
**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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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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*.

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

This part of ISO 14121 has resulted from the effort to update ISO 14121 in order that it be consistent with ISO 12100-1:2003 and ISO 12100-2:2003.

The purpose of risk assessment is to identify hazards, and to estimate and evaluate risk so that it 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, all the elements of risk are considered.

Adding protective measures to a design can increase costs and 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.

The risk assessment is performed once again when the design is finalized, when a prototype exists and after the machinery has been in use for a while.

Apart from at the design stage, during construction and during commissioning, risk assessment can also be performed during revision or modification of machinery or at any other time for the purpose of assessing existing machinery, e.g. in the case of mishaps or malfunctions.

The effectiveness of implemented protective measures will need to be verified before the carrying out of further iterations.

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Safety of machinery — Risk assessment —

Part 2: Practical guidance and examples of methods

1 Scope

This part of ISO 14121 gives practical guidance on the conducting of risk assessments for machinery in accordance with ISO 14121-1 and describes various methods and tools for each step in the process.

It also provides practical guidance on risk reduction (in accordance with ISO 12100) for machinery, giving additional guidance on the selection of appropriate protective measures for achieving safety.

The intended users of this part of ISO 14121 are those involved in the integration of safety into the design, installation or modification of machinery (e.g. designers, technicians, safety specialists).

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 14121-1:2007, *Safety of machinery — Risk assessment — Part 1: Principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14121-1 and the following apply.

3.1

supplier

entity (e.g. designer, manufacturer, contractor, installer, integrator) who provides equipment or services associated with the integrated manufacturing system (IMS) or a portion of the IMS or machines

NOTE 1 The user may also act in the capacity of a supplier to himself.

NOTE 2 Adapted from ISO 11161:2007, definition 3.24.

4 Preparation for risk assessment

4.1 General

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

NOTE See the Introduction for suggested uses 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 the following:

- a) the risk assessment approach selected;
- b) the complexity of the machine;
- 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 in remaining focused or 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.

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 and the risk is not high.

NOTE Confidence in the findings of a risk assessment can be improved by consulting others with the knowledge and expertise, as 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 14121-1:2007, Clause 9) the risk assessment are carried out and that 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, and in particular ISO 12100, and any specific safety issues associated with the machinery, and
- e) understand human factors (see ISO 14121-1:2007, 7.3.4).

4.2.3 Selection of methods and tools

This part of ISO 14121 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 assessment (see Annex A). When selecting a method or tool for performing a risk assessment, 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 Sources of information for risk assessment

The information required for risk assessment is listed in ISO 14121-1:2007, 4.2. This information can take a variety of forms, including technical drawings, diagrams, photos, video footage, information for use [including maintenance 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 is involved in practice with each step of the risk assessment process as shown in ISO 14121-1:2007, Figure 1.

5.2 Determination of the limits of the machinery

NOTE See ISO 14121-1:2007, Clause 5.

5.2.1 General

The objective of this step is to have a clear description of the 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 the manner in which 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 the following:

- power supply;
- control;
- feeding;
- processing;
- movement/travelling;
- lifting;
- machine frame or chassis which provides stability/mobility;
- attachments.

When protective 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 interact with the machinery in a given environment (e.g. 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 14121-1:2007, Table A.3, for a list of typical/generic machinery tasks.

Machinery designers, users and integrators 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;
- d) human error.

5.3 Hazard identification

NOTE See ISO 14121-1:2007, Clause 6.

5.3.1 General

The objective of hazard identification is to produce a list of hazards, hazardous situations and hazardous events that allow 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 14121-1:2007, Annex A, which can be used as a generic checklist. Other sources for hazard identification could be based on the information indicated in ISO 14121-1:2007, 4.2.

NOTE 1 A.2 gives an example hazard identification using forms.

It is useful for both hazard identification and anticipating protective measures to reference any standards that are relevant to a specific hazard or specific type of machinery.

NOTE 2 An example of a standard relevant to specific hazards is IEC 60204-1, which deals with electrical hazards.

NOTE 3 Examples of machinery-specific standards are ISO 10218, related to safety of 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 possible, taking into account the relevant aspects described in ISO 14121-1:2007, 7.3.

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, all modes of operation, all functions and all 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):

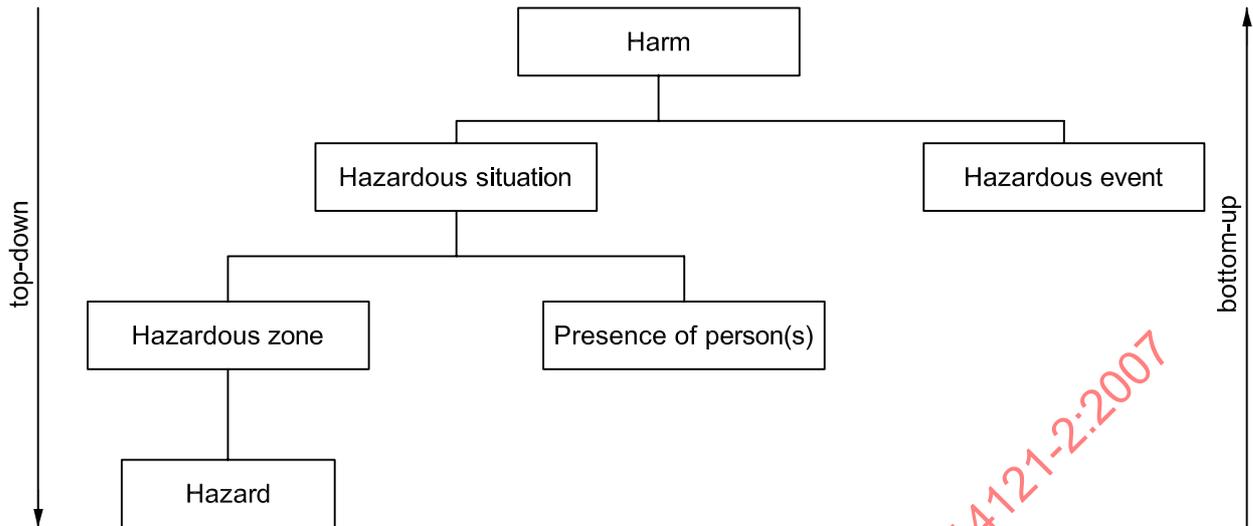


Figure 1 — Top-down and bottom-up approaches

A *top-down approach* is one that takes as its starting point a check-list of potential consequences (e.g. cutting, crushing, hearing loss — see potential consequences in ISO 14121-1:2007, Tables A.1 and A.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 cannot be complete. An inexperienced team will not necessarily appreciate this. Therefore, checklists should not be interpreted as exhaustive, but should encourage creative thinking beyond the list.

The *bottom-up approach* starts by examining all the hazards and considering all possible ways that something can go wrong in a defined hazardous situation (e.g. failure of component, human error, malfunction or unexpected action of the machinery) and how this can lead to harm. See ISO 14121-1:2007, Tables A.1 and A.2. The bottom-up approach can be more comprehensive and thorough than the top-down approach but can also be prohibitively time-consuming.

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 perform that expose them to a hazard;
- c) how the hazardous situation can lead to harm as a result of a hazardous event or prolonged exposure.

Sometimes, at this stage of the risk assessment process the following information can also be anticipated and usefully recorded:

- d) the nature and severity of the harm (consequences) in machinery-specific (e.g. fingers crushed by down-stroke of press when adjusting workpiece) rather than generic (e.g. crushing) terms;
- e) existing protective measures and their effectiveness.

5.3.4 Creative thinking

Detailed considerations of probabilities, severity of consequences or design of protective measures discourage creative thinking at this phase of the risk assessment process. This should be done later during risk estimation, evaluation and reduction.

5.3.5 Example of a tool for hazard identification

For more detail of application in practice, see the worked example in A.2.

5.4 Risk estimation

NOTE See ISO 14121-1:2007, Clause 7.

5.4.1 General

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 14121-1:2007, Figure 2) is to determine the highest risk arising from each hazardous situation or accident scenario. The estimated risk is generally expressed as a level, index or score.

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 14121-1:2007, 7.2.2.

Each hazardous event has the potential to result in several different severities of harm. However, in general, tools use only one entry for the severity of the potential harm for each hazard, so that the analyst(s) will have to choose the one that gives the highest risk. It is important to consider the worst severity of harm that can realistically occur. However, the probability of the worst credible severity of harm can be several orders of magnitude lower than the probability of a more realistic but lower severity of harm.

Moreover, choosing just one severity of harm to be considered is not always easy. The most severe can be very improbable and the most probable inconsequential, so that using either will lead to an inappropriate estimation of risk. For example, it is almost always credible that death will be the worst severity of harm: a simple cut can kill if it becomes septic or severs an artery; nevertheless, despite the probability of a cut being high, death is 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, e.g. 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 approaches described in Annex B.

5.4.3 Probability of occurrence of harm

NOTE See ISO 14121-1:2007, 7.2.3.

5.4.3.1 General

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

- a) exposure of person(s) to the hazard (see ISO 14121-1:2007, 7.2.3.2),

- b) probability of occurrence of a hazardous event (see ISO 14121-1:2007, 7.2.3.3), and
 c) technical and human possibilities to avoid or limit the harm (see ISO 14121-1:2007, 7.2.3.4).

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 14121-1:2007, 7.3, should also be considered.

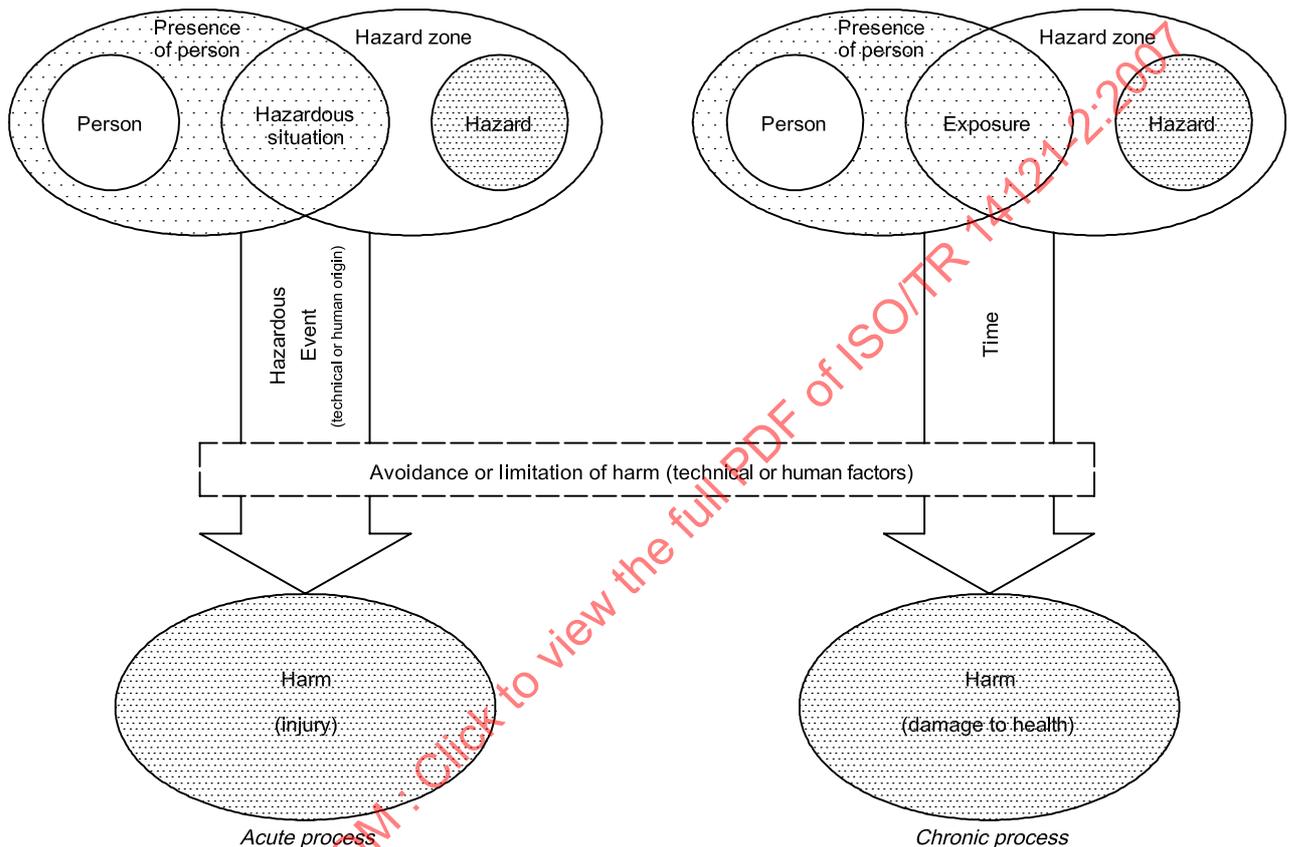


Figure 2 — Conditions of occurrence of harm

5.4.3.2 Probability of occurrence of cumulative harm (health aspects)

Hazardous situations that lead to harm due to a cumulative exposure over a period of time (such as dermatitis, occupational asthma, deafness or repetitive strain injury) need to be handled differently from those that lead to acute sudden harm (such as cuts, broken bones, amputations or short term respiratory problems).

The probability of occurrence of harm is dependent on the cumulative exposure to the hazard. Therefore, exceeding a certain level or rate of hazardous exposure, above which a cumulative exposure can result in damage to health, can be considered a hazardous event.

Total dose can be made up of a number of exposures, of different durations and associated doses. For example:

- for respiratory harm, the dose is dependent on the concentration of the substance;

- for hearing loss, it is dependent on the noise levels;
- for repetitive strain injuries, it is dependent on the strain involved and the repetitiveness of the action.

The difference between harm caused suddenly and harm caused by prolonged exposure can be illustrated by two different causes of lower back injury. The first can be caused immediately on picking up a load that is too heavy. The second can be caused by repeatedly handling relatively light loads.

5.4.4 Risk estimation tools

5.4.4.1 General

In order to support a risk estimation process, a risk estimation tool can be selected and used. Most of the available risk estimation tools use one of the following methods:

- risk matrix;
- risk graph;
- numerical scoring;
- quantified risk estimation.

There are also hybrid tools that use a combination of methods.

The choice of a specific risk estimation tool is less important than the process itself. The benefit of risk assessment comes from the discipline of the process rather than in the absolute precision of the results, as long as all the elements of risk according to ISO 14121-1:2007, 7.2 are fully considered. Moreover, resources are better directed at risk reduction efforts rather than towards an attempt to achieve absolute precision in risk estimation.

Any risk estimation tool, either qualitative or quantitative, should deal with at least two parameters representing the elements of risk. One of these parameters is severity of harm (see 5.4.2); though in relation to some tools, this is referred to as the frequency or likelihood of that harm. The other parameter is the probability of occurrence of that harm (see 5.4.3).

Some tools or methods break the two elements down into parameters such as exposure, probability of occurrence of the hazardous event and the individual's possibility to avoid or limit the harm (see ISO 14121-1:2007, 7.2).

For a specific risk estimation tool, one class for each parameter is chosen that best corresponds to the hazardous situation/hazardous event (i.e. accident scenario). The chosen classes are then combined, using simple arithmetic, tables, charts or diagrams in order to estimate the risk.

Quantitative tools are used to estimate the frequency (e.g. per year) or probability (over a specified time period) of the occurrence of a specific severity of harm.

Generally, designers can only establish that risk has been reduced as far as practicable or that the objectives of risk reduction have been achieved.

5.4.4.2 Risk matrices

A risk matrix is a multidimensional table allowing the combination of any class of severity of harm (see 5.4.2) with any class of probability of occurrence of that harm (see 5.4.3). The more common matrices are two-dimensional but a matrix can have as many as four dimensions.

The use of a risk matrix is simple. For each hazardous situation that has been identified, one class for each parameter is selected on the basis of the definitions given. The content of the cell where the columns and rows corresponding to each selected class intersect gives the estimated risk level for the identified hazardous situation. This can be expressed as an index (e.g. from 1 to 6, or A to D) or a qualitative term such as "low", "medium", "high", or similar.

The number of cells can vary widely from very small (e.g. four cells) to quite large (e.g. 36 cells). Cells can be grouped to reduce the number of classifications of risk. A classification using too-few cells is not helpful when deciding whether protective measures provide adequate risk reduction. Too many cells can make the matrix confusing to use.

There are many different matrices for estimating risk. An example is given in A.3.

5.4.4.3 Risk graphs

A risk graph is based on a decision tree. Each node in the graph represents a parameter of risk (severity, probability of occurrence, etc.) and each branch from a node represents a class of the parameter (e.g. slight severity or serious severity).

For each hazardous situation, a class should be allocated to each parameter. The path on the risk graph is then followed from the starting point. At each joint, the path proceeds on the appropriate branch in accordance with the selected class. The final branch points to the level or index of risk associated with the combination of classes (branches) that have been chosen. The end result is a level or index of risk qualified by terms such as "high", "medium", "low", a number, e.g. 1 to 6, or a letter, e.g. A to F.

Risk graphs are useful for illustrating the amount of risk reduction provided by a protective measure and by the parameter of risk it influences.

Risk graphs become very cumbersome and cluttered if there are more than two branches for more than one of the parameters of risk. For this reason, hybrid methods tend to combine a risk graph with a matrix for one of the parameters, see 5.4.4.6.

An example of a risk graph is given in A.4.

5.4.4.4 Numerical scoring

Numerical scoring tools have two to four parameters that are broken down into a number of classes in much the same way as risk matrices and risk graphs. However, different numerical values, which can range from 1 to 20, are associated with the classes instead of a qualitative term. A class is chosen for each parameter and the associated values (or scores) are then combined (e.g. by addition and/or multiplication) to give a numerical score for the estimated risk. In some instances, these assigned values are represented in table(s), so their use is very similar to that of a matrix (see 5.4.4.2).

Scoring systems allow parameters to be easily and explicitly weighted. The use of numbers can give an impression of objectivity in the risk level even though the allocation of scores for each element of risk is highly subjective. However, this can be counteracted by grouping the scores into qualitative classifications of risk such as high, medium and low.

There are many different numerical scoring tools used to estimate risk. An example is given in A.5.

5.4.4.5 Quantified risk estimation

All the above methods are qualitative in nature. Although numbers are used with some tools and others express risk levels numerically, their nature is essentially qualitative. There are no common reference data and a numerical risk level estimated using one tool cannot directly be compared to one estimated using another.

Quantified risk estimation consists of the mathematical calculation, as accurately as possible with the data available, of the probability of a specific outcome occurring during a specific duration of time. Risk is often expressed as the annual frequency of the death of an individual. Quantified risk estimation allows the

calculated risk to be compared with criteria that can be related back to an actual number of deaths per year or accident statistics. It allows risk reduction measures to be evaluated in terms of by how much they reduce the risk so that the most cost-effective solution can be chosen. Unlike qualitative methods that estimate the risk from each hazardous situation separately, quantified risk estimation is generally used to estimate the total risk from all sources to an individual.

At the time of writing this part of ISO 14121, health statistics reports provide quantified estimates of risk for machine-related harm in a very generalized way. Typically, these sources give information on total injuries on a machine type over a specific period of time. However, if performed correctly, quantified risk estimation ensures a very comprehensive analysis leading to a clear understanding of exactly how a hazardous situation can develop leading to harm. This can generate more ideas for risk reduction options, and ensure that protective measures are selected with a full understanding of how harm can occur. Quantified risk estimation also allows for numerical risk comparisons to be made between one protective measure and another when all other variables are equal.

Quantified risk estimation is very resource-intensive and requires considerable skill to be conducted successfully. It requires a detailed and comprehensive model of the chain of events that lead to the defined outcome and is dependent on the quality of data for base events such as the failure of a piece of equipment or the probability of human error. Quantified risk estimation can be subjective and prone to error.

The use of small numbers to express risk such as $1,54 \times 10^{-4}$ can give the impression of high precision, whereas in fact there can be considerable uncertainty in the data that have been used to calculate the risk. This can be an order of magnitude or more, so that it is not sensible to express risk using more than one significant figure.

To reduce some of the burden of starting with a blank sheet of paper, and in order to improve consistency, eliminate some of the subjectivity and to reduce error, guided quantified risk estimation methods are available. An example of a guided quantified tool is given in A.6.

5.4.4.6 Hybrids

Hybrid tools exist that combine two of the approaches described above. Commonly, these are risk graphs that contain within them either matrices or scoring systems for one of the elements of risk. A certain amount of quantification can also be incorporated into any of the qualitative approaches, including by giving frequency ranges to probabilities or exposures. For example, something that is "likely" can be expressed as being once a year, and a "high" exposure can be specified as being hourly.

An example of a hybrid tool is given in A.7.

5.5 Risk evaluation

NOTE See ISO 14121-1:2007, Clause 8.

The objectives of risk evaluation are

- to decide which, if any, hazardous situations require further risk reduction, and
- to determine whether the required risk reduction has been achieved without introducing further hazards or increasing other risks.

Some hazardous situations can be recorded as being excluded from further consideration due to having an extremely low (trivial) risk. Those that pose a significant risk should be reduced in accordance with ISO 12100. For those hazardous situations that pose a high risk, a more detailed risk estimation can be useful.

If relevant machinery-specific or hazard-specific standards exist (e.g. IEC 60204-1, which deals with electrical hazards), part of the risk evaluation could consist of ensuring that compliance with the standard is achieved, taking into account any limitations of the protective measures relevant to the machinery being assessed.

As part of the process of risk evaluation, the risks associated with the machinery or parts of the machinery can be compared with relevant International Standards.

For example:

- risk reduction by inherently safe design, ISO 12100-2;
- safeguarding of electrical equipment, IEC 60204-1;
- control circuit architecture, ISO 13849-1;
- safety reach distances, ISO 13852;
- temperatures of touchable surfaces, ISO 13732-1;
- machine-specific standards, e.g. textile machinery series ISO 11111.

As a general rule, the estimated risk is only one input to the decision to stop the iterative process of risk reduction. This decision should include other considerations such as regulations, laws, work organization and practices, technical limits and economics. See ISO 14121-1:2007, 8.2.

Care should be taken that simple and effective measures for reducing relatively low risks are not overlooked due to an exclusive focus on the highest risks.

6 Risk reduction

NOTE See ISO 14121-1:2007, 8.2 and ISO 12100-2.

6.1 General

Risk reduction is achieved by implementing protective measures in accordance with ISO 12100 by incorporating recommendations developed during risk assessment. During risk reduction, decisions are made regarding what needs to be done, by whom, when and at what cost.

The relative effectiveness of various protective measures to reduce risk is illustrated in Table 1, which describes the decision process (see also ISO 12100-1:2003, 5.4).

Table 1 — Effectiveness of various protective measures to reduce risk

Preferred action	Priority ^a	Alternative
Elimination of the hazard	1	Reduction of the severity of the possible harm related to the hazard
Elimination of the hazardous situation, i.e. exposure of the person to the hazard	2	Reduction of the frequency and/or duration of exposure
Elimination of possible hazardous events	3	Reduction in the probability of occurrence of possible hazardous events
Implementation of means to avoid harm	4	Implementation of means to limit harm
^a 1 is the highest priority.		

Different types of protective measure, in order of effectiveness, are given below. Explanations are provided as to their influence on the reduction of a particular risk element.

NOTE This information is provided for illustrative purposes only. It is not comprehensive. For more information, see ISO 12100-2.

6.2 Elimination of hazards by design

NOTE See ISO 12100-1:2003, Clause 4.

The first step in the risk reduction process is the elimination of the hazard by design. Eliminating hazards by design is the most effective method for reducing risk because it removes the source of harm. The following are examples of methods for elimination of the hazard:

- substitution of hazardous materials and substances;
- modification of physical features (e.g. elimination of sharp edges and shear points);
- elimination of repetitive activities and harmful postures.

6.3 Risk reduction by design

If hazards cannot be eliminated by design, risk should be reduced by means of design features or the individual's interaction with the machine itself.

Examples of methods for risk reduction by design whose greatest effect is on the severity of harm are:

- reducing energy (e.g. smaller force, lower hydraulic/pneumatic pressure, reduced working height, reduced speed);
- utilizing technical safety equipment to prevent/reduce a hazard (e.g. a ventilation system prevents explosions/reduces hazardous vapours).

Examples of methods for risk reduction by design whose greatest effect is on exposure to the hazard are:

- reducing the need to be in a hazardous situation (limiting exposure to hazards through mechanization or automation of loading/unloading or feeding/removal operations; location of the setting and maintenance points outside of danger zones);
- relocating the source(s) of harm.

Examples of methods for risk reduction by design whose greatest effect is on the occurrence of hazardous event(s) are:

- improving of reliability of components of the machine (mechanical, electrical/electronic, hydraulic/pneumatic components);
- applying safe design measures to safety related parts of control systems (basic safety principles, well-tried safety principles and/or components, redundancy).

6.4 Safeguarding

If hazards cannot be eliminated or risks reduced adequately by design measures, safeguarding (guards and protective measures) should be applied that result in restricting exposure to hazards, lowering the probability of the hazardous event, or improving the possibility of avoiding or limiting harm.

When risk is reduced with the use of safeguards such as those listed under a) and b) below, there is little, if any, impact on the severity of harm. The greatest impact is on exposure (as long as the guard is being used as intended and is functioning properly) (see ISO 12100-2:2003, 5.2 to 5.4):

- a) fixed guards, fencing or enclosures for the prevention of access to hazard zones;
- b) interlocking guards preventing access to hazardous areas (e.g. interlocks with or without guard locking, interlock keys).

When risk is reduced with the use of safeguards such as those listed under c), d) and e) below, there is little, if any, impact on the severity of harm. The greatest impact is on the occurrence of a hazardous event, with little impact on exposure:

- c) sensitive protective equipment (SPE) for the detection of persons entering into, or present in, the hazard zone (e.g. light curtains, pressure sensitive mats);
- d) devices associated with safety-related functions of the control system of the machine (e.g. enabling device, limited movement control device, hold-to-run control device);
- e) limiting devices (e.g. overloading and moment limiting devices, devices for limiting pressure or temperature, over-speed switches, devices for monitoring emissions).

6.5 Complementary protective measures

When design measures or safeguarding do not meet risk reduction objectives, complementary protective measures can be utilized to achieve further risk reduction. Examples of complementary protective measures whose greatest effect is on the ability to avoid or limit harm are:

- emergency stop (see ISO 12100-2:2003, 5.5.2);
- measures for the escape and rescue of trapped individuals (see ISO 12100-2:2003, 5.5.3);
- measures for safe access to machinery (see ISO 12100-2:2003, 5.5.6);
- provisions for easy and safe handling of machines and their heavy component parts (see ISO 12100-2:2003, 4.8.3).

Complementary protective measures whose greatest effect is on exposure are measures for isolation and energy dissipation (e.g. isolation valves or switches, locking devices, mechanical blocks to prevent movement), for example.

6.6 Information for use

NOTE See ISO 12100-1:2003, Clause 6.

6.6.1 General

The supplier should warn the user in the information for use about the risks that remain after risk reduction by design and safeguarding.

Information for use includes the following:

- information provided on the machine;
- documentation provided with the machine.

6.6.2 Information provided on the machine

Information for use provided on the machine includes the following:

- a) warning signs (pictograms);
- b) markings and labels for safe use (e.g. maximum speed of rotating parts, maximum working load, guard adjustment data, colour code);
- c) audible or visual signals (e.g. horns, bells, whistles, lights);

- d) other warning devices (e.g. awareness barriers, vibration).

Information for use only impacts the ability to avoid the harm.

6.6.3 Documentation provided with the machine

Documentation provided with the machine includes the following:

- a) instruction handbooks;
- b) technical data sheets.

6.7 Training

The supplier should give details in the instruction handbook of any training necessary to ensure that individuals know how to correctly use the machinery and apply any protective measure. Training and competency is most important when the effectiveness of the protective measure depends on human behaviour. Training should include, but not be limited to, the following:

- information for use provided with the machinery;
- information for use developed by the user;
- specialized training provided by the supplier, if available;
- specialized training provided by the user.

Regular review and checking of the effectiveness of training can be necessary to ensure its long-term effectiveness. Training and enforcement of correct behaviour is also essential. Training mainly has an impact on the ability of individuals to avoid harm and can also reduce exposure and the probability of the occurrence of a hazardous event.

6.8 Personal protective equipment

The supplier should give details in the instruction handbook of any personal protective equipment to be used to protect individuals from the hazards associated with the residual risk. Examples of common uses of personal protective equipment are:

- hearing protection;
- safety glasses/goggles;
- face shields;
- respirators;
- gloves;
- protective clothing (e.g. resistant to heat, chemical splashes, cutting);
- hard hat.

The reliability and maintenance of the personal protective equipment is very important for ensuring its long-term efficiency. Training and enforcement of correct use is also essential. The selection of any personal protective equipment should be made carefully, preferably in consultation with the person(s) to be protected, taking into consideration their needs in terms of protection, comfort, duration and frequency of use, and ability to follow their working methods, etc.

Personal protective equipment impacts the ability to avoid or limit harm.

6.9 Standard operating procedures

The supplier should give details in the instruction handbook of any standard operating procedures (SOP) that the user is to adopt in order to operate or maintain the machine. These procedures could include the following:

- work planning and organization;
- clarification/harmonization of tasks, authority, responsibilities;
- supervision;
- lock-out procedures;
- safe operating methods and procedures.

NOTE When risk reduction is provided by organizational measures, it is important to ensure, as far as possible, that they are followed and cannot be circumvented.

7 Risk assessment iteration

NOTE See ISO 12100-1:2003, 5.5.

Once protective measures have been incorporated, in order to reduce risk, all stages of risk assessment should be repeated to check whether:

- there are any changes to the limits of the machinery;
- any new hazards or hazardous situations have been introduced;
- risks from any existing hazardous situations have been increased;
- the protective measures reduce risk sufficiently;
- any additional protective measures are required;
- risk reduction objectives have been achieved.

Risk assessment iteration should be carried out taking into account the reliability, ease of use, possibility of defeating or circumventing the protective measures, and the ability to maintain them in accordance with ISO 14121-1:2007, 7.3.5, 7.3.6 and 7.3.7. Consideration should be given to the possibility of persons taking the protective measure for granted and not being prepared should it fail. This is particularly relevant for interlocks and light curtains.

8 Documentation of the risk assessment

NOTE See ISO 14121-1:2007, Clause 9.

Written records of all risk assessments should be made and retained. These should not be confused with the information for use of the machine provided by the supplier to the user. However, the risk assessment documentation can be a useful reference when writing the information for use.

It is important that the process be properly documented in order to allow examination of decisions at a later date by others who have not been directly involved in the risk assessment. This documentation should record the results of the assessment in accordance with ISO 14121-1:2007, Clause 9. It should include a description of the method(s) and tool(s) that have been used to conduct the assessment and copies of completed record sheets. Figures (photographs, diagrams, drawings, etc.) of the machinery including hazard zones, hazards and applied protective measures are useful.

When documenting protective measures that have been implemented, a description of those measures that are needed to ensure that they remain effective should be included (e.g. maintenance, periodic user inspection).

See Annex B for an example of a risk assessment and the risk reduction process.

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Annex A (informative)

Examples of methods for several steps of the risk assessment process

A.1 General

This annex includes examples of methods that can be applied during the risk assessment process. They are not the only tools available and their inclusion in this part of ISO 14121 does not indicate that they are approved or recommended above any others that are in accordance with ISO 14121-1.

These examples do not cover all possible situations, as actual situations vary from facility to facility. The choice made by the individuals performing the risk assessment is influenced by many different factors and can lead to different results.

These examples are provided to illustrate to the user of this part of ISO 14121 how an actual hazard identification or a risk estimation can look when a particular method is selected.

The examples given are for the following:

- a) hazard identification by application of forms (see A.2);
- b) risk matrices (see A.3);
- c) risk graphs (see A.4);
- d) numerical scoring (see A.5);
- e) quantified risk estimation (see A.6);
- f) hybrids (see A.7).

For particular hazards related to long-term harm (e.g. those generated by noise, materials and substances, vibration, radiation or related to ergonomics) or with very high effects (e.g. fire or an explosion), it could be appropriate to take into account specific risk estimation methods.

Risk assessments are not scientific exercises; therefore, resources are best spent on risk reduction efforts rather than the optimizing of risk ratings.

NOTE These examples only illustrate how such methods/tools could look and be used. They are not a comprehensive user guide to fully developed methods.

A.2 Hazard identification by application of forms

A.2.1 General

The aim of this clause is to show a method for hazard identification (see 5.3 and ISO 14121-1:2007, Clause 6) using as the main tool the checklists defined in ISO 14121-1:2007, A.2 to A.4.

These checklists cannot be considered complete. They should rather 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 involving similar machinery.

The method will be more effective the more complete and detailed the available information for risk assessment (see ISO 14121-1:2007, 4.2) and the determination of the limits of the machinery (see 5.2 and ISO 14121-1:2007, Clause 5).

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

A.2.2 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, e.g. 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 14121-1:2007, Table A.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 accident scenarios. This can be done 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, use ISO 14121-1:2007, Table A.1, for the description of origins of hazards, ISO 14121-1:2007, Table A.3, for the description of hazardous situations, and ISO 14121-1:2007, Table A.4, for the description of hazardous events.

A.2.3 Documentation

The form given as Table A.1 can be used to document the results of this hazard identification.

A.2.4 Application

A.2.4.1 General

This is an example of the application of the method described in A.2.2 to a punching press, operated by a pedal and manually loaded and unloaded (see Figure A.1), at the early design stage.



Figure A.1 — Hazard zone of a punching press (without any protective measures)

Table A.1 — Example of a form for hazard identification

Hazard identification			
Machine (identification)	Method/tool	Analyst	
Sources (e.g. preliminary design documentation, technical file, construction file)	Current version		
Extent (e.g. — phase of the life cycle, — part/function of the machine)	Date		
Ref. no.	Hazard zone	Task/operation (ISO 14121-1:2007, Table A.3)	Hazard (ISO 14121-1:2007, Table A.1)
		Accident scenario	
		Hazardous situation (ISO 14121-1:2007, Table A.3)	Hazardous event (ISO 14121-1:2007, Table A.4)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

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A.2.4.2 Extent of the system to be analysed

This example deals only with the hazard identification related to the operation phase of the machine at the hazard zone. It does not cover other phases of the life cycle of the machine, such as assembly, setting, maintenance or fault finding (see ISO 14121-1:2007, Table A.3).

A.2.4.3 Tasks/operations to be performed

During the operation phase of the punching press the following tasks are performed:

- a) manual loading and unloading of workpieces;
- b) positioning of workpieces;
- c) holding of workpieces during punching;
- d) minor interventions (remove waste materials and lubrication of the tool).

A.2.4.4 Relevant hazards and accident scenarios

For each of the defined tasks, by using the "hazards" column of ISO 14121-1:2007, Table A.1, and applying a bottom-up approach, all the possible origins of hazards are checked and those that are relevant are identified. For each relevant hazard, all combinations of hazardous situations and hazardous events are examined using the lists given ISO 14121-1:2007, Tables A.3 and A.4.

A.2.4.5 Results of the hazard identification

The results of the first step of this examination are documented in Table A.2.

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Table A.2 — Example of a completed form for hazard identification

Machine		Hazard identification			
Punching press		Method/tool	Checklists — ISO 14121-1:2007, Annex A		
Sources		Analyst	<Name>		
		Current version	V 1		
Extent (e.g. — phase of the life cycle, — part/function of the machine)		Date	20/05/05		
Operation		Punching function			
Punching function					
Ref. no.	Hazard zone	Task/operation	Hazard	Accident scenario	Hazardous event
1		Manual loading/unloading and positioning of the workpiece	Falling objects (workpieces) <i>Crushing (foot or fingers)</i>	Handling heavy workpieces with both hands	Falling of a workpiece
2			Sharp edges (workpieces) <i>Cutting</i>	Handling workpieces with sharp edges with both hands	Contact with sharp edges and corners of workpieces
3		Manual holding of the workpiece with both hands during punching	Moving elements (downward and upward movement of the punch and upward movement of the workpiece) <i>Crushing, severing and puncture</i>	Work near moving parts	Access to contact with moving parts due to an absence of guard or protective device
4	Puncturing zone		Moving elements (ejection of tool parts or workpiece parts) <i>Impact</i>	Operator and other people exposed to ejection of parts	Break-up of the punch or the workpiece (by several causes such as inadequate punch, punch fatigue or ageing or fragility, inadequate workpiece material)
5			Noisy manufacturing process (impact noise) <i>Discomfort</i>	Operator and other people exposed to hazards generated by noise	Emission of a level of noise that can be hazardous
6			Parts which have become live under faulty conditions <i>Electric shock</i>	Work with a machine under voltage	Indirect contact
7		Minor interventions during operation (removing waste material and lubrication of the tool)	Moving elements (downward and upward movement of the punch and upward movement of the workpiece) <i>Crushing, severing and puncture</i>	Work under powered actuators (cylinder-tool)	Human errors in the work procedure (use a cloth instead of a container with a long neck/spout for manual tool lubrication) and unexpected/unintended start-up

A.3 Risk assessment using a risk matrix

A.3.1 General

The risk matrix is applied after hazards have been identified (see ISO 14121-1:2007, Clause 6) and is used to assess risks associated with the identified hazards (see ISO 14121-1:2007, Clauses 7 and 8). A risk matrix can be used to assess risks of machinery, equipment, facilities or other situations in many industries.

The primary use of a risk matrix is to help identify risks that are unacceptably high so that risk reduction efforts can focus on these areas. The risk matrix is basically used to rank or group risks into risk levels so that decisions can be made about risk acceptability.

A risk matrix approach provides a simple, quick and effective method to derive a risk level for a hazard. The risk matrix approach is subjective; it relies on the good judgement of the persons assessing the risk. Therefore, this approach works best with a team of persons who are knowledgeable of, and experienced in, the tasks and machinery/equipment/facility being assessed (see 4.2).

The risk matrix method excels in simplicity and speed in both learning and using. However, it does not provide great precision or repeatability due to the subjective nature of the method. Persons wanting greater precision in ratings may prefer other methods. Note that greater precision typically requires more time to learn and to complete, and can result in different risk reduction measures.

A.3.2 Description of the tool or method

A.3.2.1 General

There are four steps to the risk matrix approach as follows.

A.3.2.2 Selection of a risk matrix

Risk matrices have been used for many years, and many different variations exist. Two examples are shown in Tables A.3 and A.4, in which different risk matrices use different levels for each risk factor — for example, Table A.3 has four levels of probability whereas Table A.4 has six. Levels usually range from three to up to ten, with four or five being the most common.

Table A.3 — Risk estimation matrix according to ANSI B11 TR3:2000

Probability of occurrence of harm	Severity of harm			
	Catastrophic	Serious	Moderate	Minor
Very likely	high	high	high	medium
Likely	high	high	medium	low
Unlikely	medium	medium	low	negligible
Remote	low	low	negligible	negligible

Table A.4 — Risk matrix according to IEC 61508

Frequency	Consequences			
	Catastrophic	Critical	Marginal	Negligible
Frequent	I	I	I	II
Probable	I	I	II	III
Occasional	I	II	III	III
Remote	II	III	III	IV
Improbable	III	III	IV	IV
Incredible	IV	IV	IV	IV

A.3.2.3 Assessment of severity

For each hazard or hazardous situation (task), the severity of harm or consequences that could result should be assessed. Historical data can be of great value as a baseline. Severity is often assessed as personal injury, although it can include other elements such as the following:

- the number of fatalities, injuries or illnesses;
- the value of property or equipment damaged;
- the time for which productivity will be lost;
- the extent of environmental damage;
- other factors.

Assessing severity can be accomplished using the selected risk matrix. As an example, the severity levels in Table A.3:

- **catastrophic** — death or permanent disabling injury or illness (unable to return to work);
- **serious** — severe debilitating injury or illness (able to return to work at some point);
- **moderate** — significant injury or illness requiring more than first aid (able to return to same job);
- **minor** — no injury or slight injury requiring no more than first aid (little or no lost work time).

Assessing severity usually focuses on the worst credible consequence rather than the worst conceivable consequence.

A.3.2.4 Assessment of probability

For each hazard or hazardous situation (task), the probability of occurrence of harm should be assessed. Unless empirical data are available, which would be rare, the process of selecting the probability of an incident occurring will again be subjective. For this reason, brainstorming with knowledgeable people is advantageous.

When estimating probability, the highest credible level of probability should be selected. Estimating probability should include the following:

- frequency and duration of exposure to a hazard;
- personnel who perform the tasks;
- machine/task history;
- workplace environment;
- human factors;
- reliability of safety functions;
- possibility to defeat or circumvent protective measures;
- ability to maintain protective measures;
- ability to avoid harm.

As with severity, there are many scales used to assess the probability of occurrence of harm. Some methods do not provide descriptions other than the terms used (see Table A.4). Other matrices provide additional descriptions as in Table A.3:

- **very likely** — near certain to occur;
- **likely** — can occur;
- **unlikely** — not likely to occur;
- **remote** — so unlikely as to be near zero.

In some methods, a distinction is drawn between probability and likelihood, where probability is a numerical value between 0 and 1 and likelihood a qualitative description of probability. However, many methods do not distinguish between probability and likelihood and use the two terms synonymously.

Probability should be related to an interval base of some sort, such as a unit of time or activity, events, units produced, or the life cycle of a facility, equipment, process or product. The unit of time can be the useful life of the machine.

A.3.2.5 Derivation of the risk level

Once the severity and probability are assessed, an initial risk level can be derived from the selected risk matrix. The risk matrix maps the risk factors to risk levels as shown in Tables A.3 and A.4

Using Table A.3 as an example, a “serious” severity and “likely” probability yields a “high” risk level. How the risk factors of severity and probability are combined varies with different risk matrices. The result of this evaluation will typically yield an array of low to high risks. Since the risk assessment process is usually subjective, the risk levels will also be subjective.

In many instances, the risk acceptability decision is left to the user, since the decision is culture-, situation- and/or time-dependent.

A.3.3 Application

A.3.3.1 Description of wood-working mill example

Figure A.2 shows a sawing operation in a woodworking mill. The sawyers pick up pieces of lumber from the conveyor on their left, cut out knots using a foot-activated jump saw, and place the cut boards on the conveyor on their right.



Figure A.2 — Sawing operation in a woodworking mill

A.3.3.2 Result of the risk assessment

The tasks and hazards are shown in the first two columns of Table A.5. The initial and residual risk levels have been assessed using the matrix in Table A.3.

Table A.5 — Wood working mill example for risk assessment

User/task	Hazard	Initial assessment		Risk reduction methods	Residual assessment		Status
		Severity/probability	Risk level		Severity/probability	Risk level	
Sawyer/select boards from input conveyor	Mechanical: wood splinters	Minor/very likely	Medium	Gloves	Minor/unlikely	Negligible	Complete
	Ergonomics: repetition	Moderate/likely	Medium	Job rotation, scheduled rest periods, standard procedures	Minor/unlikely	Low	Ongoing
	Ergonomics: lifting/bending/twisting	Moderate/likely	Medium	Positioning of work station at height and location to minimize reach, job rotation	Moderate/likely	Medium	Complete
Sawyer/cut knots	Mechanical: cutting/severing from rotating blade	Catastrophic/likely	High	Fixed enclosures/barriers	Catastrophic/remote	Low	Complete
	Mechanical: wood splinters	Minor/very likely	Medium	Gloves	Minor/unlikely	Negligible	Complete
	Mechanical: flying particles	Moderate/likely	Medium	Safety glasses	Moderate/remote	Negligible	Complete
	Ergonomics: repetition	Moderate/likely	Medium	Job rotation, scheduled rest periods, standard procedures	Minor/unlikely	Low	Ongoing
Sawyer/place boards on output conveyor	Noise: noise/sound levels > 85 dBA	Serious/very likely	High	Hearing protection	Serious/unlikely	Medium	Ongoing
	Mechanical: wood splinters	Minor/very likely	Medium	Gloves	Minor/unlikely	Negligible	Complete
	Ergonomics: push/pull load	Minor/unlikely	Negligible	Minimal lifting required due to guide bar. Sawyer only slides board.	Minor/unlikely	Negligible	Complete

A.3.3.3 Discussion

As shown in the example, the risk matrix method provides a simple and efficient means of assessing risk. The risk matrix can be applied to assess a single task on a specific machine, or for assessing the many tasks on an entire manufacturing process. The risk matrix method can also be used to assess consumer or industrial products.

The best approach for a particular company is to find the risk assessment method that works well in its organizational culture and design processes. Industry standards or guidelines should be considered a starting point. As long as any one risk assessment method is selected, validated, and adequately integrated into the organization, there is no “wrong” method.

A.4 Risk assessment using risk graph

A.4.1 General

This example is a method for hazard identification and risk estimation using a risk graph.

It is not the intention here to either explain in detail how the form is filled in nor to justify the way this tool has been developed. Training is required to become competent in the use of this method for risk assessment.

This example presents the application of the method to a paper trimmer press, already installed. Risk has been estimated twice: once before protective measures have been chosen and a second time after they have been implemented.

A.4.2 Description of the tool or method

Before the risk is estimated using the risk graph, the associated hazard, hazardous situation, hazardous event and possible harm is described in accordance with ISO 14121-1:2007, 5.3. A risk index is then calculated using the risk graph given in Figure A.3, based on the following four parameters, corresponding to the four elements of risk as defined in ISO 14121-1:2007, 7.2.1, and each having its particular limits.

— **Severity of harm: S**

- 1) S1 slight injury (usually reversible), for example, scratches, laceration, bruising, light wound requiring first aid)
- 2) S2 serious injury (usually irreversible, including fatality), for example, broken or torn-out or crushed limbs, fractures, serious injuries requiring stitches, major musculoskeletal troubles (MST), fatalities.

— **Frequency and/or duration of exposure to hazard: F**

- 1) F1 twice or less per work shift or less than 15 min cumulated exposure per work shift.
- 2) F2 more than twice per work shift or more than 15 min cumulated exposure per work shift.

— **Probability of occurrence of the hazardous event: O**

- 1) O1 mature technology, proven and recognized in safety application; robustness.
- 2) O2 technical failure observed in the two last years:
 - inappropriate human action by a well-trained person aware of the risks and having more than six months experience on the work station.

3) O3 technical failure regularly observed (every six months or less):

- inappropriate human action by an untrained person having less than six months experience on the work station;
- similar accident observed in the plant in the preceding ten years.

— **Possibility of avoidance or reduction of harm: A**

1) A1 possible under some conditions:

- if parts move at a speed less than 0,25 m/s

AND the exposed worker is familiar with the risks and with the indications of a hazardous situation or impending hazardous event;

- depending on particular conditions (temperature, noise, ergonomics, etc.);

2) A2 impossible.

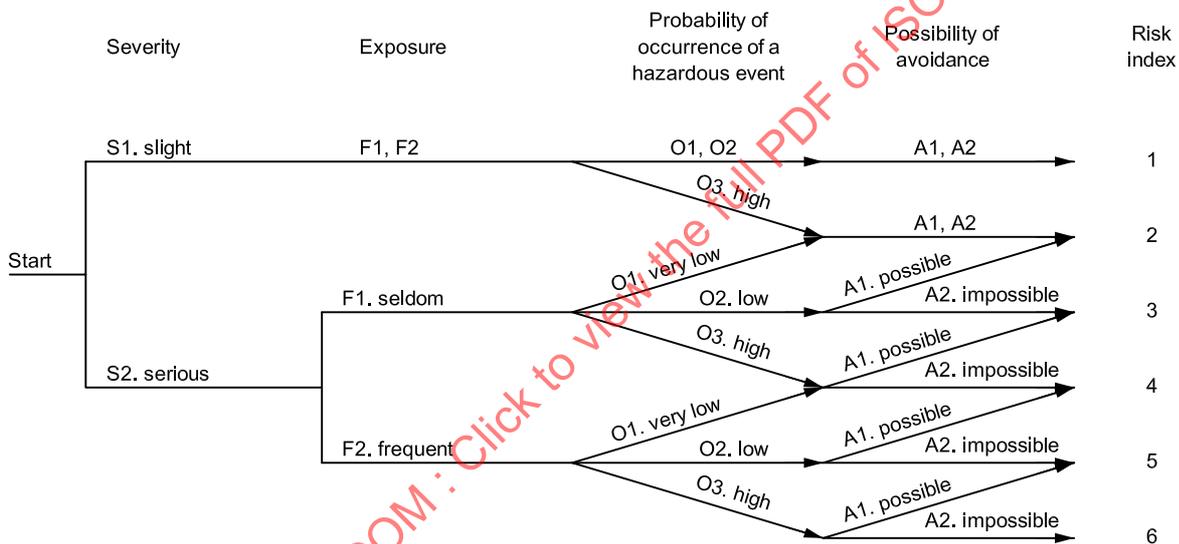


Figure A.3 — Risk graph for risk estimation

A form is filled in with the result of this first risk assessment; each hazardous situation is allocated a risk index.

In this example, the estimation of each hazardous situation is made with consideration given to the following:

- a risk index of 1 or 2 corresponds to the lowest priority of action (priority 3);
- a risk index of 3 or 4 corresponds to a medium priority of action (priority 2);
- and a risk index of 5 or 6 corresponds to the highest priority of action (priority 1).

Possible means of reducing risk are considered and the risk is then estimated for the final design using the same risk graph in the same manner as for the initial design. In this specific case, a risk index of 2 or less has been evaluated as representing the level at which no further risk reduction is required.

A.4.3 Application

A.4.3.1 Description of paper trimmer press example

This example presents the application of this method to a paper trimmer press, already installed.

The assessed working position is the feeding and cutting of a stack of paper with a paper trimmer press, powered by compressed air and electricity. Three basic tasks have been identified and analysed:

- positioning of the paper stack;
- pressure on the paper stack;
- paper cutting.

Figures A.4 and A.5 show a worker placing a stack of paper sheets before activating the cutting process.



Figure A.4 — Positioning stack of paper sheets

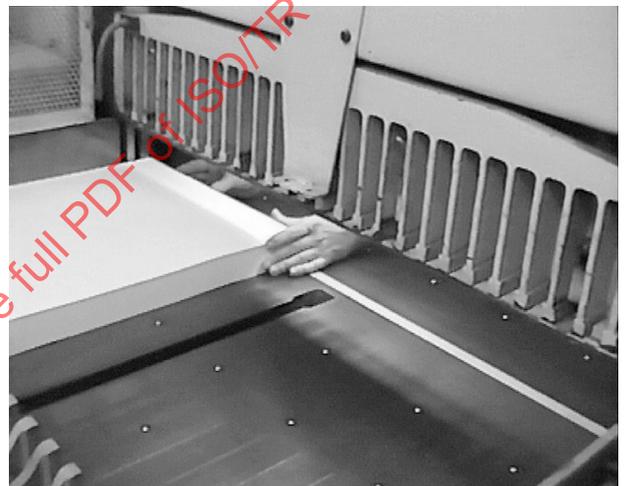


Figure A.5 — Worker's hand under cutter

A.4.3.2 Result of the risk assessment

Tables A.6 and A.7 show the results of the risk assessments. Table A.6 shows that of the initial risk analysis and Table A.7 the result of the residual risk analysis taking into account the protective measures. In some cases, several risk reduction means have been proposed in order to permit a selection.

In Table A.7, the values in bold indicate the changes introduced by the proposed protective measures.

Table A.6 — Results of initial risk analysis

Activity		Initial risk analysis				Risk estimation			
		Hazardous conditions		Possible harm	Severity (S1/S2)	Frequency/ Exposure (F1/F2)	Probability of occurrence (O1/O2/O3)	Possibility of avoidance (A1/A2)	Risk index (1 to 6)
Solution	Activity	Hazard	Hazardous situation						
1		Electrical energy available	The worker is close to a conductive metallic body	Energized frame of the machine (failed connection, worn out cable, etc.)	Worker electrocution	2	2	2	5
1.1	Positioning of the paper stack	Energized press and knife in upper position	The worker's hands are under energized mobile parts	Unexpected movement of the press or knife by action on the start pedal	Crushing, cutting of the upper limbs	2	2	2	5
—			The workers handle the paper stack	Movements of the hands on the cutting edges of the paper sheets					
1.2		Cutting edges of the paper	The workers handle the paper stack	Movements of the hands on the cutting edges of the paper sheets	Fingers or hands cut	1	2	3	2
2	Pressure on the paper stack	Vertical movement of the press (applied force of 1 000 N)	The worker holds the paper stack in position with his hands close to the press	Worker's hands under the press in movement triggered by the worker	Crushing of upper limbs	2	1	3	4
—			The worker's hands are close to the paper stack	Worker's hands under the press in movement triggered by failure of the control circuit					
3	Paper cutting	Vertical movement of the knife	The worker's hands are close to the paper stack	Worker's hands in the trajectory of the knife in movement triggered by the worker	Major cutting of upper limbs	2	1	3	4
—			The worker's hands are close to the paper stack	Worker's hands in the trajectory of the knife in movement triggered by failure of the control circuit					

Table A.7 — Results of residual risk analysis

Initial risk analysis results		Risk analysis after risk reduction						Remarks		
Solution	Activity	Hazard	Risk index (1 to 6)	Risk reduction	Severity (S1/S2)	Frequency/Exposure (F1/F2)	Probability of occurrence (O1/O2/O3)		Possibility of avoidance (A1/A2)	Risk index after risk reduction ^a
1a		Electrical energy available	5	Insulation and connections periodical check	Insulation and connections periodical check	2	1	2	4	No difference of risk index between 1a and 1b.
1b			5			Residual current sensing device	Residual current sensing device	2	2	
1.1a	Positioning of the paper stack	Press and knife in upper position under energy	5	Installation of a hood on the pedal	Installation of a hood on the pedal	2	1	2	4	No difference of risk index between 1.1a and 1.1b.
1.1b			5			Machine control circuit in accordance with ISO 13849-1	Machine control circuit in accordance with ISO 13849-1	2	1	
1.2		Cutting edges of the paper	2	Protective gloves ^b Reduce sharpness of the paper sheets	Protective gloves ^b	1	2	1	1	—

Table A.7 (continued)

Initial risk analysis results			Risk analysis after risk reduction					Remarks		
Solution	Activity	Hazard	Risk index (1 to 6)	Possible preventive measures	Selected protective measures	Severity (S1/S2)	Frequency/ Exposure (F1/F2)		Probability of occurrence (O1/O2/O3)	Possibility of avoidance (A1/A2)
2a			4	Triggering of the press movement by a two-hand control device and machine control circuit in accordance with ISO 13849-1	Triggering of the press movement by a two-hand control device and machine control circuit in accordance with ISO 13849-1	2	1	1	2	2
2b			4	Training	Training	2	1	2	2	3
2c	Pressure on the paper stack	Vertical movement of the press (applied force of 1 000 N)	3	Triggering of the press movement by a pedal control actuator with control circuit category in accordance with ISO 13849-1	Pedal control actuator with control circuit category in accordance with ISO 13849-1	2	1	1	2	2
2d			3	Reduce pressure before the press reaches the paper stack	Pedal control actuator with control circuit category in accordance with ISO 13849-1	1	1	1	2	1
3a	Paper cutting	Vertical movement of the knife	4	Triggering of the knife movement by a two-hand control device with control circuit in accordance with ISO 13849-1	Triggering of the knife movement by a two-hand control device with control circuit in accordance with ISO 13849-1	2	1	1	2	2
3b			3	Detection of presence of worker's hands with safety light curtain	Detection of presence of worker's hands with safety light curtain	2	1	1	2	2

^a The figures in bold are those that have changed as a result of the proposed protective measures.

^b For quality printing of special papers, the wearing of gloves is mandatory.

A.4.3.3 Discussion

In the example presented, a simple work activity has been analysed and protective measures have been taken to reduce the risks. The general results of these risk assessments can be considered compatible with usual practice for this kind of machinery.

This example has shown the different results of using different risk reduction means, such as in order to reduce risk induced by the vertical movement of the press:

- the most effective risk reduction measure is solution 2d, followed by solution 2a or 2c;
- solution 2b alone is not adequate to reduce the risk;
- no difference in result between solutions 1a and 1b, between solution 1.1a and 1.1b or between solutions 3a and 3b;
- in the cases of solutions 1a, 1b, 1.1a and 1.1b, the final risk index for each of these measures alone is too high, and it is therefore recommended that the risk be assessed using all these measures applied together;
- periodically check insulation, connections and the residual current sensing device against the energized frame of the machine (failed connections, worn out cables, etc.);
- install a hood on the pedal and ensure a machine control circuit category in accordance with ISO 13849-1 against any unexpected movement of the press or the knife by an action on the start pedal or by failure of the control circuit);
- complement these with training and warning.

This risk graph can be used to estimate a risk index, mainly for hazardous situations that can induce acute harm, which is generally associated with machinery (mechanical, electrical or, to a certain extent, thermal hazards). The proposed risk graph can also be used to estimate some hazards related to health, such as noise or ergonomics-related hazards. However, in these cases, the results obtained with this risk graph tool should be compared with those obtained with specific tools dedicated to noise or ergonomics.

As risk assessment has to be carried out by a team and by consensus, it cannot be expected that the detailed results will always be the same with different teams analysing different situations. Some industries have found it convenient to adapt slightly the parameters and the limits of the risk graph; these changes could induce different results.

The risk graph used in this example is equivalent to the risk matrix given in Figure A.6.

		Risk index calculation					
		O1		O2		O3	
		A1	A2	A1	A2	A1	A2
S1	F1	1				2	
	F2	1				2	
S2	F1	2		3		4	
	F2	3	4	5		6	

Figure A.6 — Equivalent risk matrix

A.5 Risk assessment using numerical scoring

A.5.1 General

Some people find it easier to think about risk and how it is derived in terms of numbers. This is not at all unusual in our digital age. Being able to see risk represented by a number somehow adds specificity to the process of risk reduction. Having an acceptable risk level at a specific number within the numerical risk range, from lowest to highest risk, can provide focus in risk reduction decision-making. The ability to select one number from within the class integer ranges can allow for more refined choices than are permitted by qualitative terms.

A.5.2 Description of the tool or method

In this example, there are two parameters, severity and probability, each divided into the four classes shown.

The severity parameter has the following severity scores (SS):

- catastrophic (SS ≥ 100);
- serious (99 ≥ SS ≥ 90);
- moderate (89 ≥ SS ≥ 30);
- minor (29 ≥ SS ≥ 0).

The probability parameter has the following probability scores (PS):

- very likely (PS ≥ 100) likely or certain to occur;
- likely (99 ≥ PS ≥ 70) can occur (but not probable);
- unlikely (69 ≥ PS ≥ 30) not likely to occur;
- remote (29 ≥ PS ≥ 0) occurrence so remote as to be essentially zero.

In this example, the formula for combining probability and severity is given by Equation (A.1):

$$PS + SS = RS \tag{A.1}$$

where RS is the risk score.

The RS can then be interpreted according to Table A.8.

Table A.8 — Risk score categories used

—	high	≥ 160
159 ≥	medium	≥ 120
119 ≥	low	≥ 90
89 ≥	negligible	≥ 0

So, for example, a task hazard associated with very severe injury may have SS = 95, and its probability may be in the likely range PS = 80. The risk value for this task hazard is then 95 + 80 = 175. This high risk would be unacceptable if the acceptable risk level has been set at 130.

A.5.3 Application

A.5.3.1 Description of the assessed task(s) or machine(s)

A machinery risk assessment for a bagel slicer (see Figure A.7) is described. The safety perspective taken is that the risk of injury is a function of the tasks and the hazards of those tasks for a given set of protective measures. This example is limited to one hazard: contact with the spinning blade. The full range of employees is considered (male and female, all shapes, sizes, with an education adequate for employment in a fast-food establishment).

An injury surveillance system was searched to identify injury cases associated with bagel slicers. The injury surveillance system sample was of sufficient size to provide estimates of injuries associated with a variety of work machines, tools and equipment.

A numeric scoring approach to risk assessment was followed. A severity score for injury and a probability score that the injury will occur was assigned for each identified hazard. This information was then entered into the numerical risk level matrix.

The risk assessment considered the current level of guarding and the manufacturer's video training for using the bagel slicer; risk control measures for other machines with a similar hazard; and views of five experts in machine safety as to how likely some specific risky behaviours are. This risk assessment addressed a bagel slicer equipped with a circular blade and did not correspond to an assessment of a particular employer's use of the machine. Workplace observation revealed that the current levels of protection provided were an adjustable barrier guard, warning signs and the supplier's recommended safe operating procedures. The possible severity of injury was deep laceration to a finger in the case of contact with the spinning blade while normal bagel slicing tasks were being performed, the clearing of jammed bagels and the cleaning of the slicer.

The bagel chute is a long, four-sided box that fully encloses the blade on the sides. The ends of the chute are open. The machine consists of a thin sharp circular blade which has a wavy edge. The blade operates at a high rotational speed and coasts to a stop (no brake). The top opening is around, or a little below, shoulder height. The guard opening size and the distance from the opening to the blade permit a hand to extend in to touch the blade.



Figure A.7 — Bagel slicer

The machine manufacturer provides the means for safe operating procedures. However, it is the responsibility of the user to ensure that these procedures are carried out by providing proper training and supervision. On the other hand, while it is recognized that the means for safe operating procedures are provided, this will not in itself ensure proper training in their use or that workers will follow the safe procedures set forth in their training.

A.5.3.2 Results of the risk assessment

The seven task/hazard pairs given in Table A.9 were identified as requiring risk scoring. The risk evaluation shows the risk level as 60 (low) for all of the identified task/hazard combinations when using this bagel slicer. For all task/hazard pairs, the injury severity is 30 (moderate) (normally reversible with no more than one week's lost work time) and the initial probability is 70 (likely) (due to there being no need to access the hazard area with power on, and no available reports of injury, but low awareness of risk and low experience level of users). The three existing protective measures — the adjustable guard, warning sign and training video — reduced the probability of injury to 30 (unlikely), which resulted in final risk scores of 60 (negligible).

Table A.9 — Risk scores before and after the introduction of risk reduction methods

Task — Hazard	Initial assessment SS and PS	Risk score	Risk reduction methods	Final assessment SS and PS	Risk score
Ignores instruction not to reach in at top to push bagel through	30 (moderate) 70 (likely)	100 (low)	Adjustable enclosures/barriers, warning label(s), standard procedures, instruction manuals	30 (moderate) 30 (unlikely)	60 (negligible)
Misunderstands seriousness of blade hazard — reaches in at top to push bagel through	30 (moderate) 70 (likely)	100 (low)	Adjustable enclosures/barriers, warning label(s), standard procedures, instruction manuals	30 (moderate) 30 (unlikely)	60 (negligible)
Ignores instruction not to reach in at bottom to pull out bagel	30 (moderate) 70 (likely)	100 (low)	Adjustable enclosures/barriers, warning label(s), standard procedures, instruction manuals	30 (moderate) 30 (unlikely)	60 (negligible)
Forgets blade is coasting and reaches in	30 (moderate) 70 (likely)	100 (low)	Adjustable enclosures/barriers, warning label(s), standard procedures, instruction manuals	30 (moderate) 30 (unlikely)	60 (negligible)
Ignores instruction and normally opens and cleans slicer while it is plugged in	30 (moderate) 70 (likely)	100 (low)	Warning label(s), standard procedures, instruction manuals, supervision	30 (moderate) 30 (unlikely)	60 (negligible)
Forgets to unplug and inadvertently hits "power on" switch	30 (moderate) 70 (likely)	100 (low)	Warning label(s), standard procedures, instruction manuals, supervision	30 (moderate) 30 (unlikely)	60 (negligible)
Another person or event diverts attention and start switch is inadvertently hit	30 (moderate) 70 (likely)	100 (low)	Warning label(s), standard procedures, instruction manuals, supervision	30 (moderate) 30 (unlikely)	60 (negligible)

A.5.3.3 Discussion

Operating and cleaning the power bagel slicer with a circular blade and enclosed feed chute presents a risk score of 60 (negligible) for young people. The existing protective measures — the adjustable guard, the warning sign, and the safe operating procedures — contribute to this low risk rating. The inclusion of automatic feeding and ejection devices would not appreciably reduce the risk level.

A.6 Quantified risk estimation

NOTE See 5.4.4.5.

IMPORTANT — The text in italics throughout this clause (A.6) relates to the illustrative example.

A.6.1 General

This is a brief overview of a method for risk estimation used to examine in more detail a single risk considered to be too complex to be easily estimated qualitatively.

Before using such a method, a thorough hazard identification will first need to be carried out in accordance with ISO 14121-1.

The forms used are based upon an underlying fault tree of accident causation. Forms 3 A and 3 B can be modified or appended according to specific needs as long as the underlying logic is checked using fault trees. The risk estimated using this method is expressed as an annual frequency of different levels of harm allowing comparisons to be made with accident statistics in the industry or numerical risk criteria. Lookup tables of suggested probabilities and guidance are provided so that the user does not have to estimate all these values from first principles. Again, these lookup tables can be modified or added to according to the user's needs or sources of data.

The use of the method is described with reference to a powered roof support used on a coalmine face. The accident scenario that will be used as an example is one cause and consequence of the hazardous situation "damaged *high voltage cables*".

A.6.2 Description of the tool or method

A.6.2.1 Form 1 — Description of accident scenario

The form given as Table A.10 is used to describe each accident scenario based on the information recorded in the hazard identification. There can be several different hazardous situations for each hazard and/or several different hazardous events for each hazardous situation. *In the example used, the damaged high voltage cables pose an electrocution hazard or ignition hazard.*

One form should be used for each combination of hazard, hazardous situation and hazardous event. Some hazardous situations are only relevant to certain types of people, e.g. maintenance technicians, others will be relevant to a range of different types of people (operators, maintenance technicians or passers-by). This should be made clear on the form.

The objective is to clearly describe, as closely as possible, everything (chain of events) that has to happen or exist for the hazardous event to occur. When doing this it is helpful to consider the aspects described in ISO 14121-1:2007, 7.3.

Table A.10 — Form 1

Definition	Description for machine
Hazard: Describe the potential source of harm.	<i>Live electrical parts at high voltage</i>
Hazardous situation: Describe the task in the use of the machine (including such activities as setting and maintenance) that exposes a person to the hazard, i.e. when is there is a potential for harm. Describe the type of person, i.e. who is exposed, e.g. operator, maintenance technician, passer-by.	<i>Heavy items left lying in path of powered roof support after non-routine tasks, posing a hazard when normal operation is resumed</i>
Hazardous event: Describe how the hazard can cause harm. It could be attributable to human error during the hazardous operation, or a random event/failure.	<p><i>Ignition of explosive atmosphere</i></p> <p><i>NOTE There is also the possibility that someone could be electrocuted by coming into contact with live parts, but this is another scenario that would be assessed using another set of forms.</i></p>
Consequences: Describe the possible harm in terms of the worst credible consequences. Also describe whether less severe consequences are more likely when taking into account the possibilities to avoid or limit the harm. Table A.18 gives examples of types of harm.	<i>Explosion — death of anyone in vicinity, possibly several deaths</i>
<p>Preconditions for hazardous event: The identified preconditions must all happen or be in place for the accident to occur. If a single precondition does not occur it is not possible for the accident scenario to occur. Conversely, if the accident will happen irrespective of something that is listed as a precondition, then it is not in fact a precondition.</p> <p>Preconditions should be resolved to sufficient detail to make probability estimation less uncertain. There may be different ways of defining the preconditions. Providing the definitions are clear and no precondition is duplicated, it is not important which way is used.</p>	<p><i>1 Girder left in path of roof support — without good training and supervision this is likely</i></p> <p><i>2 High voltage cable damaged — if the cables are not protected this is very likely</i></p> <p><i>3 Explosive atmosphere exists — without suppression of coal dust this is very likely, a methane air mixture is also possible</i></p>

A.6.2.2 Form 2 — Probability that all preconditions are met

Form 2 (see Table A.11) is used if there is more than one precondition in order to separately record their probabilities before and after consideration of common cause failure (CCF). Any precondition that has a common cause with the initiating event or an earlier precondition should be assigned a probability of one. If there is some dependence between preconditions, try to either define a single precondition that incorporates the common cause failure or limit the probability of each precondition as appropriate. If in doubt, set the probability of all but one of the preconditions susceptible to common cause failure to a probability of one. *In this example there is no common cause between preconditions so CCF value is same as initial value.*

Table A.11 — Form 2

Precondition (from list in form 1)	Initial value	Identifier	CCF Value
1 Girder left in path of roof support — use general error of omission from Table A.17	0,01	p_1	0,01
2 High voltage cable damaged	0,1	p_2	0,1
3 Explosive atmosphere exists	0,1	p_3	0,1
...	—	...	—
<i>n</i>	—	p_n	—
Probability that all preconditions are met		$\prod_{i=1, n} p_i$	1×10^{-4}
Any precondition that has a common cause with the initiating event or an earlier precondition should be assigned a probability of one. Draw a line to link those preconditions susceptible to the common cause failure. Tables A.16 and A.17 can be useful in deciding values of probabilities. Failure rates can be obtained from the supplier or estimated using Table A.15.		where π is the product of all the variables from 1 to n	

A.6.2.3 Forms 3 — Estimation of probability of hazardous event and exposure

This form is used to quantify the “exposure” and “the occurrence of a hazardous event” elements of risk. In this illustration of the method there is a choice between two forms: Use form 3 A for those hazardous events that are initiated by human error *while* exposed to the hazard. Use form 3 B for those hazardous events that are initiated by an event or failure that can happen irrespective of whether someone is exposed or not. When human error has the potential to harm someone *other than* the person who makes the error and the exposure of that other person is independent of when the error can be made, form 3 B rather than 3 A should be used. Human error can also be a precondition rather than the initiating event.

Form 3 A requires the following.

- An estimate of the number of operations per year that can expose a person to a hazardous situation: this can be done based on experience of the use of this or similar machinery, in which case simply insert this value in the third row. Alternatively, this can be calculated by multiplying the number of shifts per year by the estimated number of hazardous operations per year. If in doubt, it is best to assume 235 shifts per year. For machinery that is used seasonally, e.g. agricultural machinery used for a few months of the year, say during harvesting, use a value of 235 shifts per year, as it cannot be assumed that the operator is risk-free the rest of the year.

NOTE The number of shifts per year can vary from place to place.

- An estimate of the probability of a human error during the average duration of one hazardous event: Table A.13 can be used when estimating this.

The root cause is due to human error (girders being left lying about), but the exposure is independent of human error so form 3 B is used.

Use Form 3 A given as Table A.12 when the hazardous event is initiated by human error during exposure to the hazard.

Table A.12 — Form 3 A

Component	Identifier	Value
Number of shifts worked by operator per year: if operator works a standard year, i.e. averages one shift per day over a 5 day week and 47 week year (taking account of holidays), this would be $5 \times 47 = 235$ shifts per year. NOTE The number of shifts per year can vary from place to place.	n_1	
Fraction of standard shift using this machinery: this is the fraction of time that the operator is not available to work with other machinery.	r_1	
Number of hazardous operations per shift: this should be judged on the basis of normal patterns of use of the machine, including time for setting and maintenance.	n_2	
Number of hazardous operations per year: either multiply the two values above or insert value based on experience or other data.	$n_3 = n_1 \cdot n_2$	
Probability of human error during the average duration of one hazardous operation: use Table A.18.	P_e	
Probability that all preconditions are met: if there are no preconditions this is set to one. If there is more than one precondition use form 2 to calculate this.	P_p	
Frequency of hazardous event (per year) whilst person(s) exposed.	$F = P_e P_p n_3 / r_1$	

Use form 3 B as given in Table A.13 when the hazardous event is initiated by an event that is independent of the exposure, such as failure of a component, part or function of the machinery.

Table A.13 — Form 3 B

Component	Identifier	Value
Frequency (per year) of hazardous event: this may be obtainable from the supplier of the component concerned. Alternatively, estimate from experience, making use of Table A.1. <i>If high voltage cable is damaged and explosive atmosphere exists the arc will sooner or later lead to an ignition.</i>	f_1	1
Fraction of time spent using or in the vicinity of the machinery: this can be estimated from a knowledge of normal patterns of use of the machine, including time for setting and maintenance. The time spent performing hazardous operation divided by time involved with the machine — this prevents dilution for those who only use the machine occasionally. <i>The coal face is assumed to be operational on average for 90 % of a typical shift.</i>	r_2	0,9
Probability that all preconditions are met: if there are no preconditions this is set to 1. If there is more than one precondition, use form 2 to calculate this.	P_p	1×10^{-4}
Frequency (per year) of hazardous event whilst person(s) exposed.	$F = P_p f_1 r_2$	$0,9 \times 10^{-4}$
Alternative frequency (per year) based on experience or other data.	F	—

A.6.2.4 Form 4 — Risk estimation taking into account possibilities to avoid or limit harm

The form given as Table A.14 is used to take into account the possibilities of avoiding or limiting harm. It helps avoid either overestimating or underestimating risk when the worst conceivable risk is death, but, due to the possibility of limiting or avoiding harm, a major or minor injury is much more likely.

A.6.2.5 Complementary data

See Tables A.15 to A.18.

Table A.14 — Form 4

Component		Identifier	Value	
Frequency of hazardous event whilst person exposed from form 3 A or 3 B		F	$0,9 \times 10^{-4}$	
Severity level See Table A.18 for examples	Probability that if harm occurs it is of particular severity		Frequency of harm for each severity level (events per year)	
	Identifier	Value	Identifier	Value
Fatal and permanent serious disability	S_1	1	$F \cdot S_1$	$0,9 \times 10^{-4}$
Major — <i>very unlikely to survive explosion</i>	S_2		$F \cdot S_2$	
Minor	S_3		$F \cdot S_3$	
No — or trivial injury	S_4			
Total	$S_1 + S_2 + S_3 + S_4$	1		

Table A.15 — Frequency of selected rare events

Event	Frequency (per year)
Risk of death in Europe from all causes	1×10^{-2}
Risk of death due to work in high risk groups within relatively risky industries such as mining	1×10^{-3}
Death from a traffic accident	1×10^{-4}
Death in an accident at work in the very safest parts of industry	1×10^{-5}
Death from a fire or gas explosion at home	1×10^{-6}
Struck by lightning	1×10^{-7}

Table A.16 — Proposed probability values

Probability	Description
1	Occurs continuously
10^{-1}	Frequent and expected. Often occurs as part of the process.
10^{-2}	Possible. Known to occur during the process.
10^{-3}	Unusual. Known to occur occasionally but not normally anticipated.
10^{-4}	Remote. Has occurred somewhere, maybe within another company.
10^{-5}	Conceivable. Could occur but no evidence available that it ever has.
10^{-6}	Improbable. Extremely unlikely. Reasonable to assume it will not happen.
10^{-7}	Inconceivable. Should never occur.

Table A.17 — Probability of human error

Error probability	Task
1×10^{-4}	Routine, good feedback with time to make use of it, good appreciation of hazard
0,001	Routine, simple
0,01	General error of omission
0,1	Non-routine, complicated
0,1	High stress, time constraint 30 min
0,9	High stress, time constraint 5 min
1	High stress, time constraint 1 min
1	Error in second step, having already erred in first

Table A.18 — Examples of types of harm for each severity level

Severity level	Example injuries
Fatality and permanent serious disability	Quadriplegia Paraplegia Prolonged unconsciousness (coma) Permanent brain damage
Major injury	Any fracture (other than to fingers, thumbs or toes) Burns causing permanent scarring Damage to sight, partial or total Any amputation Loss of consciousness (not prolonged) Dislocation of shoulder, hip, knee or spine Treatment required due to exposure to fumes Anything requiring resuscitation
Minor injury	Minor broken bones (fingers, toes) Cuts and bruises Minor burns, temporary scarring Any other injury requiring first aid only
No injury and near misses	No injury, including the possibility of avoidance

A.6.2.6 Discussion

The value of estimating the risk by breaking down the accident scenario in this way is not so much the number obtained but the understanding of all the factors that influence the risk. This can assist in identifying a range of risk reduction measures. For instance, in this example, training and competence appear to be important for risk reduction.

The full risk assessment process, led by an experienced practitioner together with designers and installation/maintenance engineers, looking at a specific powered roof support system as a team required the following schedule:

- a day for familiarization/determination of limits;
- two days for hazard identification that produced a list of 41 relevant hazards and hazardous situations;
- a day for risk estimation where ten hazardous situations were looked at using a guided quantitative method similar to the one described above, the rest being estimated qualitatively;
- five days to write up the results, carry out a limited risk evaluation and do a comprehensive comparison with accident statistics, although this would have been significantly reduced had the method been computerized;
- a day to feed back the results to the team and members of the board.

The risks estimated using this tool took account of existing protective measures in the design as well as common industry working practices. The estimated risks were used to inform decisions about whether additional risk reduction measures were necessary. The design team decided that altering the design, for example, to include a protective barrier, was not practicable for this amount of risk. However, the risk and the measures required to be taken by the user to control it would be described in the information for use for the machinery.

The method is ideally used by a team led by a suitably experienced practitioner. The method helps generate detailed technical discussions and challenges the existing design and assumptions made about the hazards and risks. The extra effort required to use such a method is therefore unlikely to be cost-effective for well-established machinery for which there is standardized or widely recognized good practice in terms of appropriate protective measures.

A.7 Risk assessment using hybrid method

A.7.1 General

This risk assessment method quantifies the qualitative parameters. It is a hybrid method of numerical scoring and a matrix.

It ranges from hazard identification to risk estimation and risk evaluation, to protective measures to be implemented and the decision to consider the machine adequately safe.

Risk assessment using this method and tool can be done by an individual in the day-to-day work as a first step but should, as with all risk assessments, be reviewed or repeated by a team as described in 4.2.

Before starting to use this method, preparation has to be done as described in Clause 4 and the machinery limits determined as described in 5.2.

A.7.2 Description of the tool or method

Table A.19 should be used in conjunction with the following guidance information.

Pre-risk assessment

Ticking this box indicates that this is the first risk assessment. It is done in the concept phase where only specification and sketches are available. No detailed drawings are made at this stage. It is used to decide on the major systems of a machine, e.g. mechanical drive line or servo drives, hot air or ultrasonic sealing, movable guard or light barrier. See Table A.19.

Intermediate risk assessment

The intermediate risk assessment box is ticked for all intermediate risk assessments performed during the development of a machine. Two sets of hazards are dealt with in this phase. Where in the pre-risk assessment phase protective measures were indicated, these are implemented and assessed again in this phase. The design of the machine changes during the development. Risk assessments have to follow together with the design review along the project. New hazards are dealt with in this phase. See Table A.19.

Follow-up risk assessment

This box is ticked at the follow-up risk assessment. Follow-up is done on implemented protective measures. No new hazard should appear in this phase. Nevertheless, where a new hazard is identified when following up on protective measures, this new hazard is also estimated and evaluated in this phase. If it requires a protective measure, a follow-up has to be done again on this protective measure. See Table A.19.

Reference number (ref. no.)

The ref. no., or serial number, is used to give each identified hazard a number for reference purposes.

Type number (type no.)

Type no., hazard type or group number is used to classify the hazards. The numbers refer to those given for the type or group according to ISO 14121-1:2007, Table A.1.

Hazard

Describe the hazard. The type no. identifies the type or group of hazard. Indicate the origin of the hazard type or group. For example, if the hazard is a crushing hazard, indicate this by "1" in the type no. column and by "crushing" in the hazard column.

The same hazard could require several estimations due to different hazardous situations and hazardous events.

Severity, Se

Se is the severity of possible harm as an outcome from the identified hazard. The severity is scored as follows:

- 1 scratches, bruises that are cured by first aid or similar;
- 2 more severe scratches, bruises, stabbing, which require medical attention from professionals;
- 3 normally irreversible injury; it will be slightly difficult to continue work after healing;
- 4 irreversible injury in such a way that it will be very difficult to continue work after healing, if possible at all.

Frequency, Fr

Fr is the average interval between frequency of exposure and its duration. The frequency is scored as follows:

- 2 interval between exposure is more than a year;
- 3 interval between exposure is more than two weeks but less than or equal to a year;
- 4 interval between exposure is more than a day but less than or equal to two weeks;
- 5 interval between exposure is more than an hour but less than or equal to a day.

Where the duration is shorter than 10 min, the above values may be decreased to the next level.

- 6 interval less than or equal to an hour. This value is not to be decreased at any time.

Probability, Pr

Pr is the probability of occurrence of a hazardous event. Consider, for example, human behaviour, reliability of components, accident history and the nature of the component or system (e.g. a knife is always sharp, a pipe in a dairy environment is hot, electricity is dangerous by its nature) to determine the level of probability. The probability is scored as follows:

- 1 Negligible: for example, this kind of component never fails so that a hazardous event occurs. No possibility of human error.
- 2 Rarely: for example, it is unlikely that this kind of component will fail so that a hazardous event occurs. Human error is unlikely.
- 3 Possible: for example, this kind of component can fail so a hazardous event occurs. Human error is possible.
- 4 Likely: for example, this kind of component will probably fail so a hazardous event occurs. Human error is likely.
- 5 Very high: for example, this kind of component is not made for this application. It will fail so that a hazardous event occurs. Human behaviour is such that the likelihood of error is very high.

Avoidance, Av

Av is the possibility of avoiding or limiting harm. Consider, for example, whether the machine is to be operated by skilled or unskilled persons, how quickly a hazardous situation can lead to harm, and the awareness of risk by means of general information, direct observation or through warning signs, so as to determine the level of avoidance. The possibility of avoidance is scored as follows:

- 1 Likely: for example, it is likely that contact with moving parts behind an interlocked guard will be avoided in most cases should the interlocking fail and the movements continue.
- 3 Possible: for example, it is possible to avoid an entanglement hazard where the speed is slow.
- 5 Impossible: for example, it is impossible to avoid the sudden appearance of a powerful laser beam or a part of a machine becoming live because of a fault in electrical insulation.

Class, Cl

Cl is the class. Fr, Pr and Av are the constituent factors that form the probability of occurrence of harm as described in ISO 14121-1:2007, 7.2.1. Each of the three factors should be estimated independently. The worst credible assumption should be used for each factor. Fr, Pr and Av are added together in Cl. The Cl is the sum of Fr, Pr and Av, i.e. $Cl = Fr + Pr + Av$.

Evaluation of the risk

The risk is evaluated by using the matrix in the middle of the upper part of the form, see Table A.19.

Where the severity, Se, crosses the class, Cl, in the black area, protective measures have to be implemented to reduce risk.

Where the severity, Se, crosses the class, Cl, in the grey area, protective measures are recommended to be implemented to further reduce risk.

Where the severity, Se, crosses the class, Cl, in the remaining area, the risk is already adequately reduced.

Protective measure

Indicate the protective measure to be implemented to reduce risk.

Adequately safe

Indicate that this particular hazard is rendered adequately safe. The protective measures have to be implemented and a new estimation and evaluation made using the amended risk parameter(s) before indicating it is adequately safe. This process ensures the effectiveness of the protective measure. It has also to be ensured that no new hazards were introduced when implementing the protective measure.

Comments

Where the hazard field is too short to describe the hazard, it can be further described here. Put the hazard ref. no. for the particular hazard in the left column and describe the hazard in the right. Where photos are used, reference to them can be made here.

A.7.3 Application

A.7.3.1 Description of the assessed task(s) or machine(s)

This example shows the use of the hybrid risk assessment method on a packaging machine. It is an extract of the risk assessment relating to electrical and mechanical hazards.

The hazards were associated with coming in contact with live parts and an oscillating drive where the mechanical hazards come from a belt drive and a moving pin.

The electrical hazard exposure was during maintenance. The mechanical hazards were associated with a task to operate the machine.

A.7.3.2 Result of the risk assessment with the method

Table A.19 is a copy of an intermediate risk assessment. The worked out risk assessment refers to that table.

The first risk assessment, the pre-risk assessment, was given a document number of 672. The document is not shown.

During the pre-risk assessment, an electrical hazard was identified (ref. no. 1).

The hazard was estimated and evaluated as requiring protective measures.

The next risk assessment, the intermediate risk assessment, was given the document number 684 (see Table A.19). It references the previous risk assessment, the pre-risk assessment, as part of document 672.

During the intermediate risk assessment, hazard ref. no. 1 was assessed again, this time with its protective measure in place. It was validated to be adequately safe and is so indicated in the "Adequately safe" column of the form in Table A.19.

At the same risk assessment, Table A.19, two new hazards were identified, hazard ref. nos. 2 and 3. These hazards are estimated and evaluated to require protective measures, which are going to be interlocking guards. The last risk assessment, follow-up risk assessment, is given a new document number. The document is not shown. It would reference the previous risk assessment as part of document 684.

During the follow-up risk assessment hazard ref. nos. 2 and 3 are assessed again, now with their protective measures, the interlocking guards, in place. If they are validated to be adequately safe they are so indicated in the "Adequately safe" column of the form.

If no new hazards are identified the risk assessment is completed. If a new hazard is identified at the same time as hazard ref. nos. 2 and 3 are validated and does not require protective measures, this new one is indicated adequately safe in the "Adequately safe" column.

If the newly identified hazard requires a protective measure this is not a follow-up risk assessment but indicated as an intermediate risk assessment. A further risk assessment, follow-up risk assessment, has to be done when protective measures have been implemented for this last hazard.

This risk assessment is a follow-up risk assessment and completes the process when no further hazard is identified requiring a protective measure.

A.7.3.3 Discussion

This method has been found to be most useful when conducted by a team (see 4.2). Teams who have used this method have included electrical and mechanical designers, field service technicians and the technical editors of the instructions for use, the team leader being someone with a deep knowledge of the method.

The method when used as part of design review has saved time and ensured that safety has been integral to the design rather than an add-on resulting in adequately safe machinery.

This risk assessment method and tool has been used in the packaging industry worldwide for several years. Several surveillance authorities also use it. It can be used in any machine-related industry.

Annex B (informative)

Example application of the process of risk assessment and reduction

B.1 General

The aim of this example is to show, in a non-exhaustive way, an application of the process of the risk assessment and risk reduction during the design of a single-spindle vertical moulding machine, in accordance with the general principles set out in ISO 14121-1 and ISO 12100.

This example does not seek to embrace the complete design of this type of machine, nor to be a model to follow. It represents only an attempt to present enough information so that the reader has an overall idea of a possible way of applying the principles set out in ISO 14121-1 and ISO 12100.

B.2 and B.3 have been applied taking into account the whole life cycle of the machine. However, in B.4 the example is limited exclusively to the phase of use and, in particular to the setting and operation of the machine.

B.2 Information for the risk assessment

NOTE See ISO 14121-1:2007, 4.2.

B.2.1 Initial specifications

B.2.1.1 General

A machine is intended to be designed according to the initial specifications given in B.2.1.2 to B.2.1.4.

B.2.1.2 Basic elements

These are the following:

- a stationary single spindle vertical moulding machine;
- for indoor use;
- used by one operator;
- hand-fed;
- electrically supplied.

B.2.1.3 Work to be performed with the machine

The machine is designed to modify the profile of square or rectangular cross-section wooden pieces and analogous materials (cork, chip board, fibre board and hard plastic) by moulding, rebating and grooving.

The work to be performed with this machine is as follows.

- Straight work

This is the shaping of a workpiece with one face in contact with the table and a second with the fence, where the work starts at one end of the workpiece and continues through to the other end.

— Stopped straight work

This is the machining of only a part of the workpiece length.

— Curved work

This is the machining of a curve on a workpiece by having one side in contact with the table (or, if held in a jig, with the jig in contact with the table) and the other in contact with the vertical reference of a steady or ball ring guide when using a jig.

The machine is not intended for tenoning.

Only wood products clear of foreign objects (e.g. nails) are intended to be processed.

The machine is not intended to work metallic materials.

The work is to be performed with standard cutting tools that are available on the market.

The machine will be provided with different spindle speeds in order to use a wide range of tools and to suit most materials.

The spindle height will be adjustable to enable setting of the cutting tool height.

All adjustable parts of the machine (e.g. tool change, speed change) will be manually operated.

B.2.1.4 Description of the machine concept

NOTE See Figure B.1

The milling process is performed by a cutter tool mounted on a vertical spindle. The spindle turns in only one direction and can be raised and lowered through a hand-wheel (spindle unit). The spindle can turn at four different speeds (see spindle speeds below), driven by an electric motor and a set of pulleys (driver unit).

The spindle unit and the driver unit are anchored to a cast iron table that rests on a steel cabinet. Both the table and the cabinet provide good support for the workpiece and are of a height ensuring an ergonomically upright posture.

In order to guide the workpiece during the work, the machine incorporates appropriate guides.

The spindle speed is manually selected by changing a transmission belt from one pulley to another.

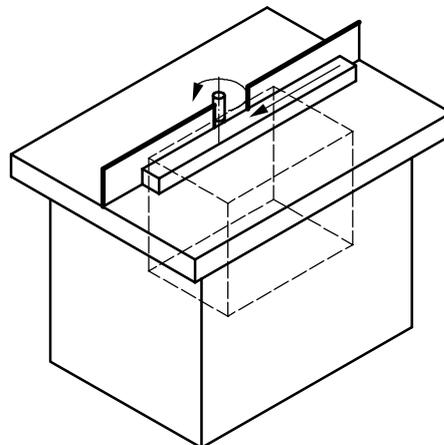


Figure B.1 — Machine concept

B.2.2 Experience of use

According to statistical information, most reported accidents happen by contact with the tool. This contact is due to workpiece kickback and tool snatching, mainly during machining straight work. Not using a guard or using an inappropriate one, not using false fences, pressure pads, jigs, templates or end stops are common causes of accidents on this kind of machine.

Other less frequent accidents are impacts due to kickback of the workpiece, the ejection of chips or parts of the tools or machine, or fire from wood dust/chips.

Damage to health can result from emissions or materials used, such as:

- noise generated at the milling process;
- wood dust;
- fumes or substances released while milling impregnated or treated (preserved) wood.

B.2.3 Regulations, normative references and technical sheets

The following standards have been initially considered: ISO 12100-2, ISO 13849-1, ISO 13849-2, ISO 13852, ISO 14118, ISO 14119, ISO 14120, IEC 60204-1 as well as EN 614-1 on ergonomics and ISO/TR 11688-1 on acoustics, etc.

Furthermore, technical sheets about this kind of machine issued by INRS, HSE, BG and OSHA¹⁾ have been consulted.

NOTE Other documents that could have been taken into account are the regional or national applicable regulations and standards such as EN 847-1 and EN 848-1; however, for the didactic objectives of this example they have not been used.

B.2.4 Preliminary design of the machine

With consideration being given to all the above information, the following technical specifications have been made:

- electrical supply (frequency, number of phases, nominal voltage): 50 Hz/3/400 V/PE;
- power supply earthing: TT system;
- motor power: 4 kW;
- table dimensions: 1 250 mm × 700 mm;
- spindle characteristics: diameter: 50 mm; useful length: 180 mm; range of vertical adjustment (manually adjustable): 200 mm;
- spindle speeds (manual change of the position of the belt on the pulleys): 3 000 min⁻¹, 4500 min⁻¹, 6 000 min⁻¹ and 7 500 min⁻¹, the selected speed depending on the material, diameter and height of the tool;
- tool diameter: e.g. from 120 mm to 220 mm (maximum diameter of the tool).

1) Institut national de la recherche scientifique (France), Health and Safety Executive (UK), Berufsgenossenschaften (Germany), Occupational Safety and Health Administration (USA).

NOTE Other specifications not relevant to the example (surface finishing of the table, flatness, run out of the spindle, etc.) have been omitted.

Consequently, a preliminary design of the machine has been drawn up as follows (see Figures B.2 and B.3).

The machine consists of a steel cabinet and a cast iron table that rests on the cabinet. Inside the cabinet there is an actuator (electric motor), the transmission system and the spindle unit (mechanism for the vertical movement and rotation of the spindle).

The cabinet is provided with an opening for access to the transmission system during speed changing. This opening is closed with a door.

The table is used as a horizontal reference for the piece of wood to be processed and has a hole through which the spindle passes. The machine is equipped with guides to perform the different operations.

The spindle has been sized to enable the use of most standard cutting tools available in the market.

The actuator is an electrical asynchronous motor of three phases, 400 V and with a power of 4 kW. The motor incorporates a brake that acts every time a stop command is given for quickly stopping the movement of the spindle. The brake can be released when some operations are performed (e.g. speed changing). This motor transmits the power to the spindle through the pulleys and a trapezoidal belt.

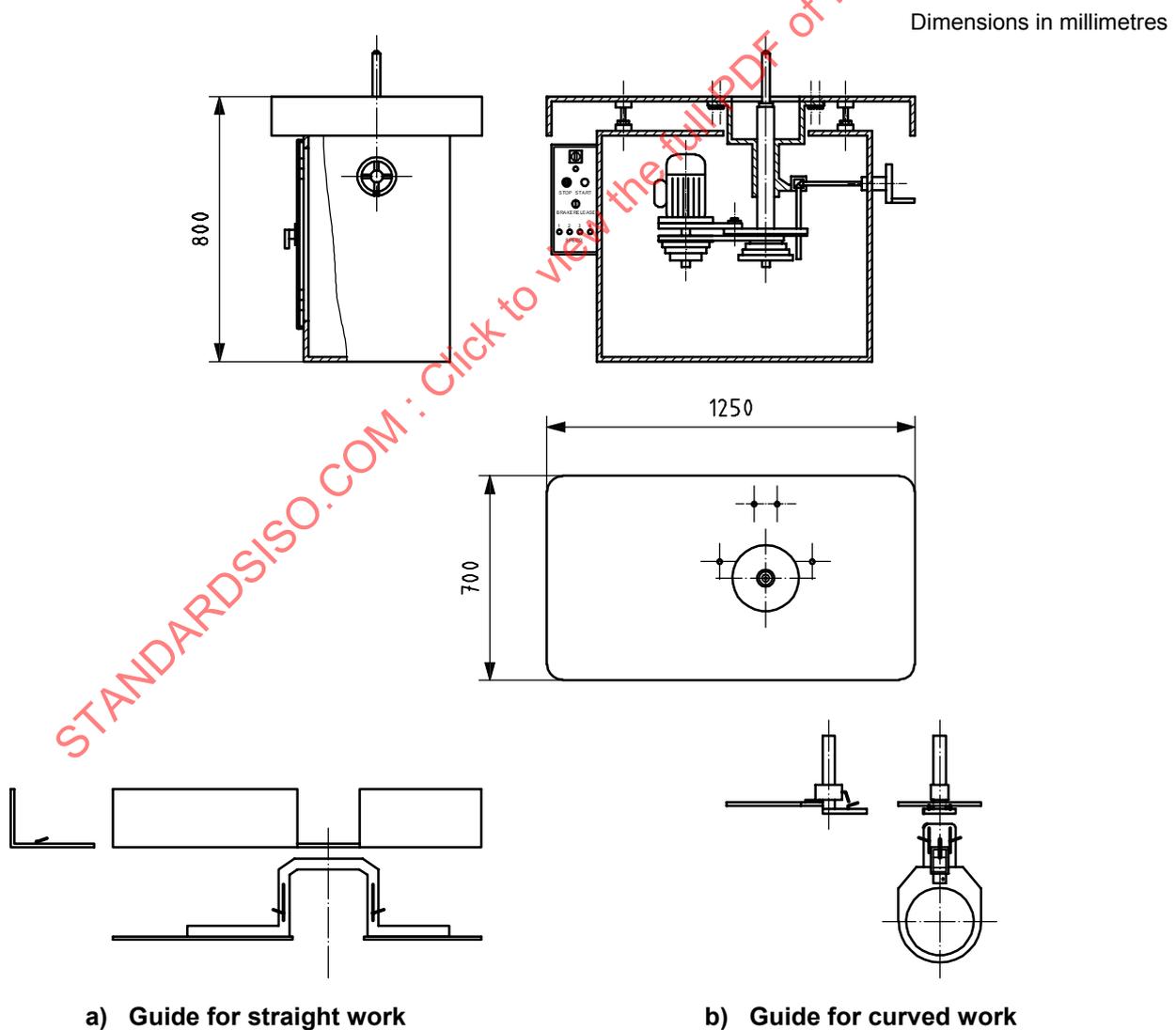


Figure B.2 — Preliminary design drawings

On the motor and on the spindle there are two sets of four pulleys that provide four different working speeds. A working speed is selected by manually changing the belt from one pulley to another one. The motor and the pulleys associated with it can be easily moved by means of a lever (without the need to use a tool) in order to change the belt. A mechanism detects the position of the belt and indicates the selected speed through a set of lamps.

The vertical adjustment of the spindle is achieved by a rack-and-pinion mechanism. It has no accessible moving elements.

The control circuit is in a cabinet placed in front of the machine. It includes, basically, the control actuators (start and stop push buttons, etc.), lamps to indicate the selected speed, and the control and power circuits (electrical protective devices, contactors, etc.). All the electrical components (conductors and cables, control devices, motor, electrical equipment protective devices, etc.) are selected, assembled and combined according to IEC 60204-1. See Figure B.3 for the circuit diagram.

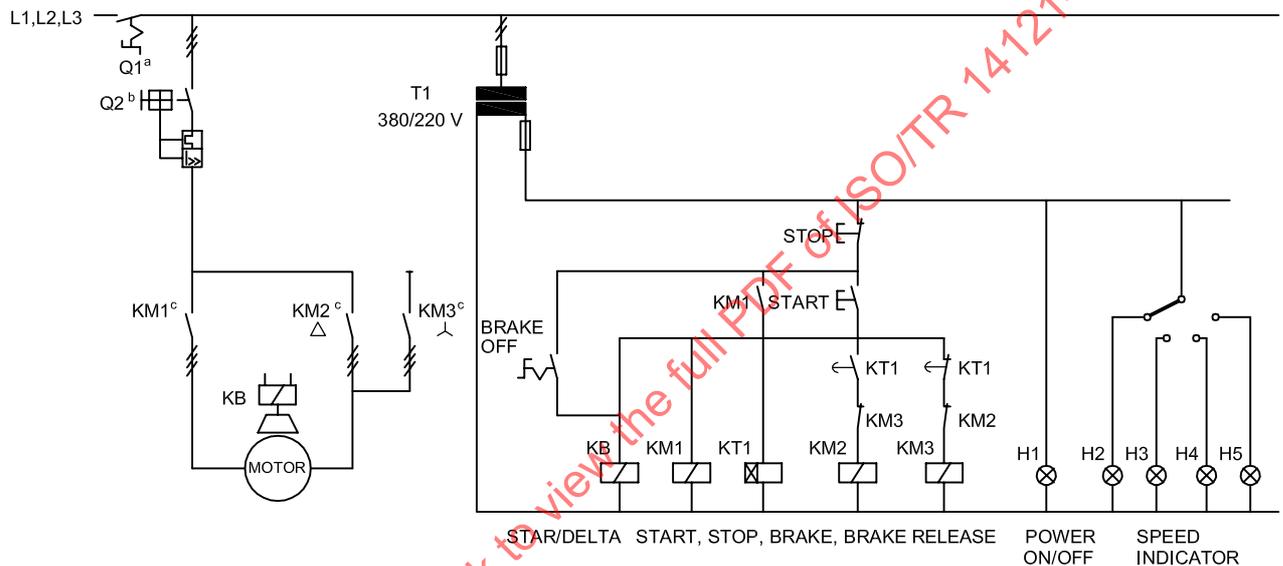


Figure B.3 — Preliminary design of circuit diagram

B.3 Determination of the limits of the machinery

B.3.1 Description of the various phases of the whole life cycle of the machinery

The phases of the life cycle of this machinery considered significant in this example are the following.

— Transport

All transport tasks that may be performed by the machine user, in this case internal transport, removing, etc.

— Assembly, installation and commissioning

Removal of transport-related parts (e.g. covers, fixing bolts), fixing the machine to the floor; connection to the electric power supply; checking of proper installation (correct direction of rotation of the tool), checking the functioning of all controls and the ability of the machine to perform its required operations.

— Setting

Changing a tool on the spindle; mounting and adjusting of guides; changing the spindle speed and trials.

— Operation

Hand fed milling.

— Cleaning, maintenance

Greasing of rotating and transmission elements, changing of belts, cleaning of internal parts of the machine.

— Fault finding/trouble shooting

Operations in case of malfunction of the machine and after the actuation of protective devices.

— Decommissioning, dismantling

Disposal by the user of all parts of the machine.

B.3.2 Use limits

B.3.2.1 Intended use

The machine is intended for modifying the profile of square or rectangular cross-section wooden pieces and analogous materials (cork, chip board, fibre board, hard plastic) by making moulding, rebating and grooving.

The work to be performed with this machine is as follows:

- straight work;
- stopped straight work;
- curved work.

The machine is intended only for professional use.

The machine is intended to be used by a person with knowledge and experience in the use of a machine of its type, without limitations in the physical abilities of the upper limbs and no visual impairment.

The machine is intended to be operated with the operator in an upright standing position. The operator holds and moves the workpiece during the milling process.

The machine is intended to be maintained by a skilled/qualified operator following the instructions given in the operating instruction manual.

The spindle can turn at four different speeds. The speed is manually selected by changing the position of the belt.

Only the use of appropriate and standardized cutting tools is considered.

B.3.2.2 Reasonably foreseeable misuse

The reasonably foreseeable misuse taken into account is as follows:

- processing materials other than those intended by the designer (see B.2.1.3), such as rubber, stone, metals or wood products not clear of foreign objects;
- processing products with unsuitable cross-sections (cylindrical, elliptical);

- tenoning;
- using the machine with home-made tools;
- replacing components or spare parts with ones other than those specified;
- use of the machine by persons under the age of sixteen.

B.3.3 Space limits

The machine is intended for use in an indoor industrial environment.

For installation and use, a flat area of at least 3 000 mm × 3 000 mm, free of obstacles, columns, etc., is required.

The machine is intended to be connected by the user to a dust extraction system.

The machine is not intended to be used at locations having an explosion or fire hazard.

The machine is intended to be connected to an electrical power supply of 400 V, three phases + PE.

B.3.4 Time limits

The machine is intended for an operational life of 20 000 h.

The machine has some parts subject to wear that need to be checked and/or replaced as follows:

- belts: verify state and tension every 500 h;
- brake: verify that the stopping time is less than 10 s, every day;
- tools: verify state and sharpen, according to the tool manufacturer's instructions.

Cleaning of visible and reachable surfaces, including moveable parts and guiding surfaces, is to be carried out every shift.

A general cleaning of the machine is to be carried out every six months.

B.4 Hazard identification

B.4.1 Extent of the system analysed

As already set out in B.1, hazard identification is limited in this example to the phase of use and, in particular, to the setting and operation of the machine.

B.4.2 Tasks to be performed

During setting of the machine, the following tasks are to be performed:

- changing the tool on the stopped spindle;
- mounting and adjusting the appropriate guide (for straight work or curved work);
- changing the spindle speed;
- trials (adjusting the spindle height and feeding/machining workpieces to check whether the cutting depth, the adjusted spindle height, etc. are appropriate).

During machine operation the following task is performed:

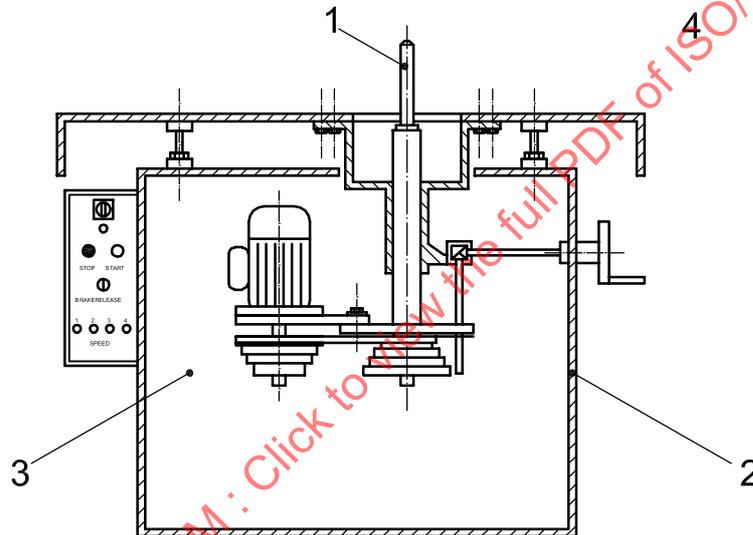
- milling or moulding the workpiece.

NOTE All adjustment tasks have been considered under the setting of the machine, so operation only deals with the milling process (manually feeding of the workpiece and holding it during the machining process).

B.4.3 Relevant hazards and accident scenarios

The following hazard zones are defined (see Figure B.4):

- zone 1: working zone;
- zone 2: machine frame;
- zone 3: transmission zone;
- zone 4: machine surrounding.



Key

1, 2, 3, 4 zones as defined in B.4.3

NOTE See Table B.1 for hazard identification.

Figure B.4 — Hazard zones