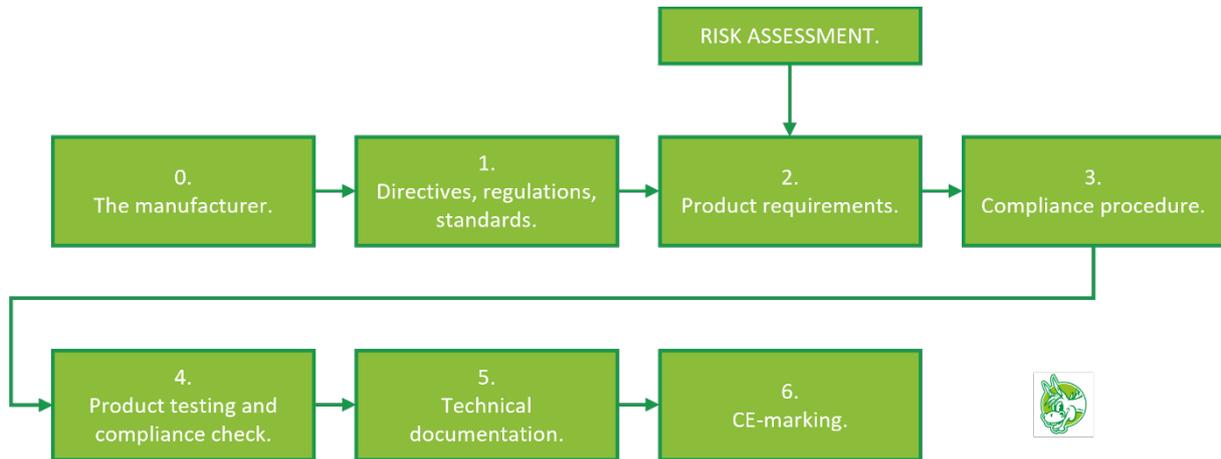


Purpose of this document

This is the user manual for the Donkey Safety Solutions | [CE-assistant](#) riskgraph-instrument.

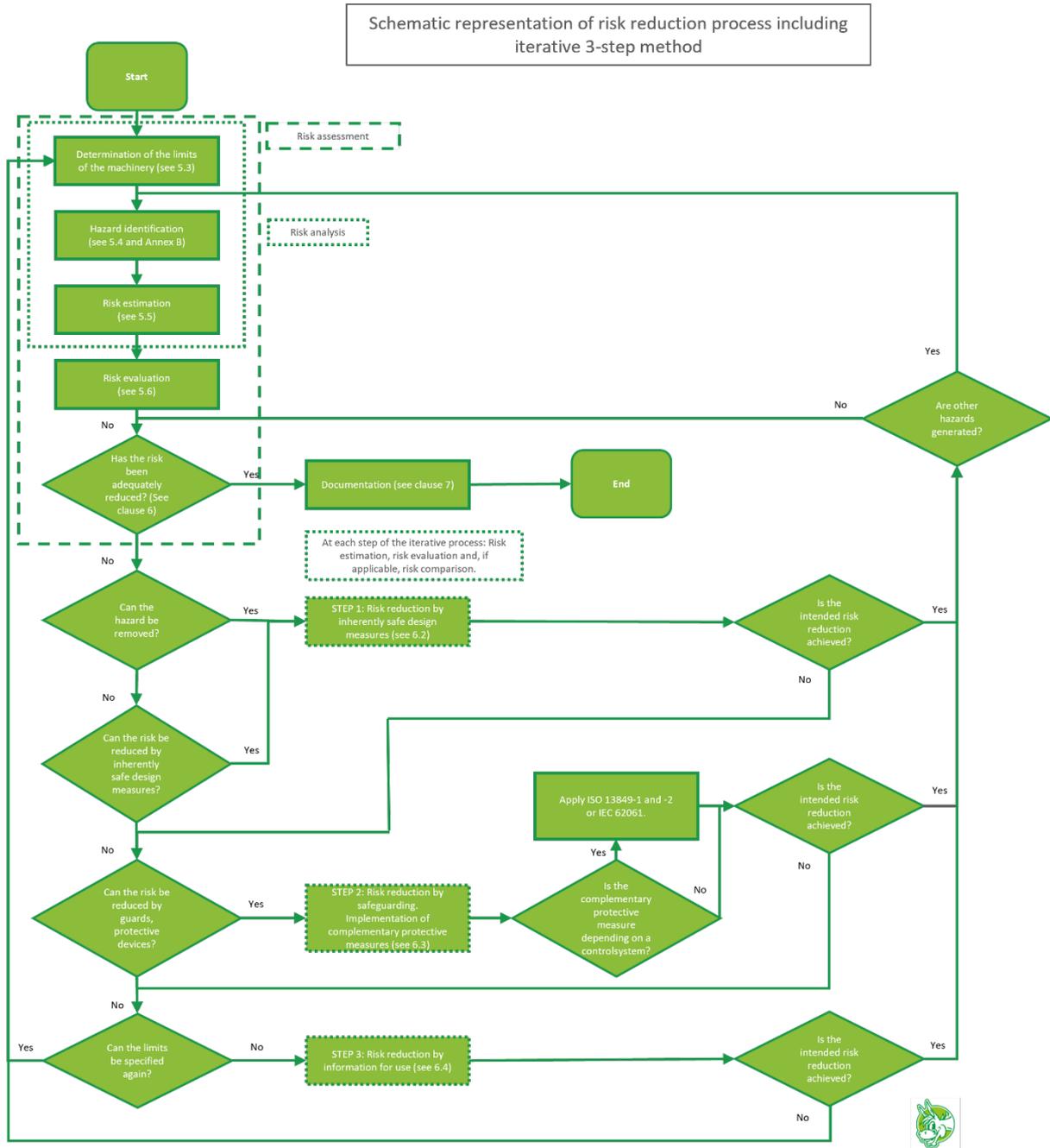
The riskgraph-instrument helps you with the obligated risk assessment during a CE-marking process as shown below. (More information about a CE-marking process wanted? Click the picture below)



This riskgraph-instrument is based on the a-standard EN-ISO 12100:2010.

The next figure shows the whole risk reduction process (based on figure 1 out of ISO 12100):

Schematic representation of risk reduction including iterative 3-step method





Worksheets in the riskgraph-instrument

The riskgraph-instrument consists of these sheets:

- **General**, this sheet describes the function of the next sheets.
- **Projectname&members**, a sheet to fill in (indeed) the projectname and projectmembers.
- **..... limits**, several sheets to fill in the limits of machinery as 5.3 of ISO 12100 dictates.
- **1 Mechanical** → **10 Combination**: ISO 12100 divides possible hazards up into 10 hazardgroups. Each of these 10 sheets handle a hazardgroup. These sheets contain the actual risk assessment.
- **Hazard examples**: This sheet contains Iso 12100's table B.1 examples of hazards. It is possible to add hazards from, for example, C-standards. These examples can be chosen in the sheets **1 Mechanical** → **10 Combination**

Each sheet will be explained further on.

Who should fill out the riskgraph-instrument?

Risk assessments must be carried out carefully. This also applies to filling out the riskgraph-instrument. Do this in a team with at least the following composition:

- Future user or someone with experience working with similar machines;
- Someone with knowledge of and influence on machine design;
- A coordinator who fills out the risk graph effectively, ensures consensus and is familiar with the risk reduction process.
- Designing complex machinery? Enlarge your team with appropriate experts.



Sheets: General

This is merely an informative sheet. It describes in short the sheets that are included in the riskgraph-instrument and the relating chapters of ISO 12100. It also includes a link to this manual.

There is nothing for you to fill in here.

What does this riskgraph do?		
<p>This riskgraph-instrument helps you with the obligated risk assessment during a CE-marking process as shown below. (More information about a CE-marking process wanted? Click the picture below)</p> <pre> graph LR 0[0. The manufacturer.] --> 1[1. Directives, regulations, standards.] 1 --> 2[2. Product requirements.] 2 --> RA[RISK ASSESSMENT.] 2 --> 3[3. Compliance procedure.] 3 --> 4[4. Product testing and compliance check.] 3 --> 5[5. Technical documentation.] 3 --> 6[6. CE-marking.] </pre>		
<p>There is a manual for this riskgraph-instrument. Click here for this manual. This riskgraph-instrument is based on the a-standard EN-ISO 12100:2010.</p>		
The tabs used in this riskgraph-instrument are:	Relation to ISO 12100	Why you fill this out
General: This is purely an informative tab.	-	-
Projectname&members: Here you fill out the required information.	-	General project info
Use limits: Here you fill out the required information	Chapter 5.3.2	Limits are used as a variable in the risk assessment
Space limits: Here you fill out the required information	Chapter 5.3.3	
Time limits: Here you fill out the required information	Chapter 5.3.4	
Other limits: Here you fill out the required information	Chapter 5.3.5	
Tabs 1-->10: The actual risk assessment based on the a-standard EN-ISO 12100:2010.	Chapters 5.5-5.6-6	
Variables: This is needed for correct working of this riskgraph. Please do not change or delete it.	-	-
Hazard examples: These are the hazards and possible consequences out of ISO 12100 & C-standards you use in the risk assessment.	Annex B	-



Sheets: Projectname&members

See example further on:

- Project name: Free text.
- Team members...: Free text. You can fill in up to 5 team members.
- Member Role: Free text. You can fill in up to 5 roles.
- Applicable hazard groups for this project: Just leave these as they are. These are the 10 hazard groups as in ISO 12100's Table B.1 mentioned.
- Status. Not all hazard groups apply to your project. As to make it easier you can choose per hazard group:
 - Applicable, not finished: This hazardgroup applies to the project but the team is still working on it.
 - Applicable and finished: This hazardgroup applies to the project and is fully assessed.
 - Not applicable: This hazardgroup does not apply to the project.

Projectname (please fill out, max. 1):	
1	Your projectname
Team members that complete this riskgraph (please fill out,max. 5):	
Member Role (please fill out,max. 5):	
1	Dennis
2	Bob
3	Bill
4	Grat
5	Emmett
Applicable danger groups for this project	
Status	
1	Mechanical dangers
2	Electrical dangers
3	Thermal dangers
4	Noise dangers
5	Vibration dangers
6	Radiation dangers
7	Material-substance dangers
8	Ergonomic dangers
9	Environmental dangers
10	Combination of dangers



Sheets: person involved / role

Who works or is involved with the machinery in any way possible?

You can fill in 9 function titles, roles descriptions of a taskgroup etc. Just as you want, it is free text. Important: Think these persons involved or roles out well. Perhaps the machinery is used by volunteers, really tall persons, by consumers etc. etc.

Below just an example:

	Person involved / Role (please fill out, max. 9)
1	Operator: process control and monitoring; brief intervention not requiring
2	Service: correction of malfunction(s) (e.g. equipment jams, event recovery and abnormal conditions);
3	Inspector: Quality inspections, verification
4	Specialist: troubleshooting, programming and verification; maintenance and repair;
5	Commissioner: Equipment installation
6	Cleaner: equipment cleaning;
7	Forklift truck driver
8	Bystanders
9	-----

These persons involved / roles will be integrated in the sheets **1 Mechanical** → **10 Combination**.



Sheets: Use limits

Here you can fill in 9 use limits:

Use limits (please fill out,max. 9)	
1	
2	
3	
4	
5	
6	
7	
8	
9	

No examples filled in this time but the description of use limits (Chapter 5.3.2 ISO 12100):

ISO 12100 information:
<p>5.3.2 Use limits</p> <p>Use limits include the intended use and the reasonably foreseeable misuse. Aspects to be taken into account include the following:</p> <p>a) the different machine operating modes and different intervention procedures for the users, including interventions required by malfunctions of the machine;</p> <p>b) the use of the machinery (for example, industrial, non-industrial and domestic) by persons identified by sex, age, dominant hand usage, or limiting physical abilities (visual or hearing impairment, size, strength, etc.);</p> <p>c) the anticipated levels of training, experience or ability of users including</p> <ol style="list-style-type: none"> 1) operators, 2) maintenance personnel or technicians, 3) trainees and apprentices, and 4) the general public; <p>d) exposure of other persons to the hazards associated with the machinery where it can be reasonably foreseen:</p> <ol style="list-style-type: none"> 1) persons likely to have a good awareness of the specific hazards, such as operators of adjacent machinery; 2) persons with little awareness of the specific hazards but likely to have a good awareness of site safety procedures, authorized routes, etc., such as administration staff; 3) persons likely to have very little awareness of the machine hazards or the site safety procedures, such as visitors or members of the general public, including children. <p>If specific information is not available in relation to b), above, the manufacturer should take into account general information on the intended user population (for example, appropriate anthropometric data).</p>

These limits can be chosen in the sheets 1 Mechanical → 10 Combination.

Sheets: Space limits

Here you can fill in 9 space limits:

Space limits (please fill out,max. 9)	
1	
2	
3	
4	
5	
6	
7	
8	
9	

No examples filled in this time but the description of use limits (Chapter 5.3.3 ISO 12100):

ISO 12100 information:

5.3.3 Space limits

Aspects of space limits to be taken into account include

- a) the range of movement,
- b) space requirements for persons interacting with the machine, such as during operation and maintenance,
- c) human interaction such as the operator–machine interface, and
- d) the machine–power supply interface.

These limits can be chosen in the sheets 1 Mechanical → 10 Combination.

Sheets: Time limits

Here you can fill in 9 time limits:

	Time limits (please fill out, max. 9)
1	
2	
3	
4	
5	
6	
7	
8	
9	

No examples filled in this time but the description of use limits (Chapter 5.3.4 ISO 12100):

ISO 12100 information:

5.3.4 Time limits

Aspects of time limits to be taken into account include

- a) the life limit of the machinery and/or of some of its components (tooling, parts that can wear, electromechanical components, etc.), taking into account its intended use and reasonably foreseeable misuse, and*
- b) recommended service intervals.*

These limits can be chosen in the sheets 1 Mechanical → 10 Combination.



Sheets: Other limits

Here you can fill in 9 other limits:

Other limits (please fill out,max. 9)	
1	
2	
3	
4	
5	
6	
7	
8	
9	

No examples filled in this time but the description of use limits (Chapter 5.3.5 ISO 12100):

ISO 12100 information:

5.3.5 Other limits
Examples of other limits include
a) properties of the material(s) to be processed,
b) housekeeping — the level of cleanliness required, and
c) environmental — the recommended minimum and maximum temperatures, whether the machine can be operated indoors or outdoors, in dry or wet weather, in direct sunlight, tolerance to dust and wet, etc.

These limits can be chosen in the sheets 1 Mechanical → 10 Combination.



Sheets 1 Mechanical → 10 Combination

These 10 sheets all work the same. Each sheet is named after a ISO 12100 hazard group. These groups are:

1. Mechanical
2. Electrical
3. Thermal
4. Noise
5. Vibration
6. Radiation
7. Material/substance
8. Ergonomic
9. Environmental
10. Combination



Sheets 1 up to 10: Hazard identification

Hazards are identified in this part of the sheet:

Hazard identification								
Nr.	Hazard	Potential consequences	Standard input	Remarks	Use limits	Space limits	Time limits	Other limits
1								
2								
3								
4								
5								

- Nr.: In total there are 90+ lines to use. It is not necessary to change these numbers.
- Hazard: This is the hazard you can choose from a dropdown box. This dropdown box is filled with values in the **Hazard examples** sheet.
- Potential consequences: This is the potential consequence (risk) you can assign to the hazard you choose. This dropdown box is filled with values in the **Hazard examples** sheet. Can you define a hazard with numerous potential consequences? Use more lines with the same hazard, but different potential consequences.
- Standard input: ISO 12001 is the regular standard input. However, also c-standards can be. This dropdown box is filled with values in the **Hazard examples** sheet.
- Remarks: The only free text cel in this part of the sheet. For example specify the potential consequence here.
- ... Limits: These are all dropdown boxes. They are filled with the values in **..... limits**

Eventually you will get something like this:

Hazard identification								
Nr.	Hazard	Potential consequences	Standard input	Remarks	Use limits	Space limits	Time limits	Other limits
1	height from the ground		ISO 12100	My remark	UL1	SL2	TL3	OL4
2		cutting or severing						
3		drawing in or trapping						
4		entanglement						
5		friction or abrasion						
6		impact						
7		injection						
8		shearing						
9		slipping tripping and falling						
		stabbing or puncture						
		suffocation.						
		.						



Sheets 1 up to 10: Risk estimation and evaluation

The next step is estimating and evaluating the identified hazards without any measures taken. In this step the existing ‘naked’ risks are estimated and evaluates. It is only in the next step that, if necessary, measures are taken to lower these risks.

This is the part of the sheet where you can determine how risky these hazards really are:

Risk estimation and evaluation																																																	
Operator: process control					Service: correction of malfunction(s) (e.g. equipment jams, event)					Inspector: Quality					Specialist: troubleshooting,					Commissioner: Equipment					Cleaner: equipment					Forklift truck driver					Bystanders					---									
S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R	S	Fr	Pr	Av	R					
				!					!					!					!					!					!					!					!					!					!
				!					!					!					!					!					!					!					!					!					!
				!					!					!					!					!					!					!					!					!					!

Notice that the person involved/role, you filled in the **Use limits** sheet, can be found here too. Do not change these here but only do that in the **Use limits** sheet.

To be filled in:

- S: Severity. A dropdown box.
- Fr: Frequency. A dropdown box.
- Pr: Probability. A dropdown box.
- Av: Avoidance. A dropdown box.
- R: Risk. A value resulting from S-Fr-Pr-Av. Do not change these cells.

There are many ways to estimate risks. But this is the way it is done in the riskgraph-instrument:



Finally the risks are evaluated as follows:

Risk figure	Risk is	Measures
1 up to 4	Low	Risk is acceptable, ALARA
5 up to 7	Medium	Additional measures needed
8 up to 10	High	Immediate additional measures needed
11 up to 14	Very high	Stop work



Remember that risk figures also depend on the person involved/role. Meaning that the same hazards and potential consequences can have other risk figures for another role resulting is for example:

Operator: process control					Service: correction of malfunction(s) (e.g. equipment jams, event				
S	Fr	Pr	Av	R	S	Fr	Pr	Av	R
1	0	1	2	2	2	2	1	1	5
2	2	2	1	7	2	2	2	2	8

When you do not use 9 persons involved/roles you can downsize the view by clicking . Expand the view again by clicking:

J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AI	AC	AD	AE	AF	AG	AI	AI	A	A	BIBI
Risk estimation and evaluation																												
Operator: process control					Service: correction of malfunction(s) (e.g. equipment jams, event					Inspector: Quality					Specialist: troubleshooting,													
S Fr Pr Av R					S Fr Pr Av R					S Fr Pr Av R					S Fr Pr Av R													
!					!					!					!													
!					!					!					!													
!					!					!					!													



Sheets 1 up to 10: Determination of PL and SIL

This can be used as an option and only by persons who know their way around Funcional Safety and standards ISO 13849-1 & -2 and/or IEC 62061.

Functional Safety will not be explained here, but for those who are familiar with it, this is the part of the sheet to determine PL and SIL:

Determination of PL (ISO 13849) and SIL (IEC 62061)					
S	Fr	Pr	Av	SIL	PLr
				-	-
				-	-
				-	-

To be filled in:

- S: Severity. A dropdown box.
- Fr: Frequency. A dropdown box.
- Pr: Probability. A dropdown box.
- Av: Avoidance. A dropdown box.
- SIL & PLr: A value resulting from S-Fr-Pr-Av (see table A.6). Do not change these cells.

Table A.6 – Matrix assignment for determining the required SIL (or PL_r) for a safety function

Consequences	Severity Se	Class CI = Fr + Pr + Av												
		3	4	5	6	7	8	9	10	11	12	13	14	15
Death, losing an eye or arm	4	SIL 1		SIL 2			SIL 2			SIL 3			SIL 3	
		PL _r b	PL _r c	PL _r d			PL _r d			PL _r e			PL _r e	
Permanent injury, losing fingers	3	No SIL (or PL) required		OM			SIL 1			SIL 2			SIL 3	
				PL _r a			PL _r b	PL _r c	PL _r d			PL _r e		
Reversible injury, medical attention	2	No SIL (or PL) required		No SIL (or PL) required			OM			SIL 1			SIL 2	
							PL _r a			PL _r b	PL _r c	PL _r d		
Reversible injury, first aid	1	No SIL (or PL) required		No SIL (or PL) required			No SIL (or PL) required			OM			SIL 1	
										PL _r a			PL _r b	PL _r c

A possible result:

Determination of PL (ISO 13849) and SIL (IEC 62061)					
S	Fr	Pr	Av	SIL	PLr
3	3	4	5	2	d
2	5	2	3	OM	a



Sheets 1 up to 10: Risk reduction measure, new risk estimation and evaluation
 Risks that are figured above 4 are too high and need to be reduced by taking measures. This certainly does not mean that taking measures to lower risk figured less than 4 is forbidden (it is admirable).

This is the part of the sheet where you read back the initial risk you filled in before, take measures if necessary and estimate and evaluate the risk after your measure(s).

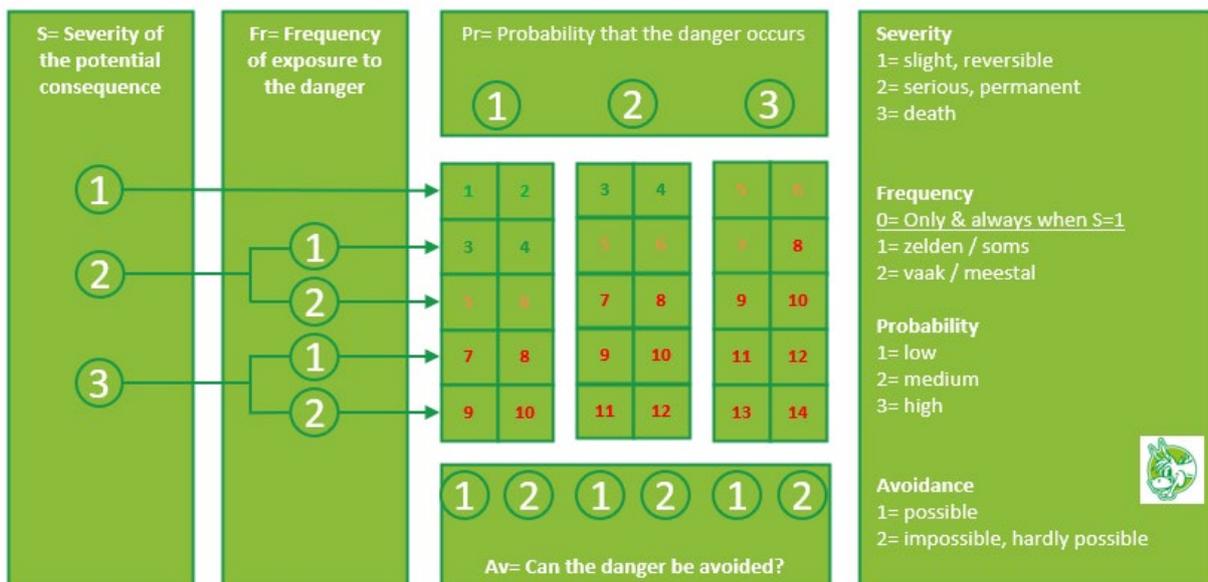
Risk reduction measure, new risk estimation and evaluation						
Service: correction of malfunction(s) (e.g. equipment jams, event recovery and abnormal conditions);						
R _{initial}	Risk reduction measure	S	Fr	Pr	Av	R _{new}
5						!
8						!
!						!

Notice again that the person involved/role, you filled in the **Use limits** sheet, can be found here too. Do not change these here but only do that in the **Use limits** sheet.

To be filled in:

- Risk reduction measure(s).
- S: Severity. A dropdown box.
- Fr: Frequency. A dropdown box.
- Pr: Probability. A dropdown box.
- Av: Avoidance. A dropdown box.
- R: Risk. A value resulting from S-Fr-Pr-Av. Do not change these cells.

Also here this method is used for estimation and evaluation:





The final risks (after your best measures) are evaluated as follows:

Risk figure	Risk is	Measures
1 up to 4	Low	Risk is acceptable, ALARA
5 up to 7	Medium	Additional measures needed
8 up to 10	High	Immediate additional measures needed
11 up to 14	Very high	Stop work

When one or more risk figures are still too high go back to [‘Schematic representation of risk reduction including iterative 3-step method’](#).

A possible result:

Risk reduction measure, new risk estimation and evaluation							
Service: correction of malfunction(s) (e.g. equipment jams, event recovery and abnormal conditions);							
R _{initial}		Risk reduction measure	S	Fr	Pr	Av	R _{new}
5		Creating more distance to dangerzone using standard ISO 13857	2	1	1	1	3
8		Changing tool to a normally closed version prevents falling pieces	2	1	1	2	4

When you do not use 9 persons involved/roles you can downsize the view by clicking . Expand the view again by clicking:



Sheets 1 up to 10: Residual risks

This part of the sheet is a reminder to yourself.

The last step of reducing risks (step 3) is risk reduction by information. When reduction implies a notice in the manual or a physical warning (for example a decal or warninglight) you can mention this here. Also when you refer to a standard you can fill that one out here as a reminder to apply in your machinery design:

Residual risks			Standard(s) to be applied
Manual issue?	Warning issue?	Remark	

To be filled in:

- Manual issue: A dropdown box.
- Warning issue: A dropdown box.
- Remark: Free text.
- Standard(s) to be applied.

A possible result:

Residual risks			Standard(s) to be applied
Manual issue?	Warning issue?	Remark	
Yes	No	To be mentioned in the user manual: Wearing of rings or other hand-jewelry is not allowed.	ISO 13857
Yes	<input type="text" value=""/>	When entering the safeguarded zone a safety cap must be worn.	
	<input type="text" value="Yes"/>		
	<input type="text" value="No"/>		



Sheets: Hazard examples

Here you will find the input for several dropboxes.

It contains all hazards and potential consequences mentioned in ISO 12100. Do not remove these.

If you want, and you know your way around in excel, you can add hazards and potential consequences form, for example, c-standards.

Sheets: Variables

These are used in risk estimations and evaluations. Please do not remove or change.

Questions:

For questions, please see our contact info at ce-assistant.com

By the way:



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