SICK AG WHITE PAPER

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

SCALABLE RISK ANALYSIS AND EVALUATION METHOD (SCRAM), 2019-02

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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 risks identified or newly emerged.

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CONTENT

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Introduction

Scope

Machine risk assessment consists of a series of steps used to examine the hazards associated with machines and 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. However, the risk associated with those hazards shall be reduced to an acceptable or tolerable level[a]. 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 the elimination of 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

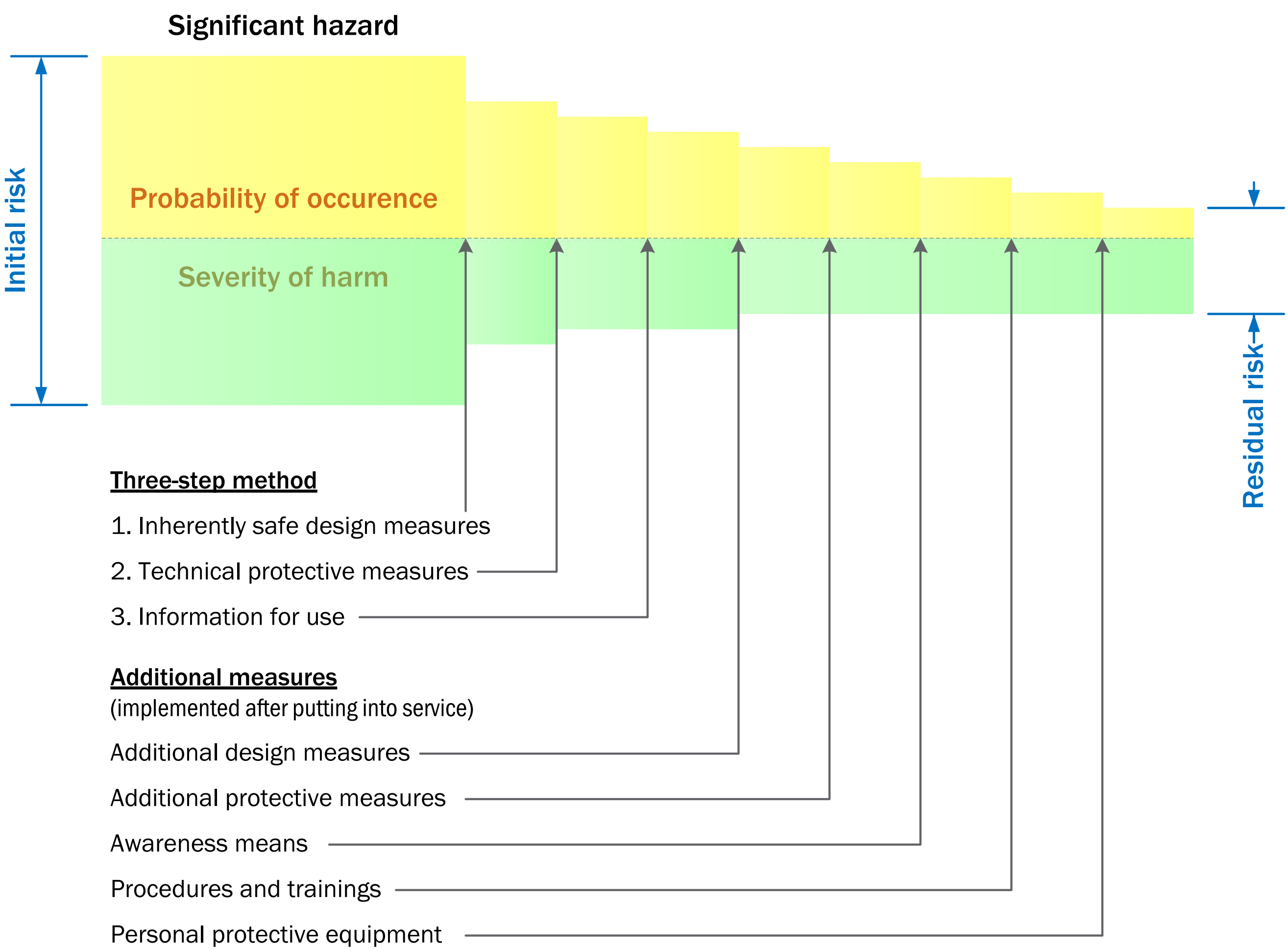


Fig. 1 – Overall risk reduction

[a] 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 chapter “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[b] 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.

[b] “Putting into service” means the first use of machinery for its intended purpose by the user.

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.

Schematic representation

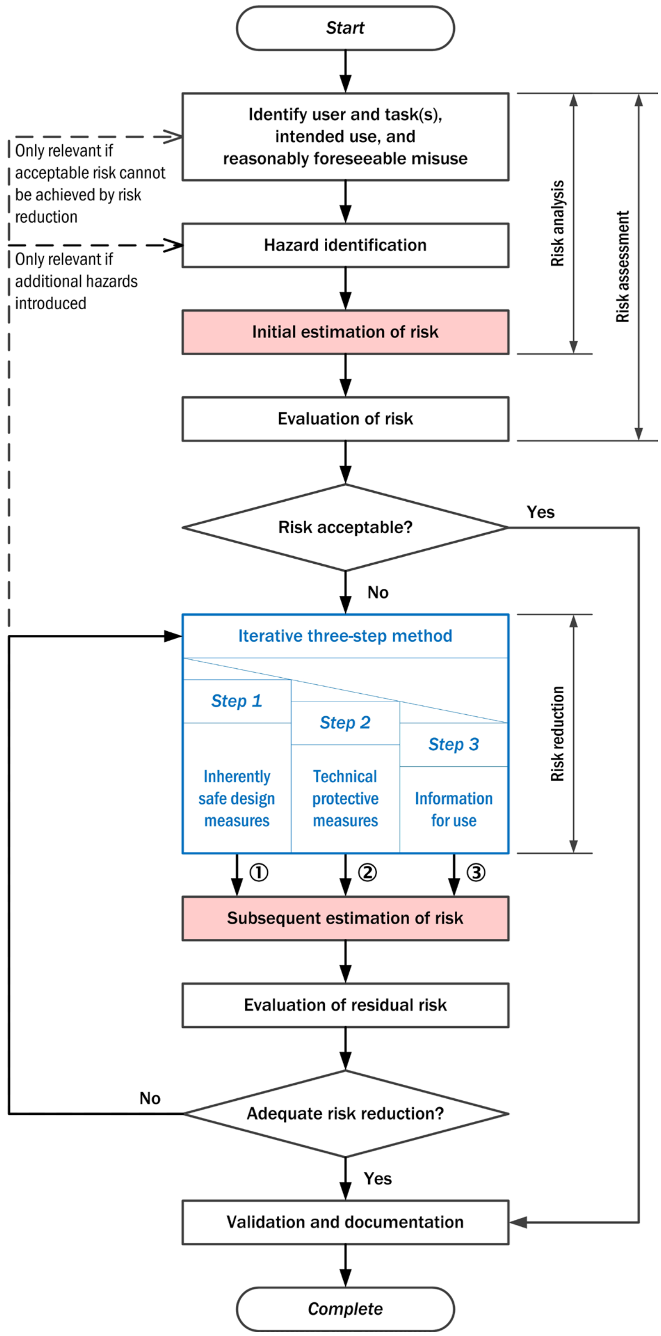


Fig. 2 – Risk reduction process [based on ISO/IEC Guide 51:2014]

Safeguarding[c]

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

[c] In the US addressed as "engineering controls."

Adequate risk reduction

Residual risk

The residual risk (risk remaining after risk reduction measures have been implemented) 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.

The residual risks 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.

Scalable Risk Analysis and Evaluation Method (SCRAM)[d]

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	Occurence			
			O1 – O3	O1	O2	O3
S1	÷	÷		0	0	0
S2	F0	÷	0 / 1			
	F1/F2	A1		0	0	1
		A2		0	1	2
S3	F0	÷	1			
	F1	A1		1	2	3
		A2		2	3	4
	F2	A1		3	4	5
		A2		4	5	6
S4	F0	÷	1			
	F1	A1		5	6	7
		A2		6	7	8
	F2	A1		7	8	9
		A2		8	9	10
			Risk index			

Tab. 1 – SCRAM (main table)

Key

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

[d] 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 chapter “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: F0 “prevented.” If functional safety is used as a risk reduction measure, the safety performance (PL) of the SRP/CS implemented has to at least meet and may exceed the minimum required safety performance (PL ≥ PLr).

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

<table>
<tr><th rowspan="2"></th><th>Risk IN</th><th colspan="2">Risk Reduction Measures</th><th>Risk OUT</th></tr>
<tr><th></th><th>STEP 2
(MSE and/or CSE)</th><th>STEP 3
(SIG, INS, ORG and/or PPE, as necessary)</th><th></th></tr>
<tr><td rowspan="5">Step 2</td><td>8 - 10</td><td>M</td><td rowspan="5">n/a</td><td rowspan="3">1</td></tr>
<tr><td>4 - 7</td><td>M</td></tr>
<tr><td>2 - 3</td><td>M</td></tr>
<tr><td>1</td><td>HR</td><td rowspan="2">0</td></tr>
<tr><td>0</td><td>R</td></tr>
<tr><td rowspan="2">Step 3</td><td>1</td><td rowspan="2">n/a</td><td>HR</td><td rowspan="2">0</td></tr>
<tr><td>0</td><td>R</td></tr>
</table>

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

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
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

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

Risk evaluation

The objectives of risk evaluation are:

- To decide which further risk reduction is required (if any)
- To determine whether the required risk reduction has been achieved without introducing further hazards or increasing other risks

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 is given:

- 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

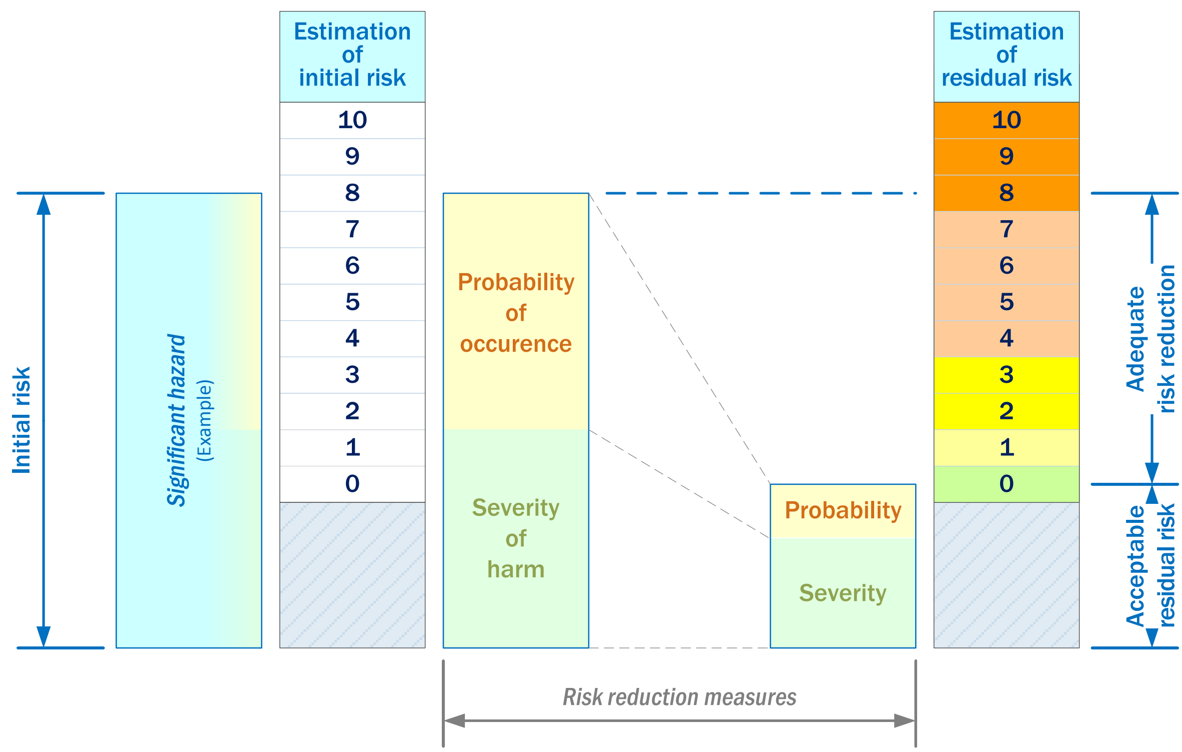


Fig. 3 – Adequate risk reduction (example)

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 PLr 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]

Risk	0	1	2 - 3	4 - 7	8 - 10
PL_r	a	b	c	d	e
SIL	÷	1		2	3

Tab. 3 – Required safety level

Progressive iterations in risk assessment

ESTIMATE INITIAL RISK

	Severity	Exposure	Avoidance	Occurence O1	Occurence O2	Occurence O3
START	S1	÷	÷	0	0	0
	S2	F1/F2	A1	0	0	1
			A2	0	1	2
	S3	F1	A1	1	2	3
			A2	2	3	4
		F2	A1	3	4	5
			A2	4	5	6
	S4	F1	A1	5	6	7
			A2	6	7	8
		F2	A1	7	8	9
			A2	8	9	10
				Risk index		

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	Occurence O1 – O3	Occurence O1	Occurence O2	Occurence O3
Step 1	S1	÷	÷		0	0	0
	S2	F0	÷	0 / 1			
		F1/F2	A1		0	0	1
			A2		0	1	2
	S3	F0	÷	1			
		F1	A1		1	2	3
			A2		2	3	4
		F2	A1		3	4	5
			A2		4	5	6
	S4	F0	÷	1			
		F1	A1		5	6	7
			A2		6	7	8
		F2	A1		7	8	9
			A2		8	9	10
				Risk index			

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

ESTIMATE RISK FOLLOWING STEP 2

	Risk IN	Risk reduction	Risk OUT
		MSE and/or CSE	[F0]
Step 2	8-10	M	1
	4-7	M	
	2+3	M	
	1	HR	0
	0	R	

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

ESTIMATE RISK FOLLOWING STEP 3

	Risk IN	Risk reduction	Risk OUT
		SIG, INS, ORG and/or PPE, as necessary	
Step 3	1	HR	0
	0	R	

The subsequent estimation following step 3 (see figure 2, ③) assumes that measures indicated by ***information for use*** have been implemented. Maintaining 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
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

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 (PLr) 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 (PLr). 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

S1 **Interpretation:**	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 **Interpretation:**	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 **Interpretation:**	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 condition[e].
S4 **Interpretation:**	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.

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

Exposure to hazard

F0 **Interpretation:**	PREVENTED 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 (PL ≥ PLr). NOTE: F0 is not an available selection during the initial risk estimation, which assumes that no risk reduction measures have been applied.
F1 **Interpretation:**	LOW Twice or less per work shift ***and*** less than 15 minutes cumulated exposure per work shift.
F2 **Interpretation:**	HIGH More than twice per work shift ***or*** more than 15 minutes cumulated exposure per work shift.

Possibility of avoidance

A1 **Interpretation:**	AVOIDABLE (AVOIDANCE POSSIBLE UNDER CERTAIN CONDITIONS) 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 **Interpretation:**	NOT AVOIDABLE (AVOIDANCE NEARLY IMPOSSIBLE) 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

Q1 **Interpretation:**	LOW Machine malfunctions (including the control system), jams, or malfunctions due to the properties of the processed materials, or inappropriate human behavior are seldom.
Q2 **Interpretation:**	MEDIUM Machine malfunctions (including the control system), jams, or malfunctions due to the properties of the processed materials, or inappropriate human behavior are foreseeable.
Q3 **Interpretation:**	HIGH Machine malfunctions (including the control system), jams, or malfunctions due to the properties of the processed materials, or inappropriate human behavior have to be expected with certain regularity.

Optional risk parameter tables

Overview

If the main criteria for the risk scoring factors according to chapter "Elements of risk" 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.

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

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.

Level 2 – Injury level[1] 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[2]	Severity of harm
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.	-	S1
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.	**Short** Recovery of medical condition within one week is expected.	S1
	Medium Recovery of medical condition within six weeks is expected.	S2
	Long Recovery of medical condition within three months is expected.[3]	S3
Serious • Injuries which require treatment by a medical practitioner but do not lead to a permanent impairing. or • Injuries which lead to the loss or permanent damage of parts of the human body (but not total loss) with reversible medical condition.	**Short** Recovery of medical condition within one week is expected.	S2
	Medium Recovery of medical condition within three months is expected.	S3
	Long Recovery of medical condition requires more than three months.	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.	-	S4

[1] Definitions describe the injury level in terms of a usual course of diagnostic, treatment, recovery.

[2] 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.

[3] For harm effect duration longer then six months the injury level shall be considered as "serious".

S1 according to EN ISO 13849-1 Annex A (blue)

S2 according to EN ISO 13849-1 Annex A (red)

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[1]	Exposure frequency	Exposure duration	Number of exposed persons[2]		
				Certain	One	More
Level 2	**Prevented** • Any exposure or access to the hazard(s) is completely prevented by guards or protective devices	-	-	F0	F0	F0
	Not required • Access to hazardous area is not required by the task or • Other non-related persons are commonly not present near the hazardous area	**Low [F < 2/shift]**	**Short [T < 1min]**	F1	F1	F1
			Medium [1min ≤ T < 3min]	F1	F1	F1
			Long [3min ≤ T]	F1	F1	F2
		Medium [2/shift ≤ F < 20/shift]	**Short [T < 1min]**	F1	F1	F2
			Medium [1min ≤ T < 3min]	F1	F1	F2
			Long [3min ≤ T]	F1	F1	F2
		High [20/shift ≤ F]	**Short [T < 1min]**	F1	F1	F2
			Medium [1min ≤ T < 3min]	F1	F2	F2
			Long [3min ≤ T]	F1	F2	F2
	Required • Access to hazardous area is required by the task or • Other non-related persons are commonly present in or near the hazardous area	**Low [F < 2/shift]**	**Short [T < 1min]**	F1	F1	F2
			Medium [1min ≤ T < 3min]	F1	F1	F2
			Long [3min ≤ T]	F1	F2	F2
		Medium [2/shift ≤ F < 20/shift]	**Short [T < 1min]**	F1	*F1 / F2[3]*	F2
			Medium [1min ≤ T < 3min]	F1	F2	F2
			Long [3min ≤ T]	F2	F2	F2
		High [20/shift ≤ F]	**Short [T < 1min]**	F2	F2	F2
			Medium [1min ≤ T < 3min]	F2	F2	F2
			Long [3min ≤ T]	F2	F2	F2
				Exposure to hazard		

[1] The need for access and the frequency of exposure are not necessarily related (e.g., command panel near a hazardous area).
[2] **Certain:** An unpredictable number of persons may ocassionally be present in the hazardous area.
One: An operator or another task-related person is present in the hazardous area.
More: Several operators or other task-related persons are present in the hazardous area.
[3] High (F2) if the cumulated exposure exceeds 15 minutes per shift.

Tab. 6 – Determination of exposure to hazard

Table for the determination of possibility of avoidance

The estimation of possibility of avoidance can be improved by combining foreseeable operator skills, the awareness to 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[1]	Avoidance experience	Avoidance possibility[1]		
				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	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	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	Unexperienced	A2	A2	A2
				Possibility of avoidance		

[1] 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	System robustness	Accident and incident history	Damage to health likelihood[1]		
				Seldom	Possible	Consequent
Level 2	Same as similar machines or systems	List similar machines or sytems and provide reliable comparison data		-	-	-
	Other than similar machines or systems	Machine or system is not prone to trouble	No accidents or heavy incidents reported (reliable data available)	O1	O1	O2
			Seldom accidents or heavy incidents reported (< 5% of running systems)	O1	O1	O2
			Several accidents or heavy incidents reported (> 5% of running systems)	O1	O2	O2
		Machine or system is prone to trouble	No accidents or heavy incidents reported (reliable data available)	O1	O2	O2
			Seldom accidents or heavy incidents reported (< 5% of running systems)	O2	O3	O3
			Several accidents or heavy incidents reported (> 5% of running systems)	O3	O3	O3
				Probability of occurrence		

[1] **Seldom:** Harm ocurrence is very seldom.
Possible: Harm occurrence is possible but not necessarily the result of an exposure.
Consequent: Harm occurrence is usually a result of the exposure.

Tab. 8 – Determination of probability of occurrence

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[1]	Warning (indirect hazard perception)[2]		
			Difficult	Possible	Easy
Level 3	**Low** 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
	Medium 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
	High Operator ist completely informed about potential hazards and operator information is available and complete	Difficult	Medium	Medium	High
		Possible	Medium	High	High
		Easy	High	High	High
			Risk awareness		

[1] **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 allways be perceived.

[2] **Indirect hazard perception**
Difficult: No hazard warnings are available, readable, or can be recognized as such.
Possible: Warnings are available (and readable) but not allways perceptible.
Easy: For all hazards the warnings are availbale, 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[1]		
				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		

[1] **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 has then to be considered in the overall risk assessment and risk reduction process.

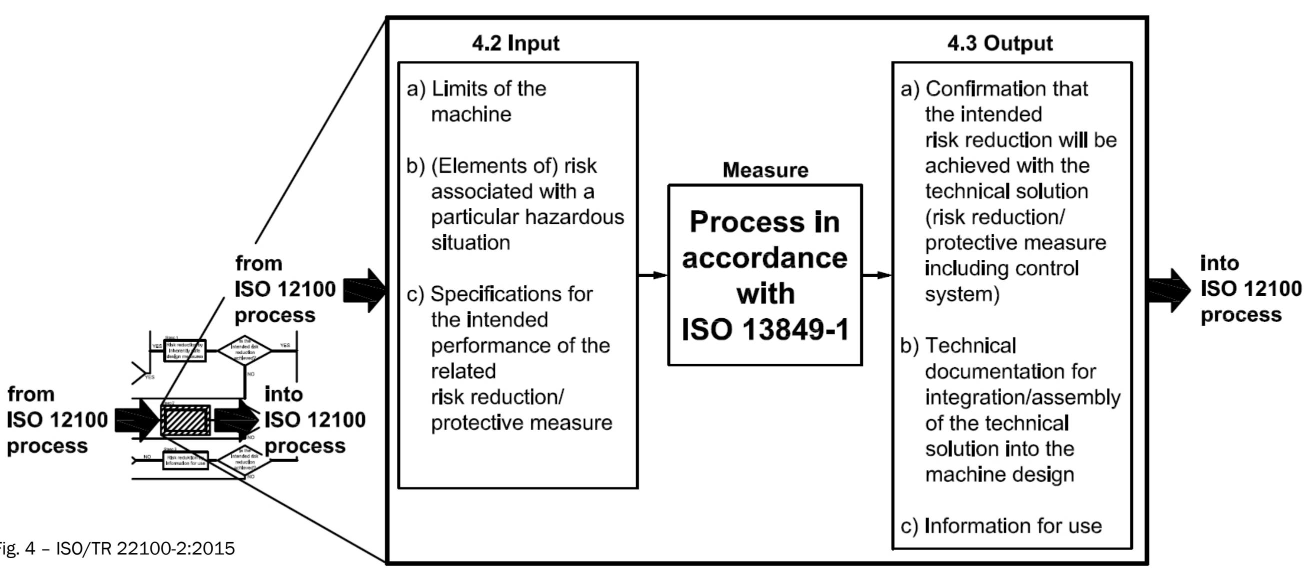


Fig. 4 – ISO/TR 22100-2:2015

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):[f]

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[g] (e.g., overloading and moment limiting devices, devices for limiting pressure or temperature, over-speed switches, devices for monitoring emissions).

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

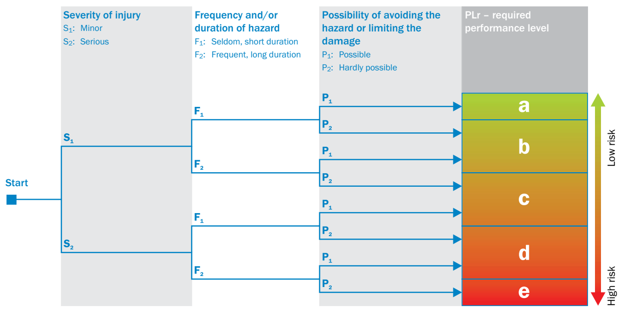
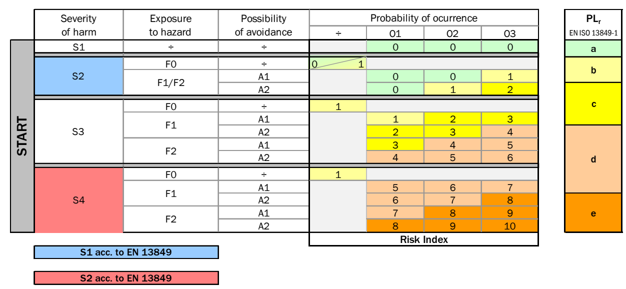
An example of complementary protective measures and equipment, whose greatest effect is on exposure, are measures for isolation and dissipation of hazardous energy (e.g., isolation valves or switches, locking devices, and mechanical blocks to prevent movement).

[f] See ISO 12100:2010, 6.3.2 to 6.3.4.
[g] The impact of limiting by controls will be considered in part 4 of the white paper series "Integrating protective devices into (existing) control systems."

Comparison of SCRAM with ISO 13849-1:2015

Selection of PLr

In order to support a risk estimation process, one of various risk estimation tools can be selected and used. The choice of a specific risk estimation tool is less important than the process itself. The benefit of risk assessment derives from the discipline of the process rather than in the absolute precision of the results, as long as the elements of risk (severity of harm and probability of occurrence) are fully considered. [Clause 6.1, ISO/TR 14121-2:2012]

ISO 13849-1 Graph for determining required PLr for safety function	SCRAM Risk index bridge
	
The methodology of ISO 13849-1 to estimate the PLr is a generic approach which assumes a worst-case probability of occurrence of a hazardous event (i.e., the probability of occurrence is 100%).	To achieve a comparable result using the SCRAM methodology, the probability of occurrence is assumed as ***high*** (O3).
Where the probability of occurrence of a hazardous event can be justified as low, the PLr may be reduced by one level	To achieve a comparable result using the SCRAM methodology, the probability of occurrence is assumed as ***low*** (O1).

Severity		Exposure	Avoidance			Occurence (SCRAM unchanged)				
SICK	ISO			PL_r - 1 (ISO13849-1)	Δ	O1	O2	O3	Δ	PL_r (ISO13849-1)
S1	S1	F1	A1/P1	a		a	a	a		a
			A2/P2	a		a	a	a	<	b
		F2	A1/P1	a		a	a	a	<	b
			A2/P2	b	>	a	a	a	<<	c
S2		F1	A1/P1	a		a	a	b	>	a
			A2/P2	a		a	b	c	>	b
		F2	A1/P1	a		a	a	b		b
			A2/P2	b	>	a	b	c		c
S3	S2	F1	A1/P1	b		b	c	c		c
			A2/P2	c		c	c	d		d
		F2	A1/P1	c		c	d	d		d
			A2/P2	d		d	d	d	<	e
S4		F1	A1/P1	b	<<	d	d	d	>	c
			A2/P2	c	<	d	d	e	>	d
		F2	A1/P1	c	<	d	e	e	>	d
			A2/P2	d	<	e	e	e		e

Probability of occurence „low“
- PL_r using ISO methodology reduced by one level
- PL_r using SCRAM methodology remains unchanged

Probability of occurence „high“

Differences for the high probability of occurrence (O3)

The differences mainly lie in the subdivision of the severity levels S1 and S2 of ISO 13849-1, which are represented in each of the two levels S1-S2 and S3-S4 in SCRAM. This division is the adaption of the results of scientific research on risk estimation methods by Canadian universities[h] and the IRSST.[i] The differences are more accentuated at both ends of the table (the lower and higher risks) because the statistical distribution of the risk does not follow a normal (natural) distribution. This is due to the fact that the risks are mainly generated by technology which is clearly an “artificial” cause.

Differences for the low probability of occurrence (O1)

The differences are given by the combination of the above-mentioned subdivision of the severity levels in conjunction with the reduction of the required performance level by one in the 2015 issue of ISO 13849-1 (clause A.2.3). This uniform reduction by one level is the consensus after long standing discussions in the drafting committee of ISO 13849-1 and does not match the risk reduction required by other methods which have been proved to be more realistic (this evaluation was done in the aforementioned scientific study). The combination of both factors leads to some very significant differences which illustrate that the result of the consensus reflected in ISO 13849-1:2015 needs to be corrected during the revision of the standard and that an estimation method with more than two severity levels more accurately reflects the reality on machinery.

[h] 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.

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

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

Injury type	Catastrophic (S4)	
Burns, thermal Hot surface[1 *] The severity of injury is relative to the amount of body surface area, the duration of exposure, and the temperature of the hot surface.	3rd degree burns typically caused by temperatures > 68 °C (> 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.	
Burns, thermal Vapor or splash of viscous material[1, 5] Vapor exposure assumes instantaneous contact; viscous materials assume continu-ous contact greater than one second.	3rd degree burns typically caused by temperatures > 60 °C (> 140 °F) and on skin surface areas over 1% or more of the body, i.e., palm of hand. Inhalation burns requiring respiratory assistance.	
Burns/injury, wave energy	Burns, injury, or wave energy exposure that could result in death or perma-nently disabling injury such as blindness or amputation.	
Lacerations or amputations[2, 5 **]	Lacerations or amputations* that could result in death or permanently disabling injury such as blindness. *For example, amputations of: • Hand • Foot • Arm • Leg • Eye	
Fractures[2, 5] 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.	399.9 kPa (58 psi) For example, fractures of spinal column.	

	Serious (S3)	**Moderate (S2)**	**Minor (S1)**
	3rd degree burns typically caused by temperatures > 68 °C (> 154 °F) with exposure durations of one second, and on skin surface areas less than 1% of the body.	2nd degree burns typically caused by temperatures 60 °C to 68 °C (140 °F to 154 °F) with exposure durations of one second.	1st degree burns typically caused by temperatures 44 °C to 59 °C (111 °F to 139 °F) with exposure durations of one second.
	3rd degree burns typically caused by temperatures > 60 °C (> 140° F) and on skin surface areas less than 1% of the body. Inhalation burns.	2nd degree burns typically caused by temperatures 44 °C to 59 °C (111 °F to 139 °F).	1st degree burns typically caused by temperatures 38 °C to 43 °C (100 °F to 110 °F).
	Loss of eye, vision impairment, or amputation (see ANSI B11.21). Central corneal abrasion. Typically caused by class 4 laser or high pressure xenon arc lamp (intense UV/Vis/IR emitted, and potential for bulb explosion).	Temporary loss of vision. Typically caused by class 3B laser, UV-B lamps (280 nm to 320 nm).	Superficial, peripherally located corneal abrasion, ulceration, burn, or foreign object. Typically caused by class 3A laser, class 2 laser, UV-A lamps (320 nm to 400nm).
	Lacerations of the head or face requiring sutures or other closure in lieu of sutures or partial blindness typically caused by: • Flying projectiles • Stationary sharp edges • Blunt, sharp edges Amputation of finger(s) or toe(s), typically caused by: • Sharp edges mechanically in motion (e.g., rotating, reciprocating, shearing)	Lacerations, not involving the face, requiring sutures or other closure in lieu of sutures typically caused by: • Stationary sharp edges • Blunt, sharp edges External (deep) lacerations (> 10 cm long on body / > 5 cm long on face) requiring stitches.	Minor/superficial cuts requiring bandaging treatment, typically caused by: • Stationary blunt surfaces • Offset, blunt edges with loads less than 28 kPa (4 psi)
	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. *For example: • Ankle • Leg (femur and lower leg) • Hip • Thigh • Skull • Spine (minor compression fracture) • Jaw (severe) • Larynx • Multiple rib fractures • Blood or air in chest	Fractures of small bones,* typically caused by loads between 297 kPa (43 psi) and 399.9 kPa (58 psi). *For example: • Extremities (finger, toe, hand, foot) • Wrist • Arm • Rib • Sternum • Nose • Tooth • Jaw • Bones around eye	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.

Injury type	Catastrophic (S4)	
Crushing[5]	• Spinal cord • Mid-low neck • Chest (massive crushing) • Brain stem	
Bruising (abrasion, contusion, swelling, edema)[2, 5]	• Brain stem • Spinal cord causing paralysis	
Dislocation[5]	• Spinal column	
Piercing, puncturing[5]	• Aorta • Heart • Bronchial tube • Deep injuries in organs (liver, kidney, bowel, etc.)	
Entrapment/pinching[5]	• Fatal suffocation/strangulation	
Concussion[5]	• Coma	
Eye injury, foreign body in eye[5]	• Permanent loss of sight (one or both eyes)	
Substances Irritation, dermatitis, inflammation, or corrosive effect of substances (inhalation, dermal)[5] Refer to OSHA, NIOSH, ACGIH, NFPA 45-2011, and EPA for details concerning specific substances.	• Lungs, requiring respiratory assistance • Asphyxia • Irreversible systemic effects	
Allergic reaction or sensitization[5] Refer to OSHA, NIOSH, ACGIH, NFPA 45-2011, and EPA for details concerning specific substances.	• Anaphylactic reaction, shock • Fatality	

	Serious (S3)	Moderate (S2)	Minor (S1)
	• 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 cm2 on face > 50 cm2 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 cm2 on face ≤ 50 cm2 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)	• Limited depth, only skin involved
	(Use as appropriate the final outcomes of bruising, crushing, fracture, dislocation, amputation, as applicable)	–	• Minor pinching
	• Prolonged unconsciousness	Very short unconsciousness (minutes)	–
	• Partial loss of sight	• Temporary loss of sight	• Temporary pain in eye without need for treatment
	• Lungs, respiratory insufficiency, chemical pneumonia • Partial loss of sight • Corrosive effects	• Reversible eye damage • Reversible systemic effects • Inflammatory effects	• Slight local irritation
	• Strong sensitization, provoking allergies to multiple substances	• Allergic reaction, widespread allergic contact dermatitis	• Mild or local allergic reaction

Injury type	Catastrophic (S4)	
Electrical 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.	• Major burns and irreversible body damage at several amps	
Sprain, strain, musculoskeletal disorder[5]	–	
Neurological disorders[5]	–	

	Serious (S3)	Moderate (S2)	Minor (S1)
	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	• Extremities • Joints • Spine (no dislocation or fracture)
	• 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.

[1] Chengalur, R.: Kodak's Ergonomic Design for People at Work. New York: Van Nostrand Reinhold, 2004.

[2] Mewes, D. and F. Mauser: "Safeguarding Crushing Points by Limitation of Forces." International Journal of Occupational Safety and Ergonomics. 9(2003): 177-191.

[3] ANSI Z136.1, Safe Use of Lasers, New York: ANSI 2007.

[4] Hagan, P.: Accident Prevention Manual for Business & Industry – Engineering & Technology. 12th Edition. NSC, Itasca, IL 2001.

[5] Official Journal of the European Union L22, 26.1, 2010 p. 64, "Table 3 Severity of Injury."

NORMATIVE REFERENCES

ANSI B11.0-2015: 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

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