SIEMENS

Risk Assessment in Accordance with EN ISO 14121-1 and EN ISO 12100:2010

Introduction

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Contents

1 General

This document was prepared conjointly by TÜV Rheinland and Siemens AG.

1.1 Warranty and Liability

This introduction guideline is provided to you free of charge. We therefore do not assume any warranty and liability – irrespective of the legal ground – particularly with regard to this guideline's correctness of contents, accuracy, completeness or technical and/or commercial usability. This disclaimer shall not apply to cases subject to mandatory liability, particularly to cases of intent or grossly negligent behavior or cases of fraudulently concealed faults.

1.2 Description of the Functionality

This document describes the following sample documents for risk assessment implementation:

- **Reference document**
- **Risk assessment document**

Risk assessment forms an integral part of the CE conformity process.
This process comprises nine phases:
Phase 1: Determination of applicable directives and standards
Phase 2: Determination of the conformity evaluation procedure
Phase 3: Determination of applicable harmonized standards
Phase 4: Assurance of compliance with requirements
Phase 5: Preparation of technical documents
Phase 6: Preparation of declaration of conformity or declaration of incorporation
Phase 7: Attachment of CE marking, putting machine into circulation
Phase 8: Quality assurance
Phase 9: Product surveillance, surveillance of regulations and standards

1.3 Prerequisites

Risk assessment should be carried out with persons involved in the conceptual design, realization, commissioning and service / maintenance of a machine. This for example comprises staff members from the departments of construction (mechanics, electrics, pneumatics, hydraulics), software development, documentation creation, ...

1.4 Manufacturer's Responsibility

Machinery directive, annex I:

The manufacturer of machinery or his authorized representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery.

The machinery must then be designed and constructed taking into account the results of the risk assessment.

2 Directives and Standards

At the start of the risk assessment process, first the relevant directives and the potentially applicable harmonized standards for the machine's design should be listed. This can also be further elaborated during the process of risk assessment.

2.1 Directives

Potentially relevant EU directives for the machine may comprise:

Directive	No. of directive	Yes	No
Machinery directive	2006/42/EC		
Electromagnetic compatibility	2004/108/EC		
Low-voltage directive	2006/95/EC		
Equipment and protective systems intended for use in potentially explosive atmospheres	94/9/EC		
Pressure equipment	97/23/EC		
Simple pressure vessels	87/404/EEC		
Outdoor	2000/14/EC		
Ecodesign of energy-using products	2005/32/EC		

This table does not purport to be complete. A complete list of all directives is available under the Internet links (chapter 6.1).

2.2 Standards

Which potentially applicable standards can be used for the machine's design?

Harmonized standards

Type of standard	Number of standard	Title of standard
Type-A standard **Basic safety standards**	EN ISO 12100-1[1)] EN ISO 12100-2[1)] EN 1070[1)] EN ISO 14121-1[1)]	Part 1: Basic concepts, general principles for design – basic terminology, methodology Part 2: Technical principles and specifications Terminology on safety of machinery Risk assessment
Type-B1 standard **Generic safety standards** **for specific safety aspects**	EN 349 EN 60204-1 EN ISO 13849-1 EN 62061[*)] EN ISO 13857 (EN 294, EN 811) EN 999	Minimum gaps to parts of the human body, safety distances to lower limbs Electrical equipment of machines Safety-related parts of control systems, safety-related electrical, electronic and programmable electronic control systems Safety distances to prevent hazard zones being reached by upper and lower limbs Positioning of safeguards with respect to the approach speeds of parts of the human body
Type-B2 standard **Generic safety standards** **for safeguards**	EN ISO 13850 EN 61496-1 EN 574 EN 1088 EN 953 EN 982	EMERGENCY-STOP devices ESPE Two-hand control devices Interlocking devices Guards Hydraulics
Type-C standard **Machine safety standards** **(product standard)**	EN 692 EN 693 EN 775 EN 12415 EN 12478 EN 201 EN 12626	Mechanical presses Hydraulic presses Industrial robots Small numerically controlled turning machines Large numerically controlled turning machines Injection molding machines Laser processing machines

A complete list of all standards is available under the Internet links.

[1)] These standards are integrated in EN 12100

[*)] Corresponds to IEC 62061

3 Basic Information

3.1 Project Data

Using the following fields, the machine can be described as project:

Rev.	**Modification contents** System modernization		
Contract No.			
Project			
Plant			
Area			
Equipment			
Document type		Referenced document	
Document title	Risk assessment	Substitute for Replaced by	
Language(s)	EN		
Customer-specific Original manufacturer: “Logo“			

	Name	**Date**	**Signature**
Made by			
Checked by			
Approved by			

3.2 Description of the Machine

The machine can be described as follows:

Product:	**"Machine"** in accordance with the machinery directive 2006/42/EC, article 2 / item a
Designation of the machine:	
Machine type:	
Year of commissioning:	
Customer:	
Installation location:	
Project code:	

The machine's limits with the intended use have to be defined first.

1	**Limits of the machine, intended use**	**Description**	**Corresponding documents**
	Intended use		
	Foreseeable use not as intended (incorrect use / misuse)		
	Use limits	Environmental conditions: EMC; network type; installation altitude; temperature range; humidity; installation site (hall or outdoor); ...	
	Space limits		
	Time limits		

Formulate all relevant information in note form in an easily comprehendible manner.

This information is included in the corresponding documents, e.g. instruction handbook.

2	Environment of use	Description		Corresponding documents
	Private	No		
	Commercial	Yes		
3	**User groups**	**Task**	**Qualification**	**Corresponding documents**
	Qualified staff			
	Non-professional users	No	No	
	Apprentices	No	No	
	Children (indicate age group)	No		
	Elderly persons (no longer fit for work)	No		
	Handicapped persons (persons with limited mental or physical abilities)	No		
4	**Materials**	**Material**	**Use**	**Corresponding documents**
	Hazardous substances			
	Hazardous materials			
	Hazardous processed materials			
5	**Life cycles**	**Description**		**Corresponding documents**
	Transport, assembly and installation	Transport of the machine or machine group for internal or external relocation		
	Commissioning	Assembly, setting, testing, teaching / programming, start-up, all operating modes, feeding of the machine, removal of product from the machine, stopping the machine, stopping the machine in case of emergency, restarting the machine after stopping, fault-finding and troubleshooting		
	Operation	Setting, testing, process changeover, start-up, all operating modes, feeding of the machine, removal of product from the machine, stopping the machine, stopping the machine in case of emergency, recovery of operation from blockage, restarting the machine after stopping, fault-finding and troubleshooting (operator intervention)		
	Maintenance	Cleaning and housekeeping, maintenance Fault-finding and troubleshooting (operator intervention)		
	De-commissioning, **dismantling,** scrapping	In the manufacturing plant By customer staff at the customer's installation site		
	Additional special life cycles	None		

3.3 Operating Modes of the Machine

The following overview shows examples of possible operating modes:

Operating mode (name)	Abbreviation	Description (e.g. functionality)
Automatic mode	Auto	
Manual mode	Manual	
Setup mode	Setup	
...		
All	All	Applies to all operating modes described here
Independent	None	No operating mode is assigned to this life cycle

The operating modes may differ from machine to machine (name, abbreviation, functionality).
The team decides whether an operating mode-dependent detection and evaluation of hazards and safety functions is required.
Different methods for operating mode documentation: 1. Detection and evaluation of hazards / safety functions applicable to all operating modes.
2. A separate note is documented for each detected and evaluated hazard / safety function.

3.4 Definition of Machine Areas

The machine is to be divided into machine areas to facilitate a more transparent structuring of the risk assessment.
The “Designation“ field of the machine areas is to be filled in shortly and concisely and may also be based on the planning documents.
The “Description“ field is to be filled in with a clear description of the machine‘s defined machine areas.

Machine areas	Designation	Description
Machine area 1		
Machine area 2		
Machine area 3		

The number of machine areas is specified individually. Also a single machine area may be sufficient for one machine.

3.5 Identification of Hazard Zones

The target lies in the identification of potential hazard zones within the individual machine areas. The consistent use of terms in the document is to be ensured.

Hazard zone	Comments

Formulate all relevant information on the hazard zone in an easily comprehendible manner.

The most important, immediately detectable dangers are to be entered in the field “Comments“ in a brain-storming manner.

4 Evaluation of Hazards

The potential hazards of each hazard zone are considered in a general manner. Every life cycle has to be taken into account.

Not all life cycles are necessarily relevant for a hazard zone. In most cases, operation and commissioning are considered a joint life cycle. Depending on the machine type, the hazards can be identified in dependence of the operating mode or operating mode-independently.

These columns list all potential types of hazards.

	Hazards in accordance with EN ISO 14121-1 and EN ISO 12100:2010									
Life cycle	**Mechanical**	**Electrical**	**Thermal**	**Noise**	**Vibration**	**Radiation**	**Substances**	**Ergonomics**	**Environment**	**Combination**
Operating mode										
Transport, assembly, installation										
Operation + commissioning										
Operating mode 1										
Operating mode 2										
Maintenance										
Operating mode 3										
Operating mode 4										
Dismantling										

4.1 Types of Hazards

- Mechanical hazards
- Electrical hazards
- Thermal hazards
- Noise hazards
- Vibration hazards
- Radiation hazards
- Material / substance hazards
- Ergonomic hazards
- Hazards associated with the environment in which the machine is used
- Combination of hazards

The specific hazard can be copied from the reference document into the actual risk assessment document.

No.	Type of hazard (electrical, ...) EN ISO 12100	Hazard (crushing, shearing, entanglement, ...) EN ISO 14121-1 and EN ISO 12100:2010 (origin, consequence)						
	Description	Further standards	Risk (before)	No.	Description of measures / solutions	Type	Risk (after)	Test criterion
	Hazard zone: “Hazard zone designation”				Operating mode			“Operating mode designation”
1.	**Mechanical**	**Crushing**						
				1		D		

Copy from reference document, clause 3.

Type of hazard (mechanical, electrical, ...) for an identified hazard zone.
If several types of hazards exist, they should be copied from the reference document successively.

Description of the measures / solutions with the target of reducing the hazard’s risk (also see 4.3 Risk Reduction According to the 3-Step Method).

4.2 Auxiliary Means for Risk Assessment (Matrix)

The determination of reasonable measures for realizing the required risk reduction is often difficult for designers and developers in practice.
The matrix (table 1) serves as auxiliary means.

Targets of risk evaluation:

1. General estimation of a danger
2. Comprehendible documentation of the estimation
3. Recommendation of measures for construction (designer) and decision-makers based on the estimation

The following procedure suggests itself:

Procedure:

1. The general (original) risk, i.e. without any measure, is evaluated on the basis of the matrix.
2. The risk is reduced after initiation of a measure (risk-reducing measure), e.g. from 3 A (risk before) to 2 B or 1 B (risk after).
3. If this is not sufficient, several risk-reducing measures have to be taken to attain the final evaluation “no further measures required.”

		Probability of occurrence		
	Severity of harm	**A** Probable	**B** Possible	**C** Improbable
4	Death, loss of an eye or arm			
3	Broken limbs, loss of finger(s)			
2	**Reversible:** Medical treatment required			
1	**Reversible:** First aid required			

Meaning of colors
The color red indicates a high risk. This has to be preferably reduced by means of design measures. Other measures for risk reduction must only be initiated in individual cases where this is not permitted by the process (production process).

The color yellow indicates a lesser risk than red. Such risk can either be reduced by means of design measures or technical protective measures.
The color green indicates residual risks which do not require any further (design) measures. However, quality assurance measures or personal protective equipment may be required.

Caution: Design measures are not necessarily quantitatively measurable.
Example: Crushing hazards have to be generally prevented by means of a protective guard or sufficient distances.
This for example applies to 3 A as well as 3 B.

Technical protective measures in connection with a control (safety functions) are qualitatively and quantitatively measurable on the basis of the required safety integrity level (SIL or PL).
Example: In 3 A, SIL 3 or PL e may be required, whereas SIL 2 or PL d may be required in 3 B.

Type of measures	Examples
Design measure	Inherently safe design measure: Travel limitation; cover
Technical protective measure	Guard: Protective fence, door or flap; light curtain; two-hand operation console
At least warnings required	Standardized pictograms: Hearing protection, ...
No further measures required	Instruction handbook; organizational if applicable

Abbreviation	Description of the protective measure
D e, f, m	Design (electrical, fluidic, mechanical)
FS	Functional safety (control technology measure) → safety function
W	Warning on the machine
IH	Note in the instruction handbook or maintenance handbook
PPE	Personal protective equipment
ORG	Organizational protective measure

Severity of harm and probability of occurrence are defined as follows:

Severity of harm

Classification	Description
4	Fatal injury; severe irreversible injury whose nature will make it very difficult for the injured person to carry out the same work after healing, if healing is possible at all
3	Major or irreversible injury whose nature will allow the injured person to carry out the same work after healing, e.g.: healed fractures of limbs never attain the same stability as before such fracture, hence irreversible!
2	Reversible injury, including severe flesh wounds, stab wounds and severe crushes, which requires medical treatment
1	Minor injury, including scratches and minor crushes, which require first aid treatment

Probability of occurrence

Classification	Possible determination on the basis of risk elements	
Probable (high)	■ Exposure to hazard: ■ Occurrence of hazardous events: ■ Possibilities of avoidance:	Normal operation; frequent (> 1 per shift, several times per day) Unexpected event; stress (time pressure) Trained or qualified staff; no sudden or rapid movements; sufficient workspace
Possible (average)	■ Exposure to hazard: ■ Occurrence of hazardous events: ■ Possibilities of avoidance:	Normal operation or maintenance; rather infrequent (< 1 per shift, < 1 per day) Conscious event and corresponding actions Qualified staff; no sudden or rapid movements
Improbable (low)	■ Exposure to hazard: ■ Occurrence of hazardous events: ■ Possibilities of avoidance:	Repair; seldom (< 1 per week or month) Conscious event and corresponding actions Qualified staff; no sudden or rapid movements

Risk elements and typical influencing factors

Risk elements	Typical influencing factors
Exposure to hazard	■ Need for access to the hazard zone (for normal operation, correction of malfunction, maintenance, ...) ■ Nature of access (e.g. manual feeding of materials) ■ Time spent in the hazard zone ■ Frequency of access
Occurrence of hazardous events	■ Foreseeability of the behavior of the machine's components (reliability data, accident history, ...) ■ Foreseeable characteristics of human behavior (stress, lack of awareness regarding the hazard, ...) ■ Data on damage to health ■ Risk comparisons
Possibilities of avoiding or limiting a harm	■ Qualified or trained staff ■ Risk awareness and practical experience ■ Human ability to avoid or limit harm (by means of reflex, agility, possibilities of escape) ■ Speed of the possible hazardous movement: Sudden, rapid or slow

4.3 Risk Reduction According to the 3-Step Method

Step 1: Elimination of the hazard on the basis of design measures (inherently safe design measures)

Inherently safe design (ISO 12100-2, clause 4)

- Geometry (minimum distances between movable parts, no sharp edges, angular parts)
- Physical aspects (limitation of the actuating force, speed or emission of noise, vibrations, ...)
- General technical design (stress, materials)
- Selection of the suitable technology
- Stability
- Ergonomics for reduction of stress
- Electrical safety (IEC 60204-1)
- Dimensioning of pneumatic and hydraulic equipment (maximum pressure, leakage – see ISO 4413 and ISO 4414)

Step 2: Risk reduction through application of technical and complementary protective measures

Guards or protective devices (ISO 12100-2, clause 5)

- Guards are used as access prevention or for the containment of materials, workpieces, chips or liquids:
  Stationary (only removable with tools) or movable versions
  (see ISO 13852, ISO 13853 and ISO 13855)
- Protective devices permit access and are always used in connection with a control (safety function)
  (e.g. electro-sensitive protective equipment such as light curtains, two-hand operation consoles, pressure-sensitive mats)

Step 3: Warning against residual risks

Information for use

- On the machine (warning signs, warnings, warning devices)
- In the handbooks (commissioning handbook, transport handbook, instruction handbook, service and maintenance handbook)

The protective measures for the operator or user are defined on the basis of the defined measures:

1. Organizational (e.g. operating procedures)
2. Additional safeguards
3. Personal protective equipment
4. Training

4.4 Documentation of Hazards

The hazards are identified with the help of the reference document (see clause 3.2)

No.	Type of hazard (electrical, ...) EN ISO 12100	Hazard (crushing, shearing, entanglement, ...) EN ISO 14121-1 and EN ISO 12100:2010 (origin, consequence)						
	Description	Further standards	Risk (before)	No.	Description of measures / solutions	Type	Risk (after)	Test criterion
	Hazard zone:	"Hazard zone designation"			Operating mode			"Operating mode designation"
1.	**Mechanical**	**Crushing**						
				1		D		

Example:

No.	Type of hazard (electrical, ...) EN ISO 12100	Hazard (crushing, shearing, entanglement, ...) EN ISO 14121-1 and EN ISO 12100:2010 (origin, consequence)						
	Description	Further standards	Risk (before)	No.	Description of measures / solutions	Type	Risk (after)	Test criterion
Life cycle: Transport								
	Hazard zone:	Compression abutment transverse displacement			Operating mode			None
1.	**Mechanical**	**Crushing**						
	Danger for hands, fingers due to unintended shifting		2 B	1	Interlocking by means of holding bolts	Dm	1 C	Visual and functional inspection
				2	Wearing of work gloves	PPE		Verification of the documentation
				3	Work instruction and warning in the instruction handbook	IH		Verification of the documentation

5.1 Methods for Determination of the Required Safety Integrity Level

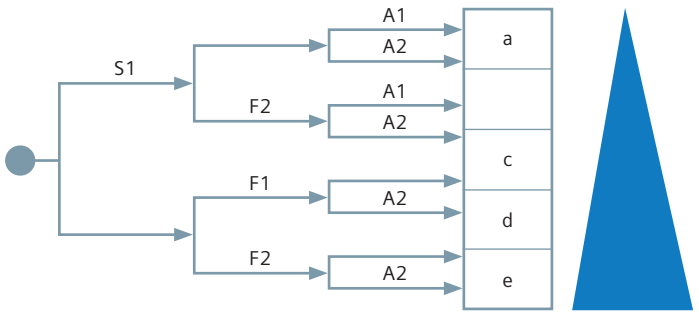
Determination of the Safety Integrity Level in accordance with EN 62061

Effects	Severity	C					Frequency and duration of exposure (F)		Probability of occurrence (P)		Possibility of avoidance (A)	
	SE	4	5–7	8–10	11–13	14–15						
Death, loss of an eye or arm	4	SIL 2	SIL 2	SIL 2	SIL 3	SIL 3	≥ 1 per h	5	Frequent	5		
Broken limbs, loss of finger(s)	3		OM	SIL 1	SIL 2	SIL 3	< 1 per h up to ≥ 1 per day	5	Probable	4		
Reversible: Medical treatment required	2			OM	SIL 1	SIL 2	< 1 per day up to ≥ 1 per every 2 weeks	4	Possible	3	Impossible	5
Reversible: First aid required	1				OM	SIL 1	< 1 per every 2 weeks up to ≥ 1 per year	3	Seldom	2	Seldom	3
							< 1 per year	2	Negligible	1	Probable	1

OM: Other measures, e.g.: inclusion in the instruction handbook; attachment of a warning label on the machine, ...
Determination of the value C: C = F + P + A

Determination of the Performance Level in accordance with EN ISO 13849-1

Severity of harm Severity of injury		Frequency and / or duration of exposure to hazard		Possibility of avoiding the hazard	
S1	Minor injury	F1	Seldom to more often and / or short duration of exposure	A1	Possible under certain conditions
S2	Severe injury (reversible) or death	F2	Frequent to constant	A2	Hardly possible



Exemplary classifications for the evaluation of risk elements:

Severity of damage, severity of injury

S1: Reversible, e.g. medical treatment or first aid required
S2: Irreversible, e.g. loss or breaking of limbs

Frequency and / or duration of exposure to hazard

F1: 1 day up to 2 weeks; 2 weeks up to 1 year
F2: Less than 1 hour; 1 hour up to 1 day

Possibility of avoiding the hazard

A1: Possible, probable
A2: Impossible

5.2 Documentation

The identified safety functions are documented with the help of the reference document (see clause 4).

Example in accordance with EN 62061

Life cycle:

	Hazard zone						Spindle chuck	Operating mode:	All
No.	Name of the safety function						Description of the safety function		
	Risk classification						Measures / test criterion		
	S Severity	F Frequency	P Proba-bility of occurrence	A Avoidance	C Class	SIL 1, 2, 3			
1.	**Rotating spindle chuck**						**Rotating spindle chuck must be stopped as soon as the door is opened.**		
	3	5	3	3	11	SIL 2	Equipment of the operating door with safety switch and tumbler. The safety-related frequency converter features the “safe stop“ function. A mechanical brake is applied while the operating door is open. The time until standstill therefore ranges between 500 ms and 1s. In addition, the brake is regularly checked for process-related reasons: The brake’s serviceability is thus verified in a process-related manner; the short overtravel time does not require the tumbler as safety function.		

Example in accordance with EN ISO 13849-1

	Hazard zone				Spindle chuck	Operating mode:	All
No.	Name of the safety function				Description of the safety function		
	Risk classification				Measures / test criterion		
	S Severity	F Frequency	A Avoidance	PL a, b, c, d, e			
1.	**Rotating spindle chuck**				**Rotating spindle chuck must be stopped as soon as the door is opened.**		
	2	2	1	PL d	Equipment of the operating door with safety switch and tumbler. The safety-related frequency converter features the “safe stop“ function. A mechanical brake is applied while the operating door is open. The time until standstill therefore ranges between 500 ms and 1s. In addition, the brake is regularly checked for process-related reasons: The brake’s serviceability is thus verified in a process-related manner; the short overtravel time does not require the tumbler as safety function.		

6 Annex

6.1 Selection of Internet Links

Subject field	Title
Safety Evaluation Tool	www.siemens.com/safety-evaluation-tool
Safety Integrated website	www.siemens.com/safety-integrated
SITRAIN	www.siemens.com/sitrain-safetyintegrated
Links to the EU Server	www.eg-richtlinien-online.de www.newapproach.org/Directives/DirectiveList.asp ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references ce-engineering.eu
Research of standards	www.vde-verlag.de/normen/suchen.html www.beuth.de www.nora.kan.de
Risk assessment CE conformity process	www.tuv.com/de/industriemaschinen.html

6.2 References

This list is by no means complete and merely reflects a selection of suitable literature.

Subject field	Title
Basics	Guideline on Standard-Compliant Risk Assessment Implementation in Accordance with the Machinery Directive (publication: 2011) Book: Functional Safety of Machines and Systems (ISBN 978-3-89578-366-1) Introduction and Terminology for Functional Safety, Order No. E86060-T1813-A101-A3

6.3 History

Version	Date	Modification
V1.0	October 2010	First edition
V1.1	March 2011	Second edition
V1.2	September 2011	Third edition

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