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Safety of machinery — Risk assessment —

Part 2:
Practical guidance and examples of methods

Sécurité des machines — Appréciation du risque —

Partie 2: Lignes directrices pratiques et exemples de méthodes

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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/TR 14121-2 was prepared by Technical Committee ISO/TC 199, *Safety of machinery*.

This second edition cancels and replaces the first edition (ISO/TR 14121-2:2007), which has been revised as follows:

— the examples previously given in Annex A, as well as the description of quantified risk estimation, have been deleted;

— the explanations of the methods or tools, taken from Annex A, are now presented in 5.3.5 for hazard identification and 5.4.4.1 for risk estimation;

— the terminology and criteria have been revised;

Consequently, the information is given more clearly and completely, and in line with ISO 12100. (ISO 14121-1 was withdrawn after having been replaced by ISO 12100:2010.)

Introduction

The purpose of risk assessment is to identify hazards, and to estimate and evaluate risks so that they can be reduced. There are many methods and tools available for this purpose and several are described in this document. The method or tool chosen will largely be a matter of industry, company or personal preference. The choice of a specific method or tool is less important than the process itself. The benefits of risk assessment come from the discipline of the process rather than the precision of the results: as long as a systematic approach is taken to get from hazard identification to risk reduction and all the elements of risk are considered.

Adding protective/risk reduction measures to a design can increase costs and can restrict the facility of use of the machine if added after a design has been finalized or the machinery itself has already been built. Changes to machinery are generally less expensive and more effective at the design stage, so it is advantageous to perform risk assessment during machinery design.

It can be useful to review the risk assessment when the design has been finalised, when a prototype exists and after experience of the use of the machinery.

Apart from the risk assessment made at the design stage, during construction and commissioning, the principles and methods presented in this document can also be applied to existing machinery during revision or modification of machinery or at any time for the purpose of assessing existing machinery, for example, in the case of mishaps or malfunctions.

Safety of machinery — Risk assessment —

Part 2:
Practical guidance and examples of methods

1 Scope

This Technical Report gives practical guidance on conducting risk assessment for machinery in accordance with ISO 12100 and describes various methods and tools for each step in the process. It gives examples of different measures that can be used to reduce risk and is intended to be used for risk assessment on a wide variety of machinery in terms of complexity and potential for harm. Its intended users are those involved in the design, installation or modification of machinery (for example, designers, technicians or safety specialists).

Annex A provides a specific example for a risk assessment and a risk reduction process.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 12100 and the following apply.

3.1
manufacturer
supplier
entity (for example, designer, manufacturer, contractor, installer, integrator) who provides equipment or services associated with machinery or parts of machinery.

Note to entry: A user can also act in the capacity of a supplier to himself.

4 Preparation for risk assessment

4.1 General

The objectives and scope for any risk assessment should be defined at the outset.

The risk assessment based on ISO 12100 covers the whole machinery, including the control system of the machinery and should be carried out by the manufacturer.

NOTE See Clause 1 for suggested uses/users of risk assessment.

4.2 Using the team approach for risk assessment

4.2.1 General

Risk assessment is generally more thorough and effective when performed by a team. The size of a team varies according to

a) the risk assessment approach selected,

b) the complexity of the machine, and

c) the process within which the machine is utilized.

The team should bring together knowledge on different disciplines and a variety of experience and expertise. However, a team that is too large can lead to difficulty remaining focused or with reaching consensus. The composition of the team can vary during the risk assessment process according to the expertise required for a specific problem. A team leader, dedicated to the project, should be clearly identified as the success of the risk assessment depends on his or her skills.

As risk estimation should be done by a team and generate consensus, it cannot be expected that the detailed results will always be the same with different teams analysing similar situations. However, it is not always practical to set up a team for risk assessment and it can be unnecessary for machinery where the hazards are well understood.

NOTE Confidence in the findings of a risk assessment can be improved by consulting others with the knowledge and expertise such as that outlined in 4.2.2 and by another competent person reviewing the risk assessment.

4.2.2 Composition and role of team members

The team should have a team leader. The team leader should be fully responsible for ensuring that all the tasks involved in planning, performing and documenting (in accordance with ISO 12100:2010, Clause 7) the risk assessment are carried out and the results/recommendations are reported to the appropriate person(s).

Team members should be selected according to the skills and expertise required for the risk assessment. The team should include those people who

a) can answer technical questions about the design and functions of the machinery,

b) have actual experience of how the machinery is operated, set-up, maintained, serviced, etc.,

c) have knowledge of the accident history of this type of machinery,

d) have a good understanding of the relevant regulations, standards, in particular ISO 12100, and any specific safety issues associated with the machinery, and

e) understand human factors (see ISO 12100:2010, 5.5.3.4).

4.2.3 Selection of methods and tools

This document is intended to be used for risk assessment on a wide variety of machinery in terms of complexity and potential for harm. There are also a variety of methods and tools for conducting risk estimation (see 5.4.4). When selecting a method or tool for estimating risk consideration should be given to the machinery, the likely nature of the hazards and the purpose of the risk assessment. Consideration should also be given to the skills, experience and preferences of the team for particular methods. Clause 5 offers additional information on criteria for the selection of appropriate methods and tools for each step of the risk assessment process.

4.2.4 Source of information for risk assessment

The information required for risk assessment is listed in ISO 12100:2010, 5.2. This information can take a variety of forms, including technical drawings, diagrams, photos, video footage, information for use [including maintenance information and standard operating procedures (SOP)] as available. Access to similar machinery or a prototype of the design, where available, is often useful.

5 Risk assessment process

5.1 General

The following subclauses explain what has to be considered at each step of the risk assessment process as shown in ISO 12100:2010, Figure 1.

5.2 Determination of the limits of the machinery

5.2.1 General

NOTE This subclause elaborates on some of the requirements of ISO 12100:2010, 5.3.

The objective of this step is to have a clear description of the mechanical and physical properties, functional capabilities of the machinery, its intended use and reasonably foreseeable misuse, and the type of environment in which it is likely to be used and maintained.

This is facilitated by an examination of the functions of the machinery and the tasks associated with how the machinery is used.

5.2.2 Functions of the machinery (machine-based)

Machinery can be described in terms of distinct parts, mechanisms or functions based on its construction and operation such as

— power supply,

— control,

— modes of operation,

— feeding,

— movement/travelling,

— lifting,

— machine frame or chassis which provides stability/mobility, and

— attachments.

When protective/risk reduction measures are introduced into the design their functions and their interaction with the other functions of the machinery should be described.

A risk assessment should include a look at each functional part in turn, making sure that every mode of operation and all phases of use are properly considered, including the human–machine interaction in relation to the identified functions or functional parts.

5.2.3 Uses of the machinery (task based)

By considering all persons who are intended to interact with the machinery in a given environment (for example, factory, domestic), the use of the machinery can be described in terms of the tasks associated with the intended use and the reasonably foreseeable misuse of the machinery.

NOTE See ISO 12100:2010, Table B.3 for a list of typical/generic machinery tasks.

Machinery manufacturer/supplier and user should communicate with one another wherever possible in order to be sure that all uses of the machinery, including reasonably foreseeable misuses, are identified. Analysis of tasks and work situations should therefore involve operation and maintenance personnel. The following should also be considered:

a) information for use supplied with the machinery as available,

b) the easiest or quickest way to carry out a task can be different from the tasks stipulated in manuals, procedures and instructions,

c) reflex behaviour of a person when faced with a malfunction, incident or failure when using the machine, and

d) human error.

The consideration of individual conditions for the use/operation of a machine are valid as far as this knowledge can reasonably be achieved by the designer/manufacturer. In those cases the manufacturer should consider the intended use and the reasonably foreseeable misuse.

5.3 Hazard identification

5.3.1 General

NOTE 1 See ISO 12100:2010, 5.4.

The objective of hazard identification is to produce a list of hazards, hazardous situations and/or hazardous events that allows the possible accident scenarios to be described in terms of how and when a hazardous situation can lead to harm. A useful starting point for relevant hazards is ISO 12100:2010, Annex B, which can be used as a generic checklist. Other sources for hazard identification could be based on the information indicated in ISO 12100:2010, 5.4.

NOTE 2 An example of a tool for hazard identification is given in 5.3.5.

It is useful for both hazard identification and anticipating protective/risk reduction measures, to reference any International Standards that are relevant to a specific hazard or safety of a specific type of machinery.

NOTE 3 An example of a standard relevant to specific hazards is IEC 60204-1, which deals with electrical hazards.

NOTE 4 Examples of machinery-specific safety standards are ISO 10218, related to robots, ISO 11111, related to textile machinery, and ISO 3691, related to industrial trucks.

Hazard identification is the most important step in any risk assessment. Only when a hazard has been identified, is it possible to take action to reduce the risks associated with it, see Clause 6. Unidentified hazards can lead to harm. It is therefore vitally important to ensure that hazard identification is as systematic and comprehensive as practicable, taking into account the relevant aspects described in ISO 12100:2010, 5.5.3.

5.3.2 Methods for hazard identification

The most effective methods or tools are those that are structured to ensure that all phases of the machinery life cycle, modes of operation, functions and tasks associated with the machinery are thoroughly examined.

Various methods for structured hazard identification are available. In general most follow one of the two approaches described below (see Figure 1):

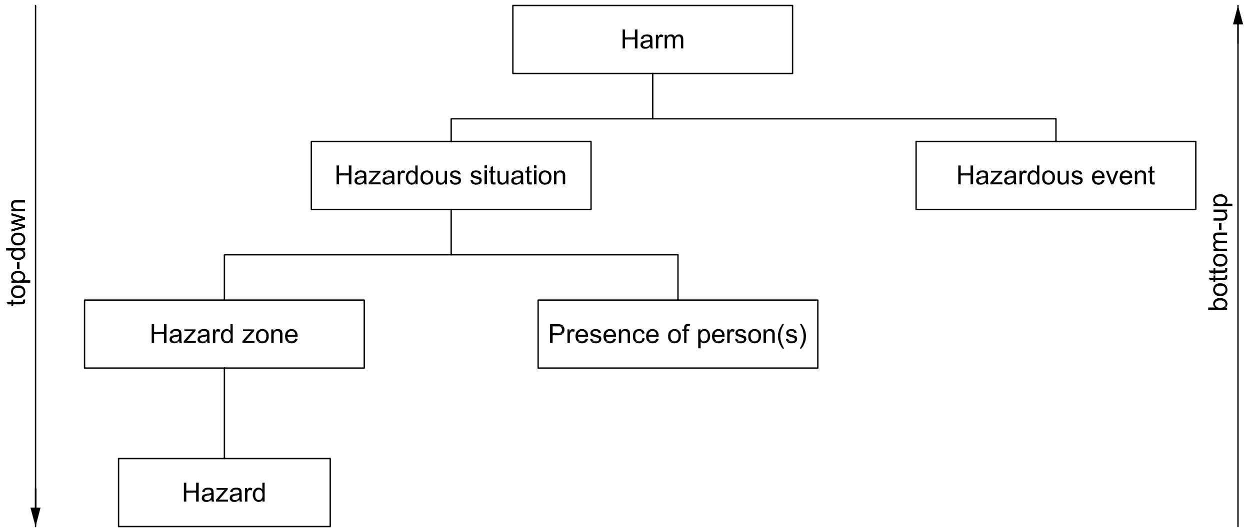

Figure 1 — Top-down and bottom-up approaches

A *top-down* approach is one that takes as its starting point a check-list of potential consequences (for example, cutting, crushing, hearing loss — see potential consequences in ISO 12100:2010, Tables B.1 and B.2) and establishes what could cause harm (working back from the hazardous event to the hazardous situation and thence the hazard itself). Every item in the checklist is applied to every phase of use of the machinery and every part/function and/or task in turn. One of the drawbacks of a top-down approach is the over-reliance of the team on the checklist, which may be incomplete. An inexperienced team will not necessarily appreciate this. Therefore, checklists should not be interpreted as exhaustive, but should encourage creative thinking beyond the list.

A *bottom-up* approach starts by examining all the hazards and considering all possible ways that something can go wrong in a defined hazardous situation (for example, failure of component, human error, malfunction or unexpected action of the machinery) and how this can lead to harm. See ISO 12100:2010, Tables B.1 and B.2. The bottom-up approach can be more comprehensive and thorough than the top-down but can also be prohibitively time-consuming.

NOTE Figure 1 explains the structure of the hazard identification approaches, but it is not intended to define relationship between hazardous situation, hazardous event and harm in the way of a flowchart.

5.3.3 Recording of information

The hazard identification should be recorded as it progresses. Any system for recording the information should be organized in such a way as to ensure that the following are clearly described, as appropriate:

a) the hazard and its location (hazard zone),

b) the hazardous situation, indicating the different types of people (such as maintenance personnel, operators, passers-by) and the tasks or activities they are intended to do that can expose them to a hazard,

c) how the hazardous situation can lead to harm as a result of a hazardous event or prolonged exposure, at which stage of the risk assessment process sometimes the following information can also be anticipated and usefully recorded:

   1) the nature and severity of the harm (consequences) in machinery-specific (for example, fingers crushed by down-stroke of press when adjusting work-piece) rather than generic (for example, crushing) terms, and

   2) existing protective/risk reduction measures and their effectiveness.

5.3.4 Example of a tool for hazard identification

5.3.4.1 Hazard identification by application of forms

5.3.4.1.1 General

The aim of this subclause is to show a method for hazard identification (see ISO 12100:2010, 5.4) using as the main tool the checklists given in ISO 12100:2010, B.2 to B.4.

These checklists should be used as the starting point for identifying relevant hazards. Then, in order to ensure a more complete hazard identification, other sources such as regulations, standards and engineering knowledge should be taken into account.

This method can be complemented with other methods based on, for example, brainstorming, comparison with similar machinery, review of data about accidents and/or incidents of similar machinery.

This method will be more effective the more complete and detailed are the available information for risk assessment (see ISO 12100:2010, 5.2) and the determination of the limits of the machinery (see 5.2 and ISO 12100:2010, 5.3).

The method is applicable to any phase of the machine life cycle.

5.3.4.1.2 Description of the tool or method

Taking into account the limits of the machine, the first step is to determine the extent of the system to be analysed, for example, the phase(s) of the machine life cycle, the part(s) and/or function(s) of the machine.

The second step is to define the tasks to be performed by people interacting with or near the machine or the operations to be performed by the machine, in each of the selected phases. In this step the list of tasks detailed in ISO 12100:2010, Table B.3, could be used.

The third step is to examine, for each task or operation in each particular hazard zone, the relevant hazards and the possible hazardous situations. This can be carried out by using either a top-down approach, if the starting point is the potential consequence (harm), or a bottom-up approach, if the starting point is the origin of the hazard. In this step, ISO 12100:2010, Table B.1, for description of origins of hazards, ISO 12100:2010, Table B.3, for description of hazardous situations, and ISO 12100:2010, Table B.4, for description of hazardous events, can be used.

5.3.4.1.3 Documentation

The blank form given in Table A.3 can be used to document the results of hazard identification.

5.4 Risk estimation

5.4.1 General

NOTE See ISO 12100:2010, 5.5.

By definition the two main elements of risk are severity of harm and the probability of occurrence of that severity of harm. The purpose of risk estimation (see ISO 12100:2010, Figure 3) is to determine the highest risk arising from each hazardous situation. The estimated risk is generally expressed as a level, index or score but can also be descriptive.

There are many different approaches to risk estimation, ranging from the simple qualitative to the detailed quantitative. The essential features of these different approaches are described below.

5.4.2 Severity of harm

NOTE 1 See ISO 12100:2010, 5.5.2.2.

Each hazard has the potential to result in several different severities of harm. It can be helpful to estimate the risk of a range of representative severities and to consider the most severe harm that can realistically occur (worst credible).

However severity of harm to be considered is not always easy. The most severe can be very improbable and the most probable severity can be inconsequential so that using either could lead to an inappropriate estimation of risk. For example, it is almost always possible that death will be the severity of harm: a cut can kill if it becomes septic or severs an artery; however, although the probability of receiving a cut is high, death is nevertheless usually a remote probability. It can, therefore, be helpful to estimate the risk of a range of representative severities and use the one that gives the highest risk.

NOTE 2 In general, the lower the energy of the hazard, the lower the severity of the related potential harm. The severity of potential harm can also be related to the part of the body that is exposed, for example, a hazard that can cause crushing injuries is generally fatal if the whole body or head is exposed.

For examples of different ways of classifying severity, see the risk estimation tools described in 5.4.4.

5.4.3 Probability of occurrence of harm

5.4.3.1 General

NOTE See ISO 12100:2010, 5.5.2.3.

All approaches to risk estimation should require the estimation of the probability of an occurrence of harm by considering the

a) exposure of person(s) to the hazard (see ISO 12100:2010, 5.5.2.3.1),

b) probability of occurrence of a hazardous event (see ISO 12100:2010, 5.5.2.3.2), and

c) technical and human possibilities to avoid or limit the harm (see ISO 12100:2010, 5.5.2.3.3).

A hazardous situation exists when one or more persons are exposed to a hazard. Harm occurs as a result of a hazardous event as illustrated in Figure 2.

When estimating the probability of harm the relevant aspects described in ISO 12100:2010, 5.5.3, should also be considered.