

FINAL
DRAFT

INTERNATIONAL
STANDARD

ISO/FDIS
13849-1

ISO/TC 199

Secretariat: DIN

Voting begins on:
2022-12-08

Voting terminates on:
2023-02-02

Safety of machinery — Safety-related parts of control systems —

Part 1: General principles for design

Sécurité des machines — Parties des systèmes de commande relatives à la sécurité —

Partie 1: Principes généraux de conception

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO 13849-1](https://standards.iteh.ai/catalog/standards/sist/0ec4d0c2-c2ee-4bac-b69f-0a883595198b/iso-13849-1)

<https://standards.iteh.ai/catalog/standards/sist/0ec4d0c2-c2ee-4bac-b69f-0a883595198b/iso-13849-1>

ISO/CEN PARALLEL PROCESSING

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.



Reference number
ISO/FDIS 13849-1:2022(E)

© ISO 2022

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 13849-1

<https://standards.iteh.ai/catalog/standards/sist/0ec4d0c2-c2ee-4bac-b69f-0a883595198b/iso-13849-1>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword.....	vi
Introduction.....	viii
1 Scope.....	1
2 Normative references.....	1
3 Terms, definitions, symbols and abbreviated terms.....	2
3.1 Terms and definitions.....	2
3.2 Symbols and abbreviated terms.....	10
4 Overview.....	12
4.1 Risk assessment and risk reduction process at the machine.....	12
4.2 Contribution to the risk reduction.....	14
4.3 Design process of an SRP/CS.....	14
4.4 Methodology.....	15
4.5 Required information.....	16
4.6 Safety function realization by using subsystems.....	17
5 Specification of safety functions.....	17
5.1 Identification and general description of the safety function.....	17
5.2 Safety requirements specification.....	18
5.2.1 General requirements.....	18
5.2.2 Requirements for specific safety functions.....	21
5.2.3 Minimizing motivation to defeat safety functions.....	24
5.2.4 Remote access.....	25
5.3 Determination of required performance level (PL _r) for each safety function.....	25
5.4 Review of the safety requirements specification (SRS).....	26
5.5 Decomposition of SRP/CS into subsystems.....	26
6 Design considerations.....	27
6.1 Evaluation of the achieved performance level.....	27
6.1.1 General overview of performance level.....	27
6.1.2 Correlation between performance level (PL) and safety integrity level (SIL).....	29
6.1.3 Architecture — Categories and their relation to MTTF _D of each channel, average diagnostic coverage and common cause failure (CCF).....	29
6.1.4 Mean time to dangerous failure (MTTF _D).....	36
6.1.5 Diagnostic coverage (DC).....	37
6.1.6 Common cause failures (CCFs).....	38
6.1.7 Systematic failures.....	38
6.1.8 Simplified procedure for estimating the performance level for subsystems.....	39
6.1.9 Alternative procedure to determine the performance level and PFH without MTTF _D	40
6.1.10 Fault consideration and fault exclusion.....	42
6.1.11 Well-tried component.....	43
6.2 Combination of subsystems to achieve an overall performance level of the safety function.....	43
6.2.1 General.....	43
6.2.2 Known PFH values.....	43
6.2.3 Unknown PFH values.....	44
6.3 Software-based manual parameterization.....	44
6.3.1 General.....	44
6.3.2 Influences on safety-related parameters.....	45
6.3.3 Requirements for software based manual parameterization.....	46
6.3.4 Verification of the parameterization tool.....	47
6.3.5 Documentation of software based manual parameterization.....	47
7 Software safety requirements.....	47
7.1 General.....	47

7.2	Limited variability language (LVL) and full variability language (FVL)	49
7.2.1	Limited variability language (LVL)	49
7.2.2	Full variability language (FVL)	49
7.2.3	Decision for limited variability language (LVL) or full variability language (FVL)	49
7.3	Safety-related embedded software (SRESW)	51
7.3.1	Design of safety-related embedded software (SRESW)	51
7.3.2	Alternative procedures for non-accessible embedded software	52
7.4	Safety-related application software (SRASW)	52
8	Verification of the achieved performance level	55
9	Ergonomic aspects of design	55
10	Validation	55
10.1	Validation principles	55
10.1.1	General	55
10.1.2	Validation plan	57
10.1.3	Generic fault lists	58
10.1.4	Specific fault lists	58
10.1.5	Information for validation	58
10.2	Validation of the safety requirements specification (SRS)	59
10.3	Validation by analysis	60
10.3.1	General	60
10.3.2	Analysis techniques	60
10.4	Validation by testing	60
10.4.1	General	60
10.4.2	Measurement accuracy	61
10.4.3	Additional requirements for testing	62
10.4.4	Number of test samples	62
10.4.5	Testing methods	62
10.5	Validation of the safety functions	63
10.6	Validation of the safety integrity of the SRP/CS	63
10.6.1	Validation of subsystem(s)	63
10.6.2	Validation of measures against systematic failures	64
10.6.3	Validation of safety-related software	65
10.6.4	Validation of combination of subsystems	66
10.6.5	Overall validation of safety integrity	66
10.7	Validation of environmental requirements	66
10.8	Validation record	67
10.9	Validation maintenance requirements	67
11	Maintainability of SRP/CS	67
12	Technical documentation	68
13	Information for use	68
13.1	General	68
13.2	Information for SRP/CS integration	68
13.3	Information for user	69
Annex A (informative)	Guidance for the determination of required performance level (PL_r)	71
Annex B (informative)	Block method and safety-related block diagram	76
Annex C (informative)	Calculating or evaluating MTTF_D values for single components	78
Annex D (informative)	Simplified method for estimating MTTF_D for each channel	86
Annex E (informative)	Estimates for diagnostic coverage (DC) for functions and subsystems	88
Annex F (informative)	Method for quantification of measures against common cause failures (CCF)	93
Annex G (informative)	Systematic failure	97

Annex H (informative) Example of a combination of several subsystems	101
Annex I (informative) Examples for the simplified procedure to estimate the PL of subsystems	104
Annex J (informative) Example of SRESW realisation	112
Annex K (informative) Numerical representation of Figure 12	116
Annex L (informative) Electromagnetic interference (EMI) immunity	121
Annex M (informative) Additional information for safety requirements specification (SRS)	125
Annex N (informative) Avoiding systematic failure in software design	127
Annex O (informative) Safety-related values of components or parts of control systems	146
Annex ZA (informative) Relationship between this European Standard and the essential requirements of EU Directive 2006/42/EC aimed to be covered	149
Bibliography	151

iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO 13849-1](#)

<https://standards.iteh.ai/catalog/standards/sist/0ec4d0c2-c2ee-4bac-b69f-0a883595198b/iso-13849-1>

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 199, *Safety of machinery*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 144, *Safety of machinery*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 13849-1:2015), which has been technically revised.

The main changes are as follows:

- the whole document was reorganized to better follow the design and development process for control systems;
- new [Clause 4](#) on recommendation for risk assessment;
- specification of the safety functions (updated [Clause 5](#));
- combination of several subsystems (updated in [Clause 6](#));
- new [Clause 7](#) on software safety requirements;
- new [Clause 9](#) on ergonomic aspects of design;
- validation (updated [Clause 8](#) and moved to [Clause 10](#));
- new [G.5](#) on management of the functional safety;
- new [Annex L](#) on electromagnetic interference (EMI) immunity;
- new [Annex M](#) with additional information for safety requirements specification;
- new [Annex N](#) on fault-avoiding measures for the design of safety related software;
- new [Annex O](#) with safety-related values of components or parts of the control systems.

A list of all parts in the ISO 13849 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 13849-1

<https://standards.iteh.ai/catalog/standards/sist/0ec4d0c2-c2ee-4bac-b69f-0a883595198b/iso-13849-1>

Introduction

The structure of safety standards in the field of machinery is as follows.

- a) Type-A standards (basis standards) give basic concepts, principles for design and general aspects that can be applied to machinery.
- b) Type-B standards (generic safety standards) deal with one or more safety aspect(s), or one or more type(s) of safeguards that can be used across a wide range of machinery:
 - type-B1 standards on particular safety aspects (e.g. safety distances, surface temperature, noise);
 - type-B2 standards on safeguards (e.g. two-hand controls, interlocking devices, pressure sensitive devices, guards).
- c) Type-C standards (machinery safety standards) deal with detailed safety requirements for a particular machine or group of machines.

This document is a type-B1 standard as defined in ISO 12100:2010.

The first edition of this document was published in 1999 based on EN 954-1:1996 (withdrawn standard). The second edition was revised in 2006 and the third edition was revised in 2015.

This document is of relevance, in particular for the following stakeholder groups with regard to machinery safety:

- machine manufacturers (small, medium and large enterprises);
- health and safety bodies (regulators, accident prevention organisations, market surveillance).

Others can be affected by the level of machinery safety achieved with the means of the document:

- machine users/employers (small, medium and large enterprises);
- machine users/employees (e.g. trade unions);
- service providers, e.g. for maintenance (small, medium and large enterprises);
- consumers (i.e. machinery intended for use by consumers).

The above-mentioned stakeholder groups have been given the possibility to participate in the drafting process of this document.

In addition, this document is intended for standardization bodies elaborating type-C standards, as defined in ISO 12100:2010.

The requirements of this document can be supplemented or modified by a type-C standard.

For machines which are covered by the scope of a type-C standard and which have been designed and built according to the requirements of that standard, the requirements of that type-C standard take precedence.

NOTE 1 The examples and basis for most content is based on stationary machines in factory applications. However, other machines are not excluded. This document was written without considering if certain machinery (e.g. mobile machinery) has specific requirements. However, this document is intended to be used across many machinery industries and as a basis for type-C standards developers, as far as applicable.

This document is intended to give guidance to those involved in the design and assessment of control systems, and those preparing type-B2 or type-C standards.

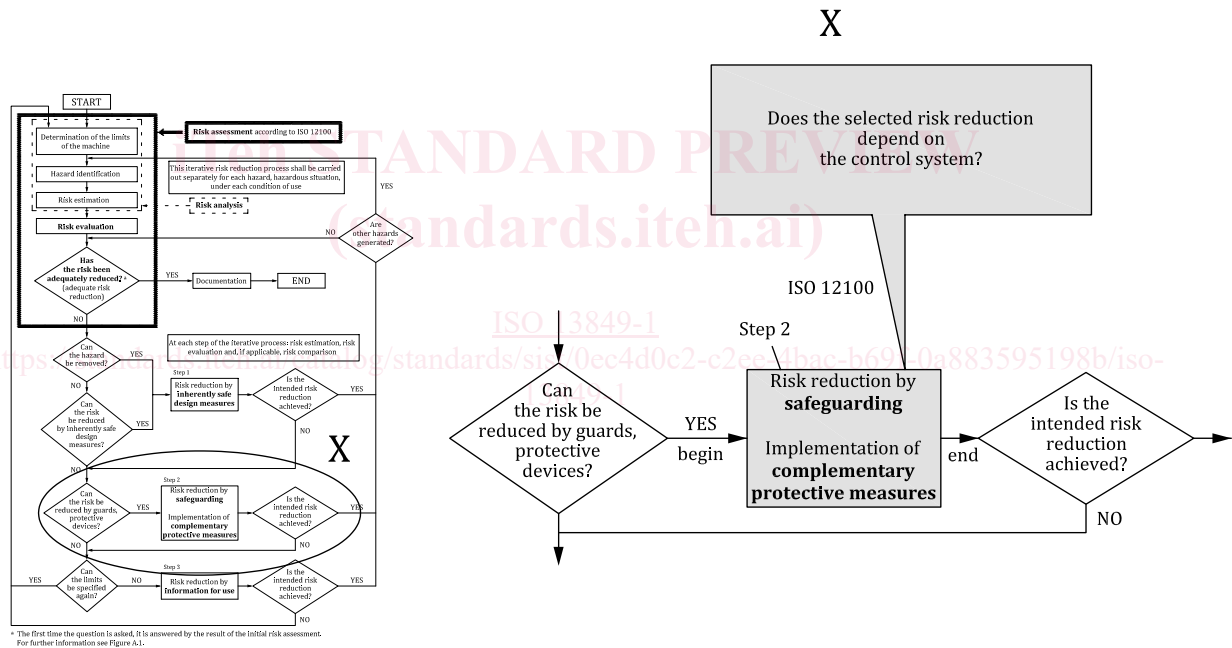
Risk reduction according to ISO 12100:2010, Clause 6, is accomplished by applying, in the following sequence, inherently safe design measures, safeguarding and/or complementary risk reduction

measures and information for use. A designer can reduce risks by risk reduction measures that can have safety functions. Parts of machinery control systems that are assigned to provide safety functions are called safety-related parts of control systems (SRP/CS). These can consist of hardware or a combination of hardware and software and can either be separate from the machine control system or an integral part of it. In addition to implementing safety functions, SRP/CS can also implement operational functions.

ISO 12100:2010 is used for risk assessment of the machine. [Annex A](#) of this document can be used for the determination of the required performance level (PL_r) of a safety function performed by the SRP/CS, where its PL_r is not specified in the applicable type-C standard. This document is relevant for the SRP/CS safety functions that are used to address risks for cases where a risk assessment conducted according to ISO 12100:2010 determines that a risk reduction measure is needed that relies on a safety function (e.g. interlocking guard). In those cases, the safety-related control system performs a safety function. This document is intended to be used to design and evaluate the SRP/CS. Only the part of the control system that is safety-related falls under the scope of this document.

Figure 1 illustrates the relationship between ISO 12100:2010 and this document. For a detailed overview see [Figure 2](#).

NOTE 2 See also ISO/TR 22100-2:2013 for further information.



NOTE Based on ISO/TR 22100-2:2013, Figure 2.

Figure 1 — Integration of this document (ISO 13849-1) within the risk reduction process of ISO 12100:2010

NOTE 3 [Figure 1](#) shows where the SRP/CS contributes to the risk reduction process of ISO 12100:2010: Step 2. The SRP/CS supports the combined risk reduction measures by the implementation of safety functions. The ability of safety-related parts of control systems to perform a safety function under foreseeable conditions is allocated one of five levels, called performance levels (PL). The required performance level (PL_r) for a particular safety function (depending on the required risk reduction) will be determined by risk estimation.

Informative [Annex A](#) of this document contains a method for risk estimation and can be used for the determination of the PL_r of a safety function performed by the SRP/CS. Any risk estimation method will show a variance because of the subjective nature of the evaluation criteria. In comparison to [Annex A](#), type-C standards can have more specific risk estimation methods for specific machine applications.

The frequency of dangerous failure of the safety function depends on several factors, including but not limited to, hardware and software structure, the extent of fault detection mechanisms [diagnostic

coverage (DC)], reliability of components [mean time to dangerous failure (MTTF_D), common cause failure (CCF)], design process, operating stress, environmental conditions and operation procedures.

In order to facilitate the design of SRP/CS and the assessment of achieved PL, this document employs a methodology based on the categorization of architectures with specific design criteria (e.g. MTTF_D, DC_{avg}) and specified behaviour under fault conditions. These architectures are allocated one of five levels termed Categories B, 1, 2, 3 and 4.

Functional safety considers the failure characteristics of elements/components performing a safety function. For each safety function, this failure characteristic is expressed as the frequency of dangerous failure per hour (PFH).

The performance levels and categories can be applied to SRP/CS, e.g.:

- control units (e.g. a logic unit for control functions, data processing, monitoring);
- electro-sensitive protective devices (e.g. photoelectric barriers), pressure sensitive devices.

The performance levels can be defined, and categories determined, for subsystems of SRP/CS using safety parts (components), e.g.:

- protective devices (e.g. two-hand control devices, interlocking devices);
- power control elements (e.g. relays, valves);
- sensors and HMI elements (e.g. position sensors, enable switches).

Machinery covered by this document can range from simple (e.g. small kitchen machines, or automatic doors and gates) to complex (e.g. packaging machines, printing machines, presses and integrated machinery into a system).

This document and IEC 62061 both specify a methodology and provide related guidance for the design and implementation of safety-related control systems of machinery.

The requirements of [Clause 10](https://standards.iteh.ai/catalog/standards/sist/0ec4d0c2-c2ee-4bac-b69f-0a883595198b/iso-13849-1-2022) of this document supersede the requirements of ISO 13849-2:2012 (excluding the informative annexes).

Safety of machinery — Safety-related parts of control systems —

Part 1: General principles for design

1 Scope

This document specifies a methodology and provides related requirements, recommendations and guidance for the design and integration of safety-related parts of control systems (SRP/CS) that perform safety functions, including the design of software.

This document applies to SRP/CS for high demand and continuous modes of operation including their subsystems, regardless of the type of technology and energy (e.g. electrical, hydraulic, pneumatic, and mechanical). This document does not apply to low demand mode of operation.

NOTE 1 See [3.1.44](#) and the IEC 61508 series for low demand mode of operation.

This document does not specify the safety functions or required performance levels (PL_r) that are to be used in particular applications.

NOTE 2 This document specifies a methodology for SRP/CS design without considering if certain machinery (e.g. mobile machinery) has specific requirements. These specific requirements can be considered in a Type-C standard.

This document does not give specific requirements for the design of products/components that are parts of SRP/CS. Specific requirements for the design of some components of SRP/CS are covered by applicable ISO and IEC standards.

This document does not provide specific measures for security aspects (e.g. physical, IT-security, cyber security).

NOTE 3 Security issues can have an effect on safety functions. See ISO/TR 22100-4 and IEC/TR 63074 for further information.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

ISO 13849-2:2012, *Safety of machinery — Safety-related parts of control systems — Part 2: Validation*

ISO 13855:2010, *Safety of machinery — Positioning of safeguards with respect to the approach speeds of parts of the human body*

ISO 20607:2019, *Safety of machinery — Instruction handbook — General drafting principles*

IEC 61508-3:2010, *Functional safety of electrical/electronic/programmable electronic safety-related systems — Part 3: Software requirements*

IEC 62046:2018, *Safety of machinery — Application of protective equipment to detect the presence of persons*

IEC 62061:2021, *Safety of machinery — Functional safety of safety-related control systems*

IEC/IEEE 82079-1:2019, *Preparation of information for use (instructions for use) of products — Part 1: Principles and general requirements*

3 Terms, definitions, symbols and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 12100:2010 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1.1

safety-related part of a control system

SRP/CS

part of a control system that performs a *safety function* (3.1.27), starting from a safety-related input(s) to generating a safety-related output(s)

Note 1 to entry: The safety-related parts of a control system start at the point where the safety-related inputs are initiated (including, for example, the actuating cam and the roller of the position switch) and end at the output of the power control elements (including, for example, the main contacts of a contactor).

3.1.2

machine control system

system which responds to input signals from parts of machine elements, operators, external control equipment or any combination of these and generates output signals causing the machine to behave in the intended manner

Note 1 to entry: The machine control system can use any technology or any combination of different technologies (e.g. electrical/electronic, hydraulic, pneumatic and mechanical).

3.1.3

safety requirements specification

SRS

specification containing the requirements for the *safety functions* (3.1.27) that have to be met by the safety-related control system in terms of characteristics of the safety functions (functional requirements) and *required performance levels* (PL_r) (3.1.6)

[SOURCE: IEC 61508-4:2010, 3.5.11, modified — Information from 3.5.12 has been included.]

3.1.4

category

classification of the *subsystem* (3.1.45) in respect to its resistance to *faults* (3.1.8) and the subsequent behaviour in the fault condition which is achieved by the structural arrangement of the parts, fault detection and/or by their reliability

3.1.5

performance level

PL

discrete level used to specify the ability of *safety-related parts of control systems* (SRP/CS) (3.1.1) to perform a *safety function* (3.1.27) under foreseeable conditions

Note 1 to entry: See 6.1 for a general overview of performance level.

3.1.6 required performance level

PL_r

performance level (3.1.5) required in order to achieve the required *risk* (3.1.19) reduction for each *safety function* (3.1.27)

Note 1 to entry: See 5.3 and Figure A.1 for further information on required performance level (PL_r).

3.1.7 safety integrity level

SIL

discrete level (one out of a possible four) for specifying the safety integrity requirements of *safety functions* (3.1.27) to be allocated to the safety-related systems, where safety integrity level 4 has the highest level of safety integrity and safety integrity level 1 has the lowest

Note 1 to entry: In this document only SIL 1 to SIL 3 are considered.

[SOURCE: IEC 61508-4:2010, 3.5.8, modified — “allocated to safety-related systems” has been added to definition, NOTES have been deleted and new Note 1 to entry has been added.]

3.1.8

fault

abnormal condition that may cause a reduction in, or loss of, the capability of a functional unit to perform a required function

Note 1 to entry: A fault is often the result of a *failure* (3.1.10) of the item itself, but can exist without prior failure.

Note 2 to entry: In this document “fault” means random fault or fault caused by a *systematic failure* (3.1.14).

[SOURCE: IEC 60050-192:2015, modified — Note 2 to entry has been amended.]

3.1.9

fault exclusion

exclusion of certain *faults* (3.1.8) within a safety-related part of a control system (SRP/CS), if this exclusion can be justified due to the negligible probability of these faults

3.1.10

failure

termination of the ability of a device to perform a required function

Note 1 to entry: After a failure, the device has a *fault* (3.1.8).

Note 2 to entry: “Failure” is an event, as distinguished from “fault”, which is a state.

Note 3 to entry: Failures which only affect the availability of the process under control are outside of the scope of this document.

[SOURCE: IEC 60050-192:2015, modified — Note 3 to entry has been amended.]

3.1.11

permanent fault

fault (3.1.8) of an item that persists until an action of corrective maintenance is performed

[SOURCE: IEC 60050-192:2015]

3.1.12

dangerous failure

failure (3.1.10) of an element and/or *subsystem* (3.1.45) and/or system that plays a part in implementing the *safety function* (3.1.27) that:

- a) prevents a safety function from operating when required (demand mode) or causes a safety function to fail (continuous mode) such that the machine/machinery is put into a hazardous or potentially hazardous state; or

b) decreases the probability that the safety function operates correctly when required

[SOURCE: IEC 61508-4:2010, 3.6.7, modified — "EUC" has been replaced by "SRP/CS".]

3.1.13

common cause failure

CCF

failure (3.1.10) that is the result of one or more events, causing concurrent failures of two or more separate *channels* (3.1.47) in a multiple channel *subsystem* (3.1.45), leading to failure of a *safety function* (3.1.27)

Note 1 to entry: Common cause failures are not identical with common mode failures (see ISO 12100:2010, 3.36).

[SOURCE: IEC 61508-4:2010, 3.6.10, modified — Note 1 to entry has been added.]

3.1.14

systematic failure

failure (3.1.10) related in a deterministic way to a certain cause, which can only be eliminated by a modification of the design or of the manufacturing process, operational procedures, documentation or other relevant factors

Note 1 to entry: Corrective maintenance without modification will usually not eliminate the failure cause.

Note 2 to entry: A systematic failure can be induced by simulating the failure cause.

Note 3 to entry: Examples of causes of systematic failures include human error in

- the *safety requirements specification (SRS)* (3.1.3),
- the design, manufacture, installation, operation of the hardware,
- the design, implementation, of the software, and
- inadequately specifying environmental conditions.

[SOURCE: IEC 60050-192:2015]

3.1.15

muting

temporary automatic suspension of a *safety function(s)* (3.1.27) by the SRP/CS

[SOURCE: IEC 61496-1:2020, 3.16]

3.1.16

harm

physical injury or damage to health

[SOURCE: ISO 12100:2010, 3.5]

3.1.17

hazard

potential source of *harm* (3.1.16)

Note 1 to entry: The term "hazard" can be qualified in order to define its origin (e.g. mechanical hazard, electrical hazard) or the nature of the potential harm (e.g. electric shock hazard, cutting hazard, toxic hazard and fire hazard).

Note 2 to entry: The hazard envisaged in this definition either:

- is permanently present during the intended use of the machine (e.g. motion of hazardous moving elements, electric arc during a welding phase, unhealthy posture, noise emission, high temperature); or
- can appear unexpectedly (e.g. explosion, crushing hazard as a consequence of an unintended/unexpected start-up, ejection as a consequence of a breakage, fall as a consequence of acceleration/deceleration).

[SOURCE: ISO 12100:2010, 3.6, modified — Note 3 to entry has been deleted.]

3.1.18

hazardous situation

circumstance in which a person is exposed to at least one *hazard* (3.1.17)

Note 1 to entry: The exposure can result in *harm* (3.1.16) immediately or over a period of time.

[SOURCE: ISO 12100:2010, 3.10]

3.1.19

risk

combination of the probability of occurrence of *harm* (3.1.16) and the severity of that harm

[SOURCE: ISO 12100:2010, 3.12]

3.1.20

residual risk

risk (3.1.19) remaining after *risk reduction measures (protective measures)* (3.1.22) have been taken

Note 1 to entry: See [Figure 3](#).

[SOURCE: ISO 12100:2010, 3.13, modified — Note 1 to entry has been modified.]

3.1.21

risk assessment

overall process comprising *risk analysis* (3.1.23) and *risk evaluation* (3.1.24)

[SOURCE: ISO 12100:2010, 3.17]

3.1.22

risk reduction measure

protective measure

action or means to eliminate *hazards* (3.1.17) or reduce *risks* (3.1.19)

EXAMPLE Inherently safe design; protective devices; personal protective equipment; information for use and installation; organization of work; training; application of equipment; supervision.

[SOURCE: ISO/IEC Guide 51:2014, 3.13]

3.1.23

risk analysis

combination of the specification of the limits of the machine, *hazard* (3.1.17) identification and *risk* (3.1.19) estimation

[SOURCE: ISO 12100:2010, 3.15]

3.1.24

risk evaluation

judgement, on the basis of *risk analysis* (3.1.23), of whether risk reduction objectives have been achieved

[SOURCE: ISO 12100:2010, 3.16]

3.1.25

intended use of the machine

use of a machine in accordance with the information provided in the instructions for use

[SOURCE: ISO 12100:2010, 3.23]