Risk assessment and reduction
The Suva method for machinery

A guide to risk assessment and risk reduction for manufacturers and distributors

suva

This brochure will help you, as a manufacturer and/or other distributor of machinery, to place safe, authorised products on the market.

It describes a practicable method for risk assessment and risk reduction. The European Machinery Directive requires both as a condition for placing new machinery on the market.

Contents

1 Placing safe machinery on the market

Those who want to place a new machine on the market in the European Union, in the European Economic Area, in Switzerland, and in other countries such as Turkey, must meet the **essential health and safety requirements** of the Machinery Directive (2006/42/EC, Annex I).

Therefore, the Machinery Directive requires **a risk assessment and a risk reduction of the machine to be built from the manufacturer**. The risk assessment and the risk reduction must be documented, and the documentation must be held available by the manufacturer as part of the technical documentation.

A guidance to the Suva method

This brochure addresses the question of how the requirements of the Machinery Directive shall be met in practical terms. For this, you can apply the procedure for risk assessment and risk reduction described herein. It is suitable for machinery as well as partly completed machinery, and can also be used in the development of technical products. The procedure meets the requirements of the following standards or technical reports:

- EN ISO 12100:2010 Safety of machinery — General principles for design — Risk assessment and risk reduction
- ISO/TR 14121-2:2012 Safety of machinery – Risk assessment – Part 2: Practical guidance and examples of methods
- ISO/TR 22100-1:2015 Safety of machinery – Relationship with ISO 12100 – Part 1: How ISO 12100 relates to type-B and type-C standards

To apply the procedure, knowledge of chapters 1 to 9 is necessary. The annexes offer more detailed information on risk assessment and risk reduction. Depending on the hazards identified, attention shall be paid to additional information on risk assessment in further standards, which are not dealt with here (see Annex A for examples).

Case example for illustration purposes

The case example of the risk assessment of a circular saw for metal, in swivel head version and with manual feed, illustrates the theory in each of the different chapters. You can find the information on the case example required for the documentation in the tables marked with «Documentation» directly at the relevant step of the procedure.

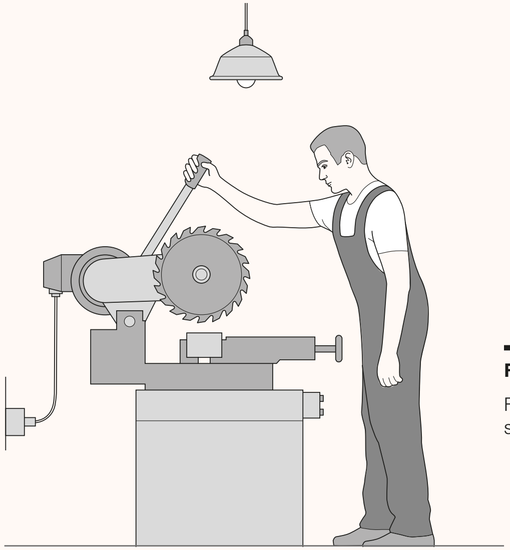

Figure 1

Functional model of a circular saw without safeguards

2 Why assess the risk and when?

Annex I of the Machinery Directive stipulates the following on the **essential health and safety requirements:**

Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.

The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.

In order for the manufacturer to be able to meet these essential requirements, a systemic assessment of the machinery during its expected lifetime is required. Therefore, Annex I of the Machinery Directive demands the following:

The manufacturer of machinery or his authorised representative must ensure that a risk assessment and a risk reduction are carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment and reduction.

The right time to carry out the risk assessment and risk reduction is the drafting phase of the machinery, after the function has been drafted. That is the point when the structure of the machine has been determined and the required protective measures can be integrated cost-effectively into the design of the machine.

In the following cases it makes sense to review the risk assessment and the risk reduction later:

- series machines after having acquired experience using the first machines
- after an accident or incident
- any change in the machine
- any change in the intended use of the machine

3 Terms and definitions

This chapter describes the terms, which are important for the risk assessment and risk reduction, as defined in the standards.

3.1 Intended use

The «intended use» (EN ISO 12100, 3.23) means the **use of a machine in accordance with the information for use provided in the instructions**.

Figure 2

The intended use of a lift truck is the lifting and transportation of loads of a maximum size and a maximum weight.

3.2 Reasonably foreseeable misuse

A «reasonably foreseeable misuse» (EN ISO 12100, 3.24) is the **use of a machine in a way not intended by the designer, but which can result from readily predictable human behaviour.**

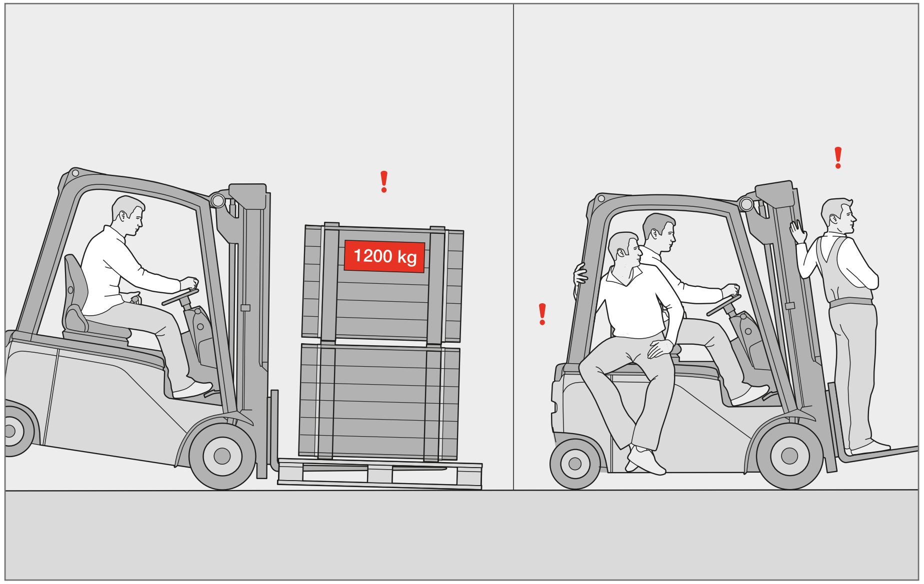

Figure 3

Examples of reasonably foreseeable misuse of a lift truck: Overloading, passenger transportation

3.3 Hazard

The central concept of the term «hazard» (EN ISO 12100, 3.6) means **a potential source of harm** (in common usage: danger). A hazard can be identified more accurately by the origin of a harmful effect (e. g. mechanical hazard, electrical hazard) or by the nature of the potential harm (e. g. cutting hazard, electric shock hazard).

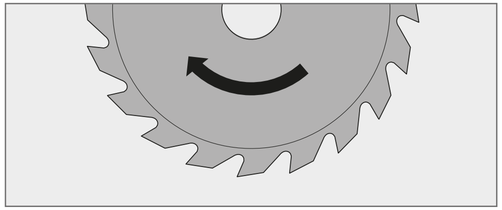

Figure 4

Cutting hazard arising out of moving saw teeth

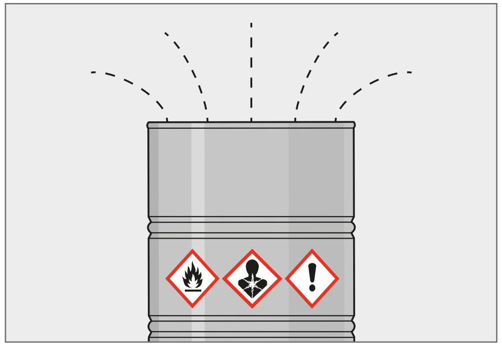

Figure 5

Hazard for the airways arising out of released harmful vapours

The hazard is either permanently present while the machine is being used (e. g. rotating saw blade), or can appear unexpectedly (e. g. explosion).

3.4 Hazard zone (danger zone)

The «hazard zone» (EN ISO 12100, 3.11) is the **space around a hazard in which a person is exposed to the hazard.**

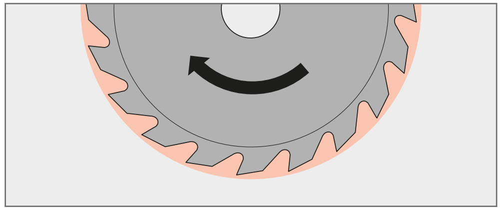

Figure 6

Hazard zone of the moving saw teeth

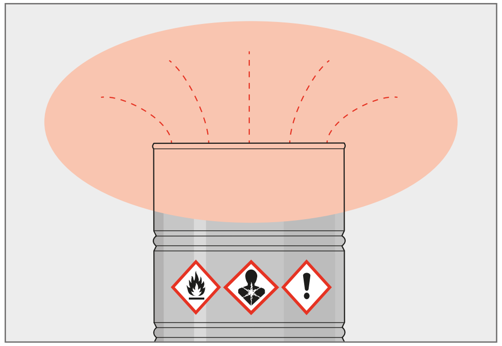

Figure 7

Hazard zone of the released vapours

3.5 Hazardous situation

A «hazardous situation» (EN ISO 12100, 3.10) exists when **a person is exposed to at least one hazard**. This situation (circumstance) can result in harm immediately or over a period of time.

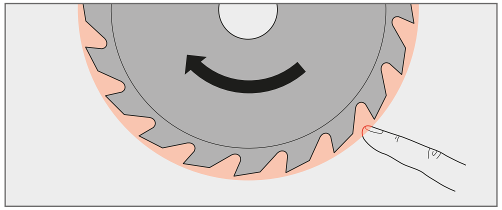

Figure 8

Hazardous situation: The finger is exposed to the hazard arising out of the moving saw teeth.

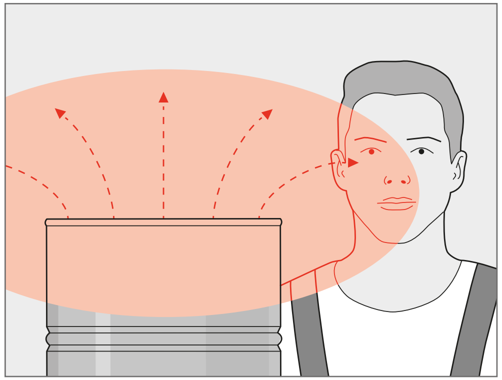

Figure 9

Hazardous situation: The airways are exposed to the hazard arising out of the harmful vapours.

3.6 Hazardous event

The term «hazardous event» (EN ISO 12100, 3.9) specifies an **event that can cause harm**. It can occur over a short period of time or over an extended period of time.

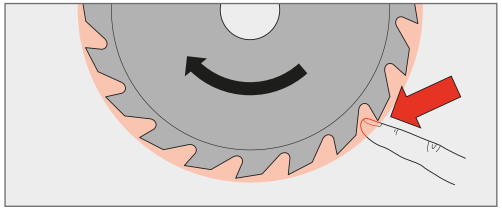

Figure 10

Hazardous event: A moving saw tooth hits the finger.

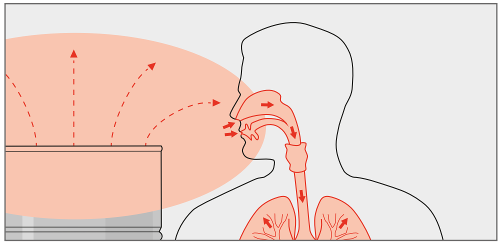

Figure 11

Hazardous event: Due to inhalation, harmful vapours reach the airways and lungs.

3.7 Harm

The word «harm» (EN ISO 12100, 3.5) always means **physical injury or damage to health**.

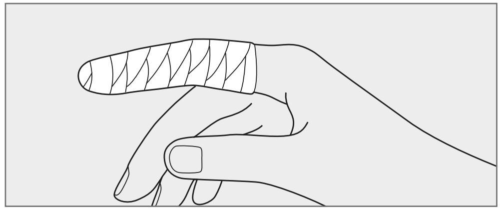

Figure 12

Physical injury: cut finger

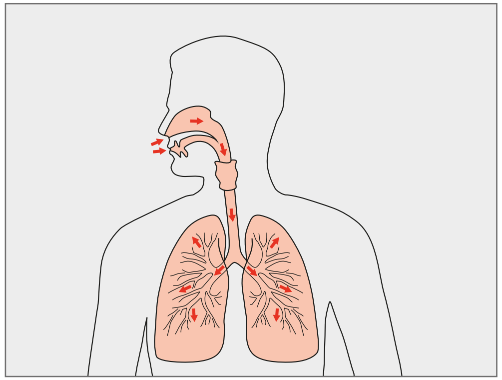

Figure 13

Damage to health of airways and lungs

3.8 Causes

«Causes» (based on EN ISO 12100 Annex B 4) are **reasons why a hazard appears, why a hazard zone is accessible and why the occurrence of harm resulting from a hazardous event cannot be prevented**.

3.9 Risk and elements of risk

The term «risk» (EN ISO 12100, 3.12) defines the **combination of the probability of harm occurring and the severity of that harm** (the two factors are also called elements of risk).

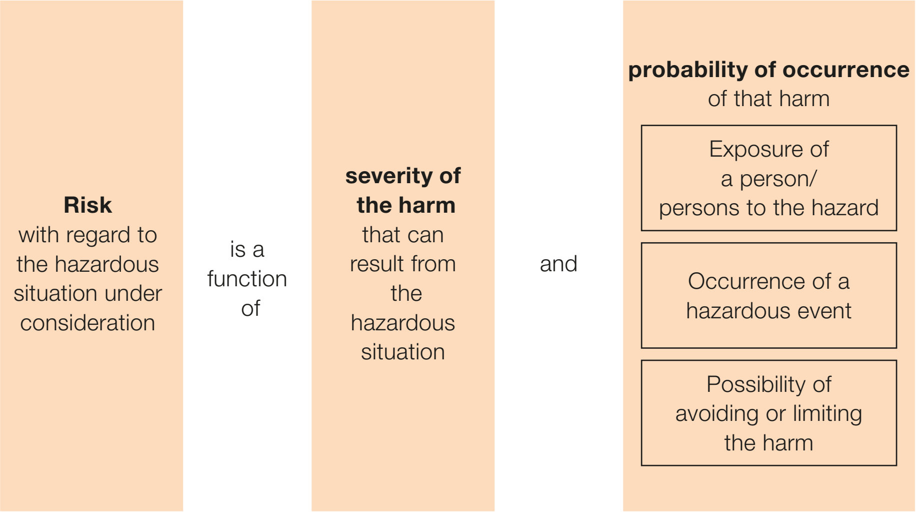

Figure 14

Elements of risk

3.10 Residual risk

«Residual risk» (EN ISO 12100, 3.13) specifies the **risk remaining after protective measures have been implemented**.

A distinction is made between:
- the residual risk after protective measures have been implemented by the designer
- the residual risk remaining after all protective measures have been implemented

3.11 Harmonised standards, presumption of conformity

«Harmonised standards» (Machinery Directive 2006/42/EC Article 2 (l), Article 7(2)) are **non-binding technical specifications drafted by consensus on behalf of the European Commission by a European standardisation body**. If a machine has been manufactured in conformity with a harmonised standard, the references of which have been published in the current Official Journal of the European Union, that machine shall be presumed to comply with the essential health and safety requirements covered by this harmonised standard (presumption of conformity).

The harmonised standards can be grouped according to the following structure:

Type-A standards (EN ISO 12100)

«Type-A standards» determine the basic terms, the terminology, and the principles for design, which are applicable to **all categories of machines**.
However, it is not enough in itself to apply type-A standards to ensure conformity with the essential health and safety requirements of the Machinery Directive.

Type-B standards

«Type-B standards» deal with certain aspects of machine safety that are **relevant for a broad range of categories of machines**, or rather with certain types of safeguards that can be used for many categories of machines.

The application of specifications of type-B standards gives presumption of conformity with regard to the requirements of the Machinery Directive covered by them. But this only if a type-C standard or the risk assessment of the manufacturer reveals that a technical solution defined by the type-B standard is appropriate for the relevant category or for the corresponding model of the machine.

The application of type-B standards that contain specifications for safety components that are independently placed on the market leads to a presumption of conformity only for the relevant safety components.

Type-C standards

«Type-C standards» contain specifications for a particular category of machines. The different types of machinery of such a category show an intended use of the same kind and hazards of the same kind. The specifications of the type-C standards have priority over the specifications of the type-A and the type-B standards.

If the manufacturer, following the risk assessment, applies specifications of a type-C standard, this will always lead to a presumption of conformity with regard to the essential health and safety requirements of the Machinery Directive covered by the standard.

4 How does harm occur?

If a hazard appears and a person remains entirely or partly in the hazard zone, a hazardous situation is generated. That person is exposed to the hazard, which leads to a hazardous event. If the person is not able to stop the hazardous event (by switching off the hazard or leaving the hazard zone), harm (physical injury) may occur.

The causes of the harm include the reasons for

- the appearance of the hazard
- the accessibility of the hazard zone
- the lack of possibility of avoiding or limiting the harm

In a hazardous situation, a particular severity of harm appears with a certain probability of occurrence. The combination of severity of harm and probability of occurrence represents the risk of the hazardous situation.

The probability of occurrence, in turn, depends on:

- the exposure to the hazard of the person (person in the hazard zone)
- the appearance of the hazard (hazardous event)
- the possibility of avoiding or limiting the harm

Example: circular saw

Cutting injury caused by the rotating saw blade
If the saw is switched on while a person›s finger is in the hazard zone of the saw teeth, a hazardous situation is generated.

In this situation, the finger is exposed to the moving saw teeth, which leads to a hazardous event. The saw teeth touch the finger.

If the person cannot stop the saw blade in time or remove the finger from the hazard zone of the saw teeth, the hazardous event can lead to harm. For that to happen, the saw teeth must cut the finger after touching it. However, the moving saw teeth might only touch the finger at the nail and push it away without inflicting injury.

The causes for the harm can be:

- unexpected start-up of the saw drive (reason for the appearance of the hazard)
- removal of a workpiece from the hazard zone of the saw blade (reason for staying in the hazard zone)
- short period between the saw teeth touching the finger and finger being cut (no possibility of avoiding or limiting the harm)

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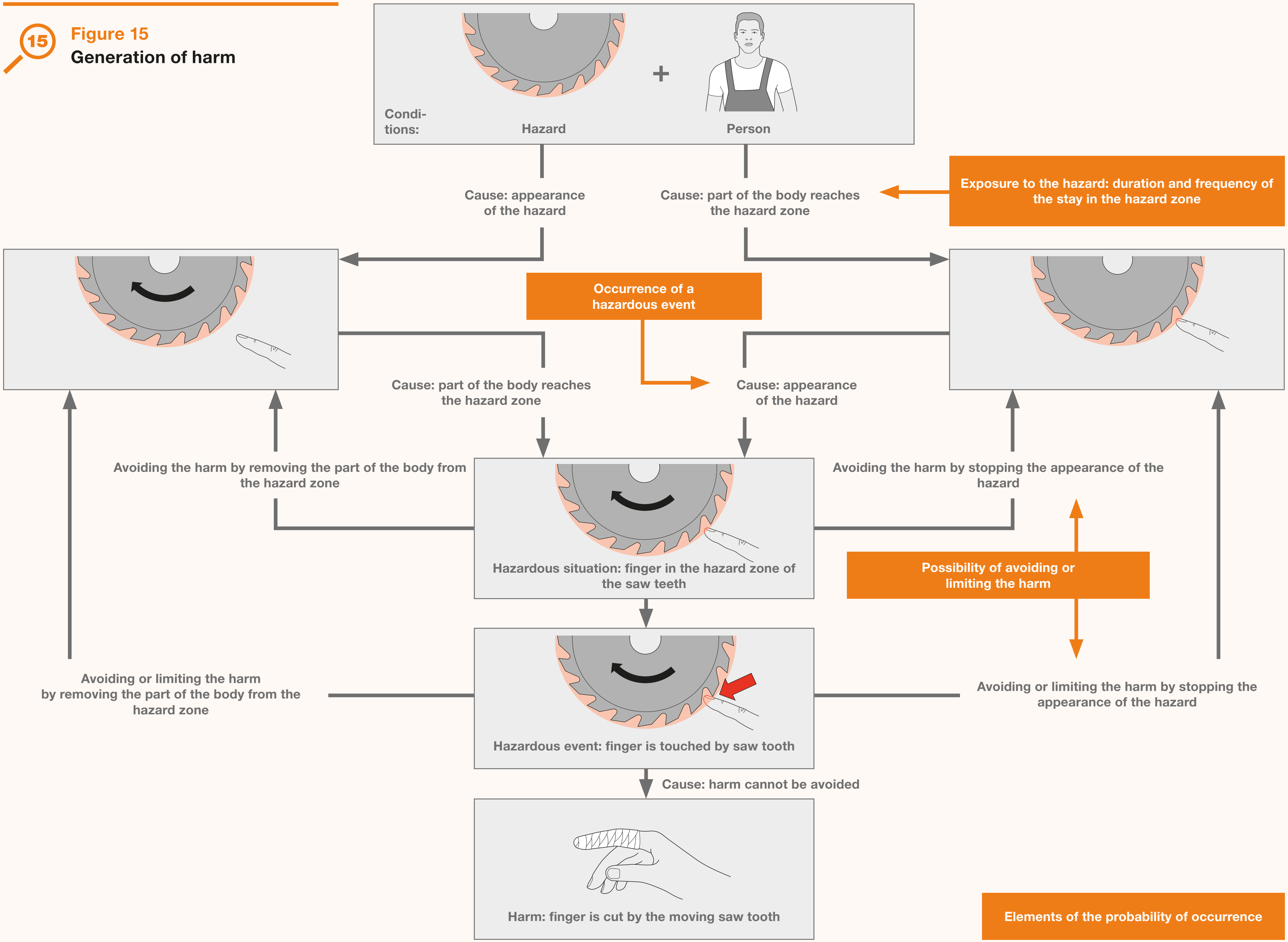
Generation of harm
Figure 15, page 12

15 **Figure 15**

Generation of harm



5 Preparations

5.1 Organisation

Groups generally perform the risk assessment and risk reduction more thoroughly and more effectively than individuals. Appoint a responsible group leader. The group shall be set up such that it has members with competence and knowledge in these areas:

- design and function(s) of the machine
- regulations and standards relevant to the machine
- practical experience with the machine: installation, operation, maintenance, etc.
- accidents and damage to health in connection with the type of machinery
- understanding of human factors (interaction between person and machinery, stress-related aspects, ergonomic aspects, etc.)

The composition of the group may change in the course of the procedure.

5.2 Point of reference

The following information shall be procured for the risk assessment and risk reduction procedure:

Information for describing the machinery

- design drawings (function design), circuit diagrams (electrical system, pneumatic system, hydraulic system, etc.)
- energy sources and how they are supplied
- description of the phases of life of the whole life cycle of the machinery
- user specification
- further information on the machinery (see chapter 8.1)

The technical file on similar machines can be a source of information for the risk assessment and risk reduction.

Relevant provisions

Depending on the structure and the substances used, the applicable regulations (European Directives, safety data sheets, etc.) shall be determined. Examine whether the machinery falls within the scope of possible regulations.

If the machinery falls within the scope of the Machinery Directive 2006/42/EC, it shall be determined whether the additional essential health and safety requirements in chapters 2 to 6 of Annex I of the Machinery Directive for certain categories of machinery or hazards must also be taken into account.

You will then search for the standards, which set out the requirements of the applicable regulations for the machinery. The titles of these standards are listed in the European Official Journal. You can access them on the Suva web site:
www.suva.ch/certification-e
> «Examples of type examinations from different areas» **>** «Machinery» **>** «Useful Links» **>** «List of harmonized standards conferring presumption of conformity under the Machinery Directive 2006/42/EC»

First, you will examine whether **a type-C** standard exists for the machine to be built. If not, protective measures according to the standard EN ISO 12100 shall be selected in the procedure for risk reduction. Once the protective measures have been determined, the **type-B standards** relevant for the protective measures are used. Please note that standards are non-binding. They do, however, provide information on the **state of the art**. This means the currently available technical options that are to be taken into account in the construction of the machinery (Machinery Directive 2006/42/EC, Annex I, General Principles, point 3).

You can obtain the standards from your national standards institute; in Switzerland from the Swiss Association for Standardization (www.snv.ch).

Experience with similar machines

Experiences related to the use of similar machines is required (e. g. accidents, diseases, ergonomic problems, incidents, malfunctions).

Example: circular saw

Applicable regulations

The circular saw consists of an assembly of linked parts with moving parts, which are motor driven. Furthermore, it is intended for a particular use, for sawing metals. Therefore, the machine falls within the scope of the Machinery Directive 2006/42/EC (see Article 2 of that Directive).

Due to the structure of the circular saw and the material to be machined with it, the health and safety requirements in chapters 2 to 6 in Annex I of the Machinery Directive need not be taken into account.

The electrical equipment of the circular saw consists of the drive with a rated voltage of 400 V and the control system (rated voltage 24 V). Regarding the electrical equipment, the Machinery Directive, in Annex I, point 1.5.1, demands that it meets the requirements of the Low Voltage Directive 2014/35/EU, which covers voltages from 50 to 1000 V.

Due to the rated voltage of the drive, the electrical equipment of the circular saw falls within the scope of the Low Voltage Directive.

As the currents of the electrical equipment may cause electromagnetic interference, the circular saw also falls within the scope of the Ordinance on Electromagnetic Compatibility (see Article 1 of that Ordinance). In the European Economic Area the European Electromagnetic Compatibility Directive 2014/30/EU must additionally be taken into account.

Relevant standards

According to the extract from the Official Journal of the European Union[1], for circular saws that are used to machine metal, there is the type-C standard EN 13898:2003 + A1:2009 «Machine tools – Safety – Sawing machines for cold metal»[2]. Based on the information on the scope, it can be ascertained that the circular saw to be built is included in this standard. The standard also contains references to other relevant standards.

At the time of writing this publication, it was foreseeable that the standard EN 13898 would be replaced by the new standard EN ISO 16093 in a few months. To provide the latest specifications for the circular saw, the standard EN ISO 16093 was taken into account.

For the cooling lubricant, the safety data sheet of the product supplier is available, in accordance with the provisions of the Chemicals Regulation.

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[1] This extract from the Official Journal of the European Union was relevant at the time of printing. To ensure that the current standards are used, the extract relevant at any given time must be taken into account.

[2] and the corrigendum to EN 13898:2003 + A1:2009/AC:2010

6 Documentation and aids

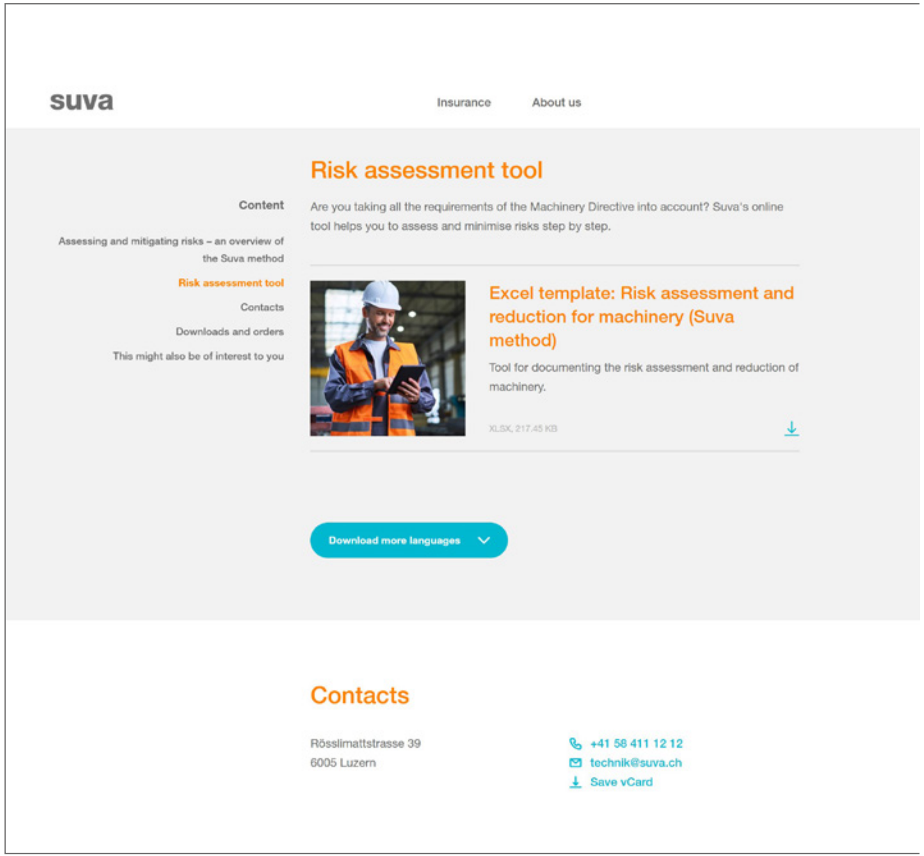
The risk assessment and risk reduction form an important part of the evidence to indicate that the machinery complies with the relevant safety provisions. Therefore, Annex VII of the Machinery Directive requires the manufacturer to store the documentation on risk assessment and reduction as part of the technical file. These documents shall be presented to a competent national authority for market surveillance in response to a duly substantiated request.

Documentation of the following must be provided:
- Assumptions (relevant provisions, limits of the machine, description of the phases of life, and operating modes)
- Procedures (hazards identified, harm, risks)
- Results (relevant health and safety requirements, protective measures, references for the protective measures).

The results are generally shown in tables. Annex B contains templates for copying tables for the documentation of the risk assessment and the risk reduction.

As an aid for the documentation, you can also use an excel template from Suva free of charge at: **www.suva.ch/risk-assessment**
Many other computer applications are available on the market for the documentation of risk assessments. When using them, please pay attention to the assumptions made in the application and make sure that all steps of the procedure are represented in it.

The additional illustration of the hazards and hazard zones in design drawings or assembly drawings can facilitate the transparency of the risk assessment and reduction.



Risk assessment tool

Are you taking all the requirements of the Machinery Directive into account? Suva's online tool helps you to assess and minimise risks step by step.

Excel template: Risk assessment and reduction for machinery (Suva method)

Tool for documenting the risk assessment and reduction of machinery.

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Figure 16

Excel template: Risk assesment and reduction for machinery

7 Overview of the procedure

With regard to the risk assessment and risk reduction, there is a basic distinction between the procedure with and the procedure without consideration of a listed[3] type-C standard.

7.1 Procedure without consideration of a listed type-C standard

The procedure shall be divided into these individual steps:

1. **Determining the limits:**
The limits of the machine determine the area, in which the risks must be considered.

2. **Identifying the hazards:**
In the product life of the machine, all situations which may appear are to be determined and the hazards in these situations identified.

3. **Estimating the risk:**
The risk of all hazardous situations is estimated by determining the severity of harm and the probability of occurrence.

4. **Evaluating the risk:**
checks are made to establish whether a reduction of the present risks is necessary.

5. **Reducing the risk:**
With the aid of protective measures, the hazards are eliminated where possible or existing risks are reduced. Checks are then made to establish whether the intended risk reduction has been achieved by this, and whether any new hazards have been generated by the protective measures.

17 **Flow chart without consideration of a listed C-standard**
Figure 17, page 17

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[3] **The term «listed standard» is used in this publication as shorthand for a harmonised standard currently published in the European Official Journal.**

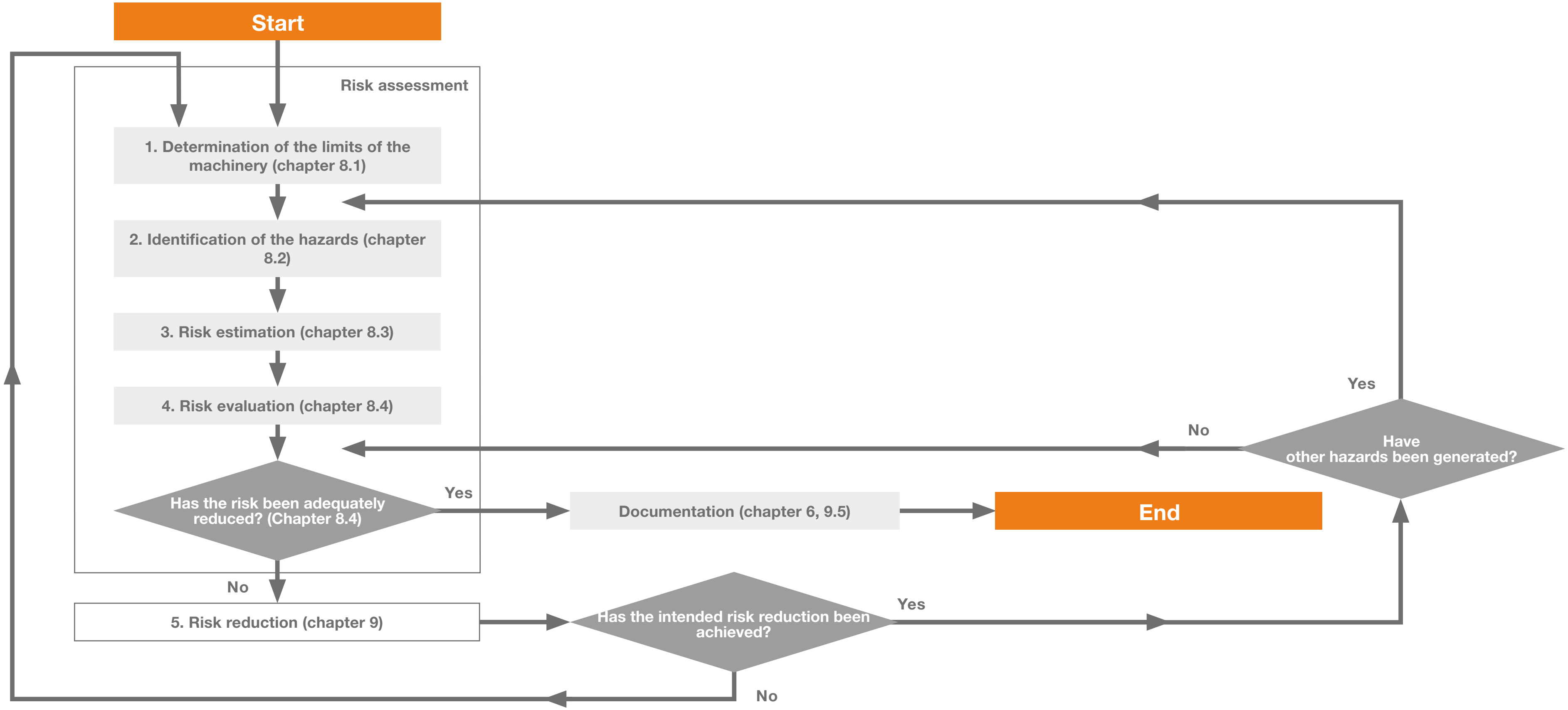

Figure 17

Schematic representation of the procedure with the individual steps of the risk assessment and the interfaces to the risk reduction. Detailed presentation of the risk reduction, see chapter 9.

7.2 Procedure with consideration of a listed type-C standard

The process is basically the same as for the procedure without consideration of a listed type-C standard. The differences are noted for each of the individual steps.

1. Determining the limits:

Additional investigations are necessary to establish whether the machines to be built fall completely within the scope of the type-C standard.

2. Identifying the hazards

3. Estimating the risk:

The risk of all hazardous situations, for which the type-C standard does not propose any protective measures, is to be determined.

4. Evaluating the risk:

An evaluation can be omitted if all the following conditions are met:

- The machine falls completely within the scope of the type-C standard.
- The hazard identified on the machine as a significant hazard is mentioned in the type-C standard.
- The type-C standard assigns a specific protective measure or a selection of protective measures with selection criteria to the significant hazard.

5. Reducing the risk:

If you intend to build according to a type-C standard, you must ensure that the protective measures assigned to the significant hazard are fully implemented.

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Flow chart with consideration of a listed C-standard
Figure 18, page 19

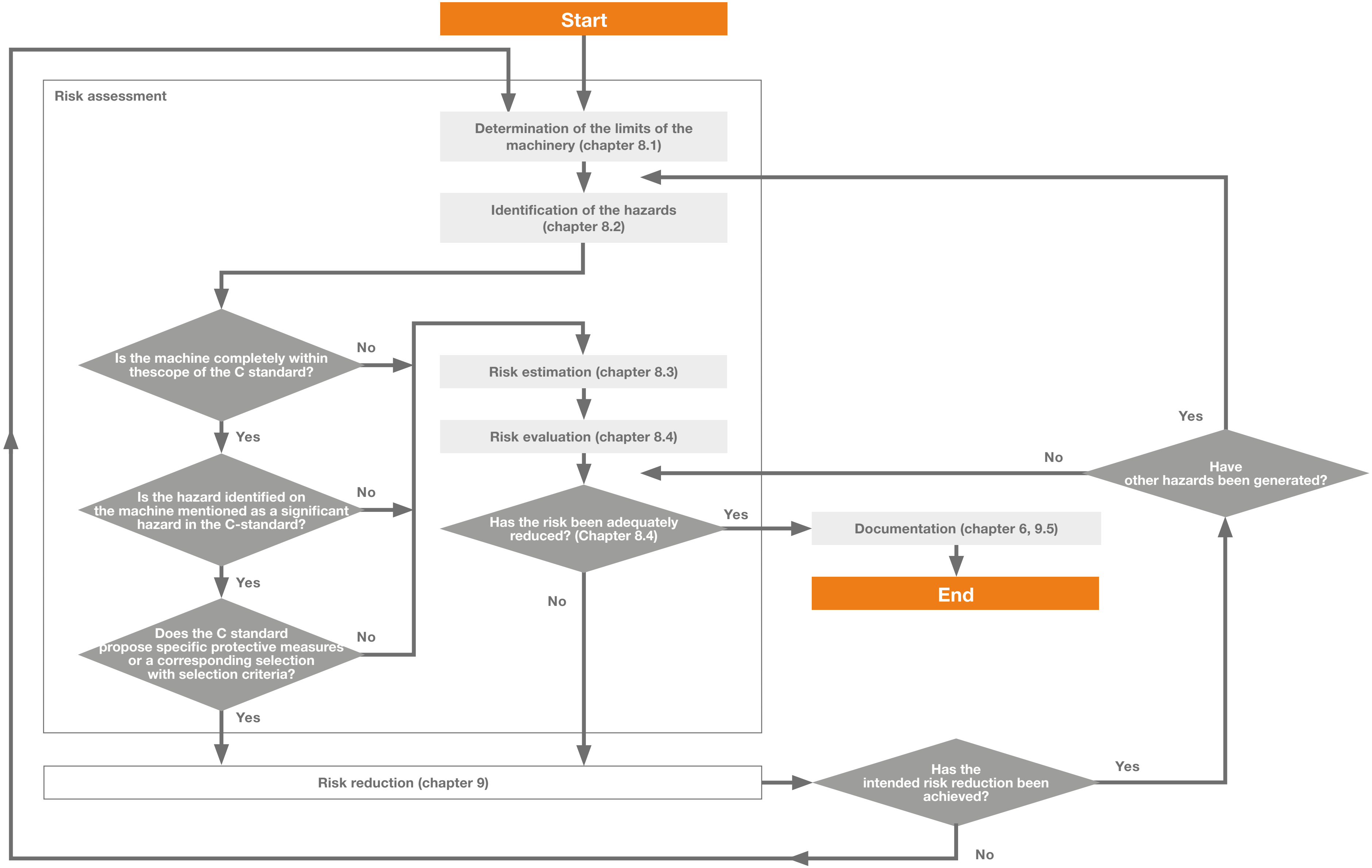

Figure 18

Schematic representation of the procedure in the event that a listed type-C standard exists.
Detailed presentation of the risk reduction, see chapter 9.

8 Assessing the risk

8.1 Determining the limits of the machinery

To perform the risk assessment, you first determine the limits within which the product life of the machinery takes place.

For this purpose, all phases of life such as transport, commissioning, use, disabling and scrapping, as well as all operating modes required for the intended use such as setting, cleaning, maintenance must be listed.

Use limits
The limits of use include both the intended use and the reasonably foreseeable misuse[4].

You then record all persons that reach into the machine or come into contact with the machine during the individual phases of life or operating modes. You need to record relevant characteristics such as sex, age, whether right-handed or left-handed, limited physical abilities such as visual or hearing impairment, height, strength. The training needs of operators and any specialists that may be required are to be determined.

Please bear in mind that persons who have nothing to do with the machinery (third parties) may also be affected; for example by the noise of the machinery inside a production hall.

Define the area of use of the machinery. This determines where the machinery is expected to be used, whether in the industrial or non-industrial environment, or in the home.

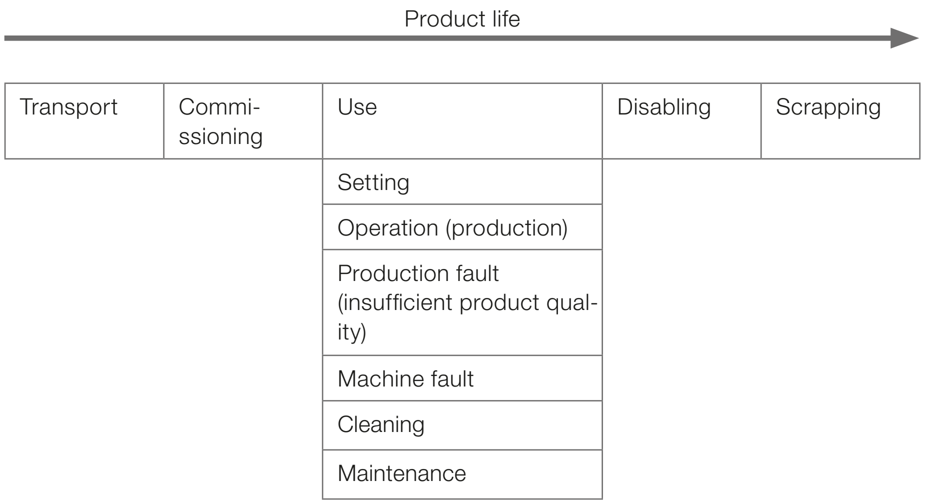

Figure 19

Examples for phases of life and operating modes of a stationary production machine

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4 Explanations of terms, see chapter 3

Space limits

Record the space limits in a design drawing, taking the following aspects into account:

- The space required by the machine movements
- Space requirements for persons interacting with the machine, for instance during operation and maintenance
- Interactions between human and machine, for instance the «human/machine» interface
- Interfaces of the machine to power supply or other supplies such as hot water

It makes sense to look at several machines whose functions mutually influence each other directly in a single risk assessment. In other words, a single boundary is to be defined around these machines.

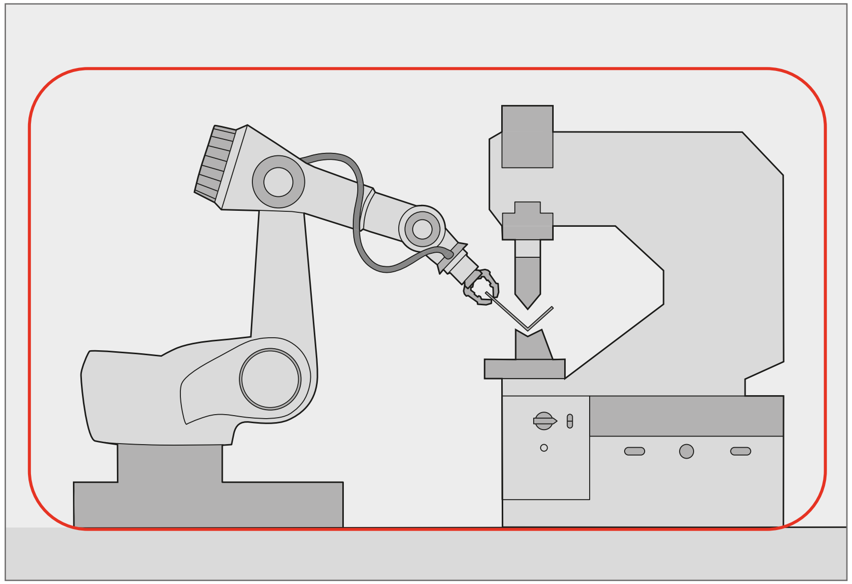


Figure 20

System boundary around a combination of two machines, robot and press brake

Time limits

First, determine the life cycle limit of the machinery. Then, define the life cycle of the parts which do not achieve the life cycle of the machinery, such as tools, wearing parts, electrical components. Here, too, the intended use and any reasonably foreseeable misuse must be taken into account.

The recommended service intervals are to be determined on this basis.

This gives an indication of the parts which must be replaced during maintenance so that the machinery remains in a functional and safe condition during its life cycle.

Further limits (examples)

- properties of the materials to be processed (dusts, vapours, fragments, etc.)
- the level of cleanliness required (for example processing of foodstuffs or pharmaceutical products)
- influences of the environment: indoors (heat, noise, dust, etc.), outdoor operation (rain, falling stones, frost, etc.)

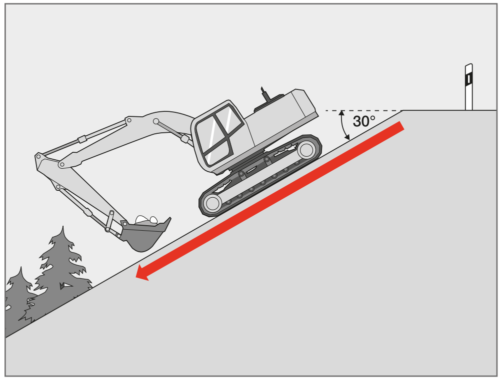


Figure 21

Example of influences from the environment: Excavator in steep terrain

An example based on a circular saw

Determination of the limits of the machinery

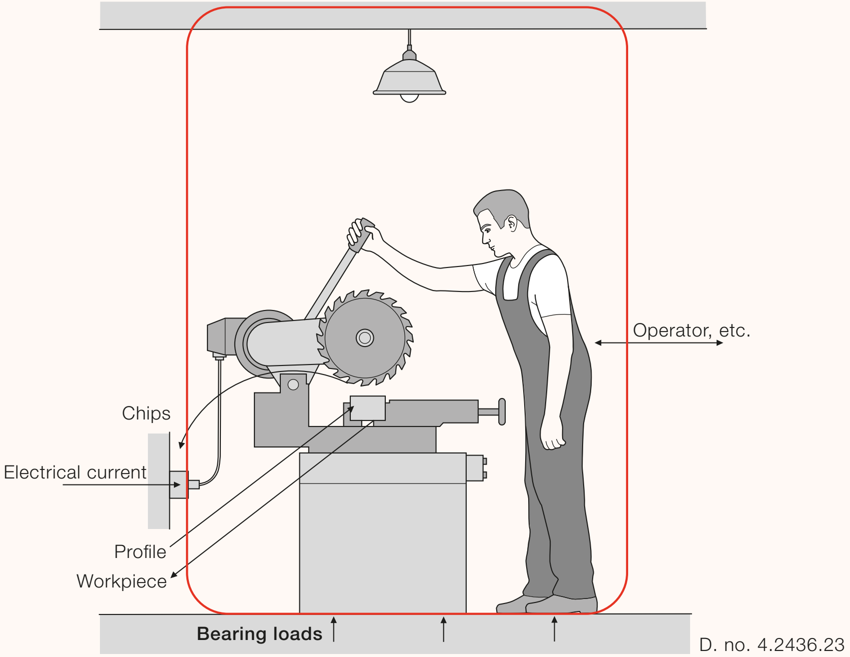


Figure 22

Illustration of the space limits in the design drawing of the functional model of the circular saw. The space limits and the influences that have an effect across the boundaries are delineated.

① Documentation: limits of the machine
Table 1, page 23

Table 1
Documentation: limits of the machine

Designation of the machinery	Circular saw	
Intended use, limits of use	Sawing ferrous and non-ferrous metals, which do not release any health-damaging substances during machining	
Reasonably foreseeable misuse	Sawing lead and other materials, which release health-damaging substances during machining	
Time limits, life cycle	20 years	
Life cycle wearing parts	Driving belt	5 years
	Circular saw blade made from tungsten-carbide steel	20 hours
	Circular saw blade with carbide teeth	60 hours
Space limits	Drawing 4.2436.23	
Subsystems	entire machine	

Phases of life, operating mode	**Persons involved**							
	User	Third parties	Mechanic	Electrician	Transport operative	Disposal specialist		
Transport		●			●			
Commissioning		●	●	●				
Operation (production)	●	●						
Production fault	●	●						
Machine fault		●	●	●				
Cleaning	●	●						
Maintenance		●	●					
Disabling		●						
Scrapping		●	●			●		

Level of training of the user	No vocational training required; knowledge of the specifications for the user in the instruction handbook
Area of use	Interior locations of trade or industry
Additional basic requirements	None
Date	15.11.2016
Author	John Doe

8.2 Identifying the hazards and hazardous situations, harm and causes

Systematically identify all hazards, hazardous situations, and hazardous events during all phases of life of the machinery. This is fundamental in order to be able to reduce all the risks involved.

Therefore start by determining all situations that occur during the life cycle of the machinery. For this purpose, describe all phases of life and operating modes of the machinery by accurately recording the sequence of the individual actions carried out by human or machine.

Use this work at the same time as basis for the instruction handbook. This is to ensure that later work on the machine is done in the way assumed during the assessment and the reduction of the risks.

If hazards appear in certain situations, they are to be recorded by assigning them to the associated working step. If the same hazards appear in connection with further working steps of the same operating mode, it is not necessary to record them a second time provided the hazardous situation is identical. A hazard can basically be covered by describing the origin of the hazard (e. g. rotating saw blade) and/or the harm (e. g. cutting hazard).

The list of possible hazards in Annex C can be used as an aid to identify the hazards.

Quote from EN ISO 12100:

It is assumed that a hazard that is present on machinery will sooner or later lead to harm if no protective measure or measures are implemented.

Determining the harm

In the following step you describe the harm that may result from each determined hazardous situation in the worst case scenario.

An example based on a circular saw

2

Description of the phases of life and operating modes
Documentation: Description of the phase of life «Transport» and the operating mode «Production»
Table 2, page 25

An example based on a circular saw

3

Identification of the hazards, determination of harm
Documentation: Hazards and harm during the actions «Lifting the machine» and «Placing profile on support»
Table 3, page 26

Table 2

Documentation: Description of the phase of life «Transport» and the operating mode «Production»

Machine: Circular saw	**Series/type:** KS 250	**Serial number:** **001**	**Space limits in drawing no.:** **4.2436.23**	**Author:** John Doe **Date:** 15.11.2016

No.	Action	No.	Hazard	Harm	Risk			Causes	No.	T/B	Measure	Residual risk			References to 2006/42/EC Ann. I, standards
					S	P	EHA					S	P	EHA	
Phases of life, operating mode Transport								**Subsystem** entire machine							
1	Connecting the circular saw to lifting gear using slings														
2	Lifting the circular saw														
3	Moving the circular saw														
4	Placing the circular saw on the floor														
5	Removing the slings														
Phases of life, operating mode Operation (production)								**Subsystem** entire machine							
1	Placing the profile on the support														
2	Positioning the profile														
3	Clamping the profile														
4	Switching the saw on														
5	Drive motor is connected to the power supply														
6	Drive motor turns the saw blade														
7	Motor of the cooling lubricant pump is connected to the power supply														
8	Cooling lubricant is transported to the saw blade														
9	…														

Table 3

Documentation: Hazards and harm during the actions «Lifting the machine» and «Placing profile on support»

Machine: Circular saw	**Series/type:** KS 250	**Serial number:** **001**	**Space limits in drawing no.:** **4.2436.23**	**Author:** John Doe **Date:** 15.11.2016

No.	Action	No.	Hazard	Harm	Risk			Causes	No.	T/B	Measure	Residual risk			References to 2006/42/EC Ann. I, standards
					S	P	EHA					S	P	EHA	
Phases of life, operating mode Transport								**Subsystem** entire machine							
1	Connecting the circular saw to lifting gear using slings														
2	Lifting the circular saw	2.1	Objects falling down	Injury to the torso											
		2.2	Lack of stability	Leg injury											
3	...														
Phases of life, operating mode Operation (production)								**Subsystem** entire machine							
1	Placing the profile on the support	1.1	Cutting parts	Hand injury											
		1.2	Electric shock	Death											
		1.3	Exertion	Back injury											
2	…														

Cause of the hazard and the harm

The standard EN ISO 12100 does not require the causes of a hazard to be determined as part of the risk assessment. It is, however, advisable to determine the causes of the hazard and the harm, as this helps to estimate the risk and to determine the required protective measures.

You can determine the causes by asking the following questions:
a) Why is the person in the hazard zone?
b) Why does the hazardous event occur?
c) Why can't the harm be avoided?

The fault tree analysis[5] is another option for determining the causes. If the harm resulting from a hazardous situation is known, the facts that are a prerequisite for it can be determined systematically. If several facts are required for the occurrence of the hazardous situation, they are connected with an «and». If one of several facts can be the sole prerequisite, these facts are connected with an «or».

---

[5] according to the standard DIN 25424-1 «Fault tree analysis; manual calculation procedures for the evaluation of a fault tree»

An example based on a circular saw

Causes of the cut on the hand by the hazardous situation «Touching the rotating saw blade»

a) Why is the person in the hazard zone?
- The hazard zone is reachable.
- The saw blade has caught the clothes of the person.

b) Why does the hazardous event occur?
- The drive of the saw has been switched on.
- When switching off, the saw blade does not stop immediately, but coasts down.

c) Why can't the harm be avoided?
- The part of the body is cut immediately after touching the saw blade.

An example based on a circular saw

Determining the causes

23 Fault tree analysis of hand injury caused by the rotating saw blade
Figure 23, page 28

4 Documentation: Causes of the hazardous events «Circular saw falling down» and «Cutting by the rotating saw blade»
Table 4, page 29

Figure 23

Fault tree analysis of the hand injury caused by the rotating saw blade

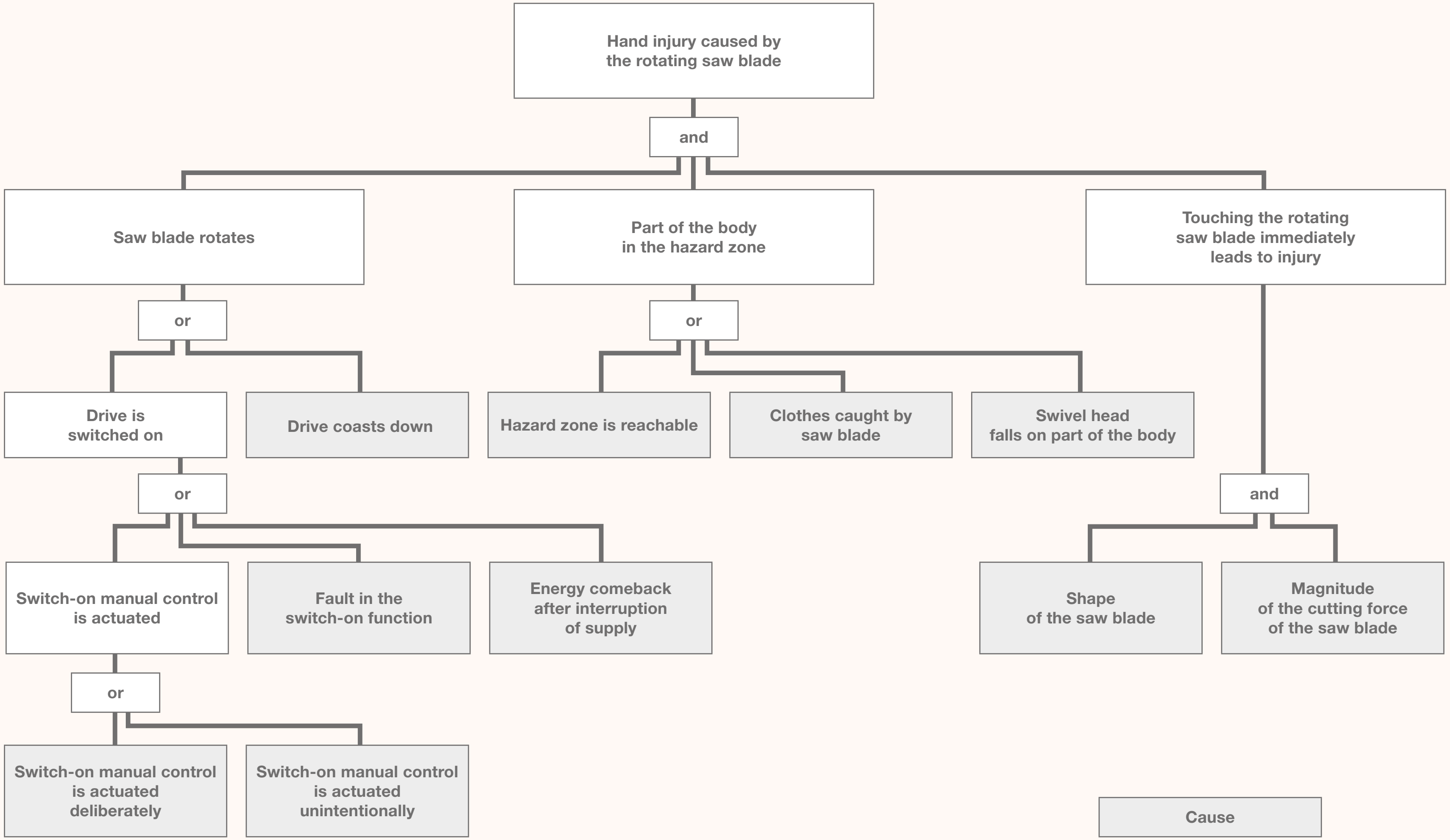


Table 4

Documentation: Causes of the hazardous events «Circular saw falling down» and «Cutting by the rotating saw blade»

Machine: Circular saw	**Series/type:** KS 250	**Serial number:** **001**	**Space limits in drawing no.:** **4.2436.23**	**Author:** John Doe **Date:** 15.11.2016

No.	Action	No.	Hazard	Harm	Risk			Causes	No.	T/B	Measure	Residual risk			References to 2006/42/EC Ann. I, standards
					S	P	EHA					S	P	EHA	
Phases of life, operating mode Transport								**Subsystem** entire machine							
1	Connecting the circular saw to lifting gear using slings														
2	Lifting the circular saw	2.1	Objects falling down	Injury to the torso				• insufficient strength of the attachment points • unsuitable attachment points • insufficient strength of the slings • insufficient strength of the lifting gear							
		2.2	Lack of stability	Leg injury				…							
3	…														
Phases of life, operating mode Operation (production)								**Subsystem** entire machine							
1	Placing the profile on the support	1.1	Cutting parts	Hand injury				• Touching the rotating saw blade immediately leads to injury (shape, cutting force) • Swivel head falls on part of the body • Unexpected start-up due to energy comeback after interruption • Unexpected start-up due to fault in the switch-on function • Unexpected start-up due to unintentional actuation of the switch-on manual control • Clothes caught by saw blade • Switched off drive coasts down • Hazard zone of the saw blade is reachable							

8.3 Estimating the risk

Risk estimation is a matter of determining **the greatest risk of each individual hazardous situation**. In order to do this, the severity of harm and the probability of occurrence need to be determined in each case. The different courses that the harm might take must also be taken into account. Harm may arise from a hazardous situation in the form of an injury (acute course) or in the form of damage to health (chronic course).

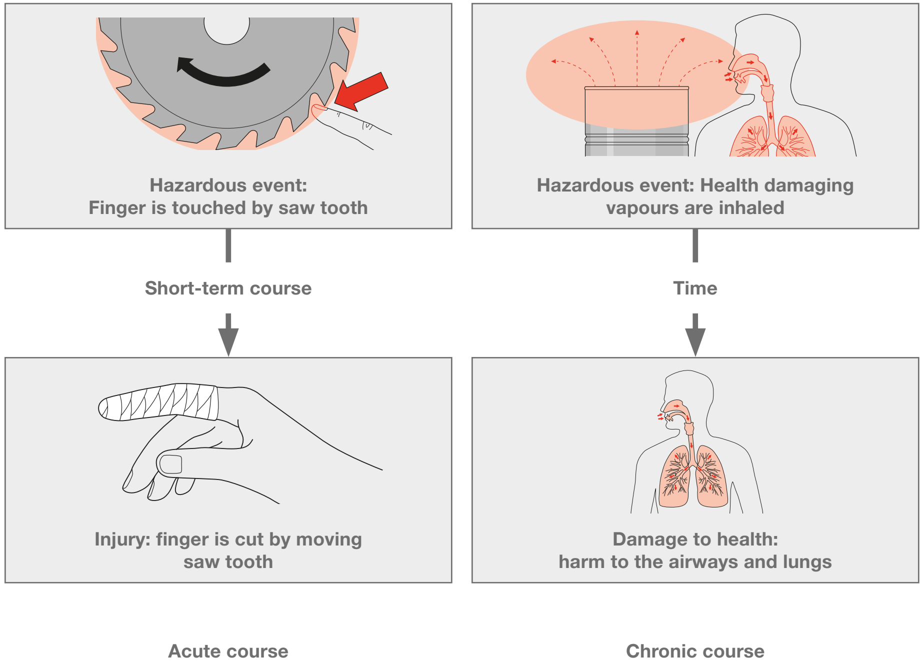


Figure 24

Conditions for occurrence of a harm

Damage to health (e. g. hearing loss) results from a cumulative exposure to a harmful level during a certain period of time. The severity of harm and probability of occurrence depend on the overall dose over the course of time. You can find information on estimating risks relating to damage to health in the relevant type-B standards (see Annex A).

As described in chapter 7.2, risk estimation is not necessary if the machinery is built in accordance with a listed type-C standard.

An example based on a circular saw

Risk estimation necessary or not?

As already mentioned in the preparations for the risk assessment and risk reduction, the standard EN ISO 16093:2017 is taken into account in this publication. Therefore, the risk assessment procedure of chapter 7.2 is to be applied. Based on the intended use of the machine and its structure (see Determination of the limits), it can be stated that the circular saw falls completely within the scope of the standard EN ISO 16093.

EN ISO 16093 classifies the hazard with the rotating saw blade as origin as significant and assigns it certain protective measures.
If these protective measures are fully implemented on the machine, it can be assumed that the essential health and safety requirements of the Machinery Directive are met. A risk estimation may therefore be omitted. The hazard with the origin «Circular saw falling down when lifting during transport» is recorded as not significant in the standard EN ISO 16093. To reduce the risk of this hazard, the risk must first be estimated.

There are a number of approaches to risk estimation. In the case of the Suva method, the procedure with a risk matrix is used. For each hazardous situation, the risk is classified into a clear, rough gradation based on the severity of harm and the probability of occurrence. Awareness of the causes helps you to estimate the risk.

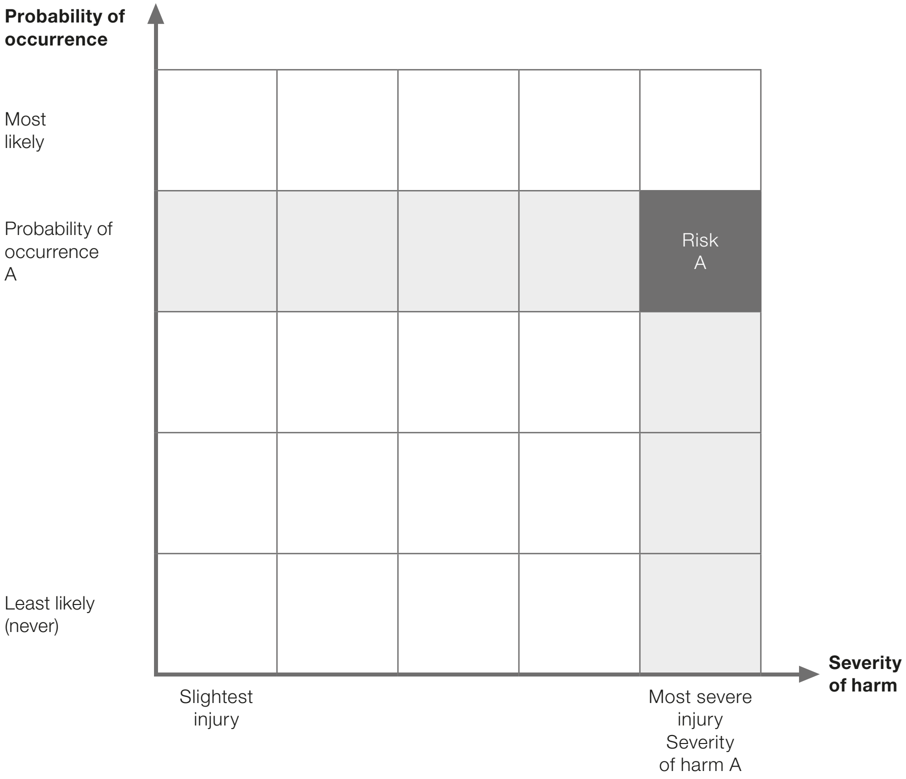


Figure 25

Risk matrix with gradation of probability of occurrence and severity of harm

Estimating the severity of harm

The Suva method divides the severity of harm into the following levels:

I **Death**
II **Serious permanent harm** = severely disabling injury/damage to health which results in occupational disability
III **Slight permanent harm** = significant injury/damage to health; after recovery it is possible to return to the same workplace
IV **Curable harm with incapacity to work** = more than just first aid is required
V **Curable harm without incapacity to work** = first aid is sufficient

The severity of the harm generally depends on the energy that affects the part of the body concerned and on its sensitivity. If, for example, an incorrectly clamped profile is slung away during sawing, the kinetic energy will cause a greater severity of harm than if only a chip is slung away. If, however, the chip hits an eye, a significant severity of harm is possible in spite of the low kinetic energy owing to the sensitivity of the eye.

The general rule is: if the permissible influence of a hazard on a part of the body (force, surface pressure, vibration, etc.) is exceeded, harm occurs. The values for the permissible influence can be taken, for example, from standards or safety data sheets.

The possible severity of harm can vary considerably in each case for the same hazardous situation. Therefore, it may be useful to estimate the risk for a range of representative severities. Accordingly, the most serious harm that can realistically occur (worst case scenario) is to be considered.

An example based on a circular saw – Hazardous situation «Lifted machine»

Estimating the severity of harm

If the lifted circular saw drops to the ground during transport, body parts may be injured. The probability of being killed by the falling circular saw may be less likely, but can realistically occur. It is for this reason that death is assumed as the worst possible severity of harm of the hazardous situation «Lifted machine».

26 Person in the hazard zone of the circular saw
Figure 26, page 33

27 Location of the severity of harm in the risk matrix
Figure 27, page 33

Figure 26
Person in the hazard zone of the circular saw

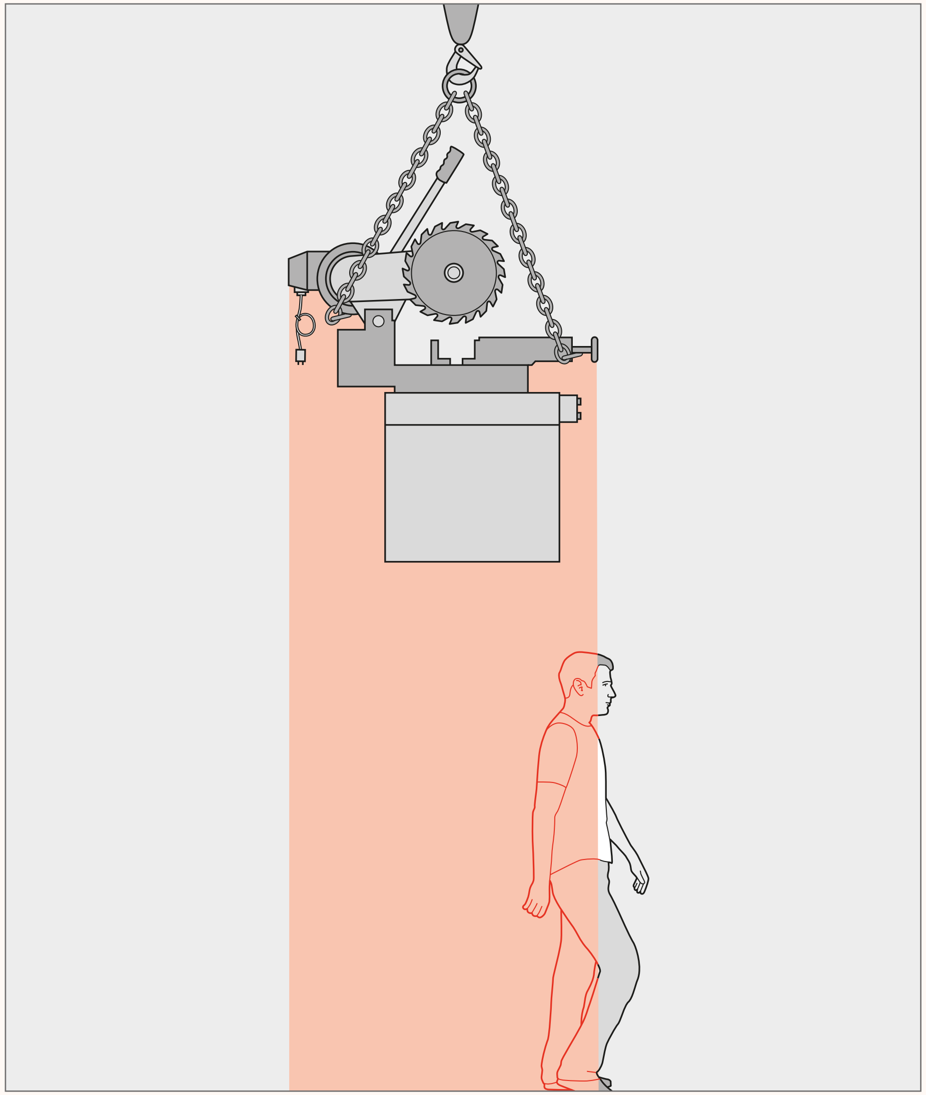
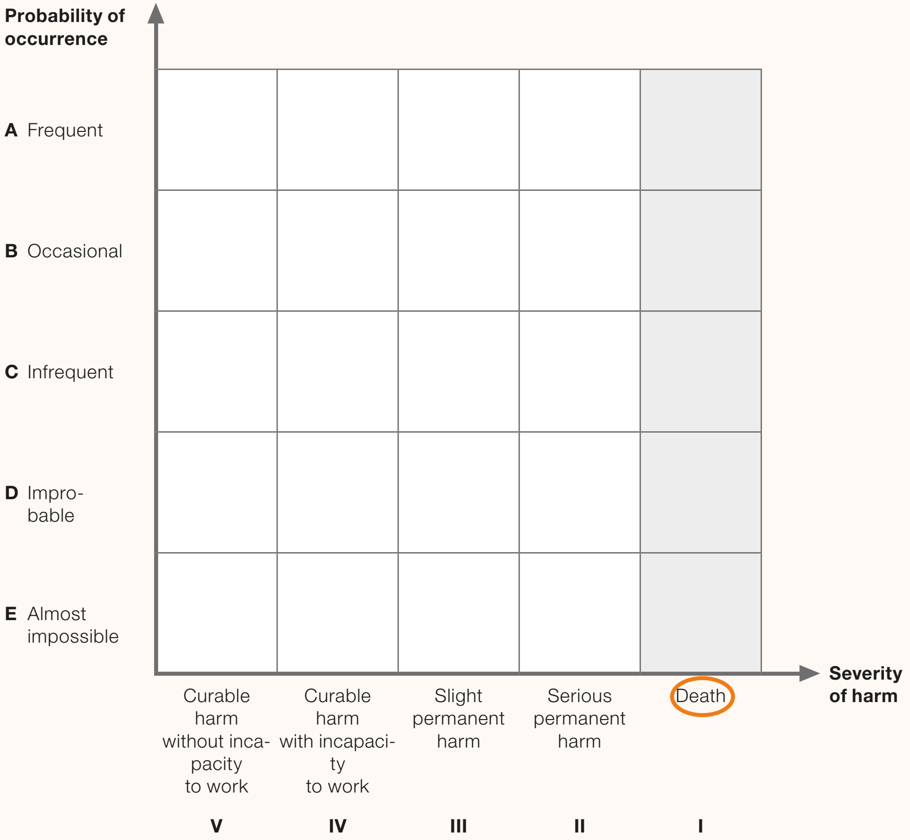


Figure 27
Location of the severity of harm in the risk matrix



Probability of occurrence of harm

The Suva method divides the probability of occurrence into the following levels:

- **A** **Frequent** = certain to occur in a short time
- **B** **Occasional** = certain to occur after some time
- **C** **Infrequent** = occurrence possible
- **D** **Improbable** = unlikely to occur
- **E** **Almost impossible** = so unlikely that the probability is almost zero

The probability always refers to a unit of time, generally the life cycle of the machinery. Experience with similar existing machines in operation (history of accidents and incidents) delivers one way of estimating the probability of occurrence. Another way of estimating the probability of occurrence of harm is to identify its three elements:

- Exposure of persons to the hazard (E)
- Probability of occurrence of hazardous events (H)
- Possibility of avoiding or limiting harm (A)

Exposure of persons to the hazard (E)

You determine the exposure to the hazard by defining the frequency and duration of stay of persons in the hazard zone. In practical terms, you consider the average interval t between the individual exposures to the hazard and categorise it into five levels. A weighting value is assigned to each level, which is required for the subsequent determination of the probability of occurrence.

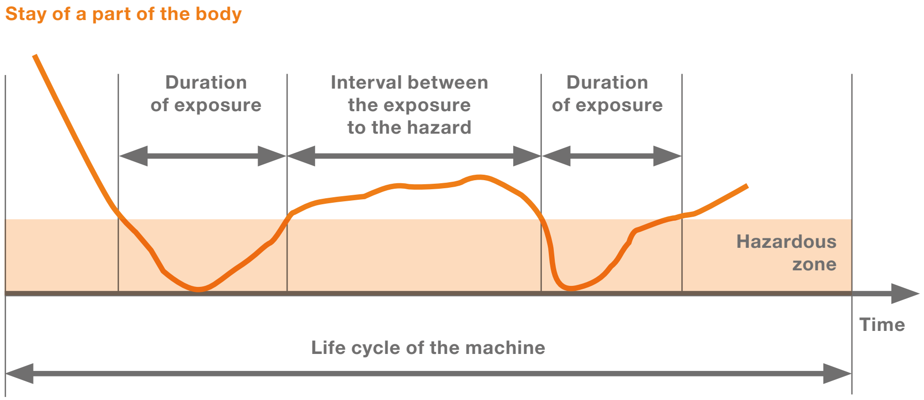


Figure 28

Illustration of the average interval t between the exposure relevant for consideration

Average interval t between the exposure to the hazard	Weighting of the level
t ≤ 1 hour	5
1 hour < t ≤ 1 day	5
1 day < t ≤ 2 weeks	4
2 weeks < t ≤ 1 year	3
t > 1 year	2

If the duration of exposure is shorter than 10 minutes, the weighting of the next level down may be used.

Table 5

Levels and allocated weighting of the exposure of persons to the hazard

The following factors are to be taken into account for determining the exposure to the hazard:

- The need for access to the hazard zone (normal operation, correction of malfunction, maintenance, repair, etc.)
- The nature of the access (manual feeding of materials, process observation, correction of malfunctions, etc.)
- The number of persons requiring access
- The reliability of protective measures
- The possibility of defeating or circumventing protective measures (incentive when the protective measures impair the function or the ease of operation of the machinery excessively)
- Information for use regarding the position of the hazard zones, the nature of the hazard and the consequences of the residual risks

Probability of occurrence of hazardous events (H)

You determine the probability of occurrence of hazardous events by defining the frequency and duration during which the hazard is active.
A hazard can, for example, be permanently present (hazardous substance) or occur frequently (required for functioning, for example electrical current for the drive motor). However, the hazard may also only be active in case of a fault (breakage of a grinding tool, unexpected start-up due to a fault in the start-up function).

It is also necessary to assess whether the activity of the hazard coincides with the presence of a person in its hazard zone. Safeguarding and complementary protective measures prevent a person or a part of the body from being in the zone of an active hazard (see also chapter 9.2).

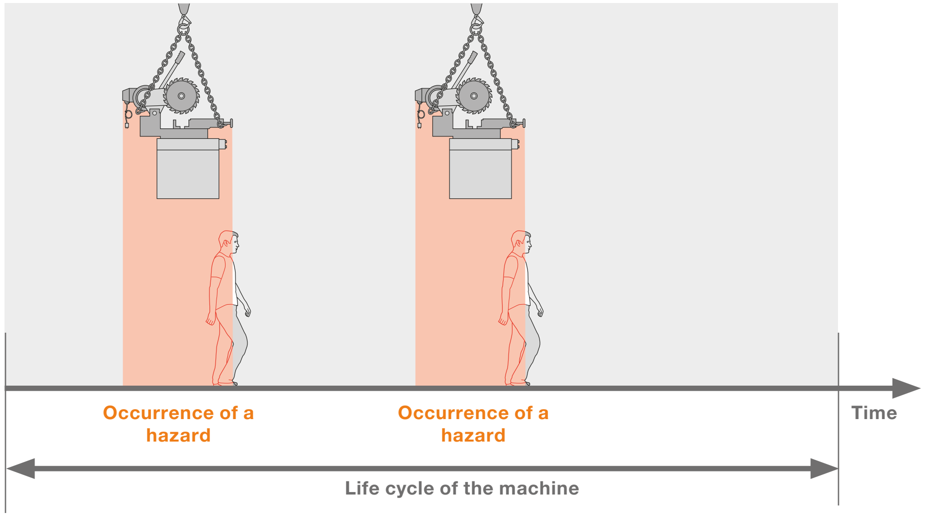


Figure 29

Occurrence of a hazard that is not permanently active during the life cycle of a machine

The Suva method categorises the probability of a hazardous event into five levels. The level, here, corresponds to the weighting value required to determine the probability of occurrence of harm.

Probability of the hazardous event	Negligible	Infrequent	Possible	Likely	Very likely
Weighting of the level	1	2	3	4	5

Table 6

The five levels of probability of a hazardous event with the associated weighting

When determining the probability of a hazardous event, the following aspects are to be taken into account:
- ergonomic design of the machinery (influence on actions such as feeding, operating, reaching into the machine taking into account encumbrances caused by personal protective equipment)
- Properties of the operators that influence their tiredness (sex, age, disabilities, etc.)
- Accident histories, known hazardous events of machinery with hazardous situations, that show a comparable risk

Possibility of avoiding or limiting harm (A)

Here, the Suva method distinguishes between three levels, to which weighting values are assigned in accordance with table 7.

Possibility of avoiding or limiting harm	Weighting of the level
Impossible	5
Possible	3
Likely	1

Table 7
Levels and weighting of the possibility of avoiding or limiting harm

The following factors are to be taken into account:
- how quickly a hazardous situation can lead to harm (suddenly, quickly, slowly)
- level of training of the persons who may be exposed to the hazards (skilled, unskilled)
- awareness of the risk (information for user, direct observation, warning signs and indicating devices on the machine)
- human ability to avoid or limit harm (reflexes, agility, possibility of escape)
- practical experience and knowledge (for example regarding the machinery or the hazard)

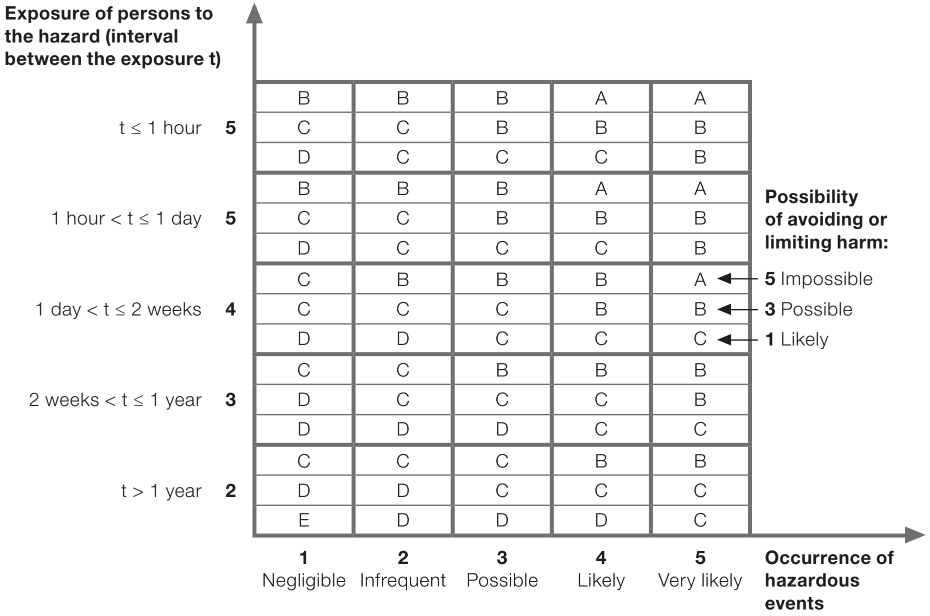
The absence of accident data does not guarantee either a low probability of occurrence of accidents or that minimal protective measures will be required.

Determining the probability of occurrence of harm

The probability of occurrence of harm is now determined with the aid of table 10. The weighting values of the previously determined levels of the individual elements E, H, and A must simply be added together. The allocation can also be represented in a matrix (Figure 30).

Levels of probability	Sum of the weightings
A Frequent = certain to occur in a short time	14 – 15
B Occasional = certain to occur after some time	11 – 13
C Infrequent = occurrence possible	8 – 10
D Improbable = occurrence unlikely to occur	5 – 7
E Almost impossible = so unlikely that the probability is almost zero	4

Table 8
Allocation of the probability of occurrence of harm to the sum of weightings of exposure to the hazard, probability of the hazardous event, and possibility of avoiding or limiting harm.



		1 Negligible	2 Infrequent	3 Possible	4 Likely	5 Very likely
t ≤ 1 hour	5	B	B	B	A	A
		C	C	B	B	B
		D	C	C	C	B
1 hour < t ≤ 1 day	5	B	B	B	A	A
		C	C	B	B	B
		D	C	C	C	B
1 day < t ≤ 2 weeks	4	C	B	B	B	A
		C	C	C	B	B
		D	D	C	C	C
2 weeks < t ≤ 1 year	3	C	C	B	B	B
		D	C	C	C	B
		D	D	D	C	C
t > 1 year	2	C	C	C	B	B
		D	D	C	C	C
		E	D	D	D	C

Figure 30

Matrix for determining the probability of occurrence of harm from the exposure to the hazard, the probability of the hazardous event, and the possibility of limiting or avoiding the harm.

An example based on a circular saw – Hazardous situation «Lifted machine»

Determination of the probability of occurence of harm

The following tables and matrices illustrate the action in this case. Table 9 is not required for documentation of the risk assessment.

9

Determining the probability of occurrence of harm, hazardous situation «Lifted machine», without protective measures
Table 9, pages 38-39

31

Matrix for determining the probability of occurrence of harm for the hazardous situation «Lifted machine»
Figure 31, page 40

32

Location of the risk for the hazardous situation «Lifted machine» in the risk matrix
Figure 32, page 41

10

Documentation: Risk of the hazardous situation in which a person is underneath the lifted circular saw
Table 10, page 42

Table 9
Determination of the probability of occurrence of harm for the hazardous situation «Lifted machine» without protective measures

Exposure of persons to the hazard

The need for access to the hazard zone (normal operation, correction of malfunction, maintenance, repair, etc.)	No access required
The nature of the access (manual feeding of materials, process observation, correction of malfunctions, etc.)	Unintentional access underneath the suspended circular saw
The number of persons requiring access	0
The reliability of protective measures	–
The possibility of defeating or circumventing protective measures (incentive when the protective measures influence the function or the ease of operation of the machinery excessively)	–
Information for use regarding the position of the hazard zones, the nature of the hazard and the consequences of the residual risks	–

Levels of the interval between the exposure to the hazard		**Weighting of the level**
t ≤ 1 hour		5
1 hour < t ≤ 1 day	If the duration of the exposure is shorter than 10 minutes, you may use the weighting of the next level down.	5
1 day < t ≤ 2 weeks		4
2 weeks < t ≤ 1 year		3
t > 1 year		[✓ 2]

Occurrence of hazardous events

The hazard is permanently active (hazardous substance) or frequently active (required for functioning, e.g. electrical current for the drive motor)	The hazard is neither frequently nor permanently active
The hazard is active only only in the event of a fault (breakage of a grinding tool, unexpected start-up due to a fault in the start-up function) and is reachable (defective safeguard or defective energy isolating unit, etc.)	The hazard is briefly active in the event of a fault, strength of attachment points has not been checked
Ergonomic design (feeding, operating, reaching into the machine taking into account encumbrances caused by personal protective equipment)	–
Aspects with regard to the tiredness of the persons involved (sex, age, disability, etc.)	–
Accident histories, known hazardous events of machinery with hazardous situations, which show a comparable risk	Known

Levels of probability of the hazardous event	**Weighting of the level**
Very likely	[✓ 5]
Likely	4
Possible	3
Infrequent	2
Negligible	1

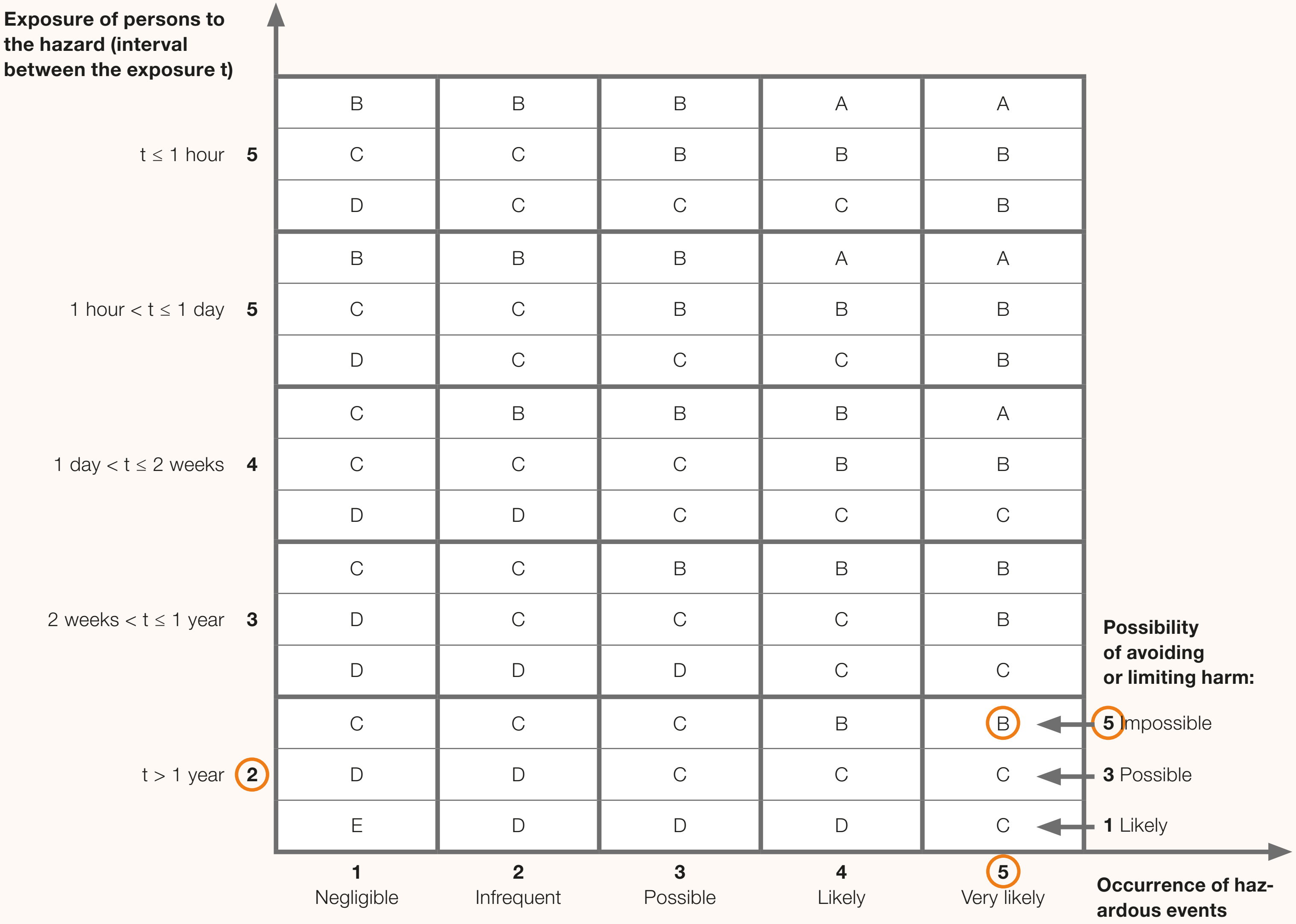
Possibility of avoiding or limiting harm

How quickly a hazardous situation can lead to harm (suddenly, quickly, slowly)	Suddenly
Level of training of persons who may be exposed to the hazards (skilled, unskilled)	Unskilled
Awareness of the risk (information for use, direct observation, warning signs and indicating devices on the machine)	No direct observation
Human ability to avoid or limit harm (e.g. reflexes, agility, possibility of escape)	The person involved does not have any possibility of escape
Practical experience and knowledge (e.g. regarding the machinery or the hazard, no experience)	Known

Levels of possibility of avoiding or limiting harm	**Weighting of the level**
Impossible	[✓ 5]
Possible	3
Likely	1

Figure 31

Matrix for determining the probability of occurrence of harm for the hazardous situation «Lifted machine»



Exposure of persons to the hazard (interval between the exposure t)	Possibility of avoiding or limiting harm:	1 Negligible	2 Infrequent	3 Possible	4 Likely	5 Very likely
t ≤ 1 hour **5**		B	B	B	A	A
		C	C	B	B	B
		D	C	C	C	B
1 hour < t ≤ 1 day **5**		B	B	B	A	A
		C	C	B	B	B
		D	C	C	C	B
1 day < t ≤ 2 weeks **4**		C	B	B	B	A
		C	C	C	B	B
		D	D	C	C	C
2 weeks < t ≤ 1 year **3**		C	C	B	B	B
		D	C	C	C	B
		D	D	D	C	C
t > 1 year **2**	**5** Impossible	C	C	C	B	B
	3 Possible	D	D	C	C	C
	1 Likely	E	D	D	D	C

Occurrence of hazardous events

Figure 32
Location of the risk for the hazardous situation «Lifted machine» in the risk matrix

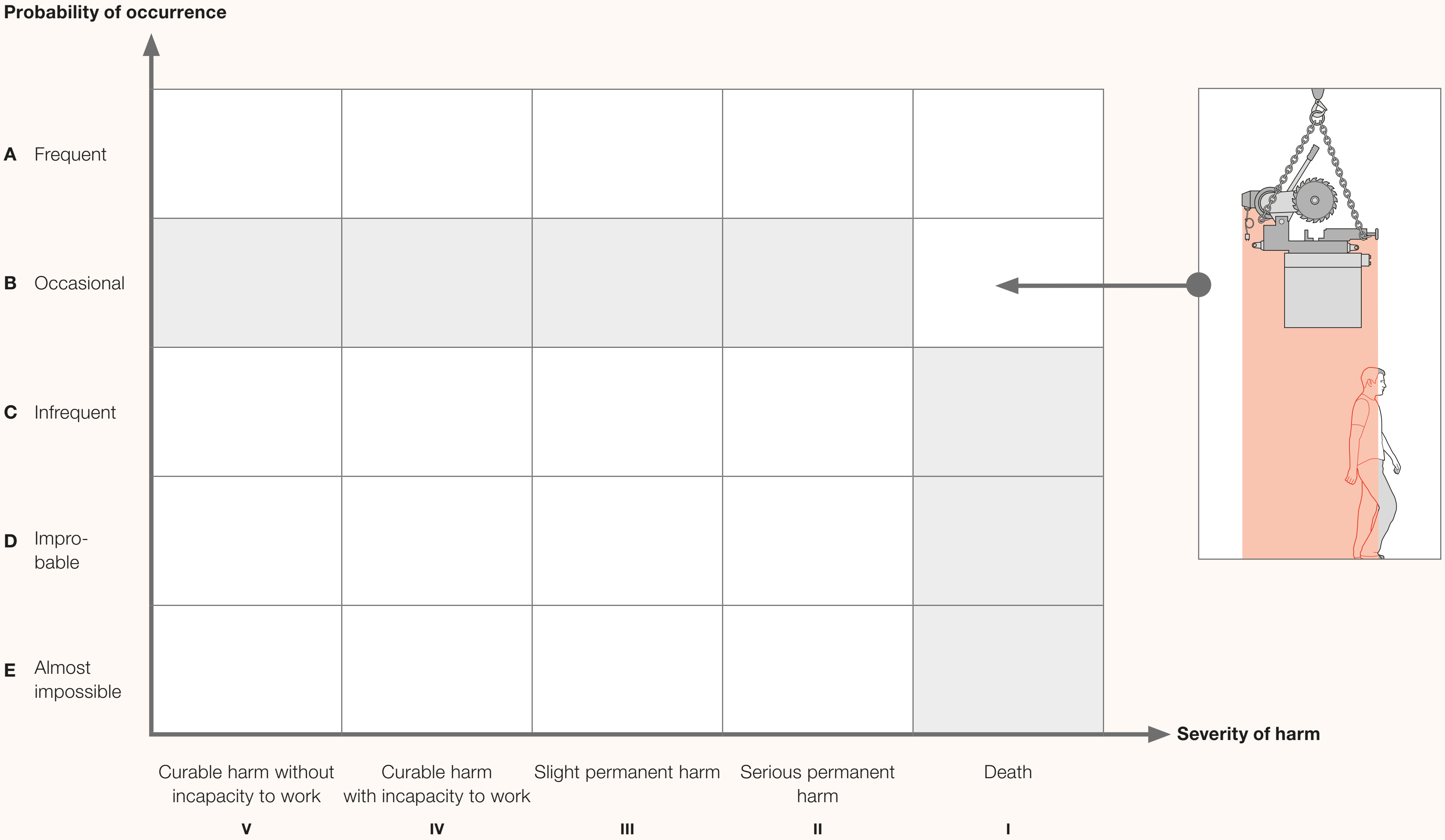


Table 10

Documentation: Risk of the hazardous situation in which a person is underneath the lifted circular saw

Machine: Circular saw	**Series / type:** KS 250	**Serial number:** **001**	**Space limits in drawing no.:** **4.2436.23**	**Author:** John Doe **Date:** 15.11.2016

No.	Action	No.	Hazard	Harm	Risk			Causes	No.	T/B	Measure	Residual risk			References to 2006 / 42 / EC Ann. I, standards
					S	P	EHA					S	P	EHA	
Phases of life, operating mode Transport								**Subsystem** entire machine							
1	Connecting the circular saw to lifting gear using slings														
2	Lifting the circular saw	2.1	Objects falling down	Injury to the torso	I	B	2 5 5	• insufficient strength of the attachment points • unsuitable attachment points • insufficient strength of the slings • insufficient strength of the lifting gear							

Legend

Severity of harm S
- I Death
- II Serious permanent damage to health
- III Slight permanent damage to health
- IV Curable damage to health with incapacity to work
- V Curable damage to health without incapacity to work

Probability P (E+H+A)
- A Frequent (14, 15)
- B Occasional (11 – 13)
- C Infrequent (8 – 10)
- D Improbable (5 – 7)
- E Almost impossible (4)

Exposure to the hazard E
- 5 t ≤ 1 hour
- 5 1 hour < t ≤ 1 day
- 4 1 day < t ≤ 2 weeks
- 3 2 weeks < t ≤ 1 year
- 2 t > 1 year
- t: interval between the exposure

Occurrence of a hazardous event H
- 1 Negligible
- 2 Infrequent
- 3 Possible
- 4 Likely
- 5 Very likely

Possibility of avoiding or limiting harm A
- 5 Impossible
- 3 Possible
- 1 Likely

- T iInherently safe design measures, safeguarding and complementary protective measures
- B Information in instruction handbook: reference to residual risks, personal protective equipment, training

8.4 Evaluating the risk

Evaluating the risk is to

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

If protective measures are provided, it is necessary to investigate whether they reduce the risk demonstrably. If a risk remains even after the implementation of the protective measures, this is to be documented in the risk assessment.
In the case of hazardous situations with an extremely small risk, there is no need to reduce the risk. Such risks are, however, to be documented (e. g. with information on tolerable surface temperatures, limit values for force and surface pressure). If possible, specify relevant standards in which these risks are mentioned as reasonable.

Presumption of conformity by harmonised standards

Using the risk evaluation it is necessary to ensure that the relevant listed standards have been taken into account, or that the safety level of these standards is met with other protective measures. Therefore, please clarify whether a type-C standard exists for the machinery to be assessed. If not, the type-A standard EN ISO 12100 or, where appropriate, additional type-B standards must be used.

The excel template at **www.suva.ch/risk-assessment** contains tables that will help you to determine relevant type-B standards depending on hazards and causes. **To ensure that a currently listed standard is used, the current publication of the titles and references of harmonised standards in the Official Journal of the European Union**[6] is to be taken into account at any given time.

When is risk reduction adequate?

Risk reduction is adequate when, taking into account the state of the art, at least the legal requirements have been observed and the following criteria are met:

- A three-step risk reduction process has been performed (1. Inherently safe design, 2. Safeguarding and complementary protective measures, 3. Information for use).
- All operating conditions and all intervention procedures have been considered.
- All hazards have been eliminated or risks reduced to the lowest practicable level.
- Hazards generated by the protective measures adopted have been considered.
- The users are informed and warned about the residual risks. The chosen protective measures are compatible with one another.
- Consideration has also been given to the consequences that can arise from the use in a non-professional/non-industrial context of a machine designed for professional/industrial use.
- The selected protective measures do not adversely affect the operator’s working conditions or the usability of the machine.

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[6] link to it at www.suva.ch/certification-e under «Examples for type-examinations»

Comparison of risks

If there is no type-C standard for a machine, you can also perform the risk evaluation by a comparison with the risks of similar machines. In order to do this, however, the following criteria must be met:

- The similar machinery is in accordance with the relevant type-C standard.
- The intended use, reasonably foreseeable misuse and the way both machines are designed and constructed are comparable.
- The hazards and the risk elements are comparable.
- The technical specifications are comparable.
- The conditions for use are comparable.

The evaluation of the risk after adopting protective measures is explained in chapter 9.3.

An example based on a circular saw

Evaluation of the risk presented by the lifted machine before protective measures are adopted

As there are no protective measures on the functional model yet,
a risk reduction is required.

9 Reducing risk

The following four aspects should be taken into account in risk reduction, with the following priority:
1. Safety of the machinery during all phases of its life cycle
2. Ability of the machine to perform its function
3. Usability of the machine
4. Manufacturing, operational and dismantling costs of the machine

The uppermost priority is to eliminate hazards. If this is not possible, the two risk elements (severity of harm and probability of occurrence) must be reduced.

By defining the causes and with awareness of the risk elements, you can determine suitable protective measures with the aid of the harmonised standards.

When selecting the protective measures, the three-step method described in the following sections is to be applied.

9.1 Inherently safe design measures (step 1)

The term «inherent» means «adherent, intrinsic». Inherently safe design measures eliminate hazards or reduce risks through design features of the machine itself and/or interaction between the exposed persons and the machine. It is very likely that inherent protective measures will remain effective during the entire life cycle of the machine.

Inherently safe design measures are the first and most important step in risk reduction,

- because inherently safe protective measures are the only possible way of eliminating hazards entirely.
- This is because, in contrast to inherently safe protective measures, even well designed safeguarding can fail or be circumvented, and information for use might not be followed.

You can find detailed information on all protective measures associated with inherently safe design measures in chapter 6.2 of the standard EN ISO 12100.

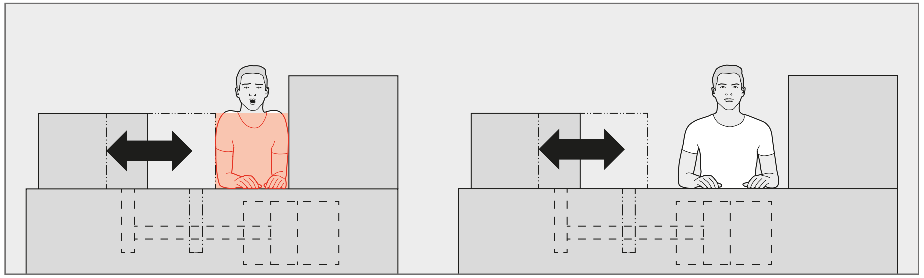

Figure 33

Elimination of a hazard (crushing point) by inherently safe design measures
(Design feature: extension of a machine element)

9.2 Safeguarding and/or complementary protective measures (step 2)

If inherently safe design measures cannot eliminate hazards or adequately reduce risks, safeguarding must be used. This includes guards and protective devices.

What is a guard, and what is a protective device?

Guards such as casings, interlocking guards or adjustable guards form physical barriers, which prevent access to the hazard zone. In contrast to this, protective devices (such as light grids, two-hand control devices, etc.) do not represent physical barriers. With these protective measures, access to the hazard zone is possible at any time. Protective devices must therefore eliminate the hazard before the hazard zone is reached.

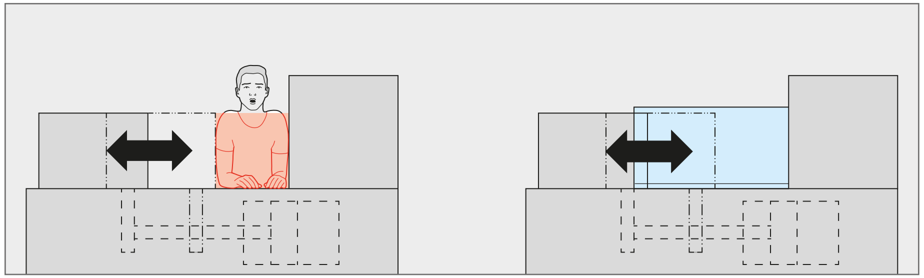

Figure 34

Fixed guard (technical safeguard)

Protective devices also include measures to ensure stability (such as anchorage bolts or movement limiters) as well as overload and torque monitoring devices.

Complementary protective measures

If necessary, additional complementary protective measures (for example emergency stop devices) must be adopted. However, complementary protective measures must never be used as a substitute for safeguarding.

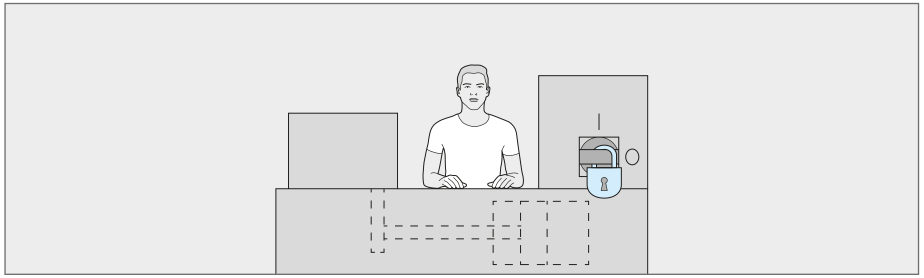

Figure 35

Lockable energy isolation device (complementary safeguard)

Influence of protective measures on usability

Safeguarding and complementary protective measures separate persons from the effects of a hazard. Therefore, when selecting the protective measure, it is necessary to consider when it is necessary to reach into the machine and whether this is prevented by the protective measure. This applies both for the intended use and for any foreseeable misuse of the machine.

Effect of protective measures on the risk

Safeguarding and complementary protective measures do not have any influence on the hazard per se. They merely avoid the hazardous event. If these protective measures fail, the potential harm is the same as would occur without them. Safeguarding and complementary protective measures therefore only influence the probability of the harm and not its severity.

Choosing the correct measures

When choosing and designing safeguarding and complementary protective measures, the following points must be observed:

- Determine and take into account the circumstances which could lead to the failure of the protective measure (for information on failures of safety functions of control systems see Annex D).
- If possible, protective measures should not impair production and operation.
- Ensure that the protective measure cannot be switched off or circumvented.
- Ensure that the life cycle of the protective measure is sufficient.
- Choose protective measures that can easily be maintained in correct working order. Otherwise, this could provide an incentive to defeat or circumvent the protective measure.
- Compare the proposed protective measure with alternative protective measures using the procedure of risk estimation.

You can find detailed information on all safeguarding and complementary protective measures in chapter 6.3 of the standard EN ISO 12100

9.3 Information for use (step 3)

Where risks remain, despite inherently safe design measures, safeguarding and the adoption of complementary protective measures, the residual risks must be identified in the information for use and shall include the following at least:

- operating procedures for the safe use of the machinery
- required training of the personnel who use the machinery and other persons who can be exposed to the hazards associated with the machinery
- information including warning of residual risks in all phases of life of the machinery
- description of the recommended personal protective equipment and the detail as to its need as well as to training needed for its use

The information for use must not be a substitute for inherently safe design measures, safeguarding, or complementary protective measures.

Compared to inherently safe design measures, safeguarding and complementary protective measures, the information for use has a relatively low reliability. This fact is to be taken into account during the risk estimation.

You can find detailed information with regard to Information for use in chapter 6.4 of the standard EN ISO 12100.

9.4 Sequence of the three-step method

In the three-step method, after each step it is necessary to assess whether the risk reduction intended is achieved with the chosen protective measures. If not, the protective measures of the next step are to be implemented. If the risk reduction intended cannot be achieved even after the third step, you must redefine the limits of the machinery.

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Flow chart: risk reduction (three-step iterative process)
Figure 36, page 49

It is also necessary to examine whether new hazards are generated by the chosen protective measures. If this is the case, the risks of these hazards are to be estimated, evaluated, and reduced if necessary.

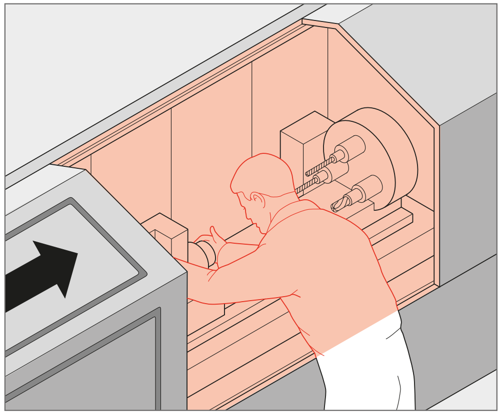


Figure 37

Example of a power-operated guard that causes a new hazard (crushing point at the closing gap)

The procedure for risk reduction is completed when the evaluation of the residual risk can be assessed as adequate.

Protective measures and the risk of long-term damage to health
As mentioned in 9.2, safeguarding and complementary protective measures as well as information for use only reduce the probability of the harm but not its severity in the case of acute injuries. This is because these protective measures can fail. Guards reduce the exposure to hazards. Protective devices lower the probability of the hazardous event. In the case of damage to health caused by long-term exposure to a hazard, such safeguards are, however, also able to reduce the severity of harm.

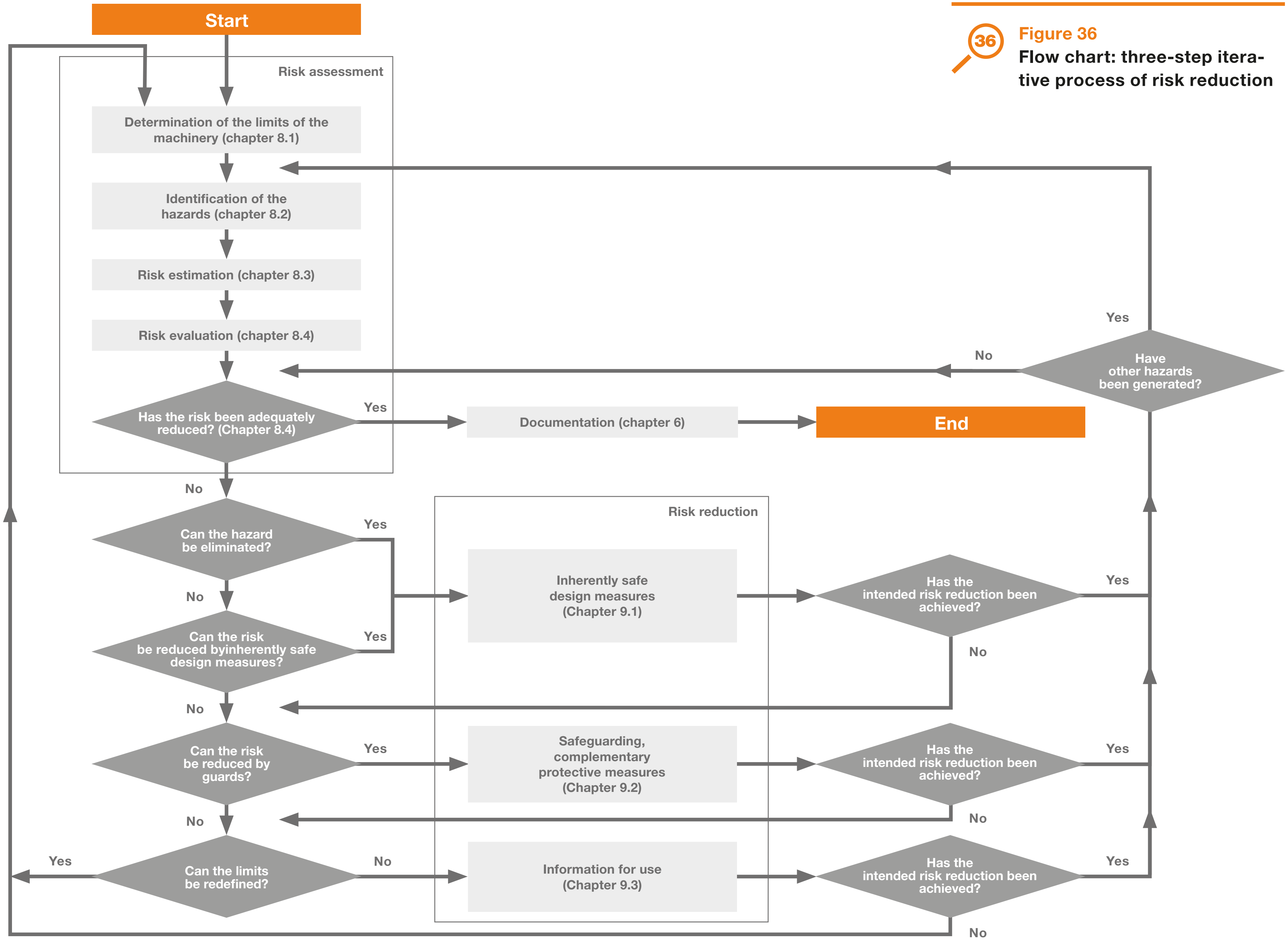


Figure 36
Flow chart: three-step iterative process of risk reduction

Risk reduction in the case of protective measures with safety functions of control systems

Protective measures may contain safety functions of control systems. (Example: interlocking of a movable guard). In this case it is necessary to consider the possibility of a fault occurring in the safety function. In the standards EN ISO 13849-1 and EN 62061 you can find information on the suitability of safety functions depending on the risk present (risk before adoption of the protective measure). The following information is required in order to apply the standards:

- limits of the machine
- elements of the risk of the hazardous situation considered (severity of harm, exposure of persons to the hazard, occurrence of a hazardous event, possibility of avoiding or limiting harm)
- performance requirement for the protective measure (example: stopping the drive when a movable guard is opened)

This enables you to determine the performance requirement for the safety function of the control system (performance level required PLr, safety integrity level SIL). The procedure for this is described in Annex D.

After applying the standards EN ISO 13849-1 or EN 62061, the following information is available:

- Confirmation that the risk reduction intended is achieved by the protective measure (including control system).
- Technical documentation for the incorporation of the protective measure in the design of the machine
- Information for use

38

Relationship between risk assessment according to EN ISO 12100 and EN ISO 13849-1 or EN 62061

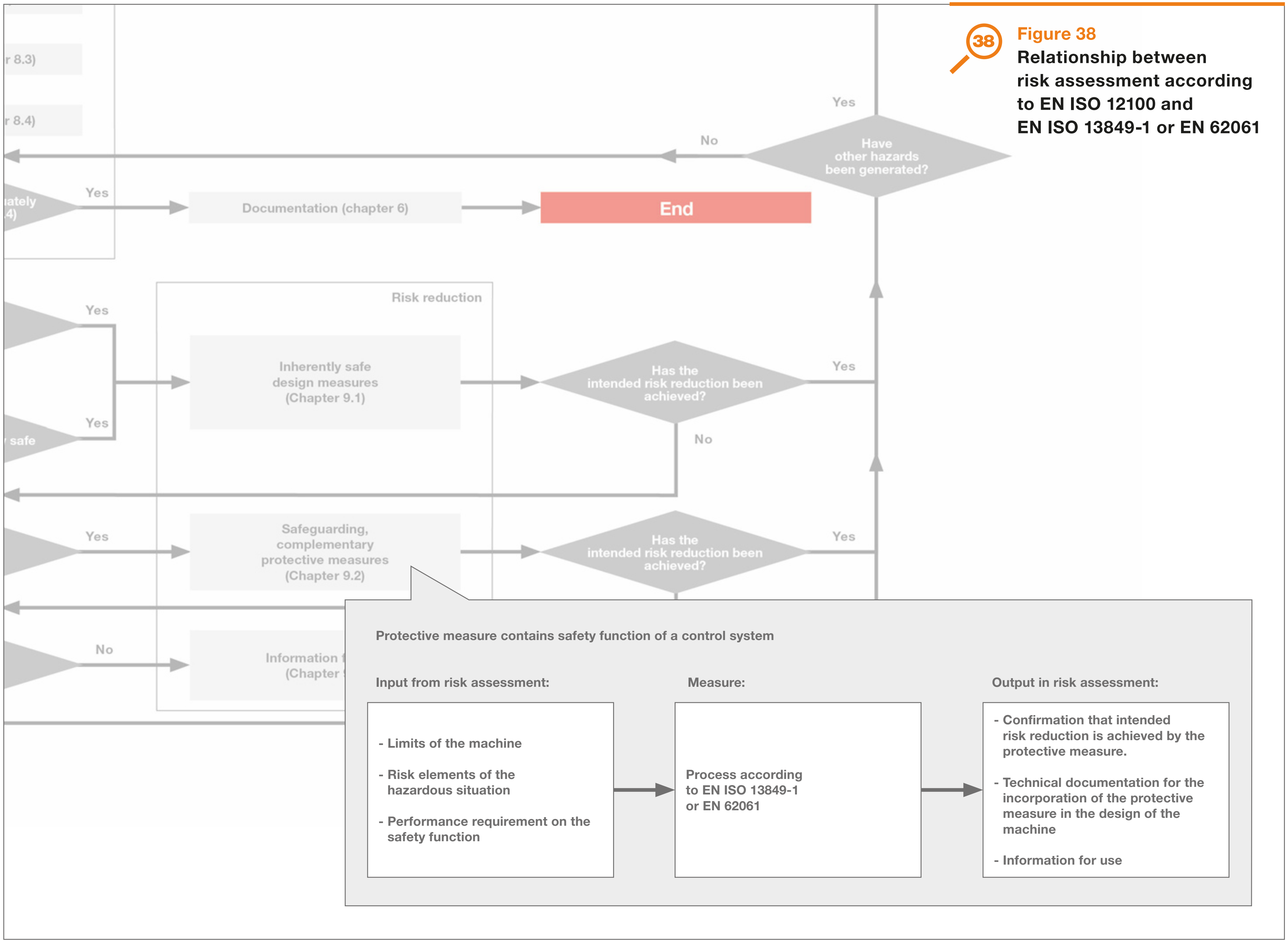
Figure 38, page 51

9.5 Documentation of protective measures

Apart from the description of the protective measure, the essential health and safety requirements and the titles of the listed standards relevant for the protective measures must also be documented. You can find the relevant essential health and safety requirements in Annex I of the Machinery Directive.

The Suva excel template **(www.suva.ch/risk assessment)** contains tables that also allow you to find the relevant essential health and safety requirements depending on hazard, cause, and protective measure.

Figure 38
Relationship between risk assessment according to EN ISO 12100 and EN ISO 13849-1 or EN 62061



Protective measure contains safety function of a control system

Input from risk assessment:

- Limits of the machine
- Risk elements of the hazardous situation
- Performance requirement on the safety function

Measure:

Process according to EN ISO 13849-1 or EN 62061

Output in risk assessment:

- Confirmation that intended risk reduction is achieved by the protective measure.
- Technical documentation for the incorporation of the protective measure in the design of the machine
- Information for use

An example based on a circular saw – Hazardous situation «Lifted machine»

Risk reduction
Taking into consideration the three-step method, protective measures from EN ISO 12100 are applied to reduce the risk.

When the causes of harm are known, you can search for protective measures to avoid the individual causes.

After implementing the protective measures of the first step (inherently safe design measures), the residual risk is estimated and an assessment is made as to whether protective measures of the second and third step must still be implemented.

No.	Cause	Protective measure which avoids the cause or reduces it	Reference of the protective measure
1		**Inherently safe design measures**	
1.1	Insufficient strength of the attachment points	Stress limitation by calculation of the stressed components and connections	EN ISO 12100, 6.2.3 a
2		**Safeguarding and complementary protective measures**	
2.1	Unsuitable attachment points used	Welding of tabs for attaching the slings to the machine	EN ISO 12100, 6.3.5.5
3		**Information for use**	
3.1	Insufficient strength of the slings, insufficient strength of the lifting gear	Labelling of the dimensions of the circular saw on the machine and information in the instruction handbook	EN ISO 12100, 6.4.4; 6.4.5.1
3.2	Unsuitable attachment points used	Illustration showing the correct attachment of the circular saw in the instruction handbook	EN ISO 12100, 6.4.5.1

Table 11
Which protective measures avoid which causes in the case of the hazardous situation «Lifted machine»?

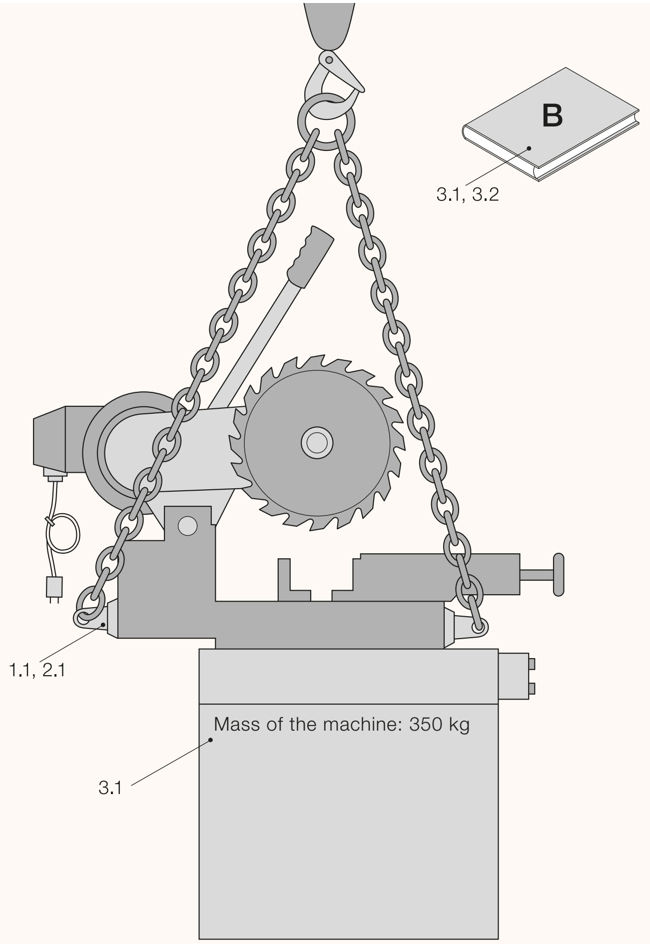


Figure 39

Protective measures from table 11 for reducing the risk when lifting the machine

Estimating the residual risk

Despite the chosen protective measures the possibility of the machine falling down remains. The severity of harm therefore remains unchanged.

12 Determination of the probability of occurrence of harm with and without protective measures
Table 12, pages 54, 55, and 56

40 Matrix for determining the probability of occurrence of harm
Figure 40, page 57

13 Documentation: risk reduction and risk estimation
Table 13, page 58

Risk evaluation

Table 14 describes the thoughts while performing the risk evaluation and is not required for the documentation of the risk assessment.

14 Risk evaluation – all items for adequate risk reduction are met
Table 14, page 59

Table 12

Determination of the probability of occurrence of harm with and without protective measures

Criterion	**Chosen protective measure**			
	None	**1. Inherently safe design measures:** Stress limitation by calculation of the stressed components and connections		
			2. Safeguarding and complementary protective measures: Welding of tabs for attaching the slings to the machine	
				3. Information for use: • Labelling of the dimensions of the circular saw on the machine and information in the instruction handbook • Illustration showing the attachment of the circular saw in the instruction handbook • Notice that lingering underneath the lifted circular saw is prohibited
Exposure of persons to the hazard				
The need for access to the hazard zone (normal operation, correction of malfunction, maintenance, repair, etc.)	No access required			
The nature of the access (manual feeding of materials, process observation, correction of malfunctions, etc.)	Unintentional access underneath the suspended circular saw during transport			
The number of persons requiring access	0			
The reliability of protective measures	None	No influence on the exposure		Influence on the exposure
The possibility of defeating or circumventing protective measures (incentive when the protective measures influence the function or the ease of operation of the machinery excessively)	–	No incentive exists		
Information for use regarding the position of the hazard zones, the nature of the hazard and the consequences of the residual risks	None			Exists
Levels of the interval between the exposure	**Weighting of the levels**			
t ≤ 1 hour	5	5	5	5
1 hour < t ≤ 1 day	5	5	5	5
1 day < t ≤ 2 weeks	4	4	4	4
2 weeks < t ≤ 1 year	3	3	3	3
t > 1 year	②	②	②	②

<table>
<tr><th rowspan="4">Criterion</th><th colspan="4">Chosen protective measure</th></tr>
<tr><td rowspan="3">None</td><td colspan="3">**1. Inherently safe design measures:**
Stress limitation by calculation of the stressed components and connections</td></tr>
<tr><td rowspan="2"></td><td colspan="2">**2. Safeguarding and complementary protective measures:**
Welding of tabs for attaching the slings to the machine</td></tr>
<tr><td></td><td>**3. Information for use:**
• Labelling of the dimensions of the circular saw on the machine and information in the instruction handbook
• Illustration showing the attachment of the circular saw in the instruction handbook
• Notice that lingering underneath the lifted circular saw is prohibited</td></tr>
<tr><th colspan="5">Occurrence of hazardous events</th></tr>
<tr><td>The hazard is permanently active (hazardous substance) or frequently active (required for functioning, e. g. electrical current for the drive motor)</td><td colspan="4">The hazard is neither frequently nor permanently active</td></tr>
<tr><td>The hazard is active only only in the event of a fault (breakage of a grinding tool, unexpected start-up due to a fault in the start-up function)</td><td>briefly active in the event of a fault</td><td colspan="3">The hazard is briefly active in the unlikely event of a fault</td></tr>
<tr><td>Ergonomic design (feeding, operating, reaching into the machine taking into account encumbrances caused by personal protective equipment)</td><td colspan="4">–</td></tr>
<tr><td>Aspects with regard to the tiredness of the persons involved (sex, age, disability, etc.)</td><td colspan="4">–</td></tr>
<tr><td>Accident histories, known hazardous events of machinery with hazardous situations, which show a comparable risk</td><td colspan="4">Known</td></tr>
<tr><th>Level of probability of the hazardous event</th><th colspan="4">Weighting of the levels</th></tr>
<tr><td>Very likely</td><td>[✓ 5]</td><td>5</td><td>5</td><td>5</td></tr>
<tr><td>Likely</td><td>4</td><td>4</td><td>4</td><td>4</td></tr>
<tr><td>Possible</td><td>3</td><td>[✓ 3]</td><td>3</td><td>3</td></tr>
<tr><td>Infrequent</td><td>2</td><td>2</td><td>[✓ 2]</td><td>[✓ 2]</td></tr>
<tr><td>Negligible</td><td>1</td><td>1</td><td>1</td><td>1</td></tr>
</table>

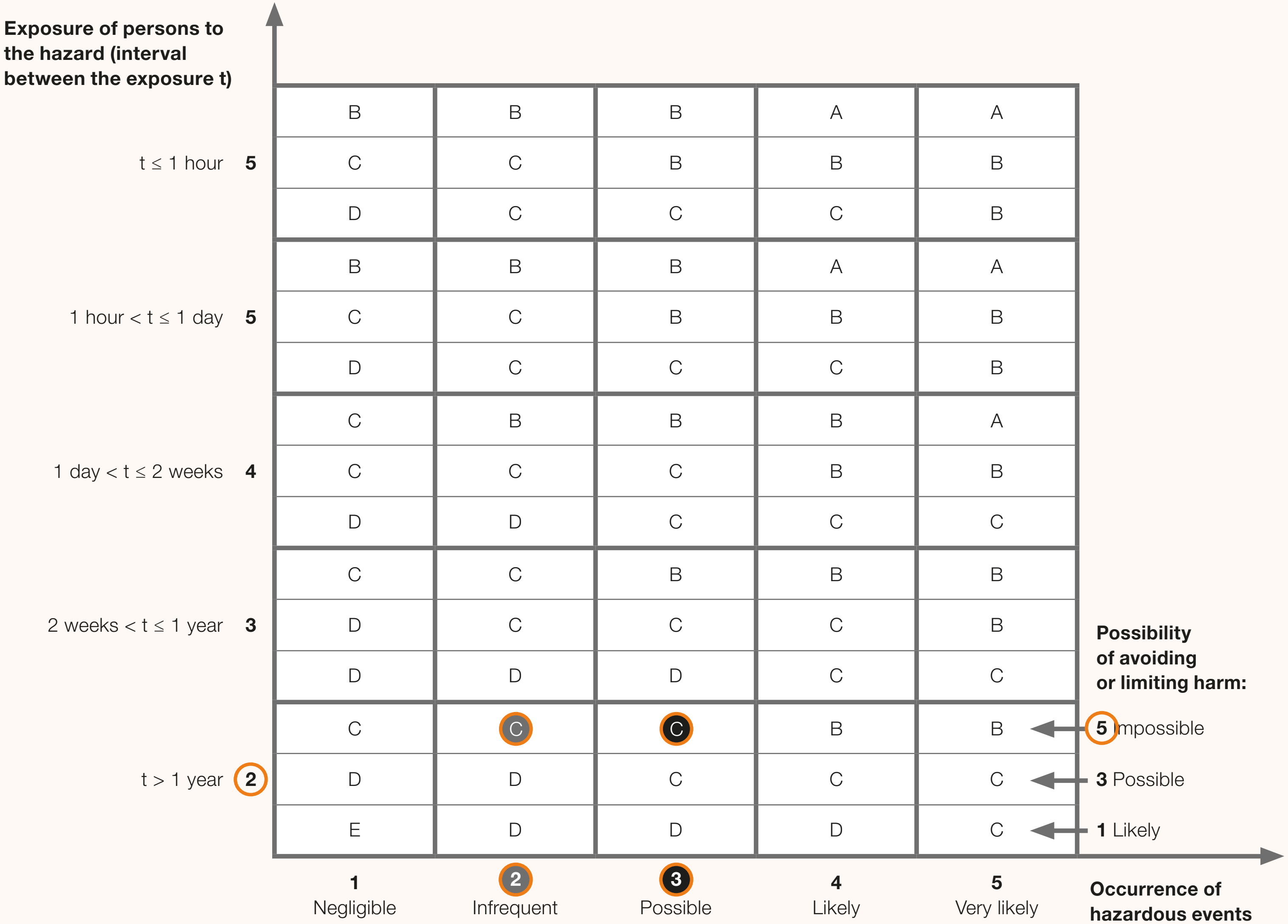
Criterion	**Chosen protective measure**			
	None	**1. Inherently safe design measures:** Stress limitation by calculation of the stressed components and connections		
			2. Safeguarding and complementary protective measures: Welding of tabs for attaching the slings to the machine	
				3. Information for use: • Labelling of the dimensions of the circular saw on the machine and information in the instruction handbook • Illustration showing the attachment of the circular saw in the instruction handbook • Notice that lingering underneath the lifted circular saw is prohibited
Possibility of avoiding or limiting harm				
How quickly a hazardous situation can lead to harm (suddenly, quickly, slowly)	Suddenly			
Level of training of persons who may be exposed to the hazards (skilled, unskilled)	Unskilled			
Awareness of the risk (information for use, direct observation, warning signs and indicating devices on the machine)	No direct observation			Information for use, no direct observation
Human ability to avoid or limit harm (e.g. reflexes, agility, possibility of escape)	The person involved does not have any possibility of escape			
Practical experience and knowledge (e. g. regarding the machinery or the hazard, no experience)	Known			
Level of probability of the hazardous event	**Weighting of the levels**			
Impossible	[✓ 5]	[✓ 5]	[✓ 5]	[✓ 5]
Possible	3	3	3	3
Likely	2	1	1	1

Figure 40

Matrix for determining the probability of occurrence of harm

● = with inherently safe design measures

● = with inherently safe design measures, safeguarding and information for use



Exposure of persons to the hazard (interval between the exposure t)	Possibility of avoiding or limiting harm:	1 Negligible	② Infrequent	③ Possible	4 Likely	5 Very likely
t ≤ 1 hour 5		B	B	B	A	A
		C	C	B	B	B
		D	C	C	C	B
1 hour < t ≤ 1 day 5		B	B	B	A	A
		C	C	B	B	B
		D	C	C	C	B
1 day < t ≤ 2 weeks 4		C	B	B	B	A
		C	C	C	B	B
		D	D	C	C	C
2 weeks < t ≤ 1 year 3		C	C	B	B	B
		D	C	C	C	B
		D	D	D	C	C
t > 1 year ②	⑤ Impossible	C	● C	● C	B	B
	3 Possible	D	D	C	C	C
	1 Likely	E	D	D	D	C

Occurrence of hazardous events

Table 13

Documentation: risk reduction and risk estimation in the case of the hazardous situation «Lifted machine»

Machine: Circular saw	**Series/type:** KS 250	**Serial number:** **001**	**Space limits in drawing no.:** **4.2436.23**	**Author:** John Doe **Date:** 15.11.2016

No.	Action	No.	Hazard	Harm	Risk			Causes	No.	T/B	Measure	Residual risk			References to 2006/42/EC Ann. I, standards
					S	P	EHA					S	P	EHA	
Phases of life, operating mode Transport								**Subsystem** entire machine							
1	Connecting the circular saw to lifting gear using slings														
2	Lifting the circular saw	2.1	Objects falling down	Injury to the torso	I	B	255	• insufficient strength of the attachment points • unsuitable attachment points • insufficient strength of the slings • insufficient strength of the lifting gear	2.1.1	T	Stress limitation by calculation of the stressed components and connections	I	C	235	1.3.2 EN ISO 12100:2010 Point 6.2.3
									2.1.2	T	Welding of tabs for attaching the slings to the machine	I	C	225	1.1.5 EN ISO 12100:2010 Point 6.3.5.5
									2.1.3	B	Information on the dimensions of the circular saw on the machine and in the instruction handbook, illustration showing the attachment in the instruction handbook	I	C	225	1.7.3, 1.7.4.2 EN ISO 12100:2010 Point 6.4.4, 6.4.5.1, EN ISO 16093:2017 Points 6.1 and 6.2

Legend

Severity of harm S
- II Death
- II Serious permanent damage to health
- III Slight permanent damage to health
- IV Curable damage to health with incapacity to work
- V Curable damage to health without incapacity to work

Probability P (E+H+A)
- A Frequent (14, 15)
- B Occasional (11–13)
- C Infrequent (8–10)
- D Improbable (5–7)
- E Almost impossible (4)

Exposure to the hazard E
- 5 t ≤ 1 hour
- 5 1 hour < t ≤ 1 day
- 4 1 day < t ≤ 2 weeks
- 3 2 weeks < t ≤ 1 year
- 2 t > 1 year
- t: interval between the exposure

Occurrence of a hazardous event H
- 1 Negligible
- 2 Infrequent
- 3 Possible
- 4 Likely
- 5 Very likely

Possibility of avoiding or limiting harm A
- 5 Impossible
- 3 Possible
- 1 Likely

- T Inherently safe design measures, safeguarding and complementary protective measures
- B Information in instruction handbook: reference to residual risks, personal protective equipment, training

Table 14
Risk evaluation – all items for adequate risk reduction are met.

Adequate risk reduction	Assessment
Three-step method of risk reduction has been applied: 1. Inherently safe design measures 2. Safeguarding and complementary protective measures 3. Information for use	Met (see measures package)
All operating conditions and all intervention procedures have been considered.	Met (see description of the phases of life/operating modes with working steps, actions)
The hazards have been eliminated and the risks have been reduced to the lowest practicable level.	The hazard cannot be eliminated due to the functioning of the machine. The risk is reduced in accordance with the functioning.
The hazards generated by the protective measures adopted have been considered.	The chosen protective measures do not generate any hazards.
Users are informed and warned about the residual risks.	Met: • Labelling of the dimensions of the circular saw on the machine and in the instruction handbook • Illustration showing the correct attachment of the machine in the instruction handbook
The chosen protective measures are compatible with one another.	Met: The protective measures do not influence one another.
The consequences that can arise from the use in a non-professional/non-industrial context of a machine designed for professional/industrial use have been considered.	Met: Apart from the information for use, there are no requirements of the operator.
The selected protective measures do not adversely affect the operator›s working conditions or the usability of the machine.	The protective measures increase the ease of use of the circular saw and do not have a negative impact on its use.
The legal requirements are observed and the state of the art is taken into account.	2006/42/EC, Annex I, Points 1.1.5, 1.3.2, 1.7.3, 1.7.4; met by EN ISO 12100:2010, Points 6.4.4, 6.4.5.1; EN ISO 16093:2017, Points 6.1 and 6.2.

An example based on a circular saw – Hazardous situation «Rotating saw blade»

Risk reduction

You can find references to the required protective measures for reducing the risk presented by the rotating saw blade in the listed Type-C standard EN ISO 16093:2017. The standard either describes the measures directly or provides references to descriptions in other standards. The following table shows how the individual protective measures avoid causes.

15 Which protective measure avoids which cause?
Table 15, pages 61, and 62

41 Protective measures for reducing the risk presented by the rotating saw blade
Figure 41, page 63

42 Protective measures for reducing the risk presented by the rotating saw blade when the saw blade is engaged
Figure 42, page 63

16 Documentation: Protective measures for reducing the risk presented by the rotating saw blade during the action «Placing the profile on the support»
Table 16, pages 64, 65, and 66

Risk evaluation

The risk reduction can be assessed as adequate because:

- the circular saw falls within the scope of the harmonised standard EN ISO 16093:2017.
- the cutting hazard presented by the rotating saw blade is covered as a significant hazard in the standard EN ISO 16093:2017.
- all the protective measures, which the standard allocates to the significant hazard mentioned above, are implemented.
- the standard does not allocate any selection of protective measures to the significant hazard.

Table 15

Which protective measure avoids which cause? – Hazardous situation «Rotating saw blade»

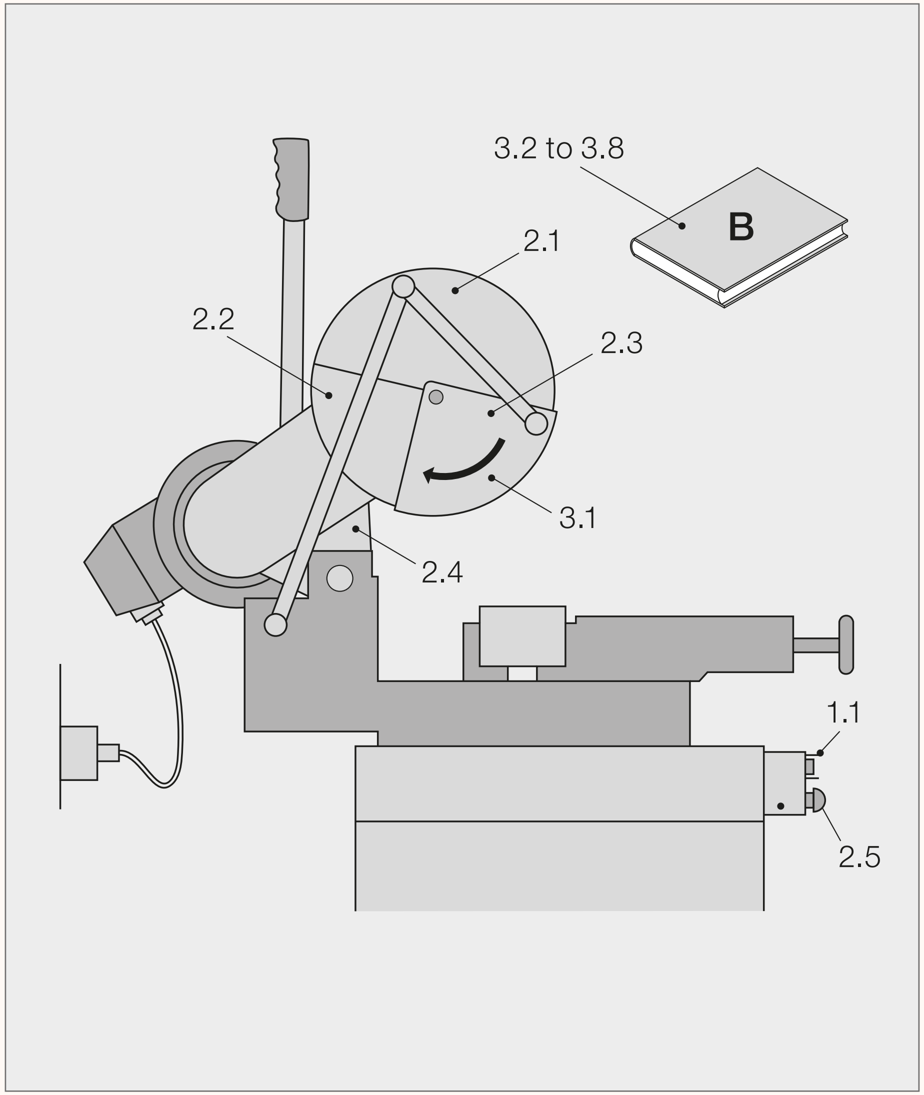
No.	Cause	Protective measure which avoids or reduces the cause	Reference of the protective measure
1	**Inherently safe design measures**		
1.1	The drive is switched on by unintentionally actuation of a switch-on control device.	The start-up control device is designed such that unintentional actuation is not possible.	EN ISO 16093:2017; EN 894-3:2000 +A1:2008
1.2	The drive is switched on by a fault in the switch-on function.	The start-up function is designed according to EN ISO 13849-1 Performance Level c, such that a fault in the start-up function cannot cause the drive to start up.	EN ISO 16093:2017, Points 5.1.3.1, 5.11.1; EN ISO 13849-1:2015; EN ISO 12100:2010, Point 6.2.11; EN 60204-1:2006, Point 9.4
1.3	The drive is switched on by the energy comeback after interruption of the supply.	The start-up function is designed such that an energy comeback after interruption of the electrical current does not cause the drive to start up.	EN ISO 16093:2017, Point 5.11.2; EN 60204-1:2006, Point 7.5
2	**Safeguarding and complementary protective measures**		
2.1	Hazard zone is reachable, clothes caught by saw blade	fixed guard to prevent access to hazard zones of the saw blade, which do not need to be accessible for the machining.	EN ISO 16093:2017, Points 5.1.1.1, 5.3.2.1, 5.3.2.2; EN ISO 14120:2015
2.2	Hazard zone is reachable, clothes caught by saw blade	movable guard with interlocking device, in accordance with EN ISO 13849 Performance Level c, for hazard zones of the saw blade, which only need to be accessible to change the saw blade	EN ISO 16093:2017, Points 5.1.1.1, 5.1.1.4, 5.1.3.1, 5.3.2.1, 5.3.2.2; EN ISO 14120:2015; EN ISO 14119:2013; EN 60204-1:2006, Point 9.2.2; EN ISO 13849-1:2015
2.3	Hazard zone is reachable, clothes caught by saw blade	self-closing guard to reduce reaching into hazard zones of the saw blade, which must be accessible for the working process	EN ISO 16093:2017, Points 5.1.1.1, 5.3.2.1, 5.3.2.2; EN ISO 14120:2015
2.4	Swivel head falls on part of the body	Restraint to prevent the saw head from falling down, the failure of a component of the restraint must not lead to the saw head falling down	EN ISO 16093:2017, Point 5.3.2.2
2.5	Touching with the saw blade immediately leads to injury	Emergency stop in accordance with EN ISO 13850, EN 60204-1:2006 Point 9.2.5.4 and EN ISO 13849-1 Performance Level c	EN ISO 16093:2017, Points 5.1.3.1, 5.1.3.5; EN ISO 13849-1:2015; EN ISO 13850:2015; EN 60204-1:2006, Point 10.7

No.	Cause	Protective measure which avoids or reduces the cause	Reference of the protective measure

3		**Information for use**	
		Information for use on the machine	
3.1	Unexpected start-up e. g. caused by contact welding, hazard zone is reachable, clothes caught by saw blade	Arrow symbol indicating the cutting direction of the saw blade	EN ISO 16093:2017, Point 6.1
		Information for use in the instruction handbook	
3.2	Unexpected start-up e.g. caused by contact welding, hazard zone is reachable, clothes caught by saw blade	Information on the labelling located on the machine	EN ISO 16093:2017, Point 6.2.2
3.3	Hazard zone is reachable, clothes caught by saw blade	Instructions on checking the safety devices prior to commissioning	EN ISO 16093:2017, Point 6.2.2
3.4	Hazard zone is reachable, clothes caught by saw blade	Instructions on setting the guards	EN ISO 16093:2017, Point 6.2.2
3.5	Hazard zone is reachable, clothes caught by saw blade	Instructions on inspecting the guards after the saw blade has been changed	EN ISO 16093:2017, Point 6.2.2
3.6	Hazard zone is reachable, clothes caught by saw blade	Requirements regarding periodic maintenance work on the guards	EN ISO 16093:2017, Point 6.2.2

41 **Figure 41**
Protective measures for reducing the risk presented by the rotating saw blade from table 15

42 **Figure 42**
Protective measures for reducing the risk presented by the rotating saw blade when the saw blade is engaged



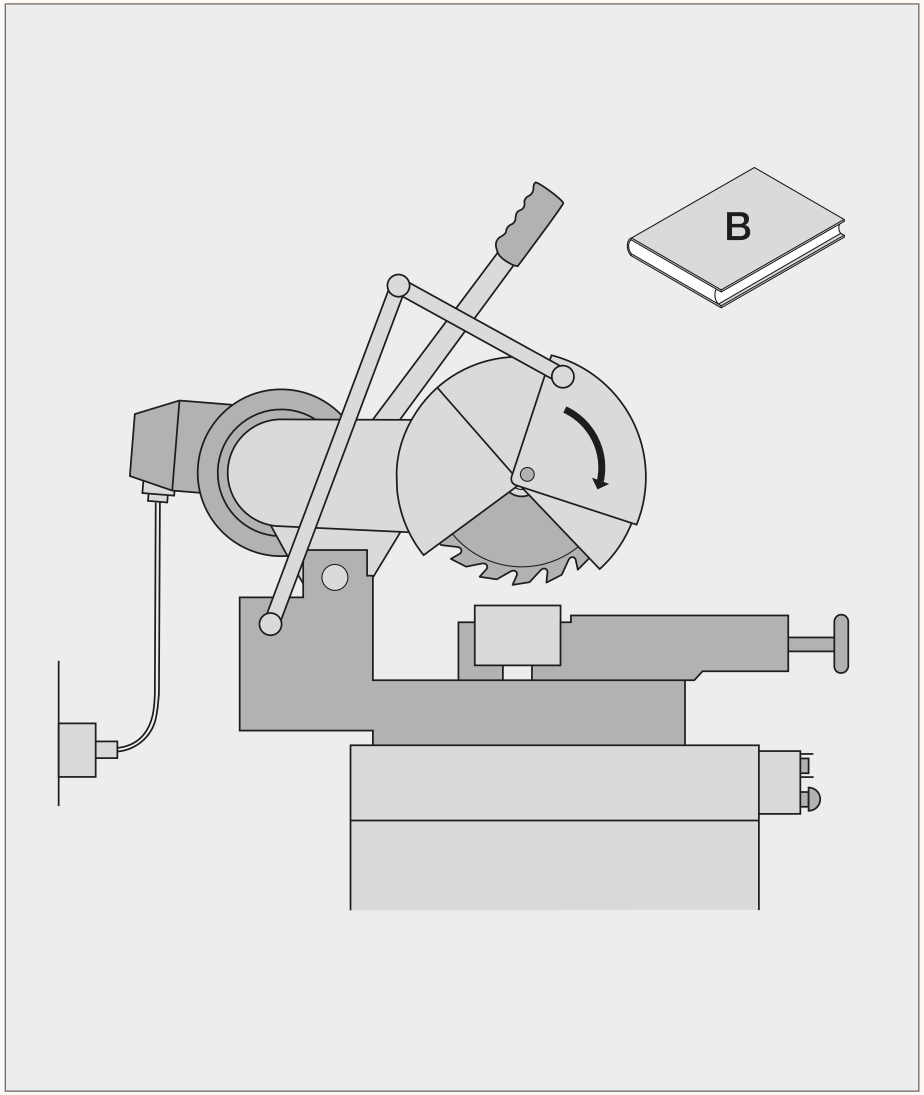


Table 16

Documentation: Protective measures for reducing the risk presented by the rotating saw blade during the action «Placing the profile on the support»

Machine: Circular saw	**Series/type:** KS 250	**Serial number:** **001**	**Space limits in drawing no.:** **4.2436.23**	**Author:** John Doe **Date:** 15.11.2016

No.	Action	No.	Hazard	Harm	Risk			Causes	No.	T/B	Measure	Residual risk			References to 2006/42/EC Ann. I, standards
					S	P	EHA					S	P	EHA	
Phases of life, operating mode Operation (production)								**Subsystem** entire machine							
1	Placing the profile on the support	1.1	Cutting parts	Hand injury				• Touching the rotating saw blade immediately leads to injury • Swivel head falls on part of the body • Unexpected start-up caused by energy comeback after interruption • Unexpected start-up due to fault in the switch-on function • Unexpected start-up by unintentional actuation of the switch-on manual control • Clothes caught by saw blade • Switched off drive coasts down • Hazard zone of the saw blade is reachable	1.1.1	T	Start-up device cannot be actuated unintentionally (collar around the manual control)				1.2.3; EN ISO 16093:2017; EN 894-3:2000+A1:2008
									1.1.2	T	Start-up function in accordance with EN ISO 13849 PLr c				1.2.1; EN ISO 16093:2017, Points 5.1.1.1, 5.1.1.4, 5.1.3.1, 5.3.2.1, 5.3.2.2; EN ISO 14120:2015; EN ISO 14119:2013; EN 60204-1:2006, Point 9.2.2; EN ISO 13849-1:2015
									1.1.3	T	Low voltage protection				1.2.3; EN ISO 16093:2017, Points 5.11.2; EN 60204-1:2006, Point 7.5
									1.1.4	T	fixed guard				1.3.7; 1.3.8; 1.4 1; 1.4.2.1; EN ISO 16093:2017, Points 5.1.1.1, 5.3.2.1, 5.3.2.2; EN ISO 14120:2015

T Inherently safe design measures, safeguarding and complementary protective measures
B Information in instruction handbook: reference to residual risks, personal protective equipment, training

No.	Action	No.	Hazard	Harm	Risk			Causes	No.	T/B	Measure	Residual risk			References to 2006/42/EC Ann. I, standards
					S	P	E H A					S	P	E H A	
Phases of life, operating mode Operation (production)								**Subsystem** entire machine							
1	Placing the profile on the support	1.1	Cutting parts	Hand injury					1.1.5	T	movable guard with interlocking device according to PLr c				1.3.7; 1.3.8; 1.4 1; 1.4.2.2; EN ISO 16093:2017 Points 5.1.1.1, 5.1.1.4, 5.1.3.1, 5.3.2.1, 5.3.2.2; EN ISO 14120:2015; EN ISO 14119:2013; EN 60204-1:2006, Point 9.2.2; EN ISO 13849-1:2015
									1.1.6	T	access restricting, self-closing guard				1.3.7; 1.3.8; 1.4.1; 1.4.2.3; EN ISO 16093:2017, Points 5.1.1.1, 5.3.2.1, 5.3.2.2; EN ISO 14120:2015
									1.1.7	T	single-fault safe restraint device of the saw head				1.3.3; EN ISO 16093:2017, Point 5.3.2.2
									1.1.8	T	Emergency stop device in accordance with EN ISO 13849 PLr c				1.2.1; 1.2.4.3; EN ISO 16093:2017, Points 5.1.3.1, 5.1.3.5; EN ISO 13849-1:2015; EN ISO 13850:2015; EN 60204-1:2006, Point 10.7
									1.1.9	T	Cutting direction of the saw blade is marked with an arrow				1.7.3 EN ISO 16093:2017, Pt. 6.1.2

No.	Action	No.	Hazard	Harm	Risk			Causes	No.	T/B	Measure	Residual risk			References to 2006/42/EC Ann. I, standards
					S	P	EHA					S	P	EHA	
Phases of life, operating mode Operation (production)								**Subsystem** entire machine							
1	Placing the profile on the support	1.1	Cutting parts	Hand injury					1.1.10	B	Illustration of the labelling (arrow symbol)				1.7.4.2; EN ISO 16093:2017, Pt. 6.2.2
									1.1.11	B	Instructions on checking the safety devices prior to commissioning of the machine				1.7.4.2; EN ISO 16093:2017, Pt. 6.2.2
									1.1.12	B	Instructions on setting the guards				1.7.4.2; EN ISO 16093:2017, Pt. 6.2.2
									1.1.13	B	Instructions on inspecting the guards after the saw blade has been changed				1.7.4.2; EN ISO 16093:2017, Pt. 6.2.2
									1.1.14	B	Information on periodic maintenance of the guards				1.7.4.2; EN ISO 16093:2017, Pt. 6.2.2

T Inherently safe design measures, safeguarding and complementary protective measures
B Information in instruction handbook: reference to residual risks, personal protective equipment, training

Annex A

Standards with information on risk assessment where certain hazards exist

Hazard	Information for risk assessment and risk reduction
Thermal hazards	• EN ISO 13732-1, Ergonomics of the thermal environment – Methods for the assessment of human responses to contact with surfaces – Part 1: Hot surfaces • EN ISO 13732-3, Ergonomics of the thermal environment – Methods for the assessment of human responses to contact with surfaces – Part 3: Cold surfaces
Noise hazards	• EN 11688-1, Acoustics – Recommended practice for the design of low-noise machinery and equipment – Part 1: Planning
Radiation hazards	• EN 12198-1 to -9, Safety of machinery – Assessment and reduction of risks arising from radiation emitted by machinery • EN 60825-1, Safety of laser products – Part 1: Equipment classification and requirements
Material/substance hazards	• EN ISO 14123-1, Safety of machinery. Reduction of risks to health from hazardous substances emitted by machinery. Part 1: Principles and specifications for machinery manufacturers • EN ISO 14123-2, Safety of machinery. Reduction of risks to health from hazardous substances emitted by machinery. Part 2: Methodology leading to verification procedures • EN 1093-1 to -9 Safety of machinery – Evaluation of the emission of airborne hazardous substances • EN 1672-2 Food processing machinery – Basic concepts – Part 2: Hygiene requirements • EN 1127-1 Explosive atmospheres – Explosion prevention and protection – Part 1: Basic concepts and methodology
Ergonomic hazards	• EN 614-1, Safety of machinery – Ergonomic design principles – Part 1: Terminology and general principles • EN 614-2, Safety of machinery – Ergonomic design principles – Part 2: Interactions between the design of machinery and work tasks • EN 1005-1 to -4, Safety of machinery – Human physical performance

Annex B
Tables for documentation

Limits of the machine								
Designation of the machinery								
Intended use, use limits								
Reasonably foreseeable misuse								
Time limits, life cycle								
Life cycle of wearable parts								
Space limits								
Subsystems								
Phases of life, operating mode	**Persons involved**							
	User	Third parties	Mechanic	Electrician	Transport operative	Disposal specialist		
Transport								
Commissioning								
Operation (production)								
Production fault								
Machine fault								
Cleaning								
Maintenance								
Disabling								
Scrapping								
User training								
Area of use								
Additional basic requirements								
Date								
Author								

Risk assessment/risk reduction				
Machine:	**Series/type:**	**Serial number:**	**Space limits in drawing no.:**	**Author:**
				Date:

No.	Action	No.	Hazard	Harm	Risk			Causes	No.	T/B	Massnahme	Residual risk			References to 2006/42/EC Ann. I, standards
					S	P	E H A					S	P	E H A	
Phases of life, operating mode:								**Subsystem:**							
1		1.1							1.1.1						

Legend

Severity of harm S
- I Death
- II Serious permanent damage to health
- III Slight permanent damage to health
- IV Curable damage to health with incapacity to work
- V Curable damage to health without incapacity to work

Probability P (E+H+A)
- A Frequent (14, 15)
- B Occasional (11 – 13)
- C Infrequent (8 – 10)
- D Improbable (5 – 7)
- E Almost impossible (4)

Exposure to the hazard E
- 5 t ≤ 1 hour
- 5 1 hour < t ≤ 1 day
- 4 1 day < t ≤ 2 weeks
- 3 2 weeks < t ≤ 1 year
- 2 t > 1 year
- t: interval between the exposure

Occurrence of a hazardous event H
- 1 Negligible
- 2 Infrequent
- 3 Possible
- 4 Likely
- 5 Very likely

Possibility of avoiding or limiting the harm A
- 5 Impossible
- 3 Possible
- 1 Likely

- T inherently safe design measures, safeguarding and complementary protective measures
- B Information in instruction handbook: reference to residual risks, personal protective equipment, training

Annex C

Examples of hazards (source: EN ISO 12100 Annex B)

No	Type or group	Origin[A]	Potential consequences[B]
1	Mechanical hazards	• acceleration/deceleration • angular parts • approach of a moving element to a fixed part • cutting parts • elastic elements • falling objects • gravity • height from the ground • high pressure • instability • kinetic energy • machinery mobility • moving elements • rotating elements • rough, slippery surface • sharp edges • stored energy • vacuum	• being run over • being thrown • crushing • cutting or severing • drawing-in or trapping • entanglement • friction or abrasion • impact • injection • shearing • slipping, tripping and falling • stabbing or puncture • suffocation
2	Electrical hazards	• arc • electromagnetic phenomena • electrostatic phenomena • live parts • not enough distance to live parts under high voltage • overload • parts which have become live under fault conditions • short-circuit • thermal radiation	• burn • chemical effects • effects on medical implants • electrocution • falling, being thrown • fire • projection of molten particles • shock
3	Thermal hazards	• explosion • flame • objects or materials with a high or low temperature • radiation from heat sources	• burn • dehydration • discomfort • frostbite • injuries by the radiation of heat sources • scald

---

A A single origin of a hazard can have several potential consequences.
B For each type of hazard or group of hazards, some potential consequences can be related to several origins of hazard..

No.	Type or group	Origin[A]	Potential consequences[B]
4	Noise hazards	• cavitation phenomena • exhausting system • gas leaking at high speed • manufacturing process (stamping, cutting, etc.) • moving parts • scraping surfaces • unbalanced rotating parts • whistling pneumatics • worn parts	• discomfort • loss of awareness • loss of balance • permanent hearing loss • stress • tinnitus • tiredness • any other (for example, mechanical, electrical) as a consequence of an interference with speech communication or with acoustic signals.
5	Vibration hazards	• cavitation phenomena • misalignment of moving parts • mobile equipment • scraping surfaces • unbalanced rotating parts • vibrating equipment • worn parts	• discomfort • low-back morbidity • neurological disorder • osteo-articular disorder • trauma of the spine • vascular disorder
6	Radiation hazards	• ionizing radiation source • low frequency electromagnetic radiation • optical radiation (infrared, visible and ultraviolet), including laser • radio frequency electromagnetic radiation	• burn • damage to eyes and skin • effects on reproductive capability • mutation • headache, insomnia, etc.
7	Material/ substance hazards	• aerosol • biological and microbiological (viral or bacterial) agent • combustible • dust • explosive • fibre • flammable • fluid • fume • gas • mist • oxidizer	• breathing difficulties, suffocation • cancer • corrosion • effects on reproductive capability • explosion • fire • infection • mutation • poisoning • sensitization

No.	Type or group	Origin[A]	Potential consequences[B]
8	Ergonomic hazards	• access • design or location of indicators and visual displays units • design, location or identification of control devices • effort • flicker, dazzling, shadow, stroboscopic effect • local lighting • mental overload/underload • posture • repetitive activity • visibility	• discomfort • fatigue • musculoskeletal disorder • stress • any other (for example, mechanical, electrical) as a consequence of a human error
9	Hazards associated with the environment in which the machine is used	• dust and fog • electromagnetic disturbance • lightning • moisture • pollution • snow • temperature • water • wind • lack of oxygen	• burn • slight disease • slipping, falling • suffocation • any other as a consequence of the effect caused by the sources of the hazards on the machine or parts of the machine
10	Combination of hazards	for example, repetitive activity + effort + high environmental temperature	for example dehydration, loss of awareness, heat stroke

---

A A single origin of a hazard can have several potential consequences.
B For each type of hazard or group of hazards, some potential consequences can be related to several origins of hazard.

Annex D

From the risk assessment to the performance requirements of safety functions in control systems (PLr or SIL)

In many cases, a measure for risk reduction is based on a safety-related part of the control system of a machine. The contribution that such a safety function makes to risk reduction must befit the risk to be reduced and must be evaluated with the help of the standard EN ISO 13849-1 or EN 62061. This frequently raises the question of how to get from the risk assessment to the required level of the safety function (PLr or SIL).

Case 1: type-C standard existent

If there is a type-C standard for the corresponding machine, the requirements for the required performance level required (PLr) or safety integrity level (SIL) can generally be obtained from this standard.

Case 2: type-C standard not existent

In cases in which no type-C standard exists, the required performance level (PLr) in accordance with EN ISO 13849-1 or safety integrity level (SIL) in accordance with EN 62061 must be determined based on the results of the risk assessment. Because there is no generally valid method, a possible procedure is demonstrated below.

Application of EN ISO 13849-1 in case 2

Annex A of EN ISO 13849-1 contains a so-called risk graph. You can use this to determine the PLr based on the three parameters:

S severity of injury

F frequency and/or duration of exposure to the hazard

P possibility of avoiding the hazard or limiting the harm

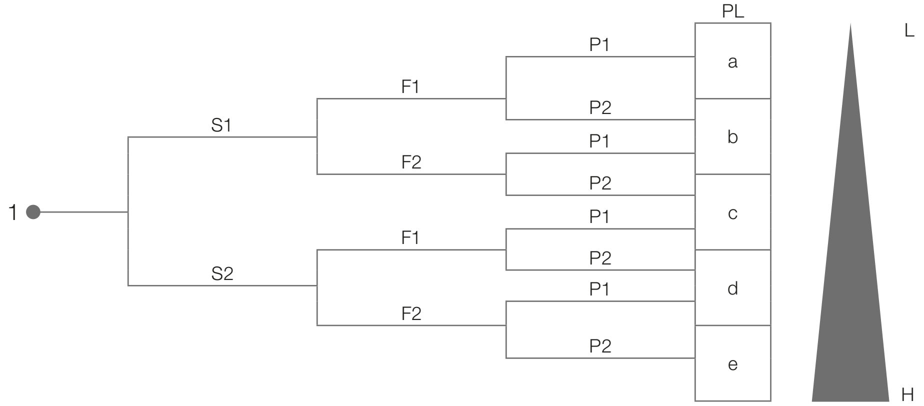


Figure D1

Risk graph – the required performance level (a to e) of the safety function in relation to S, F, and P

Meaning of the parameters in the risk graph

S severity of injury
  S1 slight (normally reversible) injury
  S2 serious (normally irreversible) injury or death
F frequency and/or duration of exposure to the hazard
  F1 seldom to less frequent exposure and/or short exposure time
  F2 frequent to continuous exposure and/or long exposure time
P possibility of avoiding the hazard or limiting the harm
  P1 possible under specific conditions
  P2 scarcely possible

In accordance with EN ISO 12100, the probability of occurrence of harm (W) is composed of the following elements:

- the exposure of persons to the hazard
- the occurrence of the hazardous event
- the possibility of avoiding or limiting the harm

In the risk graph, it is assumed that the hazardous event is definitely going to occur. Thus the element «occurence of the hazardous event» is omitted and the user is on the safe side with his assessment. Now, assign the severity of injury as laid down in EN ISO 13849-1 (S1, S2) according to the following diagram to the severity of harm (V, IV, III, II, I) of the Suva method:

Severity of harm S according to the Suva method	**Severity of injury** according to EN ISO 13849-1
V **IV**	**S1**
III **II** **I**	**S2**

Table D1

Assignment of severity of injury according to EN ISO 13849-1 to severity of harm according to the Suva method

For further consideration, it is assumed that the possibility of avoiding the hazard or of limiting the harm is small (P2). This is the case more often than not in practice.

Probability of occurrence W according to the Suva method	**Level** according to EN ISO 13849-1	
E **D**	**F1**	**P2**
C **B** **A**	**F2**	**P2**

Table D2

Assignment of level F/P according to EN ISO 13849-1 to the probability of occurrence according to the Suva method

These considerations yield the following assignment of risk to the required performance level PLr:

A	**PLr c**		**PLr e**		
B					
C					
D	**PLr b**		**PLr d**		
E					
	V	**IV**	**III**	**II**	**I**

Figure D2

Location of the various performance levels of the safety function in the risk matrix according to the Suva method.

Figure D2 illustrates the result for the case in which it is barely possible to avoid the hazard or to limit the harm (P2). If this is possible under specific conditions (P1), PLr will give results that are a level lower than those illustrated above.

In the two standards EN ISO 13849-1 and EN 62061, there are two different ways to obtain the probability of failure of safety functions. With the aid of the following table from the EN ISO 13849-1, the above-mentioned results can be transferred from the required performance level PLr to safety integrity level SIL according to EN 62061:

PLr according to EN ISO 13849-1	SIL according to EN 62061
a	no equivalence
b	1
c	1
d	2
e	3

Table D3

Assignment of PLr and SIL

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Download
www.suva.ch/66037.e

Title
Risk assesment and reduction
The Suva Method for machinery

Author
Mauritius Bollier

First edition: July 1990
Revised edition: September 2017

Publication no.
66037.e (not available in print)

The Suva model
The four pillars

- Suva is more than just insurance; it combines prevention, insurance and rehabilitation.
- Suva is managed by the social partners. The balanced composition of the Suva Council, which consists of representatives of employers, employees and the Swiss Confederation, permits widely supported, sustainable solutions.
- Suva returns any profits to its insurees in the form of lower premiums.
- Suva supports itself; it does not receive any public funding.