TECHNICAL REPORT

ISO/TR 14121-2

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Safety of machinery — Risk assessment —

Part 2: Practical guidance and examples of methods

Sécurité des machines — Appréciation du risque —

Partie 2: Lignes directrices pratiques et exemples de méthodes

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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

ISO 14121 consists of the following parts, under the general title *Safety of machinery — Risk assessment*:

— *Part 1: Principles*

— *Part 2: Practical guidance and examples of methods* [Technical Report]

Introduction

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

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

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

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

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

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

Safety of machinery — Risk assessment —

Part 2:
Practical guidance and examples of methods

1 Scope

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

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

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

2 Normative references

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

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

3 Terms and definitions

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

3.1
supplier
entity (e.g. designer, manufacturer, contractor, installer, integrator) who provides equipment or services associated with the integrated manufacturing system (IMS) or a portion of the IMS or machines

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

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

4 Preparation for risk assessment

4.1 General

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

NOTE See the Introduction for suggested uses of risk assessment.

4.2 Using the team approach for risk assessment

4.2.1 General

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

a) the risk assessment approach selected;

b) the complexity of the machine;

c) the process within which the machine is utilized;

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

However, it is not always practical to set up a team for risk assessment and it can be unnecessary for machinery where the hazards are well understood and the risk is not high.

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

4.2.2 Composition and role of team members

The team should have a team leader. The team leader should be fully responsible for ensuring that all the tasks involved in planning, performing and documenting (in accordance with ISO 14121-1:2007, Clause 9) the risk assessment are carried out and that the results/recommendations are reported to the appropriate person(s).

Team members should be selected according to the skills and expertise required for the risk assessment.

The team should include those people who

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

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

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

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

e) understand human factors (see ISO 14121-1:2007, 7.3.4).

4.2.3 Selection of methods and tools

This part of ISO 14121 is intended to be used for risk assessment on a wide variety of machinery in terms of complexity and potential for harm. There are also a variety of methods and tools for conducting risk assessment (see Annex A). When selecting a method or tool for performing a risk assessment, consideration should be given to the machinery, the likely nature of the hazards and the purpose of the risk assessment. Consideration should also be given to the skills, experience and preferences of the team for particular methods. Clause 5 offers additional information on criteria for the selection of appropriate methods and tools for each step of the risk assessment process.

4.2.4 Sources of information for risk assessment

The information required for risk assessment is listed in ISO 14121-1:2007, 4.2. This information can take a variety of forms, including technical drawings, diagrams, photos, video footage, information for use [including maintenance and standard operating procedures (SOP)], as available. Access to similar machinery or a prototype of the design, where available, is often useful.

5 Risk assessment process

5.1 General

The following subclauses explain what is involved in practice with each step of the risk assessment process as shown in ISO 14121-1:2007, Figure 1.

5.2 Determination of the limits of the machinery

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

5.2.1 General

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

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

5.2.2 Functions of the machinery (machine-based)

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

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

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

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

5.2.3 Uses of the machinery (task-based)

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

NOTE See ISO 14121-1:2007, Table A.3, for a list of typical/generic machinery tasks.

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

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

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

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

d) human error.

5.3 Hazard identification

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

5.3.1 General

The objective of hazard identification is to produce a list of hazards, hazardous situations and hazardous events that allow possible accident scenarios to be described in terms of how and when a hazardous situation can lead to harm. A useful starting point for relevant hazards is ISO 14121-1:2007, Annex A, which can be used as a generic checklist. Other sources for hazard identification could be based on the information indicated in ISO 14121-1:2007, 4.2.

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

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

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

NOTE 3 Examples of machinery-specific standards are ISO 10218, related to safety of robots, ISO 11111, related to textile machinery, and ISO 3691, related to industrial trucks.

Hazard identification is the most important step in any risk assessment. Only when a hazard has been identified, is it possible to take action to reduce the risks associated with it, see Clause 6. Unidentified hazards can lead to harm. It is therefore vitally important to ensure that hazard identification is as systematic and comprehensive as possible, taking into account the relevant aspects described in ISO 14121-1:2007, 7.3.

5.3.2 Methods for hazard identification

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

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

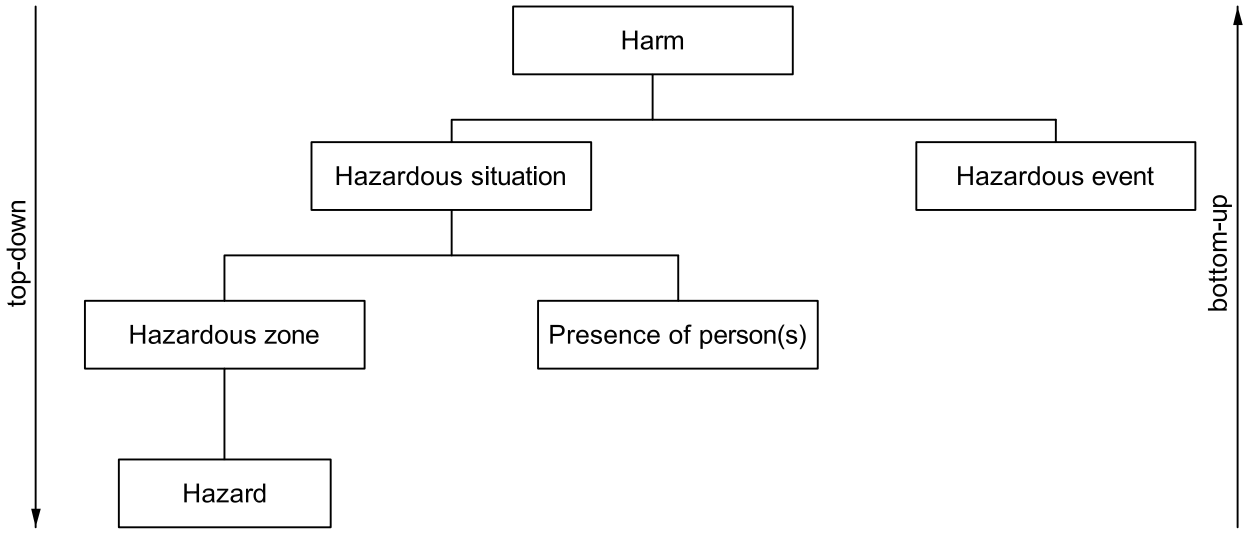

Figure 1 — Top-down and bottom-up approaches

A *top-down approach* is one that takes as its starting point a check-list of potential consequences (e.g. cutting, crushing, hearing loss — see potential consequences in ISO 14121-1:2007, Tables A.1 and A.2) and establishes what could cause harm (working back from the hazardous event, to the hazardous situation and thence the hazard itself). Every item in the checklist is applied to every phase of use of the machinery and every part/function and/or task in turn. One of the drawbacks of a top-down approach is the over reliance of the team on the checklist, which cannot be complete. An inexperienced team will not necessarily appreciate this. Therefore, checklists should not be interpreted as exhaustive, but should encourage creative thinking beyond the list.

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

5.3.3 Recording of information

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

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

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

c) how the hazardous situation can lead to harm as a result of a hazardous event or prolonged exposure.

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

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

e) existing protective measures and their effectiveness.

5.3.4 Creative thinking

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

5.3.5 Example of a tool for hazard identification

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

5.4 Risk estimation

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

5.4.1 General

By definition, the two main elements of risk are severity of harm and the probability of occurrence of that severity of harm. The purpose of risk estimation (see ISO 14121-1:2007, Figure 2) is to determine the highest risk arising from each hazardous situation or accident scenario. The estimated risk is generally expressed as a level, index or score.

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

5.4.2 Severity of harm

NOTE 1 See ISO 14121-1:2007, 7.2.2.

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

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

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

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

5.4.3 Probability of occurrence of harm

NOTE See ISO 14121-1:2007, 7.2.3.

5.4.3.1 General

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

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

b) probability of occurrence of a hazardous event (see ISO 14121-1:2007, 7.2.3.3), and

c) technical and human possibilities to avoid or limit the harm (see ISO 14121-1:2007, 7.2.3.4).

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

When estimating the probability of harm, the relevant aspects described in ISO 14121-1:2007, 7.3, should also be considered.

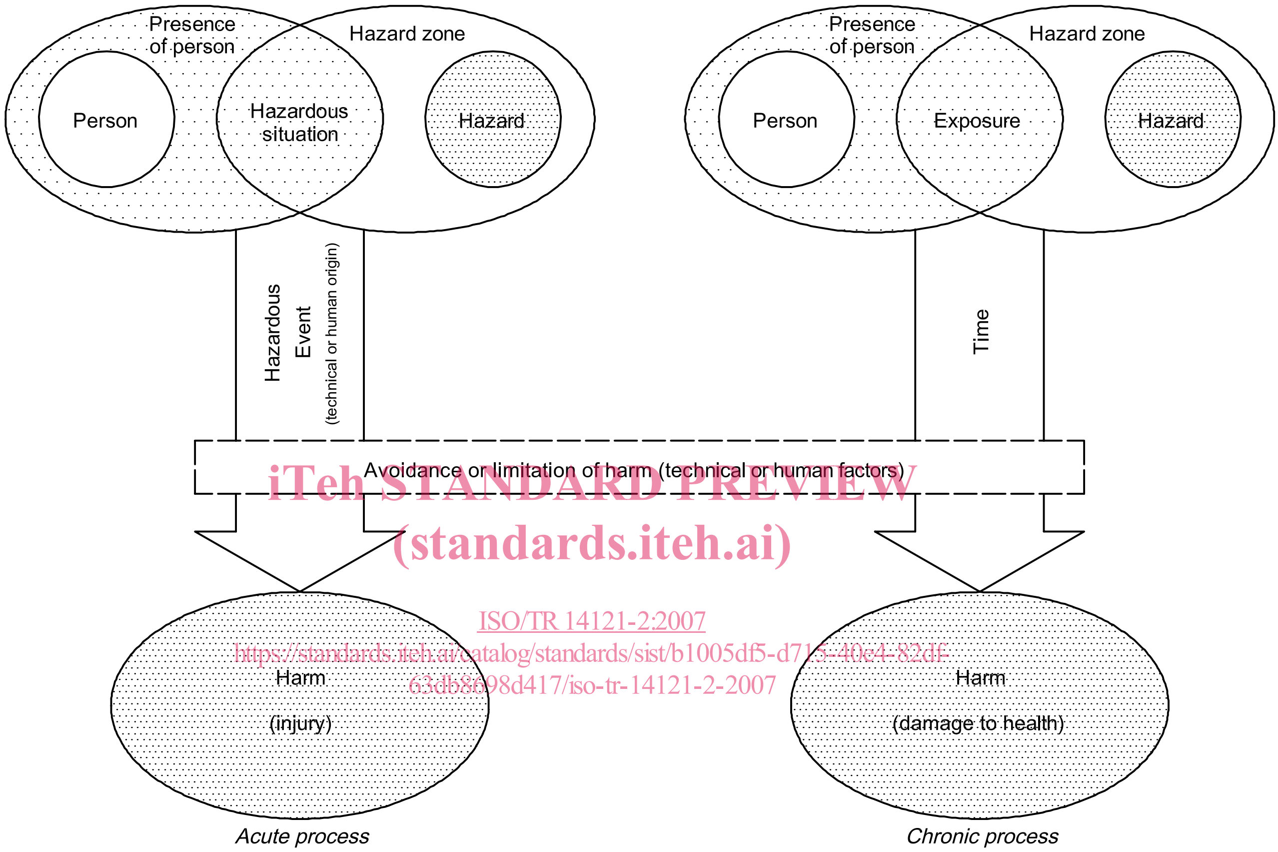

Figure 2 — Conditions of occurrence of harm

5.4.3.2 Probability of occurrence of cumulative harm (health aspects)

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

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

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

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

— for hearing loss, it is dependent on the noise levels;

— for repetitive strain injuries, it is dependent on the strain involved and the repetitiveness of the action.

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

5.4.4 Risk estimation tools

5.4.4.1 General

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

— risk matrix;

— risk graph;

— numerical scoring;

— quantified risk estimation.

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

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

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

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

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

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

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

5.4.4.2 Risk matrices

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

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

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

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

5.4.4.3 Risk graphs

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

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

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

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

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

5.4.4.4 Numerical scoring

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

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

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

5.4.4.5 Quantified risk estimation

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

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

