

---

---

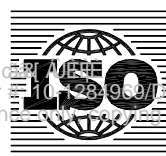
**Safety of machinery — Risk assessment —**

Part 2:

**Practical guidance and examples of  
methods**

*Sécurité des machines — Appréciation du risque —*

*Partie 2: Lignes directrices pratiques et exemples de méthodes*





**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

Licensed to ~~Österreichische~~  
ISO Store order #: 10-1284969/Downloaded: 2012-07-23  
Single user licence only, copying and networking prohibited

# Contents

Page

Foreword .....	iv
Introduction .....	v
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	1
4 Preparation for risk assessment .....	1
4.1 General .....	1
4.2 Using the team approach for risk assessment .....	2
5 Risk assessment process .....	3
5.1 General .....	3
5.2 Determination of the limits of the machinery .....	3
5.3 Hazard identification .....	4
5.4 Risk estimation .....	6
6 Risk estimation tools .....	9
6.1 General .....	9
6.2 Risk matrix .....	9
6.3 Risk graph .....	12
6.4 Numerical scoring .....	14
6.5 Hybrid tool .....	15
7 Risk evaluation .....	19
8 Risk reduction .....	19
8.1 General .....	19
8.2 Inherently safe design .....	19
8.3 Safeguarding .....	20
8.4 Complementary protective/risk reduction measures .....	21
8.5 Information for use .....	21
8.6 Standard operating procedures .....	22
9 Risk assessment iteration .....	22
10 Documentation of risk assessment .....	22
Annex A (informative) Example application of the process of risk assessment and risk reduction .....	23
Bibliography .....	38

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

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

- the examples previously given in Annex A, as well as the description of quantified risk estimation, have been deleted;
- the explanations of the methods or tools, taken from Annex A, are now presented in 5.3.5 for hazard identification and 5.4.4.1 for risk estimation;
- the terminology and criteria have been revised;

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

—	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 of occurrence of harm and severity is given by Equation (1):

$$PS + SS = RS \quad (1)$$

where RS is the risk score.

The risk score can then be interpreted according to Table 2.

**Table 2 — Risk score categories used**

—	<b>high</b>	≥ 160
159 ≥	<b>medium</b>	≥ 120
119 ≥	<b>low</b>	≥ 90
89 ≥	<b>negligible</b>	≥ 0

**EXAMPLE** A task-hazard that is associated with very severe injury can have SS = 95, and its probability can be in the likely range PS = 80. The risk score for this task-hazard is then high (95 + 80 = 175 > 160).

### 6.4.3 Discussion

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. 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 but can give a false impression of numerical accuracy.

## 6.5 Hybrid tool

### 6.5.1 General

Hybrid tools or methods for risk estimation 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, such as 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 or method for risk estimation is given in 6.5.2.

### 6.5.2 Example of a hybrid tool or method for risk estimation

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

The form reproduced on page 18 should be used in conjunction with the following guidance information.

#### Pre-risk estimation

Ticking this box indicates this is the first risk estimation. It is done in the concept phase where only specification and sketches are available. No detail drawings are made at this stage. It is used to decide on the major systems of a machine, for example, mechanical drive line or servo drives, hot air or ultra sonic sealing, movable guard or light barrier.

### Intermediate risk estimation

The intermediate risk estimation box is ticked for all intermediate risk estimations performed during the development of a machine. Two sets of hazards are dealt with in this phase. Where in the pre-risk estimation phase protective/risk reduction 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.

### Follow-up risk estimation

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

### Reference number (ref. no.)

The reference number, or serial number, is used to give each identified hazard a number for reference purposes.

### Type hazard number (type no.)

Type no., hazard type or group number is used to classify the hazards. The numbers refer to those given for the type or group according to ISO 12100:2010, Table B.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 by "crushing" in the hazard column.

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

### Severity, Se

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

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

### Frequency, Fr

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

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

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

- 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, for example, human behaviour, reliability of components, accident history and the nature of the component or system (for example, a knife is always sharp, a flue exhaust pipe is always hot, electricity is dangerous by its nature) to determine the level of probability. The probability is scored as follows.

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

**Avoidance, Av**

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

- 1 Likely: for example, it is likely that contact with moving parts behind an interlocked guard will be avoided in most cases should the interlocking fail and the movements continue.
- 3 Possible: for example, it is possible to avoid an entanglement hazard where the speed is slow and there is sufficient space or otherwise it is easy to avoid moving parts of machinery.
- 5 Impossible: for example, it is impossible to avoid a sudden appearance of a powerful laser beam, or in case of an explosion.

**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 12100:2010, 5.5.2.3. Each of the three factors should be estimated independently of each other. The worst credible assumption should be used for each factor. Fr, Pr and Av are added together in Cl. The Cl is the sum of Fr, Pr and Av, i.e.  $Cl = Fr + Pr + Av$ .

**Risk estimation**

The risk is estimated by using the matrix in the middle of the upper part of the form reproduced on the next page.

Where the severity, Se, crosses the class, Cl, in the black area, the risk is high.

Where the severity, Se, crosses the class, Cl, in the grey area, the risk is medium.

Where the severity, Se, crosses the class, Cl, in the remaining area, the risk is low.

**Details**

The accident scenario should be described here. Put the hazard reference number for the particular hazard in the left column and describe the accident scenario in the right. Where photos are used, the reference to them can be made here.

<b>Risk estimation</b>											
Document no.: _____ Part of doc. no.: _____ <input type="checkbox"/> Preliminary risk estimation											
Product: _____ Issued by: _____ Date: _____											
Black area = High risk Grey area = Medium risk White area = Low risk											
Consequences	Severity Se	Class CI (Fr+Pr+Av)									
		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	5 likely		4	
Reversible, medical attention	2						< 24 h to ≥ 1 y	4 possible		3	impossible
Reversible, first aid	1						< 2 w to ≥ 1 y	3 rarely		2	possible
							< 1 y	2 negligible		1	likely
Ref. Typ. no. Hzd. No.	Hazard	Se	Fr	Pr	Av	CI					
1											
2											
3											
Details (description of the accident scenario) of ref. no.											
1											
2											
3											