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Background

The experts of WG 5 are invited to comment, as agreed in Bilbao, on Clause 5.4 and the 'new' Annex B only!

You are requested to use for your commenting the usual ISO commenting form.

Please submit your comments to the Secretariat

by 12th May 2006 at the very latest!

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Safety of machinery — Risk assessment — Part 2: Practical guidance and examples of methods

Sécurité des machines — L'appréciation du risque — Partie 2: Guide practique et examples des méthodes

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Foreword

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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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/TR 14121 consists of the following parts, under the general title *Safety of machinery — Risk assessment*:

— Part 1: *Principles* (International Standard ISO 14121-1)

— Part 2: *Practical guidance and examples of methods* (Technical Report ISO/TR 14121-2)

Introduction

This Technical Report resulted from the effort to update ISO 14121 to 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. Which method or tool is chosen is largely a matter of industry, company or personal preference. The choice of a specific method or tool is less important than the process itself. The benefit of risk assessment comes 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 that fully considers all the elements of risk.

Adding protective measures to a design can increase costs and can restrict easy use of the machine if they are added after a design has been finalized or the machinery has been built. Changes to machinery are generally less expensive and more effective at the design stage so risk assessment should be performed during the machinery design.

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

The effectiveness of implemented protective measures should be verified before carrying out further iterations.

Safety of machinery — Risk assessment — Part 2: Practical guidance and examples of methods

1 Scope

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

This Technical Report also provides practical guidance on risk reduction (in accordance with ISO 12100) for machinery, giving some guidance on the selection of appropriate protective measures to achieve safety.

The expected users of this Technical Report are those involved in the integration of safety into the design, installation or modification of machinery (e.g. designers, technicians or safety specialists).

Apart from the risk assessment made at the design stage, during construction and commissioning, risk assessment can be performed during revision or modification of machinery or at any time in order to assess existing machinery e.g. in case of mishaps or malfunctions.

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 14121-1:200X, *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 portion of the IMS

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

[ISO/DIS 11161:2005]

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 Clause 1 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:

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 remaining focused or with reaching consensus. The composition of the team can vary during the risk assessment process according to the expertise required for a specific problem. A team leader, dedicated to the project, should be clearly identified as the success of the risk assessment depends on his or her skills.

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 such as that outlined in 4.2.2 and by another competent person reviewing the risk assessment.

4.2.2 Composition and role of team members

The team should have a team leader. The team leader should be fully responsible for ensuring that all the tasks involved in planning, performing and documenting (in accordance with ISO 14121-1:200X, 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, in particular ISO 12100, and any specific safety issues associated with the machinery;

e) understand human factors (see ISO 14121-1:200X, 7.3.4).

4.2.3 Selection of methods and tools

A wide diversity of machinery in terms of complexity and potential for harm comes within the Scope of this document. There are also a variety of methods and tools for conducting risk assessment (see A.7). 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 14121-1:200X, 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 14121-1:200X, Figure 1.

5.2 Determination of the limits of the machinery

NOTE See ISO 14121-1:200X, 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 use, reasonably foreseeable misuse, and the type of environment in which it is likely to be used and maintained.

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

5.2.2 Functions of the machinery (machine-based)

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

- power supply;
- control;
- 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 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 14121-1:200X, Table A.3 for a list of typical/generic machinery tasks.

Machinery designers, users and integrators should communicate with one another where possible to be sure that all uses of the machine and the 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 14121-1:200X, Clause 6.

5.3.1 General

The objective of hazard identification is to produce a list of hazards, hazardous situations, and hazardous events that allows the possible accident scenarios to be described in terms of how and when a hazardous situation can lead to harm. A useful starting point for relevant hazards is ISO 14121-1:200X, Annex A, that can be used as a generic checklist. Other sources for hazard identification could be based on the information indicated in ISO 14121-1:200X, 4.2.

NOTE 1 Clause A.2 gives a worded example of hazard identification.

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 that deals with electrical hazards.

NOTE 3 Examples of machinery specific standards are ISO 10218, related to safety of robots, ISO 11111 (all parts) related to textile machinery and ISO 3691 (all parts) 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 14121-1:200X, 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 lifecycle, 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):

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 14121-1:200X, 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 that 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.

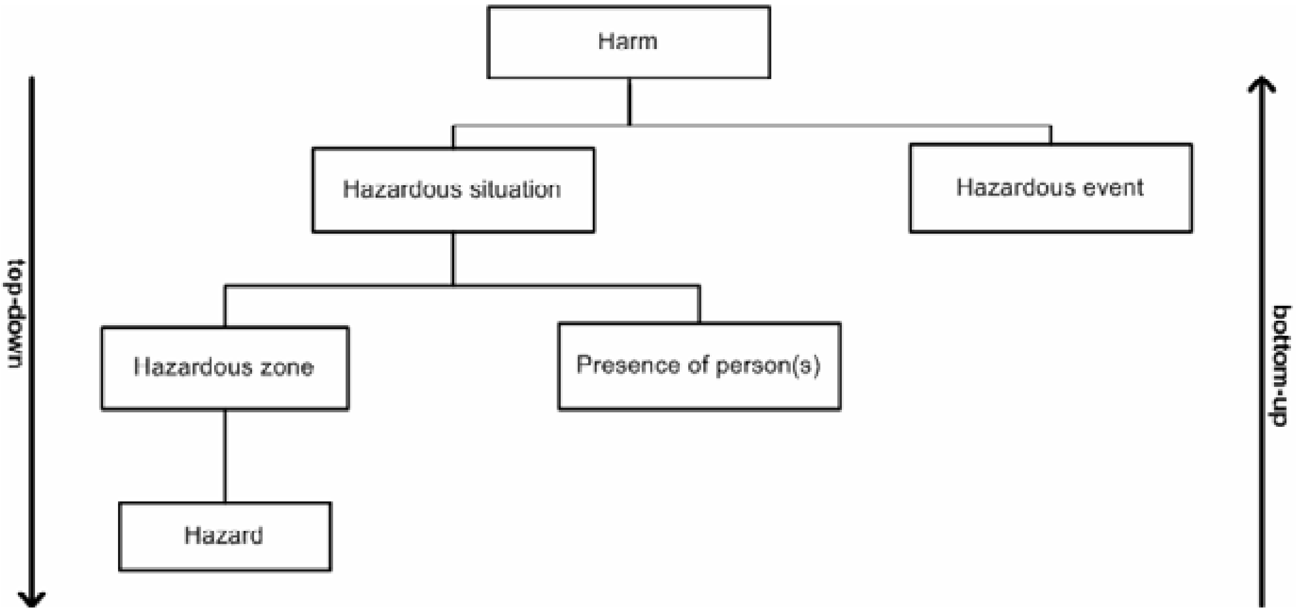

Figure 1 — Top-down and bottom-up approach

The **bottom-up approach** starts by examining all the hazards and considering all possible ways that something 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 14121-1:200X, Tables A.1 and A.2. The bottom-up approach can be more comprehensive and thorough than the top-down 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 do that exposes 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 work-piece) 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 the application in practice see worked example in A.2.

5.4 Risk estimation

NOTE See ISO 14121-1:200X, Clause 7.

5.4.1 General

The objective of risk estimation (see ISO 14121-1:200X, Figure 2) is to establish a risk magnitude expressed as a level, index or score for each possible accident scenario.

There are many different approaches to risk estimation that range 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 See ISO 14121-1:200X, 7.2.2.

All approaches to risk estimation should require the severity of possible harm to be defined in some way. For each accident scenario, a hazard can lead to several potential consequences. Most of the current approaches use only one entry for the severity of the potential consequences of each hazard; so the team estimating risk may have to choose the one that is most representative for the specific hazard under review. When doing this, the team should consider both the most likely consequence and the worst credible consequences that can realistically result from interaction with the hazard.

For example, consider the case of two machines: Machine 1 is an electrically powered (low voltage) fixed indoor machine with no conductive part in contact with the operator during operation, and no possibility of the operator being inside the machine: The second machine is a hand-held totally metallic tool operated by an electric motor. Each of them provides protection against indirect contact. In both cases there is an electrical hazard due to a contact with a metallic/conductive part that has become live under a fault condition. The potential severity of harm could be a shock with minimal discomfort, a painful shock, a shock with muscular contractions and effects on respiration, or a fibrillation with death (electrocution). For the first machine the severity of harm selected can be slight or low – discomfort or mild discomfort, the person shocked will react by releasing the conductive part. For the second machine the severity of harm selected can be serious or high - a painful shock or a shock leading to muscular contractions.

NOTE Severity of the harm is directly related to the potential for harm (hazardous properties) of the hazard under consideration. In general the lower the energy associated with a hazard, the lower the related severity of harm. The potential severity of harm will also be related to the part of the body that is exposed, e.g. a hazard that can cause crushing injuries is likely to be fatal if the head, rather than the hand is exposed.

For examples of different ways of classifying severity see the risk estimation approaches described in Annex A.

5.4.3 Probability of occurrence of harm

NOTE See ISO 14121-1:200X, 7.2.3.

5.4.3.1 General

All approaches to risk estimation should also require the estimation of the probability of an occurrence of harm resulting from an individual's interaction with a hazardous situation. This should be done by considering:

a) exposure of person(s) to the hazard (see ISO 14121-1:200X, 7.2.3.1);

b) probability of occurrence of a hazardous event (see ISO 14121-1:200X, 7.2.3.2);

c) technical and human possibilities to avoid or limit the harm (see ISO 14121-1:200X, 7.2.3.3).

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

When estimating the probability of harm the relevant aspects described in ISO 14121-1:200X, 7.3 should also be considered.

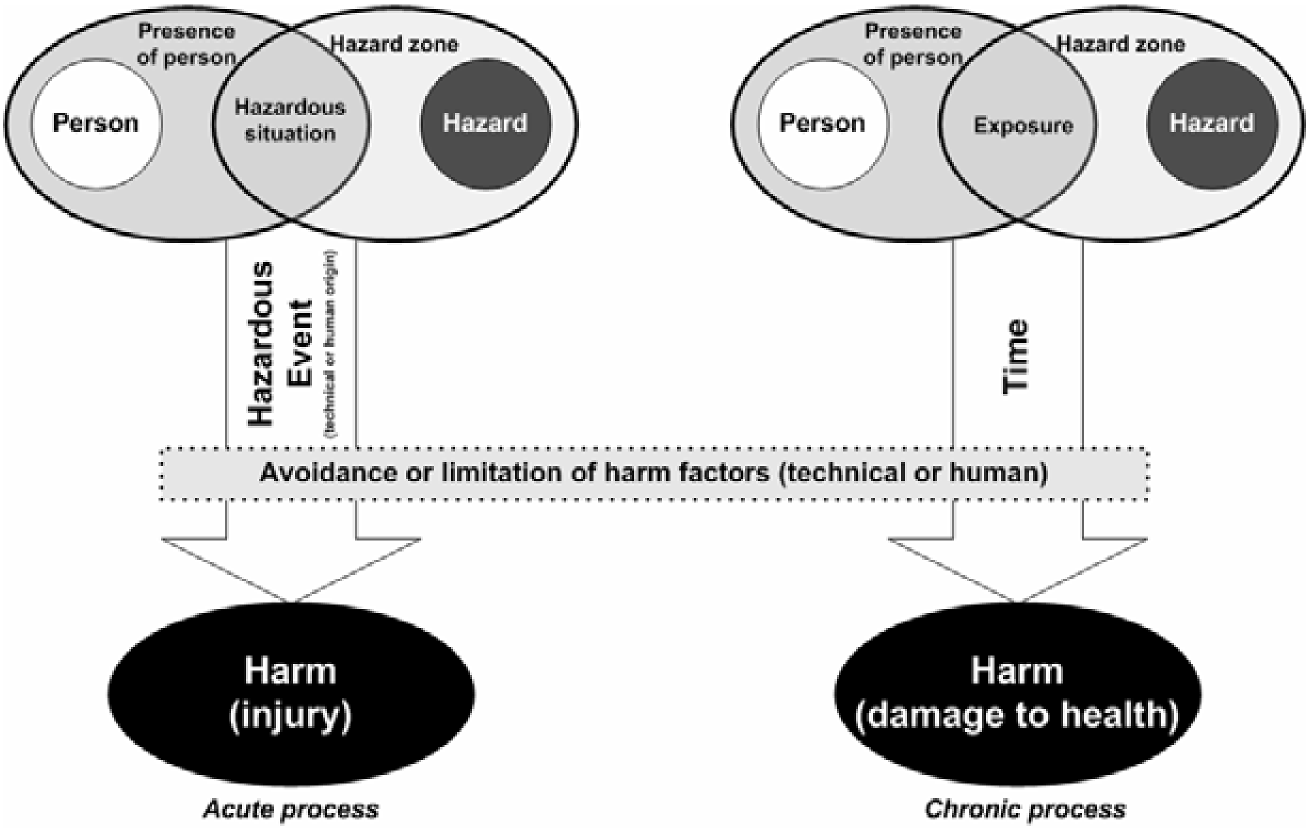

Figure 2 — Conditions of occurrence of harm

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, 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 harms the dose is dependent on the concentration of the substance;
- for deafness it is dependent on the noise levels;
- for repetitive strain injuries 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 later 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 five following methods:

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

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 validity of the results, as long as a systematic approach is taken to get from hazard identification to risk reduction that fully considers all the elements of risk, as described in ISO 14121-1:200X, 7.2. Moreover, resources are best directed at risk reduction efforts rather than optimising risk ratings.

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

Some tools/methods have additional parameters such as exposure, probability of occurrence of the hazardous event and the individual's possibility to avoid or limit the harm (see ISO 14121-1:200X, 7.2). This can cause the process to become more cumbersome, but can also help to ensure that all the factors that contribute to risk are properly considered.

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 classes chosen are then combined, using simple arithmetic, tables, charts or diagrams in order to estimate the risk.

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 they can have up to 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 from 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. Too few classifications 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 has a branched structure that is worked from left to right. Each branch represents one parameter (such as severity, probability of occurrence, exposure, the possibility to avoid or limit the harm). Each parameter has between two and four classes; each class is represented by a branch from that joint. The number of parameters should ideally be four to represent all components of risk in accordance with ISO 14121-1:200X, 7.2, however some risk graphs only have three. In general, a risk graph can also be represented as a multi-dimensional matrix.

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 at 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 with 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 which 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, either by addition, multiplication or combination 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.

One of the limitations of scoring systems is that the use of numbers can give a misguided impression of objectivity in the risk level when the choice of scores for each element of risk can have been very 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 in some tools and others express risk levels numerically their nature is essentially qualitative. There are no common reference datum and a numerical risk level estimated using one tool cannot directly be compared to one estimated with 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 the writing of this Technical Report, 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 to lead 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 mistakes.

Unfortunately 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 mistakes, e.g. if a key route to a hazardous event is overlooked. 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 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, to improve consistency, eliminate some of the subjectiveness and reduce mistakes, 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 for example by giving frequency ranges to probabilities or exposures. For example something that is ‘likely’ can be expressed as being once a year, 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 14121-1:200X, Clause 8.

The objective of risk evaluation is to decide which, if any, hazardous situation require further risk reduction. Moreover, to confirm that during previous iterations of the risk assessment process the protective measures previously selected have reduced risk sufficiently and have not introduced new hazards or increased other risks, thereby achieving the risk reduction objectives.

Some hazardous situations can be recorded as excluded from further consideration as 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 more detailed risk estimation can be useful.

If relevant machinery specific or hazard specific standard(s) exists (e.g. IEC 60204-1 dealing 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 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 14121-1:200X, 8.2.

Care should be taken so that simple and effective measures for reducing relatively low risks are not overlooked by focusing exclusively on the highest risks.

6 Risk reduction

Note — See ISO 14121-1:200X, 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 of 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 that 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	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
NOTE 1 is the highest priority.		

Different types of protective measures, in order of effectiveness, are listed below. Explanations are provided on their influence on the reduction of a particular risk element.

NOTE This list is provided for illustrative purposes only. This is not a comprehensive list. 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 to reduce risk because it removes the source of the harm. Examples of the methods for the elimination of the hazard are:

- 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 design features or the individuals interaction with the machine itself.

Examples of methods for risk reduction by design having the greatest impact on the severity of harm are:

- reducing energy (e.g. smaller drive motor, lower hydraulic/pneumatic pressure, reduced working height, reduced speed)
- utilising technical safety equipment for the prevention/reduction of hazard (e.g. the ventilation system prevents explosions/reduces hazardous vapours)

Examples of methods for risk reduction by design having the greatest impact on the exposure to the hazard are:

- reducing the need of being 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 having the greatest impact 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 cannot be 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 to avoid or limit harm.

When risk is reduced with the use of safeguards such as those shown below, it has little, if any, impact on the severity of harm. It has greatest impact 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):

- fixed guards, fencing or enclosures for the prevention of access to hazardous zones;

- 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 shown below, it has little, if any, impact on the severity of harm. It has greatest impact on the occurrence of hazardous event and little impact on exposure.

- sensitive protective equipment (SPE) for the detection of persons entering into or present in the hazard zone (e.g. light curtains, pressure sensitive mats);

- 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);

- 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 does not meet risk reduction objectives, complementary protective measures can be utilised to achieve further risk reduction. Examples of complementary protective measures having the greatest impact 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).

Examples of complementary protective measures having the greatest impact on exposure are:

- measures for isolation and energy dissipation (e.g. isolation valves or switches, locking devices, mechanical blocks to prevent movement).

6.6 Information for use

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

6.6.1 General

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

Information for use includes:

— 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:

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:

a) instruction handbooks;

b) technical data sheets.

6.7 Training

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

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

Regular review and checking 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 the harm and can also reduce exposure and the probability of occurrence of a hazardous event.

6.8 Personal protective equipment

The supplier should give details in the instruction handbook if any personal protective equipment should 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 to ensure 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 to take into consideration their needs in terms of protection, comfort, duration and frequency of use, ability to follow their working methods, etc.

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

6.9 Standard operating procedures

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

— 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 done taking into account the reliability, ease of use, possibility to defeat or circumvent the protective measures and ability to maintain them in accordance with ISO 14121-1:200X, 7.3.5, 7.3.6 and 7.3.7. Consideration should be given to the possibility of people taking the protective measure for granted and not being prepared should it fail. This is particularly true for interlocks and light curtains.

8 Documentation of the risk assessment

NOTE See ISO 14121-1:200X, 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 that is 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 is properly documented to allow decisions to be examined 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 14121-1:200X, 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 what measures 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 risk reduction process.

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 Technical Report 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 reader how an actual hazard identification or a risk estimation can look when a particular method is selected.

The examples given are for:

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, explosion), it could be appropriate to take into account specific risk estimation methods.

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

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

A.2 Hazard identification by application of forms

A.2.1 General

The aim of this subclause is to show a method for hazard identification (see 5.3 and ISO 14121-1:200X, Clause 6) using as the main tool the checklists defined in ISO 14121-1:200X, Clauses 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, engineering knowledge, etc. should be taken into account.

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

This method will be more effective the more complete and detailed are the available information for risk assessment (see ISO 14121-1:200X, 4.2) and the determination of the limits of the machinery (see 5.2 and ISO 14121-1:200X, 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 14121-1:200X, 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 carried out by using either a top-down approach, if the starting point is the potential consequence (harm), or a bottom-up approach, if the starting point is the origin of the hazard. In this step ISO 14121-1:200X, Table A.1, for description of origins of hazards, ISO 14121-1:200X, Table A.3 for description of hazardous situations and ISO 14121-1:200X, Table A.4 for description of hazardous events, are used.

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

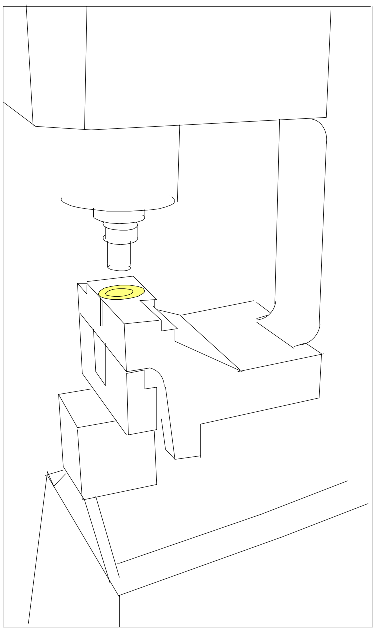

Figure A.1 — Puncturing zone of a punching press (without any protective measure)

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

HAZARDS IDENTIFICATION			
Machine (identification)		**Method/tool**	
Sources (e.g. preliminary design documentation, technical file, construction file)		**Analyst**	
		Current version	
Extent (e.g. - phase of the life cycle, - part/function of the machine		**Date**	

Ref	Hazard zone	Task / Operation (ISO 14121-1:200X, Table A.3)	ACCIDENT SCENARIO		
			Hazard (ISO 14121-1:200X, Table A.1)	**Hazardous situation** (ISO 14121-1:200X, Table A.3)	**Hazardous event** (ISO 14121-1:200X, Table A.4)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

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 puncturing zone. It does not cover other phases of the life cycle of the machine, such as assembly, setting, maintenance or fault finding (see ISO 14121-1:200X, 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 work-pieces;

b) positioning of work-pieces;

c) holding of work-pieces during puncturing;

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, going into the column “hazards” of ISO 14121-1:200X, Table A.1 and applying a bottom-up approach, all the possible origins of hazards are checked and the relevant ones identified. For each relevant hazard, all the combinations of hazardous situations and hazardous events are examined using the lists given ISO 14121-1:200X, 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.

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

<table>
<tr><th colspan="6">HAZARDS IDENTIFICATION</th></tr>
<tr><td colspan="3">Machine</td><td>Punching press</td><td>Method/tool</td><td>Checklists – Annex A of ISO 14121-1</td></tr>
<tr><td colspan="3" rowspan="2">Sources</td><td rowspan="2">Preliminary design documentation</td><td>Analyst</td><td>K. Jones</td></tr>
<tr><td>Current version</td><td>V 1</td></tr>
<tr><td colspan="3">Extent: - Phase of the life cycle</td><td>Operation</td><td>Date</td><td>20/05/05</td></tr>
<tr><td colspan="3">- Part/Function of the machine</td><td>Punching function</td><td colspan="2"></td></tr>
<tr><th rowspan="2">Ref</th><th rowspan="2">Hazard zone</th><th rowspan="2">Task / Operation</th><th colspan="3">ACCIDENT SCENARIO</th></tr>
<tr><th>Hazard</th><th>Hazardous situation</th><th>Hazardous event</th></tr>
<tr><td>1</td><td rowspan="7">Puncturing zone</td><td rowspan="2">Manual loading/unloading and positioning of the work-piece</td><td>Falling objects (work-pieces)
Crushing (foot or fingers)</td><td>Handling heavy work pieces, with both hands</td><td>Falling of a work-piece</td></tr>
<tr><td>2</td><td>Sharp edges (work-pieces)
Cutting</td><td>Handling work-pieces with sharp edges, with both hands</td><td>Contact with sharp edges and corners of work-pieces</td></tr>
<tr><td>3</td><td rowspan="4">Manual holding of the work-piece with both hands during puncturing</td><td>Moving elements (downward and upward movement of the punch and upward movement of the work-piece)
Crushing, severing and puncture</td><td>Work near moving parts</td><td>Access/Contact with moving parts due to an absence of guard or protective device</td></tr>
<tr><td>4</td><td>Moving elements (ejection of tool parts or work-piece parts)
Impact</td><td>Operator and other people exposed to ejection of parts</td><td>Break-up of the punch or the work-piece (by several causes such as inadequate punch, punch fatigue or ageing or fragility, inadequate work-piece material)</td></tr>
<tr><td>5</td><td>Noisy manufacturing process (impact noise)
Discomfort</td><td>Operator and other people exposed to hazards generated by noise</td><td>Emission of a level of noise that can be hazardous</td></tr>
<tr><td>6</td><td>Parts which have become live under faulty conditions
Electric shock</td><td>Work with a machine under voltage</td><td>Indirect contact</td></tr>
<tr><td>7</td><td>Minor interventions during operation (removing waste material and lubrication of the tool)</td><td>Moving elements (downward and upward movement of the punch und upward movement of the work-piece)
Crushing, severing and puncture</td><td>Work under powered actuators (cylinder-tool)</td><td>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</td></tr>
</table>

A.3 Risk assessment using risk matrix

A.3.1 General

The application of a risk matrix occurs after hazards have been identified (see ISO 14121-1:200X, Clause 6) and is used to assess risks associated with the identified hazards (see ISO 14121-1:200X, 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 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, more time 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.

As shown in Tables A.3 and A.4, different risk matrices use different levels for each risk factor – for example, Table A.3 has four levels of probability where 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 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; or
- other factors.

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

- **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, and that 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:

- frequency and duration of exposure to a hazard;
- personnel who perform 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.

Similar to 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

Some methods draw a distinction between probability and likelihood; where probability is a numerical value between 0 and 1 and likelihood is a qualitative description of probability. However, many methods do not distinguish between the terms probability and likelihood and use them 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 reader, since the decision is culture-, situation- and 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 wood working 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 still to be inserted here>

Figure A.2 — Sawing operation in a wood working 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	on-going
	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	on-going
	Noise: noise / sound levels > 85 dBA	serious / very likely	high	hearing protection	serious / unlikely	medium	on-going
sawyer / place boards on output conveyor	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 method of assessing risks. 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 answer.

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 to either explain in detail how the form has been 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 this method to a paper trimmer press, already installed. Risk has been estimated twice: once before protective measures have been chosen and once 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 14121-1:200X, 5.3. A risk index is then calculated using the risk graph given in Figure A.3, based on the four following parameters, corresponding to the four elements of risk as defined in ISO 14121-1:200X, 7.2.1, each one having its particular limits:

- Severity of the harm: S

➢ S1 slight injury (usually reversible; examples: scratch, laceration, bruise, light wound requiring first aid, etc.);

➢ S2 serious injury (usually irreversible, including fatality); examples : broken or torn-out or crushed limb; fracture; serious injury requiring stitches, major musculoskeletal trouble (MST), fatality, etc.

- Frequency and/or duration of exposure to hazard: F

➢ F1 twice or less by work shift or less than 15 min cumulated exposure by work shift;

➢ F2 more than twice by work shift or more than 15 min cumulated exposure by work shift.

- Probability of occurrence of the hazardous event: O

➢ O1 mature technology, proven and recognized in safety application; robustness;

➢ O2 - technical failure observed in the two last years;

- inappropriate human action by a well trained person, aware of the risks, with more than six months experience on the work station.

➢ O3 - technical failure regularly observed (every six months or less)

- inappropriate human action by an untrained person, with less than six months experience on the work station.

- similar accident observed in the plan since ten years

- Possibility of avoidance or reduction of the harm: A

➢ A1 possible under some conditions:

- If parts move at a speed less than 0,25 m s^{-1}

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

- depending of particular conditions (temperature, noise, ergonomic, etc.);

➢ A2 impossible.

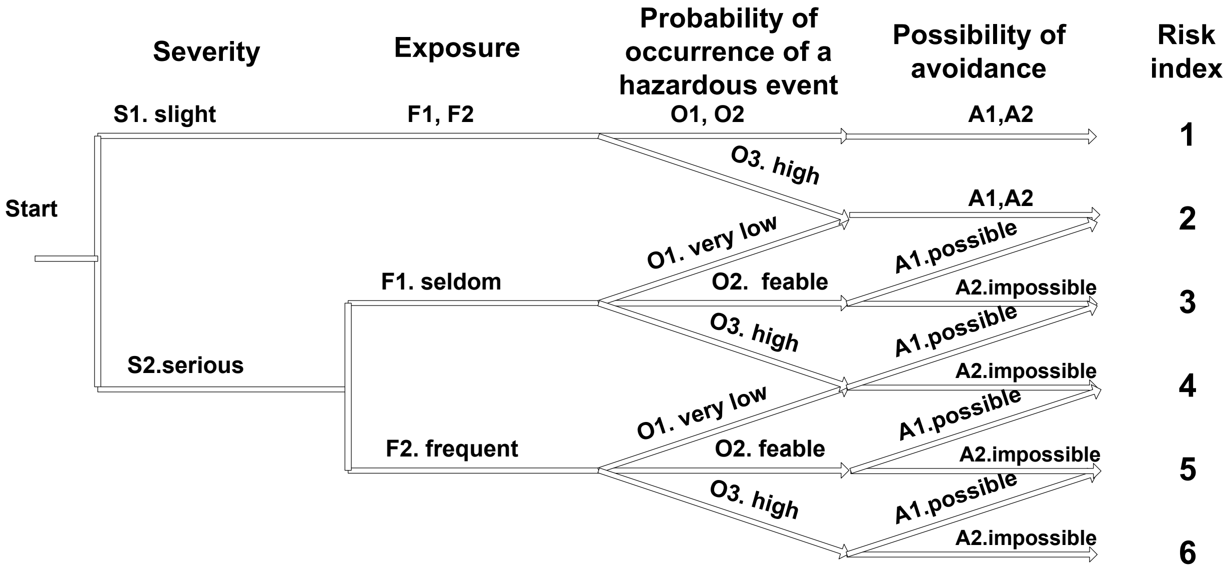

Figure A.3 — Risk graph for risk estimation

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 done considering that:

— a risk index of 1 or 2 corresponds to the lowest priority (priority 3);

— a risk index of 3 or 4 corresponds to a medium priority (priority 2);

— and a risk index of 5 or 6 corresponds to the highest priority of action (priority 1).

Possible means to reduce risk are considered and then the risk is estimated for the final design using the same risk graph in the same way 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 with compressed air and electricity. Three basic tasks have been identified and analyzed:

- 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.

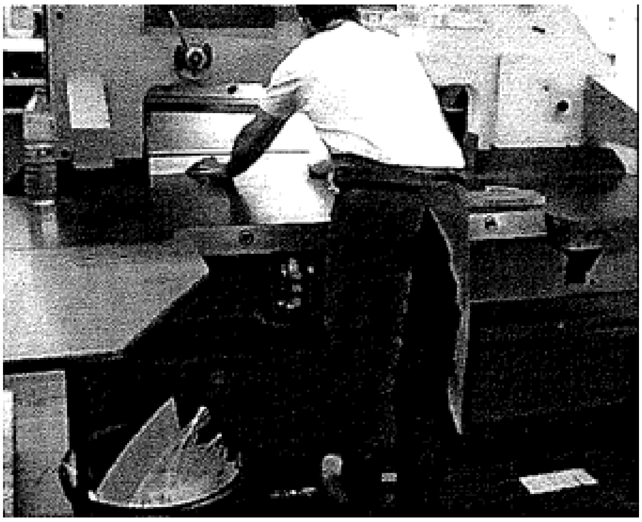

Figure A.4 — Positioning the stack of paper sheets

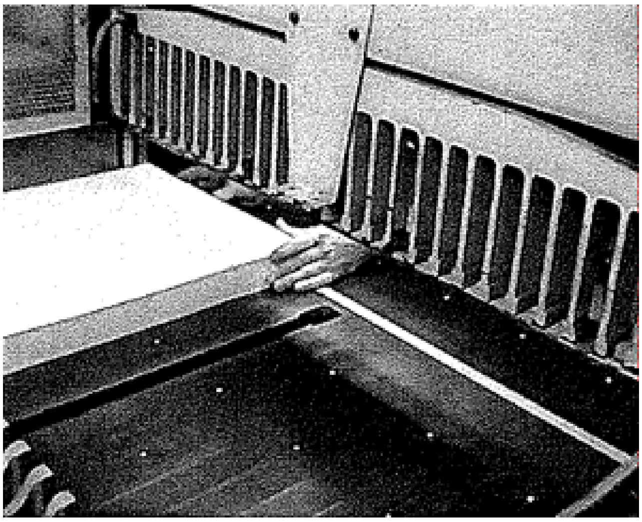

Figure A.5 — Worker's hand under the cutter

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 the result of the initial risk analysis. Table A.7 shows 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 make a selection.

In Table A.7, high lighted bold figures show the changes introduced by the proposed protective measures.

Table A.6 — Result of the initial risk analysis

Initial risk analysis											
Activity		Hazardous conditions				Risk estimation Risk index calculation					
Nr	Activity	Hazard	Hazardous situation	Hazardous event	Possible harm	Severity (S1/S2)	Frequency/ Exposure (F1/F2)	Probability of occurence (O1/O2/O3)	Possibility of avoidance (A1/A2)	Risk index (1 to 6)
1	Positioning of the paper stack	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	2	5
1.1		Press and knife in upper position under energy	The worker's hands are under mobile parts under energy	Unexpected move of the press or the knife by action on the start pedal	Crushing, cut of the upper limbs	2	2	2	2	5
—				Unexpected move of the press or the knife by failure of the control circuit		2	2	2	2	5
1.2		Cutting edges of the paper	The workers hands handle the paper stack	Movements of the hands on the cutting edges of the paper sheets	Fingers or hands cuts	1	2	3	1	2
2	Pressure on the paper stack	Vertical movement of the press (applied force 1000 N)	The worker holds the paper stack in position with his hands close to the press	Workers' hands under the press in movement triggered by the worker	Crushing of upper limbs	2	1	3	2	4
—				Workers' hands under the press in movement triggered by failure of the control circuit		2	1	2	2	3
3	Paper cutting	Vertical movement of the knife	The workers hands are close to the paper stack	Workers' hands in the trajectory of the knife in movement triggered by the worker	Major cut of upper limbs	2	1	3	2	4
				Workers' hands in the trajectory of the knife in movement triggered by failure of the control circuit		2	1	2	2	3

Table A.7 — Result of the residual risk analysis

Initial risk analysis results				Risk analysis after risk reduction							
				Risk reduction		Risk estimation after risk reduction Risk index after risk reduction					
Nr	**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)	Risk index (1 to 6)	Remarks
1a	Positioning of the paper stack	Electrical energy available	5	- Insulation and connections periodical check - Residual current sensing device	- Insulation and connections periodical check	2	2	***1***	2	***4***	No difference of risk index between 1a and 1b
1b			5		- Residual current sensing device	2	2	2	***1***	***4***	
1.1a		Press and knife in upper position under energy	5	- Installation of a hood on the pedal - Machine control circuit category in accordance with ISO 13849-1	- Installation of a hood on the pedal	2	2	***1***	2	***4***	No difference of risk index between 1.1a and 1.1b
1.1b			5		- Machine control circuit category in accordance with ISO 13849-1	2	2	***1***	2	***4***	
1.2		Cutting edges of the paper	2	- Protective gloves - Reduce sharpness of the paper sheets NOTE — For the quality of printing of special papers, wearing glove is mandatory.	- Protective gloves	1	2	**2**	1	***1***	—

Table A.7 *(continued)*

Initial risk analysis results				Risk analysis after risk reduction: Risk reduction		Risk estimation after risk reduction – Risk index after risk reduction					
Nr	**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)	Risk index (1 to 6)	Remarks
2a	Pressure on the paper stack	Vertical movement of the press (applied force 1000 N)	4	- Triggering of the press movement with a two-hand control device and machine control circuit category in accordance with ISO 13849-1 - Training - Triggering of the press movement with a pedal control actuator with control circuit category in accordance with ISO 13849-1 - Reduce pressure before the press reaches the paper stack	-Triggering of the press movement with a two-hand control device and machine control circuit category in accordance with ISO 13849-1	2	1	***1***	2	***2***	- The most efficient risk reduction mean is 2d then 2a or 2c; - The solution 2b is not recom-mended
2b			4		- Training	2	1	***2***	2	***3***	
2c			3		- Pedal control actuator with control circuit category in accordance with ISO 13849-1	2	1	***1***	2	***2***	
2d			3		- Pedal control actuator with control circuit category in accordance with ISO 13849-1 - Reduce pressure before the press reaches the paper stack	***1***	1	***1***	2	***1***	
3a	Paper cutting	Vertical movement of the knife	4	- Triggering of the knife movement with a two-hand control device with control circuit category in accordance with ISO 13849-1 - Detection of presence of worker's hands with safety light curtain	- Triggering of the knife movement with a two-hand control device with control circuit category in accordance with ISO 13849-1	2	1	***1***	2	***2***	No diffe-rence of result between 3a and 3b
3b			3		- Detection of presence of worker's hands with safety light curtain	2	1	***1***	2	***2***	

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

A.4.3.3 Discussion

In the presented example, a simple work activity has been analyzed 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; for instance, to reduce risk induced by the vertical movement of the press:

- The most efficient risk reduction measure is solution 2d, then solution 2a or solution 2c.
- Using solution 2b as the only risk reduction measure is not recommended.
- No difference of result between solution 1a and solution 1b, between solution 1.1a and solution 1.1b and between solution 3a and solution 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; it is therefore recommended to assess the risk with all of these measures applied together.
- periodically check insulation, connections and residual current sensing device against energized frame of the machine (failed connection, worn out cable, etc.).
- install of a hood on the pedal and machine control circuit category in accordance with ISO 13849-1 against any unexpected move of the press or the knife by action on the start pedal or by failure of the control circuit);
- complemented with training and warning.

This risk graph can be used to estimate a risk index mostly for hazardous situations that can induce acute harms, which are 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. However in these cases, the results obtained with this risk graph tool should be compared with the result obtained with specific tools dedicated to noise or ergonomics.

As risk assessment has to be done by a team and generates consensus, it cannot be expected that the detail results will always be the same with different teams analyzing different situations. It has been found convenient by some industries to adapt slightly the parameters and the limits of the risk graph; these changes might induce different results.

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

Figure A.6 — Equivalent risk matrix

<table>
<tr><td colspan="2" rowspan="3"></td><th colspan="6">Risk index calculation</th></tr>
<tr><td colspan="2">O1</td><td colspan="2">O2</td><td colspan="2">O3</td></tr>
<tr><td>A1</td><td>A2</td><td>A1</td><td>A2</td><td>A1</td><td>A2</td></tr>
<tr><td rowspan="2">S1</td><td>F1</td><td colspan="4" rowspan="2">1</td><td colspan="2" rowspan="2">2</td></tr>
<tr><td>F2</td></tr>
<tr><td rowspan="2">S2</td><td>F1</td><td colspan="3">2</td><td colspan="2">3</td><td>4</td></tr>
<tr><td>F2</td><td>3</td><td colspan="2">4</td><td colspan="2">5</td><td>6</td></tr>
</table>

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 integer range within classes 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) and each of these parameters is 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 as follows:

probability score (PS) + severity score (SS) = risk score (RS) (A.1)

The risk score 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 that is 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 adequate education to be employed in a fast food establishment).

An injury surveillance system was searched to identify injury cases associated with bagel slicers. The injury surveillance system sample is 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 is 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 does not correspond to an assessment of a particular employer’s use of the machine. The workplace observation revealed that the current levels of protection provided are an adjustable barrier guard, warning signs, and the suppliers recommended safe operating procedures. The possible severity of injury is deep laceration to a finger when coming in contact with the spinning blade while performing the tasks of normal bagel slicing, clearing jammed bagels, and cleaning the bagel slicer.

The bagel chute is a long, 4-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 and has a wavy edge. The blade operates at a high rotational speed and coasts to a stop (no brake). The top opening is about shoulder height, or a little below. The guard opening size and the distance from the opening to the blade permit a hand to extend in to touch the blade.

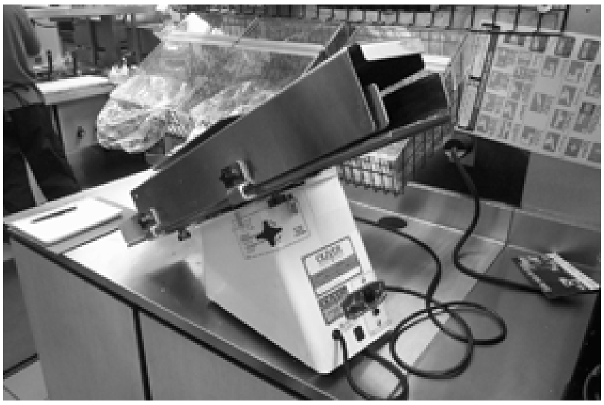

Figure A.7 — Bagel slicer

The machine manufacturer provides 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 it is recognized that although safe operating procedures are provided it does not assure 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 shown 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 lost work time) and the initial probability is 70 (likely) range (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, the warning sign, and the 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 training 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 training 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 training 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) to youth. The existing protective measures: the adjustable guard, the warning sign, and the safe operating procedures, contribute to this low risk rating. Including automatic feeding and ejection devices would not appreciably reduce the risk level.

A.6 Quantified risk estimation

NOTE See 5.4.4.5.

A.6.1 General

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

Before using such a method 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 can be modified or added to according to your 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 is 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 in accordance with 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

NOTE The text in italics relates to the illustrative example.

A.6.2.1 Form 1 — Description of accident scenario

This form given as Table A.11 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 technician, others will be relevant to a range of different types of people, operator, maintenance technician and passers-by. This should be made clear on the form.

The objective is to clearly describe, as far 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 14121-1:200X, 7.3.

Table A.10 — Form 1

Definition	**Description for machine**
Hazard Describe the potential source of harm	*Live electrical parts at high voltage*
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.	*Heavy items left lying in path of powered roof support after non-routine tasks posing a hazard when normal operation is resumed.*
Hazardous event: Describe how the hazard can cause harm. It can be a human error during the hazardous operation, or a random event/failure.	*Ignition of explosive atmosphere* *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*
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	*Explosion – death of anyone in vicinity, possibly several*
Preconditions for hazardous event: The identified preconditions all must 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. 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.	**1** *Girder left in path of roof support - without good training and supervision this is likely,* **2** *High voltage cable damaged – if the cables are not protected this is very likely* **3** *Explosive atmosphere exists – without suppression of coal dust this is very likely, a methane air mixture is also possible*

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*	10^{-1}	p_2	*0,1*
3 *Explosive atmosphere exists*	10^{-1}	p_3	*0,1*
…	—	….	—
n	—	p_n	—
Probability that all preconditions are met Note that 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.		$\prod_{i=1,n} p_i$	*1 x*10^{-4}

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 3A for those hazardous events that are initiated by human error whilst exposed to the hazard. Use form 3B for those hazardous events that are initiated by an event or failure that can happen irrespective of whether someone is exposed or not. When the 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 3B rather than 3A should be used. Human error can also be a precondition rather than the initiating event.

Form 3A requires

- 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 3 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 the human error so form 3B is used

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

Table A.12 — Form 3A

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 x 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 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	$n_3 = n_1 . n_2$	
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 are 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 3B given as 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 3B

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 1) *If high voltage cable is damaged and explosive atmosphere exists the arc will sooner or later lead to an ignition*	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 doing hazardous operation divided by time involved with the machine – this prevents dilution for those who only use machine occasionally *The coal face is assumed to be operational on average for 90% of a typical shift*	r_2	0,9
Probability that all pre-conditions are met If there are no preconditions this is set to 1. If there are more than one precondition use form 2 to calculate this.	P_p	*0,9*
Frequency (per year) of hazardous event whilst person(s) exposed	$F = P_p f_1 r_2$	*0,9 x10^-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 to avoid or limit the harm. It helps avoid over or underestimating risk when the worst conceivable risk is death but due to possibilities to limit or avoid harm a major or minor injury is much more likely.

Table A.14 — Form 4

<table>
<tr><th colspan="3">Component</th><th>Identifier</th><th>Value</th></tr>
<tr><td colspan="3">Frequency of hazardous event whilst person exposed from form 2A or 2B</td><td>F</td><td>$0,9 \times 10^{-4}$</td></tr>
<tr><td rowspan="2">Severity level
See Table A.18 for examples</td><td colspan="2">Probability that if harm occurs it is of particular severity</td><td colspan="2">Frequency of harm for each severity level (events per year)</td></tr>
<tr><td>Identifier</td><td>Value</td><td>Identifier</td><td>Value</td></tr>
<tr><td>Fatal and permanent serious disability</td><td>S_1</td><td>1</td><td>$F.\ S_1$</td><td>$0,9 \times 10^{-4}$</td></tr>
<tr><td>Major – very unlikely to survive explosion</td><td>S_2</td><td></td><td>$F.\ S_2$</td><td></td></tr>
<tr><td>Minor</td><td>S_3</td><td></td><td>$F.\ S_3$</td><td></td></tr>
<tr><td>No or trivial injury</td><td>S_4</td><td></td><td></td><td></td></tr>
<tr><td>Total</td><td>$S_{1+} S_{2+} S_{3+} S_4$</td><td>1</td><td></td><td></td></tr>
</table>

Table A.15 — Frequencies 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 the shoulder, hip, knee or spine - treatment required due to fume exposure - anything requiring resuscitation
Minor injury	- minor broken bones (fingers, toes) - cuts and bruises - minor burns, temporary scarring - anything else requiring first aid only
No injury and near misses	- no injury including the possibility of avoidance

A.6.2.5 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 example in this example training and competence appears to be important for risk reduction.

The full risk assessment process led by an experienced practitioner with designers and installation/ maintenance engineers looking at a specific powered roof support system in the team took:

- one day for familiarisation/determination of limits;
- two days for hazard identification that produced a list of 41 relevant hazards and hazardous situations;
- one 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. This would be reduced significantly if the method were computerised.
- one 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 and also 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 challenge 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 standardised or widely recognised 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 through 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 using this method, preparation has to be done as described in Clause 4 and the machinery limits has to be 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 this is the first risk assessment. It is done in the concept phase where only specification and sketches are available. No detail drawings are made at this stage. This is to decide on the major systems of a machine e.g. mechanical drive line or servo drives, hot air or ultra sonic 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.20.

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. Although where a new hazard is identified when follow 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. See Table A.20.

Reference number, Ref. No

The Ref. No., serial number, is to give each identified hazard a reference number.

Type number, Type. No

Type. No., hazard type or group number, is to classify the hazards. The numbers refers to the numbers given in type or group in ISO 14121-1:200X, 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 this is indicated by "1" in the Type No. column and crushing in the hazard column.

The same hazard may 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:

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 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:

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 a hour but less than or equal to a day. Where the duration is shorter than 10 min, the value may be decreased to the next level.

5 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 e.g. 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 dairy environment is hot, electricity is dangerous by its nature) to determine the level of probability. The probability is scored as:

1 Negligible. E.g. this kind of component never fails so a hazardous event occurs. No possibility of human mistakes.

2 Rarely. E.g. it is unlikely this kind of component fails so a hazardous event occurs. Human mistakes are unlikely to occur.

3 Possible. E.g. this kind of component may fail so a hazardous event occurs. Human mistakes are possible to occur.

4 Likely. E.g. this kind of component will probably fail so a hazardous event occurs. Human mistakes are likely to occur.

5 Very high. E.g. this kind of component is not made for this application. It will fail so a hazardous event occurs. Human behavior is such that the likelihood of mistakes is very high.

Avoidance, Av

Av is the possibility to avoid or limit the harm. Consider e.g. the machine to be operated by skilled or unskilled persons, how quickly a hazardous situation can lead to harm, and awareness of the risk by general information, direct observation or through warning signs, to determine the level of avoidance. The possibility of avoidance is scored as:

1 Likely. E.g. it is likely to avoid contact with moving parts behind an interlocked guard, in most cases, should the interlocking fail where the movements continue.

3 Possible. E.g. it is possible to avoid an entanglement hazard where the speed is slow.

5 Impossible. E.g. it is impossible to avoid an inhalation of harmful gas hazard where there are no warning signs.

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 14121-1:200X, 7.2.1. Each of the three factors should be estimated independently of each other. 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.20.

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 the 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 are 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 is 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 this Table.

The first risk assessment, pre-risk assessment, is given a document number 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 to require protective measures.

The next risk assessment, intermediate risk assessment, is 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 is assessed again, now with its protective measure in place. It is validated to be adequately safe and is so indicated in the "Adeq. Safe"- column of the form, Table A.19.

At the same risk assessment, Table B.19, two new hazards were identified, hazard Ref. No. 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. No. 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 "Adeq. 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. No 2 and 3 are validated and does not require protective measure this new one is indicated adequately safe in the "Adeq. safe"- column.

If the newly identified hazard requires 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.

Table A.19 — Example of a completed hybrid method form

Document No.: 684
Part of doc. No: 672

Risk assessment and protective measures

Product: Oscillating drive
Issued by: Johnny Persson
Date: 2003-03-17

☐ Pre risk assessment
☒ Intermediate risk assessment
☐ Follow up risk assessment

Black area = Safety measures required
Grey area = Safety measures recommended

Consequences	Severity Se	Class Cl (Fr+Pr+Av) 3 - 4	5 - 7	8 - 10	11 - 13	14 - 15	Frequency Fr		Probability Pr		Avoidance Av	
Death, losing an eye or arm	4						≤ 1 h	5	very high	5		
Permanent, losing fingers	3						> 1 h to ≤ 24 h	4	likely	4		
Reversible, medical attention	2						> 24 h to ≤ 2 w	3	possible	3	impossible	5
Reversible, first aid	1						> 2 w to ≤ 1 y	2	rarely	2	possible	3
							> 1 y	1	negligible	1	likely	1

Ser. No.	Hzd. No.	Hazard	Se	Fr	Pr	Av	Cl	Protective measure	Adeq. safe
1	2	Shock from live parts							Yes
2	1	Finger crushing	3	4	2	3	9	Interlocking guard	
3	1	Finger between moving pin and frame	2	3	2	3	8	Interlocking guard	

Comments to ref. No.

2	Finger crushing between belt and belt pulley

Annex B
(informative)

Example of application of the process of the risk assessment and risk 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 doesn't seek to embrace the complete design of this type of machines, neither to be a model to follow. It only tries to present enough information so that the reader has a global idea on a possible way of applying the principles set out in ISO 14121-1 and ISO 12100.

Clauses B.2 and B.3 have been elaborated taking into account the whole life cycle of the machine. But, from Clause 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 14121-1:200X, 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 Basics

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

B.2.1.3 Work to be performed with the machine

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

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

— straight work

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

— stopped straight work

  Machining of only a part of the workpiece length.

— curved work

  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 in 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 handwheel (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 which rests on a steel cabinet. Both the table and the cabinet provide good support for the workpiece and are of a height to ensure an ergonomic 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.

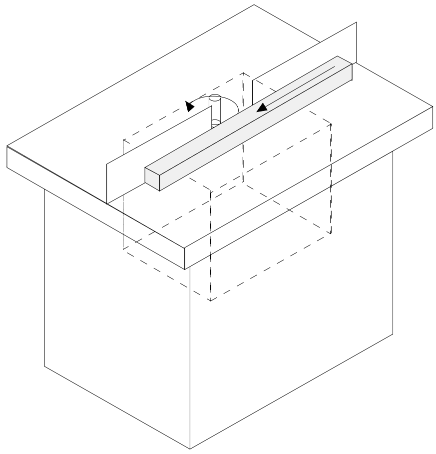

Figure B.1 — Machine concept

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 works. Not using a guard or using an inappropriate one, not using false fences, pressure pads, jigs, templates, end stops are common causes of accidents on this kind of machine.

Other less frequent accidents are impacts due to kickback of the workpiece and the ejection of chips, parts of the tools or of the machine, and fire of 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 normative texts are 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 OSHA have been consulted.

NOTE Other documents that should be taken into account are the regional or national applicable regulations and EN 848-1 which deals with this kind of machine and EN 847-1 which deals with milling tools, although for the didactic objectives of this example they have not been used.

B.2.4 Preliminary design of the machine

Taking into account all the information above, the following technical specifications have been set up:

— 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: 1250 mm x 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):

  3000 min-1, 4500 min-1, 6000 min-1 and 7500 min-1; the selected speed will depend on the material, diameter and height of the tool

— tool diameter: e.g. from 120 mm to 220 mm (maximum diameter of the tool).

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 is made up by a steel cabinet and a cast iron table that rests on the cabinet. Inside the cabinet there are 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 which acts every time that a stop command is given for stopping the movement of the spindle in a short time. The brake can be released when performing some operations (e.g., speed changing). This motor transmits the power to the spindle through the pulleys and a trapezoidal belt.

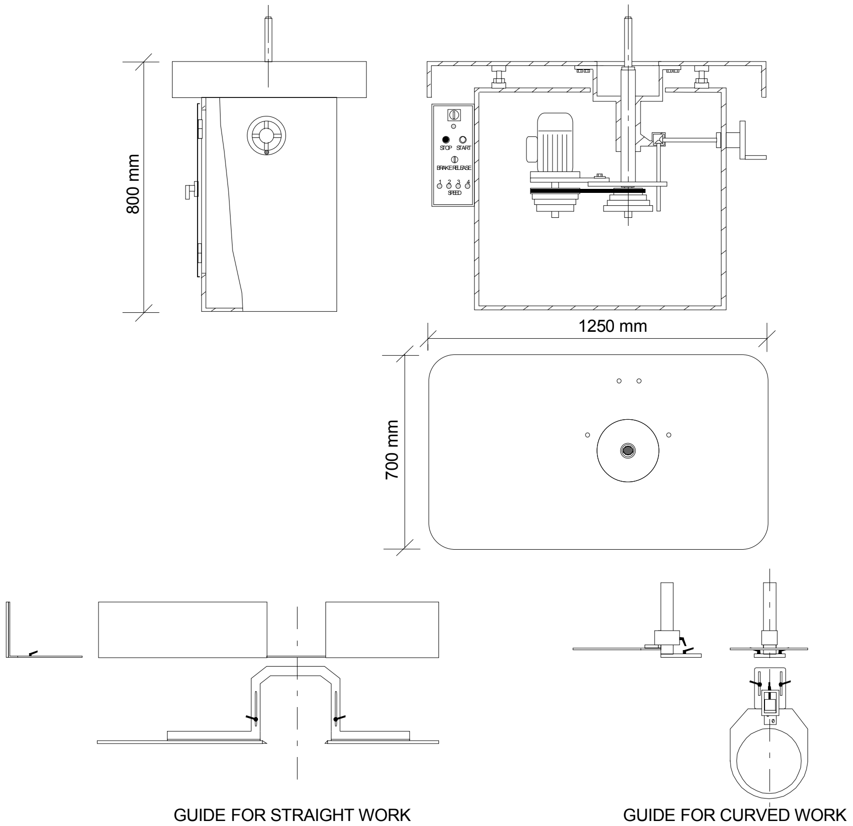

Figure B.2 — Preliminary design drawings

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 (no 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 not accessible moving elements.

The control circuit is in a cabinet placed in front of the machine and basically includes 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.

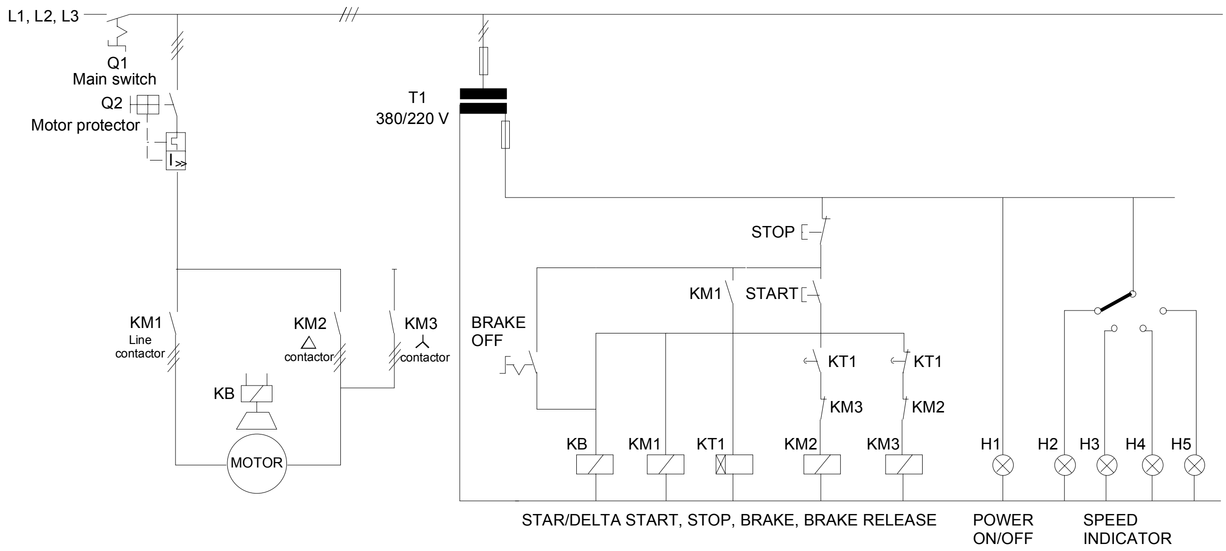

Figure B.3 — Preliminary design of circuit diagram

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 on the floor; connection to the electric power supply; checking of proper installation (correct direction of rotating 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 of 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.

— de-commissioning, 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 to modify the profile of square or rectangular cross section wooden pieces and analogous materials (cork, chip board, fibre board and 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 this kind of machine, without limited physical abilities of the upper limbs and no visual impairment.

The machine is intended to be operated 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 appropriate and standardized cutting tools which provide complete technical guarantee must be used.

B.3.2.2 Reasonably foreseeable misuse

The reasonably foreseeable misuse taken into account is as follows:

— processing materials other than the foreseen like rubber, stone, metals or wood products not clear from foreign objects;

— processing products with unsuitable cross sections (cylindrical, eliptical);

— tenoning;

— using the machine with customized or home made tools;

— replacing components or spare parts with other different from the supplied (e.g. transmission belts);

— using the machine by persons under 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 3000 mm x 3000 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 with an explosion or fire hazards.

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 wear parts 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 intended every shift.

A general cleaning of the machine is intended every six months.

B.4 Hazard identification

B.4.1 Extent of the system to be analysed

As it has already been set out in Clause 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 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 if the cutting depth, the adjusted spindle height, etc., are appropriate).

At the machine operation the following task is to be 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 have been defined (see Figure B.4):

— Zone 1: Working zone;

— Zone 2: Machine frame;

— Zone 3: Transmission zone;

— Zone 4: Machine surrounding.

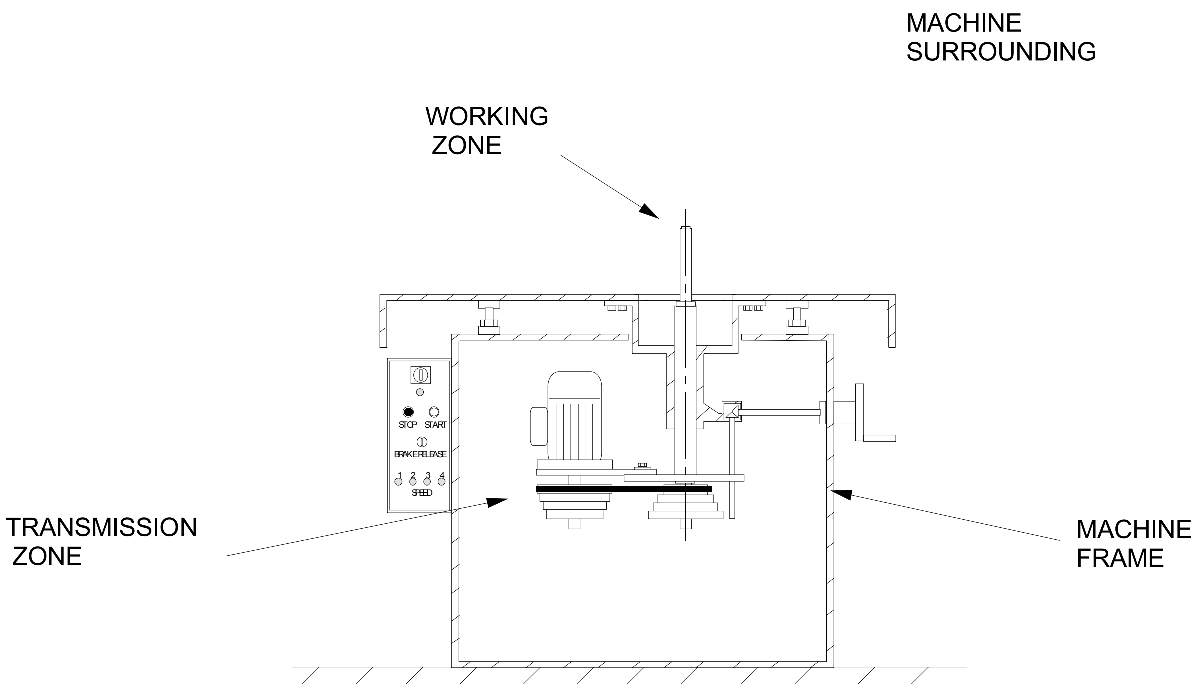

Figure B.4 — Hazard zones

See Table B.1 for hazard identification.

Table B.1 — Hazard identification

RISK ASSESSMENT (HAZARD IDENTIFICATION)			
Machine	Vertical spindle moulding machine	**Analyst**	Mr. Comaba
Sources	Specifications, preliminary design	**Current version**	2.0
Extent	Use phase: setting and operation	**Date**	September 2005
Method	Checklists - ISO 14121-1:200X, Annex A	**Page**	1

Ref	Life cycle	Task	Hazard zone	Accident scenario			Ref
				Hazard	Hazardous situation	Hazardous event	
1	Use phase: Setting	Changing tool	Working zone	Cutting fingers or hands at sharp tool edges	Working near/with the tool (handling/mounting)	Contact with sharp edges due to carelessness or loss of balance	**1**
2					Working near/with the tool (fastening/unfastening)	Contact with sharp edges due to spindle rotation caused by fastening/unfastening force	**2**
3						Contact with sharp edges due to loss of control, tool slipping by use of unsuitable hand tools	**3**
4					Working near/with the tool (handling, mounting and fastening)	Unexpected start-up inducing contact with moving parts	**4**
5		Mounting, adjusting guide			Working near the tool	Contact with sharp edges due to carelessness	**5**
6						Unexpected start-up inducing contact with moving parts	**6**
7	Use phase: Setting	Changing spindle speed	Trans-mission zone	Crushing fingers or hands by rotating elements (between pulleys and belt)	Working near the transmission system (e.g., check/ inspection of transmission with machine running)	Access /contact to /with moving parts due to a design error NOTE — The access to the transmission system is a predictable human behaviour (reasonably foreseeable misuse), for instance, for checking, inspection, etc., that should be prevented by an appropriate design of the machine	**7**

Table B.1 *(continued)*

RISK ASSESSMENT (HAZARD IDENTIFICATION)			
Machine	Vertical spindle moulding machine	**Analyst**	Mr. Comaba
Sources	Specifications, preliminary design	**Current version**	2.0
Extent	Use phase: setting and operation	**Date**	September 2005
Method	Checklists - ISO 14121-1:200X, Annex A	**Page**	2

Ref	**Life cycle**	**Task**	**Hazard zone**	**Accident scenario**			**Ref**
				Hazard	**Hazardous situation**	**Hazardous event**	
8	Use phase: Setting	Changing spindle speed	Trans-mission zone	Crushing fingers or hands by rotating elements (between pulleys and belt)	Working near the transmission system (while machine is stopped)	Unexpected start-up inducing contact with moving parts	**8**
9				Parts which have become live under fault conditions	Work with a machine under voltage	Indirect contact	**9**
10		Trials	Working zone	Cutting fingers or hands, entanglement by rotating elements (tool)	Working near the tool (feeding workpieces)	Contact with moving parts due to loss of workpiece control (inadequate workpieces by their material, size or shape, inadequate tool, inadequate speed of the tool, feeding the workpiece in the same direction as the rotation of the tool - climb cutting-, excessive cutting depth etc.)	**10**
11						Contact with moving parts due to loss of workpiece control caused by a guide discontinuity (gaps)	**11**
12						Contact with moving parts due to loss of workpiece control caused by a table discontinuity (table hole)	**12**
13						Contact with moving parts due to absence of protective measures	**13**
14						Contact with moving parts due to getting caught the wearing loose clothes, necklaces, earrings, not tied back hair	**14**

Table B.1 *(continued)*

RISK ASSESSMENT (HAZARD IDENTIFICATION)								
Machine			Vertical spindle moulding machine		**Analyst**	Mr. Comaba		
Sources			Specifications, preliminary design		**Current version**	2.0		
Extent			Use phase: setting and operation		**Date**	September 2005		
Method			Checklists - ISO 14121-1:200X, Annex A		**Page**	3		
Ref	**Life cycle**	**Task**	**Hazard zone**	**Accident scenario**				**Ref**
				Hazard	**Hazardous situation**	**Hazardous event**		
15	Use phase: Setting	Trials	Working zone	Cutting fingers or hands, entanglement by rotating elements (tool)	Working near the tool (adjusting guide while machine running)	Contact with moving parts due to inappropriate work procedure		**15**
16			Working zone and machine surrounding	Impact by ejected tools, parts of the machine (e.g., guide)	Operator and other people exposed to ejection of parts (adjusting the spindle height, feeding workpieces)	Break-up of the tool or parts of the guide (caused by an incorrect adjustment of the spindle height, an undue adjustment of the guide, inadequate workpiece by their material, size or shape, inadequate tool, inadequate speed of the tool, inadequate fastening etc.)		**16**
17				Impact by ejected workpieces or parts of them	Operator and other people exposed to ejection of parts (feeding workpieces, especially stopped straight work and curved work)	Fierce initial contact of the workpiece with the tool. Some causes of the events leading to cutting hazards, might also produce impact hazards by ejected workpieces or parts of them (see refs. 10, 11 and 12).		**17**

Table B.1 *(continued)*

<table>
<tr><th colspan="8">RISK ASSESSMENT (HAZARD IDENTIFICATION)</th></tr>
<tr><td colspan="3">Machine</td><td colspan="2">Vertical spindle moulding machine</td><td>Analyst</td><td colspan="2">Mr. Comaba</td></tr>
<tr><td colspan="3">Sources</td><td colspan="2">Specifications, preliminary design</td><td>Current version</td><td colspan="2">2.0</td></tr>
<tr><td colspan="3">Extent</td><td colspan="2">Use phase: setting and operation</td><td>Date</td><td colspan="2">September 2005</td></tr>
<tr><td colspan="3">Method</td><td colspan="2">Checklists - ISO 14121-1:200X, Annex A</td><td>Page</td><td colspan="2">3</td></tr>
<tr><th rowspan="2">Ref</th><th rowspan="2">Life cycle</th><th rowspan="2">Task</th><th rowspan="2">Hazard zone</th><th colspan="3">Accident scenario</th><th rowspan="2">Ref</th></tr>
<tr><th>Hazard</th><th>Hazardous situation</th><th>Hazardous event</th></tr>
<tr><td>18</td><td rowspan="6">Use phase: Operation</td><td rowspan="6">Milling</td><td rowspan="6">Working zone</td><td rowspan="6">Cutting fingers or hands, entanglement by rotating elements (tool)</td><td rowspan="5">Working near the tool (feeding workpieces)</td><td>Contact with moving parts due to loss of workpiece control (defective workpiece material, feeding the workpiece in the same direction as the rotation of the tool -climb cutting-, inadequate workpiece feeding speed…)</td><td>18</td></tr>
<tr><td>19</td><td>Contact with moving parts due to loss of workpiece control caused by a guide discontinuity (gaps)</td><td>19</td></tr>
<tr><td>20</td><td>Contact with moving parts due to loss of workpiece control caused by a table discontinuity (table hole)</td><td>20</td></tr>
<tr><td>21</td><td>Contact with moving parts due to absence of protective measures</td><td>21</td></tr>
<tr><td>22</td><td>Contact with moving parts due to getting caught the wearing loose clothes, necklaces, earrings, not tied back hair</td><td>22</td></tr>
<tr><td>23</td><td>Working near the tool (e.g., remove waste material or a workpiece just after giving a stop command and having the brake released)</td><td>Contact with moving parts due to an unsuitable design of the control circuit</td><td>23</td></tr>
</table>

Table B.1 *(continued)*

RISK ASSESSMENT (HAZARD IDENTIFICATION)			
Machine	Vertical spindle moulding machine	**Analyst**	Mr. Comaba
Sources	Specifications, preliminary design	**Current version**	2.0
Extent	Use phase: setting and operation	**Date**	September 2005
Method	Checklists - ISO 14121-1:200X, Annex A	**Page**	4

Ref	**Life cycle**	**Task**	**Hazard zone**	**Accident scenario**			**Ref**
				Hazard	**Hazardous situation**	**Hazardous event**	
24	Use phase: Operation	Milling	Working zone and machine surrounding	Impact by ejected tools, parts of the machine (e.g., guide)	Operator and other people exposed to ejection of parts (adjusting the spindle height, feeding workpieces)	Break-up of the tool or parts of the guide (caused by an incorrect adjustment of the spindle height, an undue adjustment of the guide, an inadequate workpiece by their material, size or shape, inadequate tool, inadequate speed of the tool, an inadequate fastening etc.)	**24**
25				Impact by ejected workpieces or parts of it	Operator and other people exposed to ejection of parts (feeding workpieces, especially stopped straight work and curved work)	Fierce initial contact of the workpiece with the tool. Some causes of the events leading to cutting hazards, might also produce impact hazards by ejected workpieces or parts (see refs. 10, 11 and 12).	**25**
26				Word dust	Operator and other people exposed to hazards generated by wood dust	Emission of wood dust that can be hazardous	**26**
27				Fumes	Operator and other people exposed to hazards generated by fumes	Emission of fumes from treated workpieces that can be hazardous	**27**
28				Fire	Operator and other people exposed	Ignition of dust/chips due to electrical sources	**28**

Table B.1 *(continued)*

RISK ASSESSMENT (HAZARD IDENTIFICATION)							
Machine		**Vertical spindle moulding machine**			**Analyst**	**Mr. Comaba**	
Sources		**Specifications, preliminary design**			**Current version**	**2.0**	
Extent		**Use phase: setting and operation**			**Date**	**September 2005**	
Method		**Checklists - ISO 14121-1:200X, Annex A**			**Page**	**5**	

Ref	**Life cycle**	**Task**	**Hazard zone**	**Accident scenario**			**Ref**
				Hazard	**Hazardous situation**	**Hazardous event**	
29	Use phase: Operation	Milling	Working zone and machine surrounding	Slipping and falling	Working at/with the machine	Slipping at dust or chip covered floor	**29**
30				Noisy manufacturing process	Operator and other people exposed to hazards generated by noise.	Emission of a level of noise that can be hazardous	**30**
31				Musculoskeletal disorder	Feeding workpieces	Painful and tiring posture due to excessive weight of the workpiece	**31**
32			Machine frame	Parts which have become live under fault conditions	Work with a machine under voltage	Indirect contact	**32**

B.5 Risk estimation, Risk evaluation and Risk reduction

B.5.1 Risk estimation method

For risk estimation, the risk graph method of Clause A.4 has been used.

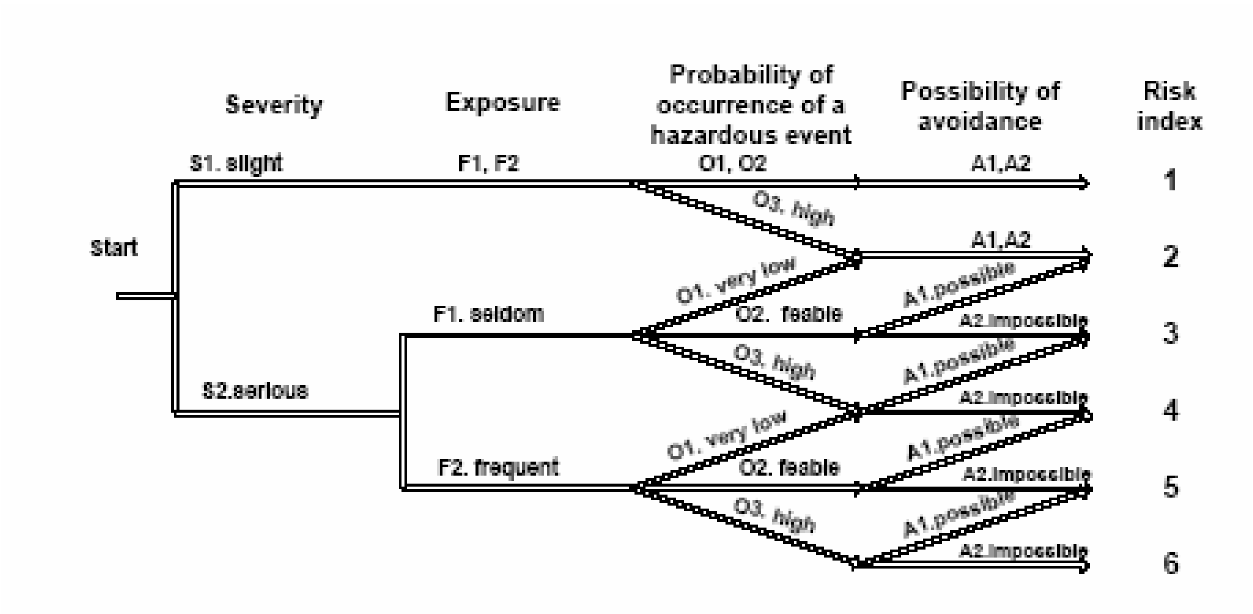

Figure B.5 — Risk graph for risk estimation used in this example

As this method is not very appropriate to estimate risks related with hygienic hazards, ergonomic hazards and fire/explosion, the following assumptions have been applied for these risks:

— Hygiene and ergonomic hazards:

  Hygiene risks mainly depend on the type of toxic (hazardous properties), the concentration and the duration of exposure. Similarly ergonomic risks are estimated considering factors like repetitiveness, force, posture, movements, duration and time to recovery, which might be distributed also under the parameters of severity and exposure.

  So for these types of risks it seems that the estimation of the probability of occurrence of a hazardous event and the possibility of avoidance has little sense.

  For this reason, from the method above only severity and exposure have been considered and for the probability of occurrence of a hazardous event and the possibility of avoidance the most conservative value has been taken/assumed.

— Fire:

  The risk of fire depends on the presence of combustible substances or materials, the comburent and the ignition sources. The parameters of severity, exposure and probability of the hazardous event can be associated respectively to the size and strength of the potential fire, the duration of the hazardous situation and the probability of getting fire of the machine. In case of the possibility of avoidance it appears difficult to make a real estimation so the most conservative value has been assumed.

Despite the rough estimation of the risk index, if after application of well tried protective measures it is considered that the risk is adequately reduced, no further actions will be required. Otherwise, a specific risk estimation method should be used.

B.5.2 Risk estimation, Risk evaluation and Risk reduction

See Table B.2 for risk estimation, risk evaluation and risk reduction.

The abbreviations used in Table B.2 are as follows:

S severity

- S1 slight
- S2 serious

F exposure

- F1 seldom
- F2 frequent

O probability of occurrence of the hazardous event

- O1 very low
- O2 feasible
- O3 high

A possibility of avoidance

- A1 possible
- A2 impossible

RI risk index: From 1 (min) to 6 (max)

NOTE 1 In the setting of the machine it is considered that hygiene hazards (wood dust, fumes and noise) as well as ergonomic hazards are not significant because the exposure to these hazards is too low to produce any risk. Similarly, for fire/explosion and slipping hazards it is considered that the amount of wood dust produced when the machine is properly installed is too little to create a meaningful risk.

NOTE 2 Some protective measures indicated in Table B.2 would be the result of several iterations. For example, in reference 12 it is proposed to reduce the table hole by table rings; the additional requirement of soft material would be in fact the result of a second hazard identification in order to avoid the break-up of the tool in case of contact with the ring.

NOTE 3 In reference 18 a demountable power feed unit is proposed as a protective measure. The iterative process of the risk assessment would require, taking into account the instructions given by its manufacturer, a further consideration of the potential hazards generated by this unit during the whole life cycle of the machine and if necessary to take new risk reduction measures (for example, appropriate interlocking between the control functions of the spindle unit and the power feed unit; providing an emergency stop control, appropriate adjustment).

Table B.2 — Risk assessment (Risk estimation and Risk evaluation) and Risk reduction

RISK ASSESSMENT (RISK ESTIMATION AND RISK EVALUATION) AND RISK REDUCTION			
Machine	Vertical spindle moulding machine	**Analyst**	Mr. Comaba
Sources	Specifications, preliminary design	**Current version**	2.0
Extent	Use phase: setting and operation	**Date**	July 2005
Method	Risk-graph	**Page**	1

Ref	**Risk estimation (initial risk)**					**Risk reduction**	**Risk estimation (after risk reduction)**					**Further risk reduction required**	**Ref**
	S	**F**	**O**	**A**	**RI**	**Protective measures**	**S**	**F**	**O**	**A**	**RI**		
1	1	1	2	2	1	Instructions to use of protective gloves and for carrying tools in boxes instead of by hand	1	1	2	1	1	No	**1**
2	1	1	3	2	2	Providing an integral spindle locking system (see Figure B.6) and instructions to use	1	1	1	2	1	No	**2**
3	1	1	3	2	2	Providing suitable hand tool(s) and instructions to use	1	1	1	2	1	No	**3**
4	2	1	2	2	3	Electrical equipment in accordance with IEC 60204-1 (e.g., protection against earth faults, interlocking of brake release function with the start function) (see Figure B.7) and instructions to use recommending isolating the machine from the power supply (by means of the main switch)	2	1	1	2	2	No	**4**
5	1	1	2	2	1	See protective measures for Ref. 1	1	1	2	1	1	No	**5**
6	2	1	2	2	3	Electrical equipment in accordance with IEC 60204-1 (e.g. protection against earth faults, interlocking of brake release function with the start function (see Figure B.7)	2	1	1	2	2	No	**6**
7	2	1	2	2	3	Fitting the door with an interlocking device in accordance with ISO 14119 and control circuit of category 1 in accordance with ISO 13849-1 and 2 with periodical inspections	2	1	1	2	2	No	**7**
8	2	1	2	2	3	See protective measures for Ref. 4 and 7	2	1	1	2	2	No	**8**
9	2	1	2	2	3	Electrical equipment in accordance with IEC 60204-1 (protective bonding of exposed conductive parts of the machine and residual current sensing device by the user) (see Figure B.7)	1	1	1	1	2	No	**9**

Table B.2 *(continued)*

RISK ASSESSMENT (RISK ESTIMATION AND RISK EVALUATION) AND RISK REDUCTION			
Machine	Vertical spindle moulding machine	**Analyst**	Mr. Comaba
Sources	Specifications, preliminary design	**Current version**	2.0
Extent	Use phase: setting and operation	**Date**	July 2005
Method	Risk-graph	**Page**	2

Ref	**Risk estimation (initial risk)**					**Risk reduction**	**Risk estimation (after risk reduction)**					**Further risk reduction required**	**Ref**
	S	**F**	**O**	**A**	**RI**	**Protective measures**	**S**	**F**	**O**	**A**	**RI**		
10	2	1	2	2	3	Providing a depth gauge and instructions to use Providing push blocks and sticks and instruction for use. Also instruction to use jigs and templates. Instruction for checking workpiece quality Instruction to use tools designed according to relevant standards Providing a marking with a diagram of speed vs tool diameter and instructions to use Instructions for avoiding climb cutting Instructions to use recommending progressive machining (to avoid excessive cutting depth)	2	1	1	1	2	No	**10**
11	2	1	2	2	3	Reducing the gap of the guide for straight work by design (see Figure B.6) and instructions for reducing the gap of the guide and for use false guides.	2	1	1	2	2	No	**11**
12	2	1	2	2	3	Reducing table hole by providing table rings (see Figure B.6) made of soft material and instructions to use. See Note 2.	2	1	1	2	2	No	**12**
13	2	1	3	2	4	Providing adjustable guards for straight and curved works (see Figure B.6) and instructions for installation, adjustment and use.	2	1	1	2	2	No	**13**
14	2	1	2	1	2	Instructions to use recommending to wear tight clothes and not to wear ties, necklaces, earrings, loose long hair	2	1	1	1	2	No	**14**
15	2	1	3	2	4	Pictograms and instructions for not adjusting the guide while machine is running.	2	1	2	1	2	No	**15**

Table B.2 *(continued)*

RISK ASSESSMENT (RISK ESTIMATION AND RISK EVALUATION) AND RISK REDUCTION			
Machine	Vertical spindle moulding machine	**Analyst**	Mr. Comaba
Sources	Specifications, preliminary design	**Current version**	2.0
Extent	Use phase: setting and operation	**Date**	July 2005
Method	Risk-graph	**Page**	3

Ref	**Risk estimation (initial risk)**					**Risk reduction**	**Risk estimation (after risk reduction)**					**Further risk reduction required**	**Ref**
	S	**F**	**O**	**A**	**RI**	**Protective measures**	**S**	**F**	**O**	**A**	**RI**		
16	2	1	2	2	3	Making the part of the guide closer to the tool of a soft material (e.g., light alloy, plastic, wood) Providing an indicator of the height of the spindle near the height adjustment wheel. Instructions for proper fastening of the tool. See also protective measures for Ref. 10	2	1	1	2	2	No	**16**
17	1	1	3	2	2	Providing in the guard a "lead-in" for curved work~~s~~ and instructions to use. Providing means to fix end stops. Instructions to use jigs and end stops for stopped straight work~~s~~. See also protective measures for Ref. 10, 11 and 12	1	1	1	2	1	No	**17**
18	2	2	2	2	5	Providing a demountable power feed unit for straight work (for clarity, it has not been represented in Figure B.6, neither in Figure B.7). Providing push blocks and sticks and instructions to use. Also instructions to use jigs and templates. Instructions for checking workpiece quality. Instructions for avoiding climb cutting. Instructions for avoiding inadequate feeding speed.	2	1	1	1	2	Yes (See Note 3)	**18**
19	2	2	2	2	5	See protective measures for Ref. 11	2	1	1	2	2	No	**19**
20	2	2	2	2	5	See protective measures for Ref. 12	2	1	1	2	2	No	**20**

Table B.2 *(continued)*

RISK ASSESSMENT (RISK ESTIMATION AND RISK EVALUATION) AND RISK REDUCTION			
Machine	Vertical spindle moulding machine	**Analyst**	Mr. Comaba
Sources	Specifications, preliminary design	**Current version**	2.0
Extent	Use phase: setting and operation	**Date**	July 2005
Method	Risk-graph	**Page**	4

21	2	2	3	2	6	See protective measures for Ref. 13	2	1	1	2	2	No	**21**
22	2	2	2	1	4	See information to use for Ref. 14	2	2	1	1	3	No	**22**
23	2	1	3	2	4	Interlocking of brake release function with the start function in the electrical circuit (see Figure B.7) of category 1, in accordance with ISO 13849-1 and ISO 13849-2 and instructions for checking periodically the braking time.	2	1	2	1	2	No	**23**
24	2	2	2	2	5	See protective measures for Ref. 15 and also Ref. 17	2	2	1	2	4	No	**24**
25	1	2	3	2	2	See protective measures for Ref. 16 and also Ref. 17, 18 and 19	1	2	1	2	1	No	**25**
26	2	2	3	2	6	Providing outlets to connect an external dust extraction system with a minimum airflow of 1500 $m^3 h^{-1}$ and minimum conveying air velocity of 20 $m s^{-1}$ (see Figure B.6)	1	2	3	2	2	No	**26**
27	2	1	3	2	4	See protective measures for Ref. 24. Instructions for wearing PPE. Instructions against working treated wood or similar materials.	1	1	3	2	2	No	**27**
28	1	2	2	1	2	Electric equipment in accordance with IEC 60204-1 (minimum degree of protection IP 54, dimensioning of components, sufficient cooling etc). Instructions to use the dust extraction system	1	2	1	1	1	No	**28**
29	1	2	2	2	1	Instruction for use the exhausting system and cleaning	1	2	1	2	1	No	**29**
30	2	2	3	2	6	Appling measurements in design to reduce noise in the source (spindle balance, bearings, anti-vibration mounts, shielding)	1	2	3	2	2	No	**30**
31	1	2	3	2	2	Providing machine arrangements to fix extension tables.	1	1	3	2	2	No	**31**
32	1	2	2	2	1	See protective measures for Ref. 10	1	2	2	1	1	No	**32**

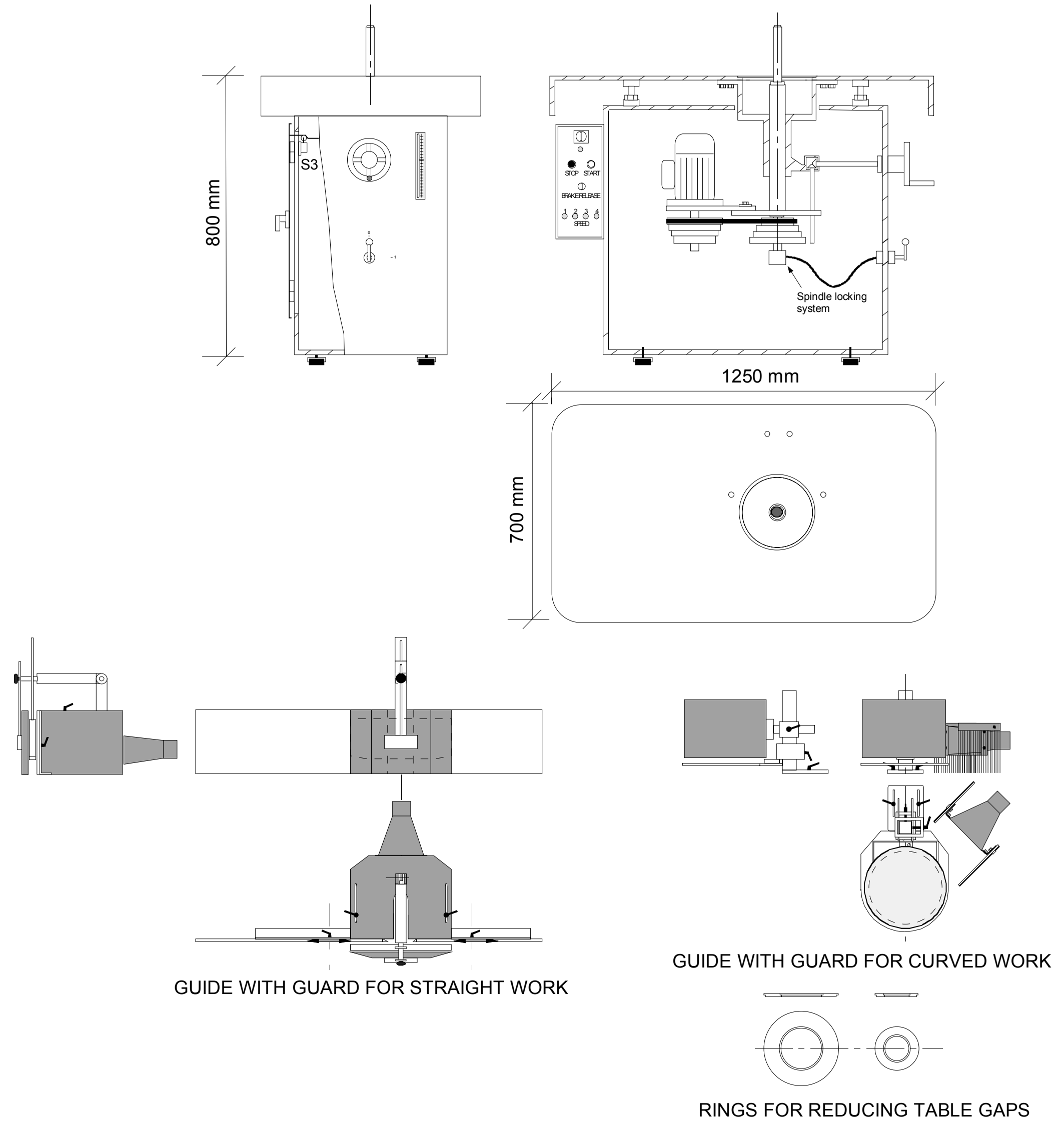

Figure B.6 — Final design of the machine

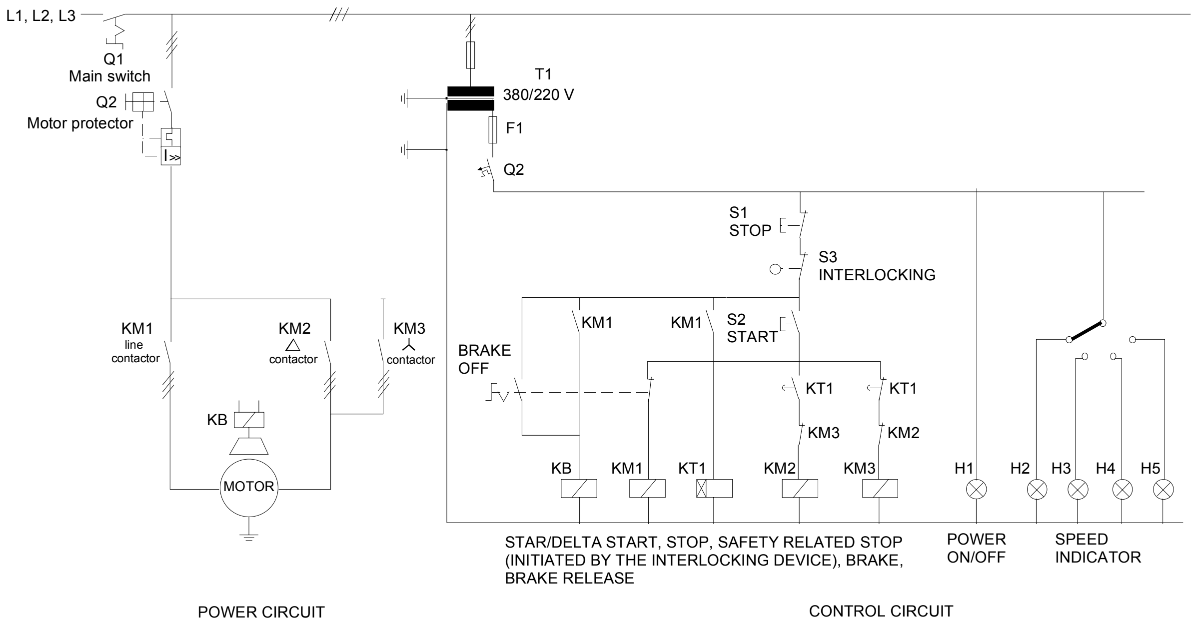

Figure B.7 — Final circuit diagram

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