etc., such as administration staff;
 - 3) persons likely to have very little awareness of the machine hazards or the site safety procedures, such as visitors or members of the general public, including children.

If specific information is not available in relation to b), above, the manufacturer should take into account general information on the intended user population (for example, appropriate anthropometric data).

5.3.3 Space limits

Aspects of space limits to be taken into account include

- a) the range of movement,
- b) space requirements for persons interacting with the machine, such as during operation and maintenance,
- c) human interaction such as the operator-machine interface, and
- d) the machine-power supply interface.

5.3.4 Time limits

Aspects of time limits to be taken into account include

- a) the life limit of the machinery and/or of some of its components (tooling, parts that can wear, electromechanical components, etc.), taking into account its intended use and reasonably foreseeable misuse, and
- b) recommended service intervals.

5.3.5 Other limits

Examples of other limits include

- a) properties of the material(s) to be processed,
- b) housekeeping — the level of cleanliness required, and
- c) environmental — the recommended minimum and maximum temperatures, whether the machine can be operated indoors or outdoors, in dry or wet weather, in direct sunlight, tolerance to dust and wet, etc.

5.4 Hazard identification

After determination of the limits of the machinery, the essential step in any risk assessment of the machinery is the systematic identification of reasonably foreseeable hazards (permanent hazards and those which can appear unexpectedly), hazardous situations and/or hazardous events during all phases of the machine life cycle, i.e.:

- transport, assembly and installation;
- commissioning;
- use;
- dismantling, disabling and scrapping.

Only when hazards have been identified can steps be taken to eliminate them or to reduce risks. To accomplish this hazard identification, it is necessary to identify the operations to be performed by the machinery and the tasks to be performed by persons who interact with it, taking into account the different parts, mechanisms or functions of the machine, the materials to be processed, if any, and the environment in which the machine can be used.

The designer shall identify hazards taking into account the following.

a) Human interaction during the whole life cycle of the machine

Task identification should consider all tasks associated with every phase of the machine life cycle as given above. Task identification should also take into account, but not be limited to, the following task categories:

- setting;
- testing;
- teaching/programming;
- process/tool changeover;
- start-up;
- all modes of operation;
- feeding the machine;
- removal of product from machine;
- stopping the machine;
- stopping the machine in case of emergency;
- recovery of operation from jam or blockage;
- restart after unscheduled stop;
- fault-finding/trouble-shooting (operator intervention);
- cleaning and housekeeping;
- preventive maintenance;
- corrective maintenance.

All reasonably foreseeable hazards, hazardous situations or hazardous events associated with the various tasks shall then be identified. Annex B gives examples of hazards, hazardous situations and hazardous events to assist in this process. Several methods are available for the systematic identification of hazards. See also ISO/TR 14121-2.

In addition, reasonably foreseeable hazards, hazardous situations or hazardous events not directly related to tasks shall be identified.

EXAMPLE Seismic events, lightning, excessive snow loads, noise, break-up of machinery, hydraulic hose burst.

b) Possible states of the machine

These are as follows:

- 1) the machine performs the intended function (the machine operates normally);
- 2) the machine does not perform the intended function (i.e., it malfunctions) due to a variety of reasons, including
 - variation of a property or of a dimension of the processed material or of the workpiece,
 - failure of one or more of its component parts or services,
 - external disturbances (for example, shocks, vibration, electromagnetic interference),
 - design error or deficiency (for example, software errors),
 - disturbance of its power supply, and
 - surrounding conditions (for example, damaged floor surfaces).

c) Unintended behavior of the operator or reasonably foreseeable misuse of the machine

Examples include

- loss of control of the machine by the operator (especially for hand-held or mobile machines),
- reflex behavior of a person in case of malfunction, incident or failure during the use of the machine,
- behavior resulting from lack of concentration or carelessness,
- behavior resulting from taking the “line of least resistance” in carrying out a task,
- behavior resulting from pressures to keep the machine running in all circumstances, and
- behavior of certain persons (for example, children, disabled persons).

NOTE Examination of the available design documentation can be a useful means of identifying hazards related to the machinery, particularly those associated with moving elements such as motors or hydraulic cylinders.

5.5 Risk estimation**5.5.1 General**

After hazard identification, risk estimation shall be carried out for each hazardous situation by determining the elements of risk given in 5.5.2. When determining these elements, it is necessary to take into account the aspects given in 5.5.3.

If standardized (or other suitable) measurement methods exist for an emission, they should be used, in conjunction with existing machinery or prototypes, to determine emission values and comparative emission data. This makes it possible for the designer to

- estimate the risk associated with the emissions,
- evaluate the effectiveness of the protective measures implemented at the design stage,
- provide potential buyers with quantitative information on emissions in the technical documentation, and
- provide users with quantitative information on emissions in the information for use.

Hazards other than emissions that are described by measurable parameters can be dealt with in a similar manner.

5.5.2 Elements of risk

5.5.2.1 General

The risk associated with a particular hazardous situation depends on the following elements:

- a) the severity of harm;
- b) the probability of occurrence of that harm, which is a function of
 - 1) the exposure of person(s) to the hazard,
 - 2) the occurrence of a hazardous event, and
 - 3) the technical and human possibilities to avoid or limit the harm.

The elements of risk are shown in Figure 3. Additional details are given in 5.5.2.2, 5.5.2.3 and 5.5.3.

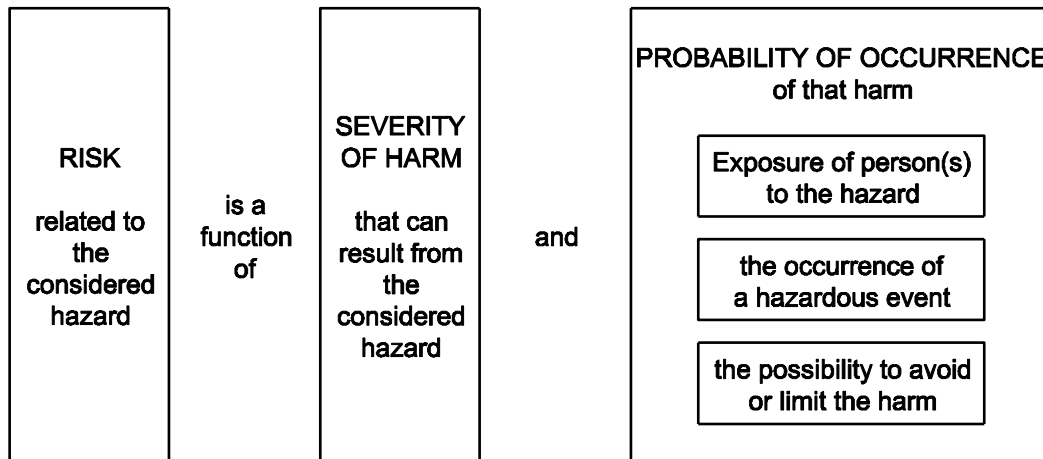


Figure 3 — Elements of risk

5.5.2.2 Severity of harm

The severity can be estimated by taking into account the following:

- a) the severity of injuries or damage to health, for example,
 - slight,
 - serious,
 - death.
- b) the extent of harm, for example, to
 - one person,
 - several persons.

When carrying out a risk assessment, the risk from the most likely severity of the harm that is likely to occur from each identified hazard shall be considered, but the highest foreseeable severity shall also be taken into account, even if the probability of such an occurrence is not high.

5.5.2.3 Probability of occurrence of harm

5.5.2.3.1 Exposure of persons to the hazard

The exposure of a person to the hazard influences the probability of the occurrence of harm. Factors to be taken into account when estimating the exposure are, among others,

- a) the need for access to the hazard zone (for normal operation, correction of malfunction, maintenance or repair, etc.),
- b) the nature of access (for example, manual feeding of materials),
- c) the time spent in the hazard zone,
- d) the number of persons requiring access, and
- e) the frequency of access.

5.5.2.3.2 Occurrence of a hazardous event

The occurrence of a hazardous event influences the probability of occurrence of harm. Factors to be taken into account when estimating the occurrence of a hazardous event are, among others,

- a) reliability and other statistical data,
- b) accident history,
- c) history of damage to health, and
- d) comparison of risks (see 5.6.3).

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

5.5.2.3.3 Possibility of avoiding or limiting harm

The possibility of avoiding or limiting harm influences the probability of occurrence of harm. Factors to be taken into account when estimating the possibility of avoiding or limiting harm are, among others, the following:

- a) different persons who can be exposed to the hazard(s), for example,
 - skilled,
 - unskilled;
- b) how quickly the hazardous situation could lead to harm, for example,
 - suddenly,
 - quickly,
 - slowly;
- c) any awareness of risk, for example,
 - by general information, in particular, information for use,
 - by direct observation,
 - through warning signs and indicating devices, in particular, on the machinery;

- d) the human ability to avoid or limit harm (for example, reflex, agility, possibility of escape);
- e) practical experience and knowledge, for example,
 - of the machinery,
 - of similar machinery,
 - no experience.

5.5.3 Aspects to be considered during risk estimation

5.5.3.1 Persons exposed

Risk estimation shall take into account all persons (operators and others) for whom exposure to the hazard is reasonably foreseeable.

5.5.3.2 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, the analysis shall account for the needs for access during loading/unloading, setting, teaching, process changeover or correction, cleaning, fault-finding and maintenance.

The risk estimation shall also take into account tasks, for which it is necessary to suspend protective measures.

5.5.3.3 Relationship between exposure and effects

The relationship between an exposure to a hazard and its effects shall be taken into account for each hazardous situation considered. The effects of accumulated exposure and combinations of hazards shall also be considered. When considering these effects, risk estimation shall, as far as practicable, be based on appropriate recognized data.

NOTE 1 Accident data can assist in establishing the probability and severity of injury associated with the use of a particular type of machinery with a particular type of protective measure.

NOTE 2 Zero accident data is, however, no guarantee of the low probability and severity of an injury.

5.5.3.4 Human factors

Human factors can affect risk and shall be taken into account in the risk estimation, including, for example,

- a) the interaction of person(s) with the machinery, including correction of malfunction,
- b) interaction between persons,
- c) stress-related aspects,
- d) ergonomic aspects,
- e) the capacity of persons to be aware of risks in a given situation depending on their training, experience and ability,
- f) fatigue aspects, and
- g) aspects of limited abilities (due to disability, age, etc.).

Risk estimation shall take into account the suitability of protective measures and shall

- When estimating risk, those components and systems identified as immediately increasing the risk in case of failure need special attention.

For the continued safe operation of a machine, it is important that the protective measures allow its easy use and do not hinder its intended use. Otherwise, there is a possibility that protective measures might be bypassed in order for maximum utility of the machine to be achieved.

Whether or not a protective measure can be defeated depends on both the type of protective measure, such as an adjustable guard or programmable trip device, and its design details.

Risk estimation shall consider whether the protective measures can be maintained in the condition necessary to provide the required level of protection.

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5.5.3.8 Information for use

Risk estimation shall take into account the information for use, as available. See also 6.4.

5.6 Risk evaluation

5.6.1 General

After risk estimation has been completed, risk evaluation shall be carried out to determine if risk reduction is required. If risk reduction is required, then appropriate protective measures shall be selected and applied (see Clause 6). As shown in Figure 1, the adequacy of the risk reduction shall be determined after applying each of the three steps of risk reduction described in Clause 6. As part of this iterative process, the designer shall also check whether additional hazards are introduced or other risks increased when new protective measures are applied. If additional hazards do occur, they shall be added to the list of identified hazards and appropriate protective measures will be required to address them.

Achieving the objectives of risk reduction and a favorable outcome of risk comparison applied when practicable gives confidence that risk has been adequately reduced.

5.6.2 Adequate risk reduction

Application of the three-step method described in 6.1 is essential in achieving adequate risk reduction.

Following the application of the three-step method, adequate risk reduction is achieved when

- all operating conditions and all intervention procedures have been considered,
- the hazards have been eliminated or risks reduced to the lowest practicable level,
- any new hazards introduced by the protective measures have been properly addressed,
- users are sufficiently informed and warned about the residual risks (see 6.1, step 3),
- protective measures are compatible with one another,
- sufficient consideration has been given to the consequences that can arise from the use in a non-professional/non-industrial context of a machine designed for professional/industrial use, and
- the protective measures do not adversely affect the operator's working conditions or the usability of the machine.

5.6.3 Comparison of risks

As part of the process of risk evaluation, the risks associated with the machinery or parts of machinery can be compared with those of similar machinery or parts of machinery, provided the following criteria apply:

- the similar machinery is in accordance with the relevant type-C standard(s);
- the intended use, reasonably foreseeable misuse and the way both machines are designed and constructed are comparable;
- the hazards and the elements of risk are comparable;
- the technical specifications are comparable;
- the conditions for use are comparable.

The use of this comparison method does not eliminate the need to follow the risk assessment process as described in this International Standard for the specific conditions of use. For example, when a band saw