

# SICK AG

# WHITE PAPER

## RISK ASSESSMENT AND RISK REDUCTION FOR MACHINERY PART 3: CONDUCTING RISK ESTIMATION

PART 3A: SCALABLE RISK ANALYSIS AND EVALUATION METHOD (SCRAM), 2022-05

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### ABSTRACT

When designing, modifying, or using a machine, the possible risks must be analyzed and, where necessary, additional risk reduction measures must be taken to protect the operator from any hazards that may occur.

This white paper takes a closer look at the process of risk reduction, which is achieved by applying suitable risk reduction measures. Should a new risk arise from the application of risk reduction measures; it shall also be assessed and reduced. A repetition of the entire process (risk assessment and risk reduction) may be necessary to eliminate hazards as far as possible and to sufficiently reduce the identified or newly emerged risks.

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## Introduction

### Scope

Machine risk assessment consists of a series of steps used to examine the hazards associated with machines. It consists of two stages, namely risk analysis and risk evaluation, as laid out in ISO 12100:2012. Risk analysis comprises three stages: determining the limits of the machine, identifying hazards, and estimating the risk.

After having completed the hazard identification phase, risk estimation is carried out for each identified hazard and hazardous situation. Risk is defined as a combination of the severity of harm and the probability of occurrence of that harm.

According to ISO 12100:2012, the probability of occurrence of harm can be estimated taking into account the frequency and duration of exposure to the hazard, the probability of occurrence of a hazardous event, and the technical and human possibilities to avoid or limit the harm. The combination of the severity of the possible harm with these three probability parameters will be used to estimate risk values which can then be used for comparison purposes. At the last stage of the assessment process, risk evaluation allows decisions on risk reduction measures to be applied to the machine.

The scope of this white paper is to provide a risk estimation methodology that has proved to be robust and reliable while preventing errors when estimating risks.

### Preface

This white paper is part of a series of papers describing the SICK process of risk assessment in combination with risk reduction:

- Part 1: Defining the scope of the risk assessment
- Part 2: Identifying task/hazard pairs
- Part 3: Conducting risk estimation
- Part 4: Integrating protective devices into (existing) control systems
- Part 5: Implementing emergency operations
- Part 6: Carrying out substantial modifications

## Risk reduction process

### General

All products and systems include hazards and, therefore, some level of risk. The risk associated with those hazards, however, shall be reduced to an acceptable or tolerable level. The iterative process of risk assessment and risk reduction for each task and hazard combination is essential in achieving acceptable risk (level of risk that is accepted in a given context based on the current values of society).

The objective of risk reduction can be achieved by eliminating significant hazards, or by reducing each of the two elements (separately or simultaneously) that determine the associated risk:

- Severity of harm from the hazard under consideration
- Probability of occurrence of that harm

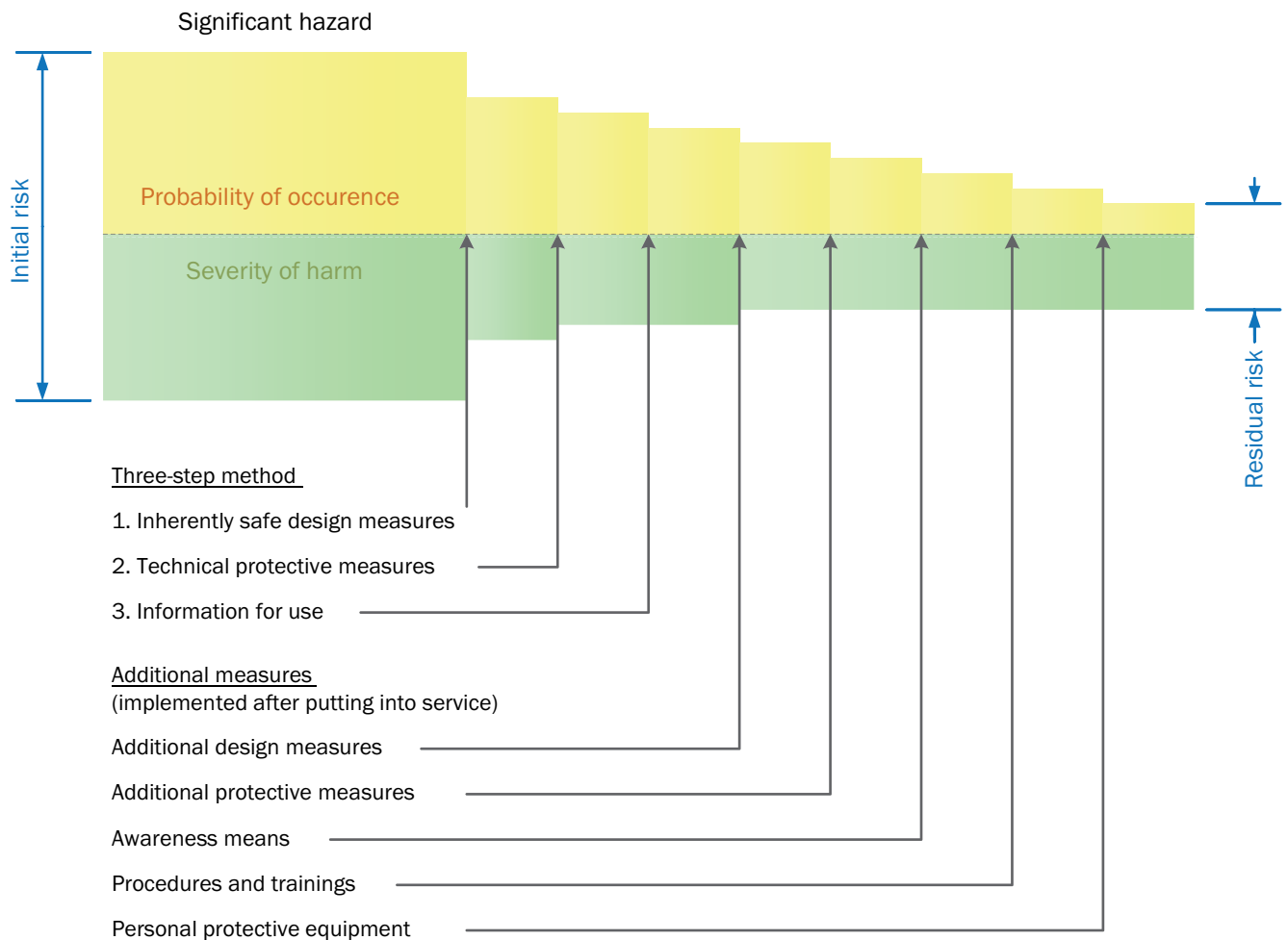


Fig. 1 – Overall risk reduction

<sup>a</sup> For the purpose of this document, the terms “acceptable risk” and “tolerable risk” are considered to be synonymous.

**Three-step method**

All risk reduction measures intended for reaching this objective shall be applied in the following sequence, referred to as the three-step method:

**STEP 1: INHERENTLY SAFE DESIGN MEASURES**

Inherently safe design measures are achieved by avoiding hazards or reducing risks by implementing a suitable choice of design features for the machine itself and/or interaction between the exposed persons and the machine.

Inherently safe design measures are the first and most important step in the risk reduction process. This is because risk reduction measures inherent to the characteristics of the machine are likely to remain effective, whereas experience has shown that even well-designed safeguarding can fail or be defeated and information for use may not be followed.

**STEP 2: TECHNICAL PROTECTIVE MEASURES**

Guards and protective devices (also known as “safeguarding” or “engineering controls”) shall be used to protect persons whenever an inherently safe design measure does not reasonably make it possible either to remove hazards or to sufficiently reduce risks (for details, see section “Technical protective measures”). Complementary protective measures involving additional equipment (for example, emergency stop equipment) may also be necessary.

**STEP 3: INFORMATION FOR USE**

Information for use consists of communication means, such as texts, words, signs, signals, symbols, or diagrams, used separately or in combination to provide information to the user (employer and/or affected persons).

The information shall contain all directions required for safe and intended use of a machine. To achieve this purpose, it shall also inform and warn the user about residual risk.

- The information shall indicate, as appropriate, the requirements for additional measures that the user shall implement:
- The possible need for additional guards or protective devices
- The consideration of regular inspections
- The consideration of safe work procedures and training
- The consideration of personal protective equipment

**Information for use shall not be a substitute for the correct application of inherently safe design measures, technical protective measures, or complementary protective measures.**

**Additional measures (implemented after putting into service)**

Measures which can be incorporated at the design stage are preferable to those implemented by the user after putting into service<sup>b</sup> and usually prove to be more effective. However, additional measures may be necessary to further reduce risk to an acceptable level. These additional measures are typically implemented by the equipment integrator, modifier, or user prior to the machine being put into service.

**ADDITIONAL DESIGN MEASURES**

Alternative materials, methods, or energy levels shall be substituted to reduce the risk of harm from hazards, where practicable.

**ADDITIONAL PROTECTIVE MEASURES**

Additional guards, safeguarding devices, and complementary protective measures shall be provided to reduce risk, where practicable.

**AWARENESS MEANS**

Awareness means shall be used where appropriate to inform affected persons of hazards.

**PROCEDURES AND TRAINING**

Safe work procedures and training shall be implemented to reduce residual risk where guards, safeguarding devices, and awareness means are insufficient to achieve acceptable risk for a task related to an industrial machine system.

**PERSONAL PROTECTIVE EQUIPMENT**

Personal protective equipment (PPE) shall be used in conjunction with – but not as a substitute for – other risk reduction measures or when no other control method is available or feasible.

<sup>b</sup> “Putting into service” means the first use of machinery for its intended purpose by the user.

Schematic representation

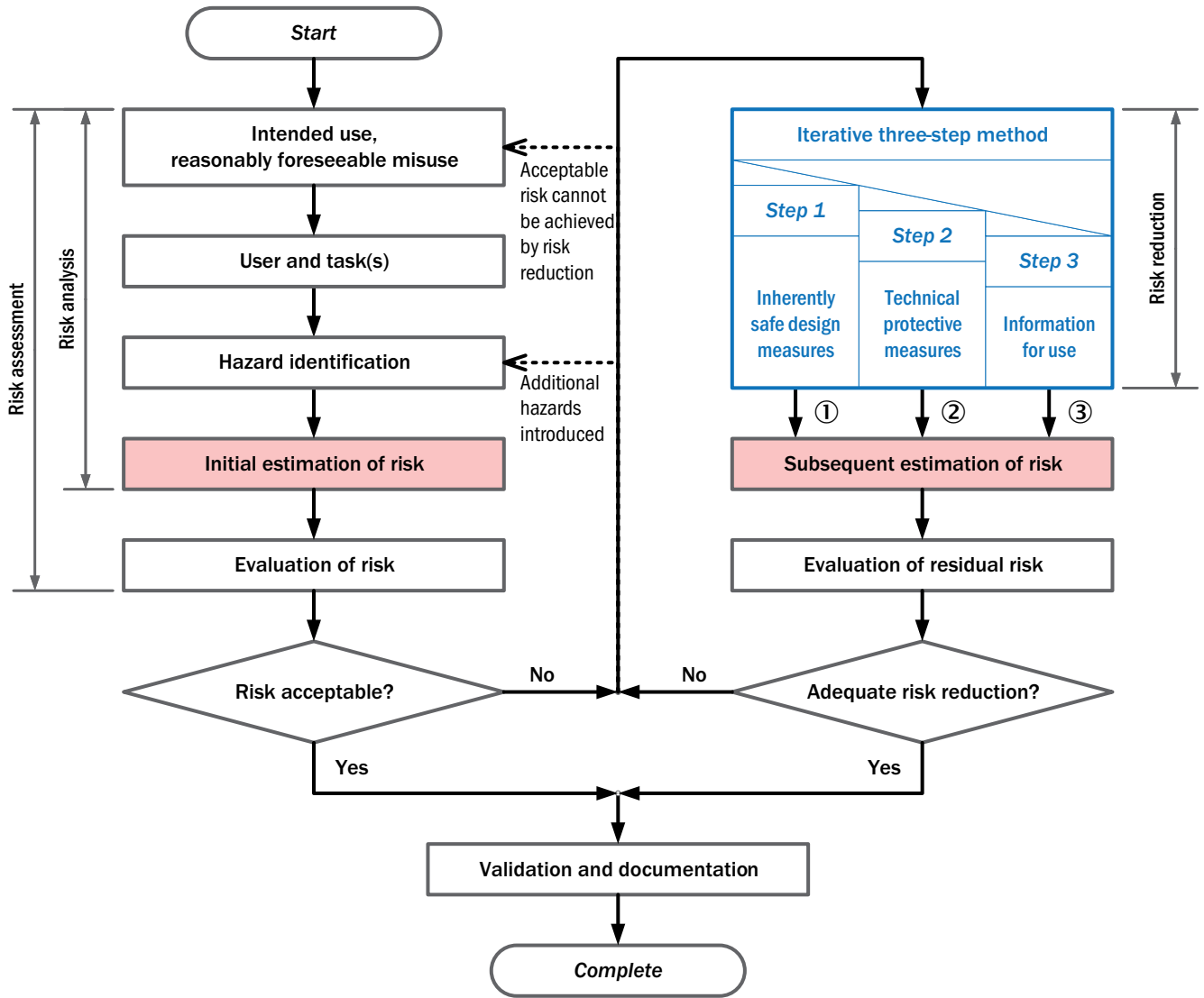


Fig. 2 – Risk reduction process [based on ISO/IEC Guide 51:2014]

## Safeguarding<sup>c</sup>

### Terms and definitions

Taking into account the intended use and the reasonably foreseeable misuse, appropriately selected safeguarding can be used to reduce risk when it is not practicable to eliminate a hazard or reduce its associated risk sufficiently using inherently safe design measures.

### SAFEGUARDING

Risk reduction measures using guards or protective devices to protect persons from the hazards which cannot reasonably be eliminated or risks which cannot be sufficiently reduced by inherently safe design measures.

### GUARDS

Physical barriers, designed to provide protection, include:

- Fixed guards
- Movable guards
- Adjustable guards
- Self-adjusting guards
- Perimeter guards
- Interlocking guards
- Interlocking guards with guard locking
- Interlocking guards with a start function

### PROTECTIVE DEVICES

Examples of types of protective devices are:

- Interlocking devices
- Enabling devices
- Hold-to-run control devices
- Two-hand control devices
- Electro-sensitive protective equipment (ESPE)
- Pressure sensitive protective equipment (PSPE)
- Mechanical restraint devices
- Limiting devices
- Limited movement control devices

<sup>c</sup> In the US addressed as “engineering controls.”

## Adequate risk reduction

### Residual risk

The residual risk (risk remaining after each risk reduction measure has been applied) has to be estimated after each step of the risk reduction process.

When risk is reduced with the use of sensing protective equipment, there is little impact on the severity of harm and the exposure of the worker to the hazardous situation. Even well-designed technical protective measures which separate humans and machines by means of distance and/or time can fail or may be defeated.

### Acceptable risk

When all the risk reduction measures have been applied, the final residual risk shall not exceed a level of risk that is accepted in a given context based on the current values of society.

The final residual risk shall be identified in the information for use where risks remain despite inherently safe design measures, safeguarding, and the adoption of complementary protective measures.

### Estimation of risk

Risk estimation, carried out for each hazardous situation by determining the combination of the probability of occurrence of harm and the severity of that harm, shall take into account all persons (operators and others) for whom exposure to the hazard is reasonably foreseeable.

The estimation of the exposure to the hazard under consideration (including long-term health damage) requires analysis of, and shall account for, all modes of operation of the machinery and methods of working. In particular, the analysis shall account for the needs for access during loading/unloading, setting, teaching, process changeover or correction, cleaning, observation, fault-finding, maintenance, and other tasks.

### Selection of methods and tools

The choice of a specific risk estimation tool is less important than the process itself. The benefit of risk assessment comes from the discipline of the process rather than in the absolute precision of the results, as long as all the elements of risk as described in ISO 12100 are fully considered.

SICK offers two different methods for the estimation of risk:

- SCRAM – Scalable Risk Estimation and Evaluation Method,
- COHeReNT – Collaboration Oriented Hazard Rating Number Tool.

Recommendations for the use of COHeReNT<sup>d</sup>

COHeReNT has been developed with a strong focus on collaborative interactions between the human and equipment. These applications are characterized by one or more of the following aspects:

- there is no classic separation between human and equipment,
- there is a stronger interaction between human and equipment,
- risk reduction is achieved without a protective stop of the equipment,
- risk reduction is planned with multi layered safety functions,
- it is necessary to indicate the contribution to the risk reduction of each safety function,
- the safety functions are based on sensor fusion (combination of multiple sensors),
- risk assessments for 'other' sectors (where there is stronger interaction), e.g.:
  - process industry,
  - tractor vehicles and machinery for agricultural and forestry applications
  - earth moving machines
  - road construction machines.

<sup>d</sup> COHeReNT extends the original HRN (Hazard- Rating- Number) method which has been further developed by SICK to fit the purposes of collaborative applications



Recommendations for the use of SCRAM <sup>e</sup>

SCRAM has been developed with a strong focus on industrial applications of machinery. These applications are characterized by one or more of the following aspects:

- implementation of established safety concepts,
- applications with a structured human – machine interaction,
- known application fields,
- structured and static environments,
- applications where the risk reduction can be implemented with qualified products or subsystem,
- applications where the risk reduction measures are applied in accordance with type-B standards
- machines where a type-C standard is applicable.

**Scalable Risk Analysis and Evaluation Method (SCRAM)**

This methodology consists mainly of two different two-dimensional matrices. Table 1 allows the combination of the severity of harm with the probability of occurrence of that harm. It is designed to assess the initial risk. It can also be used to estimate the risk after applying inherent safe design measures. In cases where the main criteria for the elements of risk are not entirely fitting the application, there are optional tables for determining each individual factor to improve the estimation.

Severity	Exposure	Avoidance	Occurrence			
			01 - 03	01	02	03
S1	E0	÷	< 1			
	E1 - E3	A1, A2		< 1	< 1	< 1
S2	E0	÷	≤ 1			
		A1		< 1	< 1	1
	A2	< 1		1	1	
	E2	A1		1	2	2
		A2		1	2	2
	E3	A1		2	3	3
A2		2		3	3	
S3	E0	÷	1			
		A1		3	4	4
	A2	3		4	4	
	E2	A1		4	5	5
		A2		5	5	5
	E3	A1		5	6	6
A2		6		6	6	
S4	E0	÷	1			
		A1		6	7	7
	A2	7		7	7	
	E2	A1		7	8	8
		A2		8	8	8
	E3	A1		8	9	9
A2		9		10	10	
<b>Risk index</b>						

**Key**

- S** Severity of harm                   negligible (1), slight (2), serious (3), severe (4)
- E** Exposure to hazard               prevented (0), low (1), medium (2), high (3)
- A** Possibility of avoidance       avoidable (1), not avoidable (2)
- O** Probability of occurrence       low (1), medium (2), high (3)

Tab. 1 – SCRAM (main table)

<sup>e</sup> The method itself and the corresponding definitions are developed by SICK.

The risk scoring criteria for the severity, exposure, avoidance, and occurrence factors are summarized in section “Elements of risk.” To enable the designer of the risk reduction measures to estimate the risk after measures have been applied, a new factor for the exposure to hazard is established: FO “prevented.” If functional safety is used as a risk reduction measure, the safety performance (PL) of the implemented SRP/CS has to at least meet and may exceed the minimum required safety performance (PL ≥ PL<sub>r</sub>).

Table 2 allows estimating the effectiveness of implemented technical protective measures and/or the information for use given.

	IN	Risk Reduction Measures			OUT
	Risk index	MSE and/or CSE	SIG and/or INS	ORG and/or PPE	Risk index
②	8 - 10	M	n/a	n/a	1
	4 - 7	M			
	2 - 3	M			
	1	HR			< 1
	< 1	R			
③	1	n/a	M	n/a	< 1
	< 1		HR		
	< 1	n/a	n/a	to be implemented by the employer	AR

**Key**

- MSE** Mechanical safeguarding equipment
- CSE** Control-related safeguarding equipment
- SIG** Information at machine (e.g., signal or signs)
- INS** Information in instruction handbook
- ORG** Safe working procedures
- PPE** Personal protective equipment

- M** One or a combination of these measures is **mandatory** for this risk level when reasonably practicable
- HR** One or a combination of these measures is **highly recommended** for this risk level
- R** One or a combination of these measures is **recommended** for this risk level as a lower recommendation to an HR recommendation
- AR** As low as reasonably practicable (ALARP)

How to consider existing risk reduction measures will be explained in part 6 of the white paper series “Carrying out substantial modifications.”

Tab. 2 – SCRAM (risk reduction measures to be implemented)

**Risk evaluation**

Care should be taken that simple and effective measures for reducing relatively low risks are not overlooked due to an exclusive focus on the highest risks.

A significant hazard is a hazard which has been identified as both relevant (i.e., being present at, or associated with, the machine), as well as requiring specific action to eliminate or reduce the risk according to the initial estimation of risk.

When risk reduction measures are applied as a result of the risk evaluation, a new iteration of the risk assessment shall be made to verify its effectiveness in risk reduction.

According to recognized standards, adequate risk reduction is achieved when the following requirements are met:

- All operating conditions and all intervention procedures have been considered
- The hazards have been eliminated or risks reduced to the lowest practicable level
- Any new hazards introduced by the risk reduction measures have been properly addressed
- Users and affected persons are sufficiently informed and warned about the residual risks
- Risk reduction measures are compatible with one another
- Sufficient consideration has 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 risk reduction measures do not adversely affect the working conditions for the operator or the usability of the machine

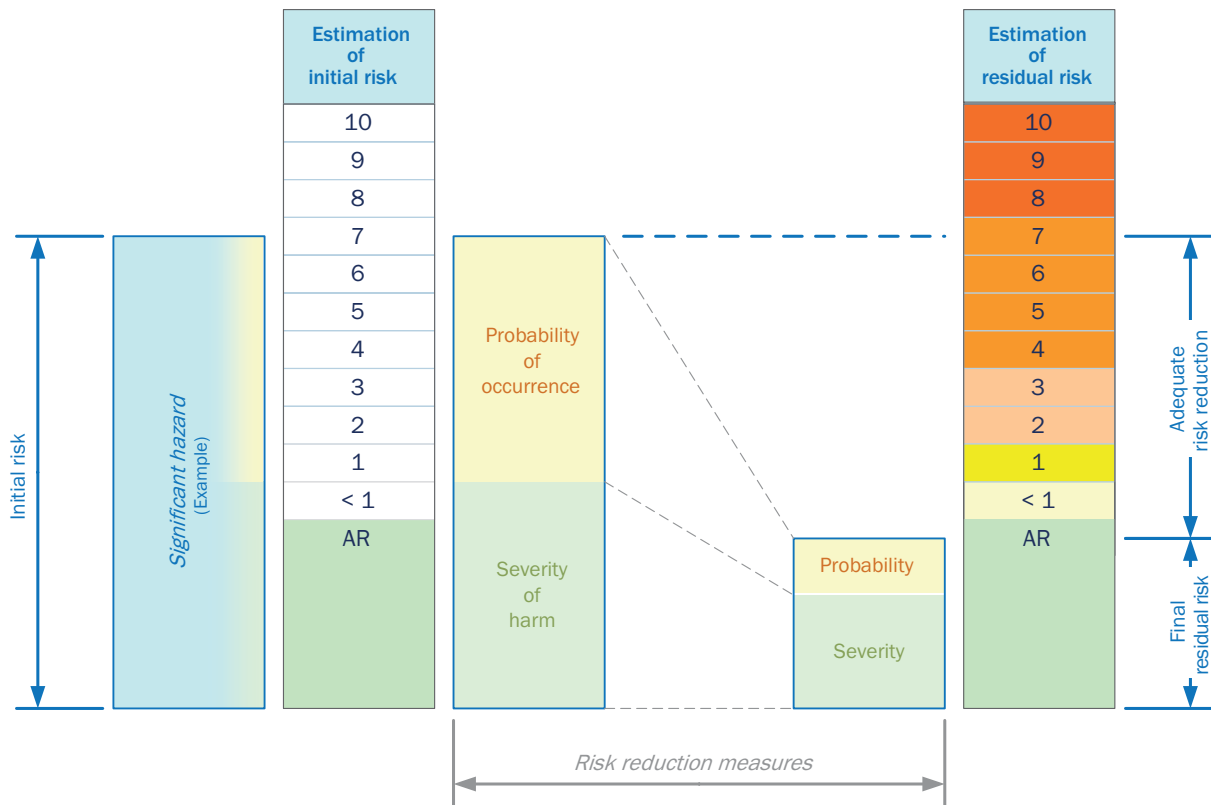


Fig. 3 – Adequate risk reduction (example)

**Risk index bridge**

In cases where a scale is used for the overall risk assessment and risk reduction process to determine the elements of risk, the output from the risk assessment tool used should be mapped appropriately to the performance level (PL) scale given in ISO 13849-1 or safety integrity level (SIL) scale given in IEC 62061. All necessary input information for the selection of the PL<sub>r</sub> is available from the overall risk assessment and risk reduction process according to ISO 12100. Therefore, a separate risk estimation for the application of ISO 13849-1 is not necessary. [Clause 5.2, ISO/TR 22100-2:2013, modified]

<b>Risk Index</b>	< 1	1	2 - 3	4 - 7	8 - 10
<b>PL<sub>r</sub></b> (ISO 13849-1)	a	b	c	d	e
<b>SIL</b> (IEC 62061)	÷	1		2	3

Tab. 3 – Required safety level

**Progressive iterations in risk assessment**

ESTIMATE INITIAL RISK

	Severity	Exposure	Avoidance	Occurrence		
				O1	O2	O3
Estimate initial risk	S1	E1-E3	A1, A2	< 1	< 1	< 1
	S2	E1	A1	< 1	< 1	1
			A2	< 1	1	1
		E2	A1	1	2	2
			A2	1	2	2
	S3	E3	A1	2	3	3
			A2	2	3	3
		E1	A1	3	4	4
			A2	3	4	4
	S4	E2	A1	4	5	5
			A2	5	5	5
		E3	A1	5	6	6
			A2	6	6	6
	S4	E1	A1	6	7	7
			A2	7	7	7
		E2	A1	7	8	8
A2			8	8	8	
E3		A1	8	9	9	
		A2	9	10	10	

The *initial* estimation shall start with the assumption that no risk reduction measures have been implemented. Personnel skills or competence and policies or procedures involving safety training, safe working procedures, or personal protective equipment are not taken into account.

ESTIMATE RISK FOLLOWING STEP 1

	Severity	Exposure	Avoidance	Occurrence				
				O1-O3	O1	O2	O3	
①	S1	E0	÷	< 1				
		E1-E3	A1, A2		< 1	< 1	< 1	
	S2	E0	÷		≤ 1			
			A1, A2			< 1	< 1	1
		E1	A1			< 1	1	1
			A2			1	2	2
		E2	A1			1	2	2
			A2			2	3	3
	E3	A1			2	3	3	
		A2			2	3	3	
	S3	E0	÷		1			
		E1	A1			3	4	4
			A2			3	4	4
		E2	A1			4	5	5
			A2			5	5	5
		E3	A1			5	6	6
A2				6	6	6		
S4	E0	÷		1				
	E1	A1			6	7	7	
		A2			7	7	7	
	E2	A1			7	8	8	
		A2			8	8	8	
	E3	A1			8	9	9	
A2				9	10	10		

The subsequent estimation following step 1 (see figure 2, ①) assumes that all *inherently safe design measures* have been implemented correctly.

S1 acc. to EN ISO 13849-1

S2 acc. to EN ISO 13849-1

ESTIMATE RISK FOLLOWING COMPLETION OF STEP 2

	Risk IN	Design and/or deployment	Risk OUT
		MSE and/or CSE	E0
②	8 - 10	M	1
	4 - 7	M	
	2 - 3	M	
	1	HR	< 1
	< 1	R	

The subsequent estimation following step 2 (see figure 2, ②) assumes that all **technical protective measures** have been implemented in accordance with relevant standards.

ESTIMATE RISK FOLLOWING COMPLETION OF STEP 3 BY THE DESIGNER

	Risk IN	Design and/or deployment	Risk OUT
		SIG and/or INS	
③	1	M	< 1
	< 1	HR	

The subsequent estimation following step 3 (see figure 2, ③) assumes that all **information for use measures** have been provided by the designer.

ESTIMATE RISK FOLLOWING COMPLETION OF STEP 3 BY THE USER

	Risk IN	Deployment only	Risk OUT
		ORG and/or PPE, as necessary	
③	< 1	HR	< 1
		HR	AR

The subsequent estimation following step 3 (see figure 2, ③) assumes that all the **information for use measures** provided by the designer have been implemented by the user. Achieving this level of residual risk depends on the user's ability to maintain risk reduction measures in good working order throughout the life cycle of the equipment.

Key

- MSE** Mechanical safeguarding equipment
- CSE** Control-related safeguarding equipment
- SIG** Information at machine (e.g., signal or signs)
- INS** Information in instruction handbook
- ORG** Safe working procedures
- PPE** Personal protective equipment

- M** One or a combination of these measures is **mandatory** for this risk level when reasonably practicable
- HR** One or a combination of these measures is **highly recommended** for this risk level
- R** One or a combination of these measures is **recommended** for this risk level as a lower recommendation to an HR recommendation

\* e.g. the loss of a part of the ear lobe may not impair the hearing ability (= medical condition)

**Quantification of the performance level (PL) achieved**

For each selected safety function to be carried out by safety-related parts of the control system (SRP/CS), the required performance level ( $PL_r$ ) shall be determined and documented. The determination of the required performance level is the result of the risk assessment and refers to the amount of risk reduction to be achieved by the safety-related parts of the control system.

For each individual safety function, the PL of the related SRP/CS shall match or exceed the required performance level ( $PL_r$ ). If this is not reasonably possible, an additional iteration of risk reduction may be necessary.

Situations in which the user is unable to make any change to existing designs (i.e., subsystems like power control elements), will be considered in part 4 of the white paper series "Integrating protective devices into (existing) control systems."

**Verification and validation of safety functions**

The validation of safety functions shall demonstrate that the SRP/CS, or combination of multiple SRP/CS, provides the safety function(s) in accordance with their characteristics as specified in the safety concept.

Validation of the specified characteristics of the safety functions shall be achieved by the application of appropriate measures from the following list:

- Functional analysis of schematics
- Review of the software
- Simulation
- Check if the hardware components are installed in the machine and integrated into the control system so they provide the part of the safety function as set out in the design rationale
- Check of the hardware components installed in the machine and details of the associated software to confirm their correspondence with the documentation (e.g., manufacturer, model, type, version)
- Functional testing of the safety functions in all operating modes of the machine to establish whether they meet the specified characteristics. The functional tests shall ensure that all safety-related outputs are achieved over their complete ranges and that they respond to safety-related input signals in accordance with the specification. The test cases are normally derived from the specifications, but could also include some cases derived from analysis of the schematics or software
- Extended functional testing to check incorrect operations as well as foreseeable abnormal signals or combinations of signals from any input source, including power interruption and restoration
- Check of the operator interface to the SRP/CS for meeting ergonomic principles

## Elements of risk

According to recognized standards, the risk associated with a particular hazardous situation depends on the following elements:

- a. The severity of harm
- b. The probability of occurrence of that harm, which is a function of:
  1. The exposure of person(s) to the hazard
  2. The occurrence of a hazardous event
  3. The technical and human possibilities to avoid or limit the harm

The SCRAM method uses the following definitions for the risk elements:

### Severity

Element		Simplified estimation (for comprehensive estimations use the relevant level 2 table)
S1	NEGLIGIBLE	None or negligible (trivial) injury (e.g., small bruises or superficial cuts) which either do not require any treatment or only treatment that is limited to simple and normally available first aid methods and equipment.
S2	SLIGHT	Injuries which can be treated with normally available first aid equipment but require the help of medically trained personnel. or The injury (medical condition) will be reversed within three months without treatment, but under monitoring of a medical practitioner.  NOTE: S2 corresponds to the S1 injury severity factor according to ISO 13849-1:2015, Annex A.
S3	SERIOUS	Injuries which require treatment by a medical practitioner but do not lead to permanent impairment. or Injuries which lead to the loss or permanent damage of parts of the human body (but not total loss) with reversible medical conditions.
S4	SEVERE	Injuries which lead to the death of one or more persons. or Injuries which require treatment by a medical practitioner in a hospital and may lead to a permanent impairment or loss of parts of the body, limbs, or senses/abilities.  NOTE: S4 corresponds to the S2 injury severity factor according to ISO 13849-1:2015, Annex A.

**Exposure to hazard**

Element		Simplified estimation (for comprehensive estimations use the relevant level 2 table)
E0	PREVENTED	<p>Foreseeable exposure or access to the hazard(s) is:                      eliminated / controlled / limited by inherently safe design measures,                      or                      exposure is prevented by mechanical and/or control-related safeguarding equipment which is selected and implemented as appropriate for the application. The implemented functional safety performance of the related SRP/CS must meet or exceed the required functional safety performance (<math>PL \geq PL_r</math>).</p> <p>NOTE: E0 is not an available selection during the initial risk estimation, which assumes that no risk reduction measures have been applied.</p>
E1	LOW	<p>LOW (E1) can always be assumed if:                      the exposure frequency is once per work shift,                      and                      the exposure duration is less than 3 minutes.</p> <p>NOTE: For values other than those listed, use Table 6 – Determination of exposure to hazard.</p>
E2	MEDIUM	Use Table 6 – Determination of exposure to hazard.
E3	HIGH	<p>HIGH (E3) can always be assumed, if:                      access to the hazard zone is required,                      and                      the exposure frequency is at least twice per work shift,                      and                      each time the exposure duration is equal to or higher than 1 minute.</p> <p>NOTE: For values other than those listed, use Table 6 – Determination of exposure to hazard.</p>

**Possibility of avoidance**

Element		Simplified estimation (for comprehensive estimations use the relevant level 2 table)
A1	AVOIDABLE	There are certain conditions that allow the avoidance of harm (such as skilled workers, slow movements, infrequent intervention, low-complexity processes, no sudden or unexpected movements with high acceleration).
A2	NOT AVOIDABLE	The avoidance is nearly impossible due to the lack of indication or awareness of the hazardous situation (such as fast hazardous events, insufficient surrounding space for evasion, high complexity processes, and/or the effect of routine on hazard awareness).

**Possibility of occurrence**

Element		Simplified estimation (for comprehensive estimations use the relevant level 2 table)
O1	LOW	<p>LOW (O1) can always be assumed if:                      the system is not prone to trouble,                      and                      the hazard frequency is less than 33% of the presence time.</p> <p>NOTE: For values other than those listed, use Table 8 – Determination of probability of occurrence.</p>
O2	MEDIUM	Use Table 8 – Determination of probability of occurrence.
O3	HIGH	<p>HIGH (O3) can always be assumed if:                      the system is prone to trouble,                      and                      the hazard frequency is equal to or higher than 66% of the presence time.</p> <p>NOTE: For values other than those listed, use Table 8 – Determination of probability of occurrence.</p>



### Optional risk parameter tables

**Overview**

If the main criteria for the risk scoring factors according to the “Elements of risk” section are not entirely suitable for a special application, there are additional tables for determining each factor on level 2 to improve the estimation. If this is still not adequate, there are two further tables related to the factors **Risk awareness** and **Avoiding possibility** on level 3.

	Level 1	Level 2	Level 3	
Elements of risk	Severity of harm	Injury level		
		Effect duration		
	Exposure to hazard	Need for access		
		Exposure frequency		
		Exposure duration		
		Exposed persons		
	Possibility of avoidance	Operator skills		Operator Information
		Risk awareness		Direct hazard perception
				Warning (indirect hazard perception)
		Avoidance experience		
		Avoidance possibility	Physical ability	
			Hazard appearance or speed	
			Surrounding space (allows avoidance)	
			Other circumstances	
	Probability of occurrence	Risk comparison		
		Hazard frequency		
		System reliability		
Accident history				
Damage to health likelihood				

Tab. 4 – Overview of risk parameter tables

**Table for the determination of harm severity**

The estimation of harm severity can be improved by combining the injury level and the effect duration of the harm.

	Injury level <sup>1</sup> Assess the worst possible effect to health. Consider if a repeated exposure to harm is possible and if accumulation of this exposure leads to such an effect	Harm effect duration <sup>2</sup>	Severity of harm
Level 2	<b>Negligible</b> <ul style="list-style-type: none"> <li>None or negligible (trivial) injury (e.g., small bruises or superficial cuts) which either do not require any treatment or only treatment that is limited to simple and normally available first aid methods and equipment.</li> </ul>	–	S1
	<b>Slight</b> <ul style="list-style-type: none"> <li>Injuries which can be treated with normally available first aid equipment but require the help of medically trained personnel.</li> </ul> or <ul style="list-style-type: none"> <li>The injury (medical condition) will be reversed within three months without treatment, but under monitoring of a medical practitioner.</li> </ul>	<b>Short</b> Recovery of medical condition within one week is expected.	S1
		<b>Medium</b> Recovery of medical condition within six weeks is expected.	S2
		<b>Long</b> Recovery of medical condition within three months is expected. <sup>3</sup>	S3
	<b>Serious</b> <ul style="list-style-type: none"> <li>Injuries which require treatment by a medical practitioner but do not lead to a permanent impairing.</li> </ul> or <ul style="list-style-type: none"> <li>Injuries which lead to the loss or permanent damage of parts of the human body (but not total loss) with reversible medical condition.</li> </ul>	<b>Short</b> Recovery of medical condition within one week is expected.	S2
		<b>Medium</b> Recovery of medical condition within three months is expected.	S3
		<b>Long</b> Recovery of medical condition requires more than three months.	S4
	<b>Severe</b> <ul style="list-style-type: none"> <li>Injuries which lead to the death of one or more persons.</li> </ul> or <ul style="list-style-type: none"> <li>Injuries which require treatment by a medical practitioner in a hospital and may lead to a permanent impairment or loss of parts of the body, limbs, or senses/abilities.</li> </ul>	–	S4

<sup>1</sup> Definitions describe the injury level in terms of a usual course of diagnostics, treatment, recovery.

<sup>2</sup> Definitions of harm effect duration are not applicable to the loss of parts of the body. In such cases the highest severity within the injury level shall be applied.

<sup>3</sup> For harm effect duration longer than 6 months, the injury level shall be considered as "serious".

S1 according to EN ISO 13849-1 Annex A

S2 according to EN ISO 13849-1 Annex A

Tab. 5 – Determination of harm severity

**Table for the determination of exposure to hazard**

The estimation of exposure to hazard can be improved by combining the need for access to the hazardous area by the affected persons during the intended task, the exposure frequency, and the duration and number of reasonably foreseeable persons exposed.

	Need for access or stay <sup>1</sup>	Exposure frequency [F]	Exposure duration [T]	Exposed persons <sup>2</sup>	
				One	More
Level 2	<b>Prevented</b> • Any exposure or access to the hazard(s) is completely prevented by guards or protective devices	-	-	E0	E0
	<b>Not required</b> • Access to hazard zone is not required by the task or • Other non-related persons are commonly not present near the hazard zone	Low [F < 2/shift]  A higher frequency implies that access is required or exposure is unavoidable	Short [T < 1min]	E1	E1
			Medium [1min ≤ T < 3min]	E1	E1
			Long [3min ≤ T < 15min]	E2	E2
			Continuous [15min ≤ T]	To be evaluated as "Need for access required"	
	<b>Required</b> • Access to hazard zone is required by the task or • Other non-related persons are commonly present in or near the hazard zone	Low [F < 2/shift]	Short [T < 1min]	E1	E1
			Medium [1min ≤ T < 3min]	E1	E1
			Long [3min ≤ T < 15min]	E1	E2
			Continuous [15min ≤ T]	E2	E3
		Medium [2/shift ≤ F < 20/shift]	Short [T < 1min]	E2	E2
			Medium [1min ≤ T < 3min]	E2	E3
			Long [3min ≤ T < 15min]	E3	E3
			Continuous [15min ≤ T]	E3	E3
		High [20/shift ≤ F]	Short [T < 1min]	E2	E2
			Medium [1min ≤ T < 3min]	E3	E3
			Long [3min ≤ T < 15min]	E3	E3
Continuous [15min ≤ T]			E3	E3	
				<b>Harm Exposure</b>	

<sup>1</sup> The need for access and the frequency of exposure are not necessarily related (e.g., command panel near a hazard zone).

<sup>2</sup> **One:** An operator or another task-related person is present in the hazard zone.

**More:** Several operators or other task-related persons are present in the hazard zone.

Tab. 6 – Determination of exposure to hazard

<sup>†</sup> See ISO 12100:2010, 6.3.2 to 6.3.4.

<sup>‡</sup> The impact of limiting by controls will be considered in part 4 of the white paper series “Integrating protective devices into (existing) control systems.”

**Table for the determination of possibility of avoidance**

The estimation of possibility of avoidance can be improved by combining foreseeable operator skills, the awareness of the risk, the possible experience of the operator on the avoidance of the risk as well as the possibility of such an avoidance.

	Operator skills	Risk awareness <sup>1</sup>	Avoidance experience	Avoidance possibility <sup>1</sup>		
				Almost possible (AP1)	Possible under certain circumstances (AP2)	Impossible (AP3)
Level 2	Skilled	High	Experienced	A1	A1	A1
			Unexperienced	A1	A1	A2
		Medium	Experienced	A1	A1	A2
			Unexperienced	A1	A1	A2
		Low	Experienced	A1	A2	A2
			Unexperienced	A1	A2	A2
	Unskilled or untrained	High	Experienced	A1	A1	A2
			Unexperienced	A1	A2	A2
		Medium	Experienced	A1	A2	A2
			Unexperienced	A1	A2	A2
		Low	Experienced	A2	A2	A2
			Unexperienced	A2	A2	A2
Unmanned operation or endangered persons are not related to the task	High	Experienced	A1	A1	A2	
		Unexperienced	A1	A1	A2	
	Medium	Experienced	A1	A1	A2	
		Unexperienced	A1	A2	A2	
	Low	Experienced	A2	A2	A2	
		Unexperienced	A2	A2	A2	
<b>Possibility of avoidance</b>						

<sup>1</sup> See subsequent tables if a more detailed analysis is required.

Tab. 7 - Determination of possibility of avoidance

**Table for the determination of probability of occurrence**

The estimation of probability of occurrence can be improved by combining the comparison of the risks on similar machinery, the system robustness, the accident and incident history, and the likelihood that the foreseen situation will lead to the assumed damage to health.

	Risk comparison	Harm occurrence frequency <sup>1</sup> (due to intended machine function)	Accident and incident history	Damage to health likelihood <sup>2</sup>						
				System is not prone to trouble <sup>3</sup>			System is prone to trouble <sup>3</sup>			
				Seldom	Possible	Definite	Seldom	Possible	Definite	
<b>Level 2</b>	Same as similar machines or systems	List similar machines or systems and provide reliable comparison data		-	-	-	-	-	-	
	Other than similar machines or systems	Hazard frequency < 33% of exposure time	No accidents or heavy incidents reported (reliable data available)	01	01	01	02	02	02	
			Seldom accidents or heavy incidents reported ( $\leq 5\%$ of running systems)	01	01	01	02	02	02	
			Several accidents or heavy incidents reported ( $> 5\%$ of running systems)	01	01	01	02	02	02	
		Hazard frequency $33\% \leq x < 66\%$ of exposure time	No accidents or heavy incidents reported (reliable data available)	01	01	02	02	02	03	
			Seldom accidents or heavy incidents reported ( $\leq 5\%$ of running systems)	01	02	02	02	03	03	
			Several accidents or heavy incidents reported ( $> 5\%$ of running systems)	01	02	03	02	03	03	
		Hazard frequency $\geq 66\%$ of exposure time	No accidents or heavy incidents reported (reliable data available)	01	02	02	02	03	03	
			Seldom accidents or heavy incidents reported ( $\leq 5\%$ of running systems)	02	02	03	03	03	03	
			Several accidents or heavy incidents reported ( $> 5\%$ of running systems)	03	03	03	03	03	03	
					<b>Probability of occurrence</b>					

<sup>1</sup> **Harm occurrence frequency** is based on intended machine function with a statistical hazard presence, e.g. from infrequent or noncyclical machine functions.

<sup>2</sup> **Seldom:** Harm occurrence is very seldom.

**Possible:** Harm occurrence is possible but not necessarily the result of an exposure.

**Definite:** Harm occurrence is usually a result of the exposure.

<sup>3</sup> **Harm occurrence frequency is increased** by effects of non-intended machine behavior, e.g. from machine malfunction (system reliability).

Tab. 8 – Determination of probability of occurrence

<sup>h</sup> Experimental Analysis of Tools Used for Estimating Risk Associated with Industrial Machines. Y. Chinniah et al. IRSST Report R-684. ISBN: 978-2-89631-537-6 (PDF) February 2011.

<sup>i</sup> Institut de recherche Robert-Sauvé en santé et en sécurité du travail. De Maisonneuve Ouest, Montréal (Québec) H3A 3C2. Canada.

**Method for the determination of probability of occurrence**

- In a first step, wherever there is data or experience available, compare the risk(s) with the risk of similar machinery.
- Where this is not possible, the harm occurrence frequency due to the intended machine function shall be evaluated, i.e., the percentage of hazard presence in relation to the exposure time of a person.  
 Note: If the hazard is constantly present, the hazard frequency should be set to  $\geq 66\%$ .
- In a second step, if reliable accident or incident history information is available, it should be considered.  
 Note: If no machine specific information is available, it is also possible to utilize information based on experience from similar machinery.
- In a third step, the system robustness shall be evaluated based on the non-intended behavior of the machine, i.e., whether the machine or its process is prone to trouble or not.
- Finally, the damage to health likelihood shall be considered, i.e., if the occurrence of the hazard is definitely or possibly or seldom leading to a damage of health.

**Table for the determination of risk awareness**

The estimation of possible risk awareness can be improved by combining the availability and quality of the information for the operator, the possibility of the direct risk perception, and the availability of warning means (i.e., alarms and warning signs).

	Operator Information	Direct hazard perception <sup>1</sup>	Warning (indirect hazard perception) <sup>2</sup>		
			Difficult	Possible	Easy
Level 3	<b>Low</b> Operator is not informed about potential hazards or no operator information is available	Difficult	Low	Medium	High
		Possible	Low	Medium	High
		Easy	Medium	Medium	High
	<b>Medium</b> Operator is not completely informed about potential hazards or operator information is available, but incomplete	Difficult	Low	Medium	High
		Possible	Medium	Medium	High
		Easy	Medium	Medium	High
	<b>High</b> Operator is completely informed about potential hazards and operator information is available and complete	Difficult	Medium	Medium	High
		Possible	Medium	High	High
		Easy	High	High	High
<b>Risk awareness</b>					

<sup>1</sup> **Direct hazard perception**

- Difficult:** Due to its nature, hazard is difficult to perceive (e.g., rotating blank shaft).
- Possible:** In some circumstances the hazards can not be perceived.
- Easy:** Hazards will almost always be perceived.

<sup>2</sup> **Indirect hazard perception**

- Difficult:** No hazard warnings are available, readable, or can be recognized as such.
- Possible:** Warnings are available (and readable) but not always perceptible.
- Easy:** For all hazards the warnings are available, readable, and perceptible.

Tab. 9 – Determination of risk awareness

**Table for the determination of avoiding possibility**

The estimation of possibility to avoid the harm can be improved by combining the foreseen physical ability of the operator, the speed at which the hazard or the hazardous situation may appear, the surrounding space which may improve (or hinder) the avoidance of the harm, and other circumstances which depend on the specific machine or application.

	Physical ability	Hazard appearance or speed	Surrounding space allows avoidance	Other avoidance circumstances <sup>1</sup>		
				Hinder	No effect	Assist
Level 3	Hindered Endangered person is physically unable to avoid the hazard	Sudden	No	AP3	AP3	AP2
			Yes	AP3	AP3	AP2
		Fast	No	AP3	AP3	AP2
			Yes	AP3	AP2	AP2
		Slow	No	AP3	AP3	AP2
			Yes	AP3	AP2	AP1
	Possible Endangered person is physically able to avoid the hazard	Sudden	No	AP3	AP2	AP1
			Yes	AP3	AP2	AP1
		Fast	No	AP3	AP2	AP1
			Yes	AP2	AP1	AP1
		Slow	No	AP2	AP1	AP1
			Yes	AP2	AP1	AP1
				Avoidance possibility		

<sup>1</sup> **Hinder** prevents hazard avoidance.

**No effect** to avoid the hazard.

**Assist** hazard avoidance.

Tab. 10 – Determination of avoidance possibility

## Technical protective measures

### Interrelation between ISO 12100 and ISO 13849-1

ISO 13849-1 is relevant for cases in which a risk assessment has resulted in a risk reduction measure (e.g., interlocking guard) that relies on a safety-related control system. In those cases, the safety-related control system has to perform a safety function. The application of ISO 13849-1 is restricted to those cases only.

For the correct application of ISO 13849-1, basic input information resulting from the application of the overall risk assessment and risk reduction process for the particular machine design is necessary. Based on this input information, the safety-related parts of the control system can be appropriately designed according to ISO 13849-1. The information (resulting from a detailed design of safety-related parts of the control system) relevant for the integration of the SRP/CS into the machine design then needs to be considered in the overall risk assessment and risk reduction process.

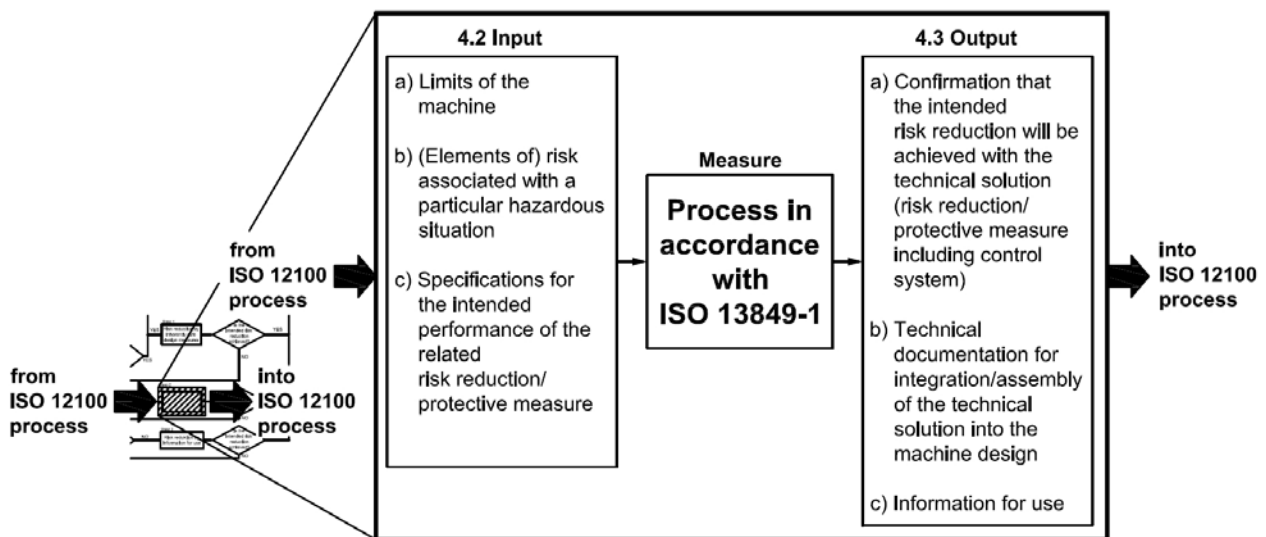


Fig. 4 – Figure 3, ISO/TR 22100-2:2013

### Safeguarding [Clause 8.3, ISO/TR 14121-2:2012]

If hazards cannot be eliminated or risks cannot be reduced adequately by design measures, safeguarding (risk reduction measures using guards and protective devices) should be applied. Such risk reduction measures shall either restrict exposure to hazards (lower the probability of the hazardous event) or improve the possibility of avoiding or limiting harm.

When risk is reduced with the use of safeguards such as those listed below in a) and b), there is little, if any, impact on the severity of harm. The greatest impact is on exposure (as long as the safeguard is being used as intended and is functioning properly):<sup>f</sup>

- a) Fixed guards, fencing, or enclosures for the prevention of access to hazardous areas
- b) Interlocking guards preventing access to hazardous areas (e.g., interlocks with or without guard locking or interlock keys).

When risk is reduced with the use of safeguards such as those listed below in c) to e), there is little, if any, impact on the severity of harm. The greatest impact is on the occurrence of a hazardous event, with little impact on exposure:

- c) Sensitive protective equipment (SPE) for the detection of persons entering into, or being present in, the hazardous area (e.g., light curtains, pressure-sensitive mats)
- d) Devices associated with safety-related functions of the control system of the machine (e.g., enabling devices, limited movement control devices, hold-to-run control devices)
- e) Limiting devices<sup>g</sup> (e.g., overloading and moment limiting devices, devices for limiting pressure or temperature, over-speed switches, devices for monitoring emissions).

<sup>f</sup> See ISO 12100:2010, 6.3.2 to 6.3.4.

<sup>g</sup> The impact of limiting by controls will be considered in part 4 of the white paper series "Integrating protective devices into (existing) control systems."



**Complementary protective measures and equipment**

Complementary protective measures and equipment may have to be implemented as required by the intended use and the reasonably foreseeable misuse of the machine to achieve further risk reduction. Examples of complementary protective measures and equipment whose greatest effect is on the ability of avoiding or limiting harm are:

- Elements to achieve emergency stop function
- Measures for the escape and rescue of trapped persons
- Measures for safe access to machinery
- Provision of means for isolation and dissipation of hazardous energy
- Provisions for easy and safe handling of machines and their heavy component parts

An example of complementary protective measures and equipment, whose greatest effect is on exposure, are measures for isolation and dissipation of hazardous energy (e.g., isolation valves or switches, locking devices, and mechanical blocks to prevent movement).

ANNEX: Examples of the evaluation of harm severity, ANSI B11.0-2019 3<sup>rd</sup> edition

Injury type	Catastrophic (S4)
<p><b>Burns, thermal</b> <b>Hot surface<sup>1 *</sup></b></p> <p>The severity of injury is relative to the amount of body surface area, the duration of exposure, and the temperature of the hot surface.</p>	<p>3rd degree burns typically caused by temperatures &gt; 68 °C (&gt; 154 °F) with exposure durations of one second, and on skin surface areas over 1% or more of the body, i.e., palm of hand.</p>
<p><b>Burns, thermal</b> <b>Vapor or splash of viscous material<sup>1, 5</sup></b></p> <p>Vapor exposure assumes instantaneous contact; viscous materials assume continuous contact greater than one second.</p>	<p>3rd degree burns typically caused by temperatures &gt; 60 °C (&gt; 140 °F) and on skin surface areas over 1% or more of the body, i.e., palm of hand.</p> <p>Inhalation burns requiring respiratory assistance.</p>
<p><b>Burns/injury, wave energy</b></p>	<p>Burns, injury, or wave energy exposure that could result in death or permanently disabling injury such as blindness or amputation.</p>
<p><b>Lacerations or amputations<sup>2, 5 **</sup></b></p>	<p>Lacerations or amputations* that could result in death or permanently disabling injury such as blindness.</p> <p>* For example, amputations of:</p> <ul style="list-style-type: none"> <li>• Hand</li> <li>• Foot</li> <li>• Arm</li> <li>• Leg</li> <li>• Eye</li> </ul>
<p><b>Fractures<sup>2, 5</sup></b></p> <p>Fracture forces are derived from literature search that identified pain and fracture thresholds at 150 N (33.7 lbf), 400 N (89.9 lbf) and 2000 N (449.6 lbf) using an 80 mm (3.15 in) diameter load cell.</p>	<p><b>399.9 kPa (58 psi)</b></p> <p>For example, fractures of spinal column.</p>

Serious (S3)	Moderate (S2)	Minor (S1)
<p>3rd degree burns typically caused by temperatures &gt; 68 °C (&gt; 154 °F) with exposure durations of one second, and on skin surface areas less than 1% of the body.</p>	<p>2nd degree burns typically caused by temperatures 60 °C to 68 °C (140 °F to 154 °F) with exposure durations of one second.</p>	<p>1st degree burns typically caused by temperatures 44 °C to 59 °C (111 °F to 139 °F) with exposure durations of one second.</p>
<p>3rd degree burns typically caused by temperatures &gt; 60 °C (&gt; 140° F) and on skin surface areas less than 1% of the body.</p> <p>Inhalation burns.</p>	<p>2nd degree burns typically caused by temperatures 44 °C to 59 °C (111 °F to 139 °F).</p>	<p>1st degree burns typically caused by temperatures 38 °C to 43 °C (100 °F to 110 °F).</p>
<p>Loss of eye, vision impairment, or amputation (see ANSI B11.21).</p> <p>Central corneal abrasion.</p> <p>Typically caused by class 4 laser or high pressure xenon arc lamp (intense UV/Vis/IR emitted, and potential for bulb explosion).</p>	<p>Temporary loss of vision.</p> <p>Typically caused by class 3B laser, UV-B lamps (280 nm to 320 nm).</p>	<p>Superficial, peripherally located corneal abrasion, ulceration, burn, or foreign object.</p> <p>Typically caused by class 3A laser, class 2 laser, UV-A lamps (320 nm to 400nm).</p>
<p>Lacerations of the head or face requiring sutures or other closure in lieu of sutures or partial blindness typically caused by:</p> <ul style="list-style-type: none"> <li>• Flying projectiles</li> <li>• Stationary sharp edges</li> <li>• Blunt, sharp edges</li> </ul> <p>Amputation of finger(s) or toe(s), typically caused by:</p> <ul style="list-style-type: none"> <li>• Sharp edges mechanically in motion (e.g., rotating, reciprocating, shearing)</li> </ul>	<p>Lacerations, not involving the face, requiring sutures or other closure in lieu of sutures typically caused by:</p> <ul style="list-style-type: none"> <li>• Stationary sharp edges</li> <li>• Blunt, sharp edges</li> </ul> <p>External (deep) lacerations (&gt; 10 cm long on body / &gt; 5 cm long on face) requiring stitches.</p>	<p>Minor/superficial cuts requiring bandaging treatment, typically caused by:</p> <ul style="list-style-type: none"> <li>• Stationary blunt surfaces</li> <li>• Offset, blunt edges with loads less than 28 kPa (4 psi)</li> </ul>
<p>Fractures of long bones in arms or legs or fractures of the skull or spine,* typically caused by loads exceeding 297 kPa (43 psi) and 399.9 kPa (58 psi) under certain test conditions.</p> <p>* For example:</p> <ul style="list-style-type: none"> <li>• Ankle</li> <li>• Leg (femur and lower leg)</li> <li>• Hip</li> <li>• Thigh</li> <li>• Skull</li> <li>• Spine (minor compression fracture)</li> <li>• Jaw (severe)</li> <li>• Larynx</li> <li>• Multiple rib fractures</li> <li>• Blood or air in chest</li> </ul>	<p>Fractures of small bones,* typically caused by loads between 297 kPa (43 psi) and 399.9 kPa (58 psi).</p> <p>* For example:</p> <ul style="list-style-type: none"> <li>• Extremities (finger, toe, hand, foot)</li> <li>• Wrist</li> <li>• Arm</li> <li>• Rib</li> <li>• Sternum</li> <li>• Nose</li> <li>• Tooth</li> <li>• Jaw</li> <li>• Bones around eye</li> </ul>	<p>Contusions and skin abrasions typically caused by loads between 83 kPa (12 psi) and 297 kPa (43 psi) under certain test conditions. No physical signs typically caused by dynamic loads less than 83 kPa (12 psi) under certain test conditions.</p>

Injury type	Catastrophic (S4)	
Crushing <sup>5</sup>	Spinal cord Mid-low neck Chest (massive crushing) Brain stem	
Bruising (abrasion, contusion, swelling, edema) <sup>2, 5</sup>	Brain stem Spinal cord causing paralysis	
Dislocation <sup>5</sup>	Spinal column	
Piercing, puncturing <sup>5</sup>	Aorta Heart Bronchial tube Deep injuries in organs (liver, kidney, bowel, etc.)	
Entrapment/pinching <sup>5</sup>	Fatal suffocation/strangulation	
Concussion <sup>5</sup>	Coma	
Eye injury, foreign body in eye <sup>5</sup>	Permanent loss of sight (one or both eyes)	
Hearing injury, foreign body in ear <sup>5</sup>	Permanent loss of hearing (one or both ears)	

	<b>Serious (S3)</b>	<b>Moderate (S2)</b>	<b>Minor (S1)</b>
	Extremities (fingers, toe, hand, foot) Elbow Ankle Wrist Forearm Leg Shoulder Trachea Larynx Pelvis	-	-
	Trachea Internal organs (minor) Heart Brain Lung, with blood or air in chest	Major > 25 cm <sup>2</sup> on face > 50 cm <sup>2</sup> on body	Contusions and skin abrasions typically caused by loads between 83 kPa (12 psi) and 297 kPa (43 psi) under certain test conditions. No physical signs typically caused by loads less than 83 kPa (12 psi) under certain test conditions.  Superficial ≤ 25 cm <sup>2</sup> on face ≤ 50 cm <sup>2</sup> on body
	Ankle Wrist Shoulder Hip Knee Spine	Extremities (finger, toe, hand, foot) Elbow Jaw Loosening of tooth	-
	Eye (with no permanent loss of sight) Internal organs Chest wall	Deeper than skin Abdominal wall (no organ involved)	<ul style="list-style-type: none"> <li>Limited depth, only skin involved</li> </ul>
	(Use as appropriate the final outcomes of bruising, crushing, fracture, dislocation, amputation, as applicable)	-	<ul style="list-style-type: none"> <li>Minor pinching</li> </ul>
	Prolonged unconsciousness	Very short unconsciousness (minutes)	-
	Partial loss of sight	Temporary loss of sight	<ul style="list-style-type: none"> <li>Temporary pain in eye without need for treatment</li> </ul>
	Partial loss of hearing	Temporary impairment of hearing	<ul style="list-style-type: none"> <li>Temporary pain in ear without need for treatment</li> </ul>

Injury type	Catastrophic (S4)	
<p><b>Substances</b>  <b>Irritation, dermatitis, inflammation, or corrosive effect of substances (inhalation, dermal)<sup>5</sup></b>                      Refer to OSHA, NIOSH, ACGIH, NFPA 45-2011, and EPA for details concerning specific substances.</p>	<p>Lungs, requiring respiratory assistance                      Asphyxia                      Irreversible systemic effects</p>	
<p><b>Allergic reaction or sensitization<sup>5</sup></b>                      Refer to OSHA, NIOSH, ACGIH, NFPA 45-2011, and EPA for details concerning specific substances.</p>	<p>Anaphylactic reaction, shock                      Fatality</p>	
<p><b>Electrical</b>                      Shock factors affecting the human body include current and voltage, resistance, path through the body, duration of contact, the individual's health, and promptness of first aid. Refer to NFPA 70E and 29 CFR 1910.333.</p>	<p>Major burns and irreversible body damage at several amps</p>	
<p><b>Sprain, strain, musculoskeletal disorder<sup>5</sup></b></p>	<p>-</p>	
<p><b>Neurological disorders<sup>5</sup></b></p>	<p>-</p>	

	<b>Serious (S3)</b>	<b>Moderate (S2)</b>	<b>Minor (S1)</b>
	Lungs, respiratory insufficiency, chemical pneumonia Partial loss of sight Corrosive effects	Reversible eye damage Reversible systemic effects Inflammatory effects	<ul style="list-style-type: none"> <li>Slight local irritation</li> </ul>
	Strong sensitization, provoking allergies to multiple substances	Allergic reaction, widespread allergic contact dermatitis	<ul style="list-style-type: none"> <li>Mild or local allergic reaction</li> </ul>
	Breathing difficulties / unconsciousness at 30 mA; possible heart fibrillation at 50 mA to 100 mA (fatal if continued); severe burns and muscle contractions at 200 mA to 300 mA	Painful shock at 3 mA; muscle contractions at 5 mA; person can let go at an average of 10 mA	No physical signs but threshold of feeling; tingling sensation can be felt at 1 mA to 2 mA
	Ligament or tendon Rupture/tear* Muscle tear* Whiplash *If not leading to permanent functional losses	Knee ligaments strain	<ul style="list-style-type: none"> <li>Extremities</li> <li>Joints</li> <li>Spine (no dislocation or fracture)</li> </ul>
	Triggered epileptic seizure	-	-

### Injury and severity correlations

This informative table will be published in the upcoming (third) issue of ANSI B11.0. This table provides guidance on evaluating severity and has been developed based on “post-incident” and test data. The values in the table should not be used as strict definitions of severity. The reader should be cautioned that variations to this table are acceptable.

This table provides values which have been determined from literature referenced below. Values may differ based on application-specific data or individual susceptibilities. Some detailed injury information presented below may be useful in evaluating historical data with known hazardous events.

\*Note: Contact with a hot surface is based upon contact with aluminum less than one second. Temperature threshold will vary dependent upon the material contacted and the duration of contact. For data on burn thresholds of contact with other materials and for more information on assessing the risk of burning, see ISO 13732-1.

\*\*Note: Fracture and amputation force are derived from literature search that identified pain and fracture thresholds at 150 N (33.7 lbf), 400 N (89.9 lbf), and 2000 N (449.6 lbf) using an 80 mm (3.15 in) diameter load cell.

<sup>1</sup> Chengalur, R.: Kodak’s Ergonomic Design for People at Work. New York: Van Nostrand Reinhold, 2004.

<sup>2</sup> Mewes, D. and F. Mauser: “Safeguarding Crushing Points by Limitation of Forces.” International Journal of Occupational Safety and Ergonomics. 9(2003): 177-191.

<sup>3</sup> ANSI Z136.1, Safe Use of Lasers, New York: ANSI 2007.

<sup>4</sup> Hagan, P.: Accident Prevention Manual for Business & Industry – Engineering & Technology. 12th Edition. NSC, Itasca, IL 2001.

<sup>5</sup> Official Journal of the European Union L22, 26.1, 2010 p. 64, “Table 3 Severity of Injury.”

#### NORMATIVE REFERENCES

ANSI B11.0-2020:	Safety of Machinery
ISO 12100:2010:	Safety of machinery – General principles for design – Risk assessment and risk reduction
ISO 13849-1:2015:	Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design
ISO/TR 14121-2:2012:	Safety of machinery – Risk assessment – Part 2: Practical guidance and examples of methods
ISO/TR 22100-2:2013:	Safety of machinery – Relationship with ISO 12100 – Part 2: How ISO 12100 relates to ISO 13849-1
ISO/IEC Guide 51:2014:	Safety aspects – Guidelines for their inclusion in standards
IEC 62061:2005:	Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems
RIA TR R15.306-2016:	Technical Report for Industrial Robots and Robot Systems – Safety Requirements – Task-based Risk Assessment Methodology