Standards Functional Safety and Risk Assessment
EN ISO 12100, ISO 13849 and EN IEC 62061

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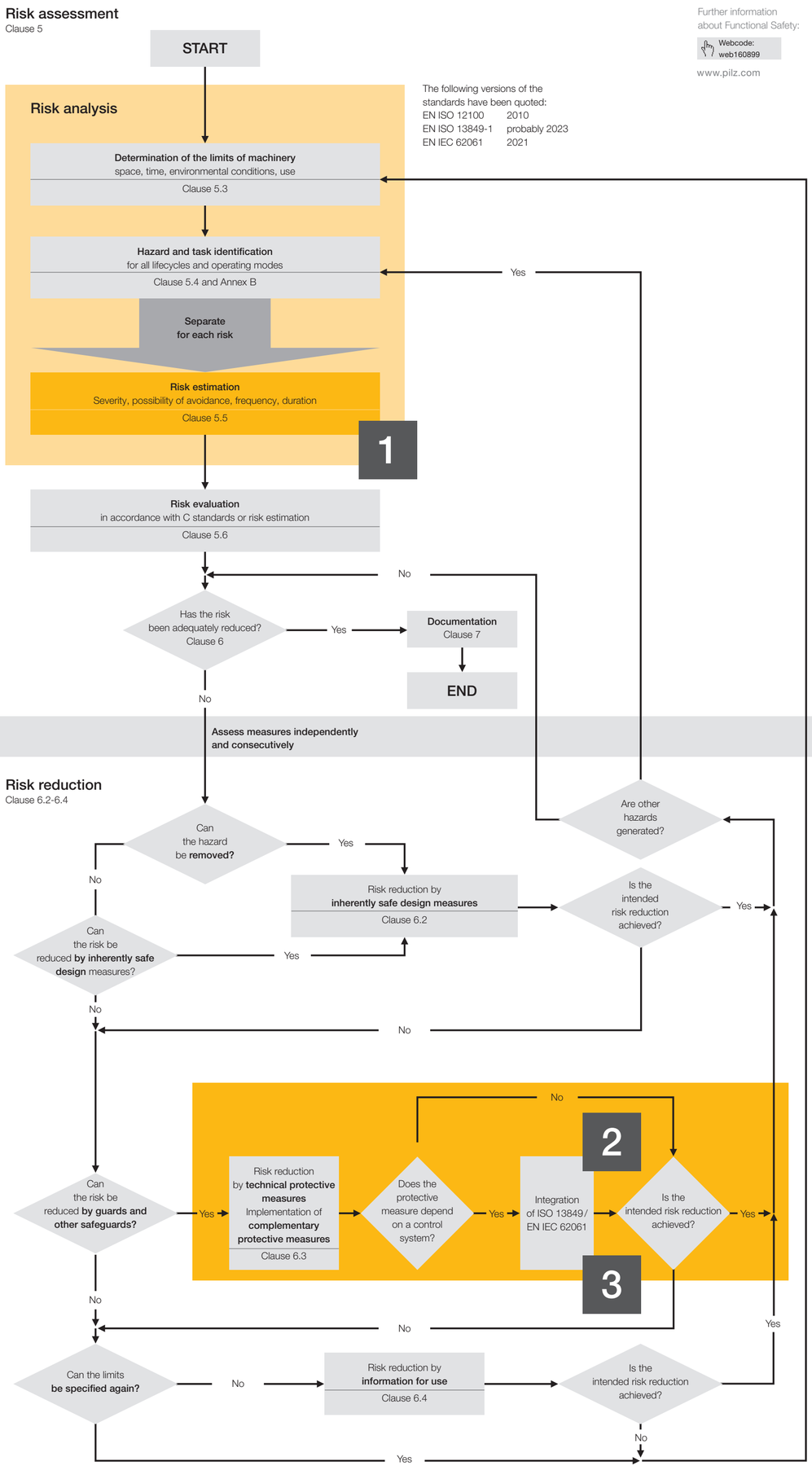
EN ISO 12100
Risk assessment and risk reduction



Further information about Functional Safety:
Webcode: web160899
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The following versions of the standards have been quoted:

EN ISO 12100	2010
EN ISO 13849-1	probably 2023
EN IEC 62061	2021

1 EN ISO 12100

Risk assessment based on the following risk parameters for each danger zone

Risk	is a function of	Severity	+	Probability of occurrence
with regard to the hazard to be considered		of the possible injury that results from the hazard to be considered		**Frequency and duration** of exposure to the hazard **Likelihood** of the hazard occurring **Avoidability** or limit

ISO 13849-1

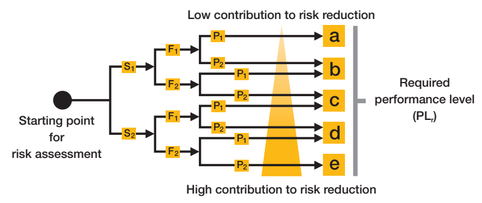
Safety of machinery – Safety-related parts of control systems: Part 1: General principles for design

EN IEC 62061

Safety of machinery – Functional safety of safety-related control systems

2 PL_r and SIL determination for each safety function

Determination of the required performance level (PL_r)



- **S – Severity of injury**
  S_1 = Slight (normally reversible injury)
  S_2 = Serious (normally irreversible injury including death)
- **F – Frequency and/or duration of exposure to a hazard**
  F_1 = Seldom to quite often and/or the exposure time is short
  F_2 = Frequent to continuous and/or the exposure time is long
- **P – Possibility of avoiding or limiting harm**
  P_1 = Possible under specific conditions
  P_2 = Scarcely possible
- **A low probability can reduce the PL, by one level**

Determination of the parameter P – Factors	A	B	C
Use of the machine by	Skilled person	Unskilled person	
Speed of the part that can create a hazardous event	Low or very low speed event	Medium speed event	High speed event
Spatial possibility to withdraw from the hazard	Possible in more or equal to 50 % of the cases	Possible in less than 50 % of the cases	Not possible
Possibility of recognition of the hazard/ awareness of the hazard	Possible in more or equal to 50 % of the cases	Possible only in less than 50 % of the cases	Not possible
Complexity of the operations	Low complexity or no interaction	Medium to High complexity	
if "C" is selected OR "B" is selected at least 3 times; avoidance "P2": # „C" >=1; #"B" >=3 ➔ P2 if "C" is not selected AND "B" is selected at most 2 times; avoidance "P1": # „C" =0 AND #"B" <=2 ➔ P1			

Determination of the required Safety Integrity Level (SIL)

Frequency and duration	Fr > 10 min	Fr ≤ 10 min	Probability of hazardous event	Pr	Avoidance	Av
≥ 1 per h	5	5	Very high	5		
< 1 per h to ≥ 1 per day	5	4	Likely	4		
< 1 per day to ≥ 1 per 2 weeks	4	3	Possible	3	Impossible	5
< 1 per 2 weeks to ≥ 1 per year	3	2	Rarely	2	Possible	3
< 1 per year	2	1	Negligible	1	Likely	1

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

Example for calculating the class Cl:
For a specific hazard with an 'Se' assigned as 3, an 'Fr' as 4, a 'Pr' as 3 and an 'Av' as 5 then: Cl = Fr + Pr + Av = 5 + 4 + 3 = 12

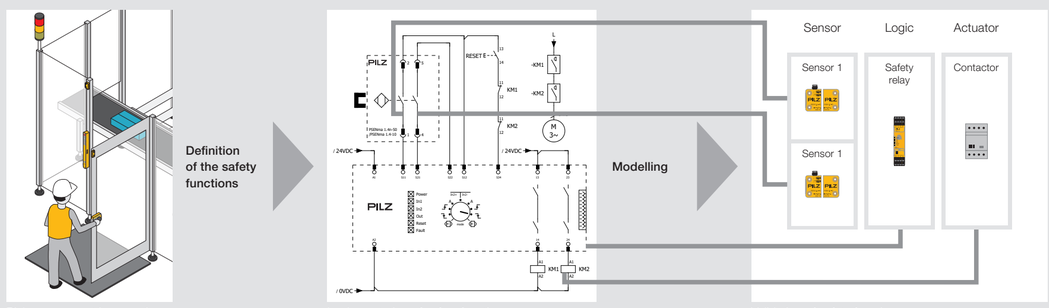
3 Calculation of safety function failure rate

Necessary safety performance data

ISO 13849-1		Unit type			EN IEC 62061	
Data provided by the manufacturer	Data determined by the designer				Data provided by the manufacturer	Data determined by the designer
PFH, PL Category, T_M	-	**Units with internal diagnostics**		Safety control, safety relay	PFH, SIL, T_M	-
$MTTF_D$	DC, CCF, Category	**Units without internal diagnostics**	Components not subject to wearing	Sensors	$MTTF_D$	DC, CCF, Subsystem type
$B10_D$	DC, CCF, Category, n_{op}		**With** wearing components	Emergency stops, relays, switches, valves	$B10_D$	DC, CCF, Subsystem type, n_{op}

Evaluation procedure

From the machine … **… to the safety function …** **… to their assessment.**



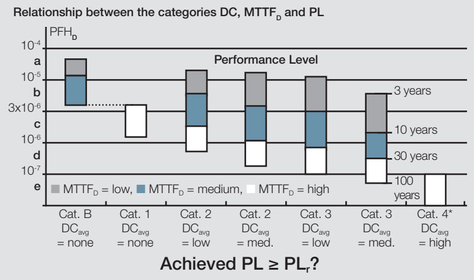
Risk assessment in accordance with EN ISO 12100
Implementation of safety functions
Validation of safety functions

Specification of categories – in this case on the sensor subsystem, for example

Probability of a dangerous failure per hour – comparison PL_r / SIL

Performance Level (PL_r) in accordance with ISO 13849-1

Relationship between the categories DC, $MTTF_D$ and PL



* In Cat. 4, $MTTF_D$ up to 2,500 years is possible

Safety Integrity Level (SIL) in accordance with EN IEC 62061

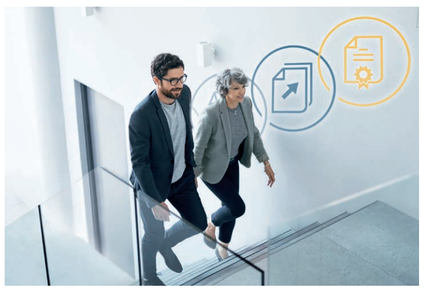
Safety Integrity Level	Probability of a dangerous failure per hour (PFH)
3	PFH < 10^{-7}
2	PFH < 10^{-6}
1	PFH < 10^{-5}

Achieved SIL ≥ required SIL?

Glossary of terms

- **Architecture**
  Specific configuration of hard-ware and software elements in a safety-related control system (SCS)
- **B_{10D}**
  Number of cycles of products before 10% of the product range fails "dangerously"
- **Category**
  Classification of the subsystem in respect to its resistance to faults and the subsequent behaviour in the fault condi-tion which is achieved by the structural arrangement of the parts, fault detection and/or by their reliability
- **CCF**
  Common cause failure
- **Diagnostic coverage (DC)**
  Measure of the effectiveness of diagnostics, which is detemined as the ratio between the failure rate of detected dangerous failures and the failure rate of total dangerous failures
- **DC_{avg}**
  Average diagnostic coverage
- **Fault**
  Abnormal condition that may cause a reduction in, or loss of, the capability of a functional unit to perform a required function
- **λ**
  Average probability of failure
- **$λ_D$**
  Dangerous failure rate
- **$λ_S$**
  Safe failure rate
- **Mission time**
  Period of time covering the intended use of a safety-related part of a control system
- **$MTTF_D$**
  Mean time to dangerous failure
- **n_{op}**
  Mean frequency of operation per annum
- **Performance level (PL)**
  Discrete level to specify the ability of safety-related parts of control systems to perform a safety function under foreseeable conditions
- **Performance level, required (PL_r)**
  Performance level (PL) in order to achieve the required risk reduction for each safety function
- **PFH**
  Average rate of dangerous failure
- **Risk**
  Combination of the probability of occurrence of harm and the severity of that harm
- **Safety function**
  Function of the machine whose failure can result in an immediate increase of the risk(s)
- **Safety Integrity Level (SIL)**
  Discrete level (one out of a possible three) for describing the capability to perform a safety function where SIL 3 has the highest level of safety integrity and SIL 1 has the lowest
- **Safety-related control system (SCS)**
  Part of the control system of a machine which implements a safety function by one or more "subsystems"
- **Subsystem**
  Entity of the top-level architec-tural design of a safety-related system where a dangerous failure of the subsystem results in dangerous failure of a safety function

The measures outlined on this sheet are simplified descriptions and are intended to provide an overview of the standards EN ISO 12100, ISO 13849-1 and EN IEC 62061. Detailed understanding and correct application of all relevant standards and directives are needed for validation of safety circuits. As a result, we cannot accept any liability for omissions or incomplete information.



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