



IEC 62061

Edition 2.1 2024-03  
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD



---

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

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

---

ICS 13.110; 25.040.99; 29.020

ISBN 978-2-8322-8675-3

**Warning! Make sure that you obtained this publication from an authorized distributor.**

## CONTENTS

FOREWORD.....	8
INTRODUCTION.....	10
1 Scope.....	11
2 Normative references .....	12
3 Terms, definitions and abbreviations .....	13
3.1 Alphabetical list of definitions.....	13
3.2 Terms and definitions.....	15
3.3 Abbreviations.....	28
4 Design process of an SCS and management of functional safety.....	28
4.1 Objective .....	28
4.2 Design process .....	29
4.3 Management of functional safety using a functional safety plan .....	31
4.4 Configuration management .....	33
4.5 Modification .....	33
5 Specification of a safety function .....	34
5.1 Objective .....	34
5.2 Safety requirements specification (SRS).....	34
5.2.1 General .....	34
5.2.2 Information to be available.....	34
5.2.3 Functional requirements specification .....	35
5.2.4 Estimation of demand mode of operation .....	35
5.2.5 Safety integrity requirements specification.....	36
6 Design of an SCS .....	37
6.1 General.....	37
6.2 Subsystem architecture based on top down decomposition .....	37
6.3 Basic methodology – Use of subsystem .....	37
6.3.1 General .....	37
6.3.2 SCS decomposition .....	38
6.3.3 Sub-function allocation .....	39
6.3.4 Use of a pre-designed subsystem.....	39
6.4 Determination of safety integrity of the SCS.....	40
6.4.1 General .....	40
6.4.2 PFH.....	40
6.5 Requirements for systematic safety integrity of the SCS .....	41
6.5.1 Requirements for the avoidance of systematic hardware failures .....	41
6.5.2 Requirements for the control of systematic faults.....	42
6.6 Electromagnetic immunity .....	43
6.7 Software based manual parameterization.....	43
6.7.1 General .....	43
6.7.2 Influences on safety-related parameters .....	43
6.7.3 Requirements for software based manual parameterization .....	44
6.7.4 Verification of the parameterization tool.....	45
6.7.5 Performance of software based manual parameterization .....	45
6.8 Security aspects .....	45
6.9 Aspects of periodic testing .....	46
7 Design and development of a subsystem.....	46

7.1	General.....	46
7.2	Subsystem architecture design .....	47
7.3	Requirements for the selection and design of subsystem and subsystem elements .....	48
7.3.1	General .....	48
7.3.2	Systematic integrity .....	48
7.3.3	Fault consideration and fault exclusion .....	51
7.3.4	Failure rate of subsystem element .....	52
7.4	Architectural constraints of a subsystem .....	55
7.4.1	General .....	55
7.4.2	Estimation of safe failure fraction ( <i>SFF</i> ) .....	56
7.4.3	Behaviour (of the SCS) on detection of a fault in a subsystem .....	58
7.4.4	Realization of diagnostic functions .....	59
7.5	Subsystem design architectures.....	60
7.5.1	General .....	60
7.5.2	Basic subsystem architectures.....	60
7.5.3	Basic requirements .....	61
7.6	<i>PFH</i> of subsystems .....	62
7.6.1	General .....	62
7.6.2	Methods to estimate the <i>PFH</i> of a subsystem .....	62
7.6.3	Simplified approach to estimation of contribution of common cause failure ( <i>CCF</i> ).....	63
8	Software.....	63
8.1	General.....	63
8.2	Definition of software levels .....	63
8.3	Software – Level 1 .....	64
8.3.1	Software safety lifecycle – SW level 1 .....	64
8.3.2	Software design – SW level 1 .....	65
8.3.3	Module design – SW level 1.....	67
8.3.4	Coding – SW level 1 .....	68
8.3.5	Module test – SW level 1 .....	68
8.3.6	Software testing – SW level 1 .....	68
8.3.7	Documentation – SW level 1.....	69
8.3.8	Configuration and modification management process – SW level 1.....	69
8.4	Software level 2 .....	70
8.4.1	Software safety lifecycle – SW level 2 .....	70
8.4.2	Software design – SW level 2 .....	72
8.4.3	Software system design – SW level 2 .....	73
8.4.4	Module design – SW level 2.....	74
8.4.5	Coding – SW level 2 .....	75
8.4.6	Module test – SW level 2 .....	75
8.4.7	Software integration testing SW level 2.....	76
8.4.8	Software testing SW level 2.....	76
8.4.9	Documentation – SW level 2.....	77
8.4.10	Configuration and modification management process – SW level 2.....	77
9	Validation .....	78
9.1	Validation principles.....	78
9.1.1	Validation plan.....	81
9.1.2	Use of generic fault lists .....	81

9.1.3	Specific fault lists .....	81
9.1.4	Information for validation .....	82
9.1.5	Validation record .....	82
9.2	Analysis as part of validation .....	83
9.2.1	General .....	83
9.2.2	Analysis techniques .....	83
9.2.3	Verification of safety requirements specification (SRS) .....	83
9.3	Testing as part of validation .....	84
9.3.1	General .....	84
9.3.2	Measurement accuracy .....	84
9.3.3	More stringent requirements .....	85
9.3.4	Test samples .....	85
9.4	Validation of the safety function .....	85
9.4.1	General .....	85
9.4.2	Analysis and testing .....	86
9.5	Validation of the safety integrity of the SCS .....	86
9.5.1	General .....	86
9.5.2	Validation of subsystem(s) .....	86
9.5.3	Validation of measures against systematic failures .....	87
9.5.4	Validation of safety-related software .....	87
9.5.5	Validation of combination of subsystems .....	88
10	Documentation .....	88
10.1	General .....	88
10.2	Technical documentation .....	88
10.3	Information for use of the SCS .....	90
10.3.1	General .....	90
10.3.2	Information for use given by the manufacturer of subsystems .....	90
10.3.3	Information for use given by the SCS integrator .....	91
Annex A (informative)	Determination of required safety integrity .....	93
A.1	General .....	93
A.2	Matrix assignment for the required SIL .....	93
A.2.1	Hazard identification/indication .....	93
A.2.2	Risk estimation .....	93
A.2.3	Severity (Se) .....	94
A.2.4	Probability of occurrence of harm .....	94
A.2.5	Class of probability of harm (Cl) .....	97
A.2.6	SIL assignment .....	97
A.3	Overlapping hazards .....	99
Annex B (informative)	Example of SCS design methodology .....	100
B.1	General .....	100
B.2	Safety requirements specification .....	100
B.3	Decomposition of the safety function .....	100
B.4	Design of the SCS by using subsystems .....	101
B.4.1	General .....	101
B.4.2	Subsystem 1 design – “guard door monitoring” .....	101
B.4.3	Subsystem 2 design – “evaluation logic” .....	103
B.4.4	Subsystem 3 design – “motor control” .....	104
B.4.5	Evaluation of the SCS .....	104
B.4.6	PFH .....	105

B.5	Verification.....	105
B.5.1	General .....	105
B.5.2	Analysis.....	105
B.5.3	Tests .....	106
Annex C (informative)	Examples of $MTTF_D$ values for single components .....	107
C.1	General.....	107
C.2	Good engineering practices method .....	107
C.3	Hydraulic components.....	107
C.4	$MTTF_D$ of pneumatic, mechanical and electromechanical components .....	108
Annex D (informative)	Examples for diagnostic coverage ( $DC$ ).....	110
Annex E (informative)	Methodology for the estimation of susceptibility to common cause failures (CCF).....	112
E.1	General.....	112
E.2	Methodology .....	112
E.2.1	Requirements for CCF .....	112
E.2.2	Estimation of effect of CCF .....	112
Annex F (informative)	Guideline for software level 1 .....	115
F.1	Software safety requirements.....	115
F.2	Coding guidelines .....	116
F.3	Specification of safety functions .....	117
F.4	Specification of hardware design .....	118
F.5	Software system design specification.....	120
F.6	Protocols .....	122
Annex G (informative)	Examples of safety functions.....	125
Annex H (informative)	Simplified approaches to evaluate the $PFH$ value of a subsystem .....	126
H.1	Table allocation approach .....	126
H.2	Simplified formulas for the estimation of $PFH$ .....	128
H.2.1	General .....	128
H.2.2	Basic subsystem architecture A: single channel without a diagnostic function .....	128
H.2.3	Basic subsystem architecture B: dual channel without a diagnostic function .....	129
H.2.4	Basic subsystem architecture C: single channel with a diagnostic function .....	129
H.2.5	Basic subsystem architecture D: dual channel with a diagnostic function(s).....	135
H.3	Parts count method.....	136
Annex I (informative)	The functional safety plan and design activities .....	137
I.1	General.....	137
I.2	Example of a machine design plan including a safety plan .....	137
I.3	Example of activities, documents and roles.....	137
Annex J (informative)	Independence for reviews and testing/verification/validation activities .....	141
J.1	Software design .....	141
J.2	Validation.....	141
Bibliography	.....	143
Figure 1 – Scope of this document	.....	12

Figure 2 – Integration within the risk reduction process of ISO 12100 (extract) .....	29
Figure 3 – Iterative process for design of the safety-related control system .....	30
Figure 4 – Example of a combination of subsystems as one SCS.....	31
Figure 5 – By activating a low demand safety function at least once per year it can be assumed to be high demand .....	36
Figure 6 – Examples of typical decomposition of a safety function into sub-functions and its allocation to subsystems .....	39
Figure 7 – Example of safety integrity of a safety function based on allocated subsystems as one SCS .....	40
Figure 8 – Basic subsystem architecture A logical representation .....	60
Figure 9 – Basic subsystem architecture B logical representation .....	60
Figure 10 – Basic subsystem architecture C logical representation .....	61
Figure 11 – Basic subsystem architecture D logical representation .....	61
Figure 12 – V-model for SW level 1.....	65
Figure 13 – V-model for software modules customized by the designer for SW level 1 .....	65
Figure 14 – V-model of software safety lifecycle for SW level 2.....	71
Figure 15 – Overview of the validation process .....	80
Figure A.1 – Parameters used in risk estimation .....	93
Figure A.2 – Example proforma for SIL assignment process .....	99
Figure B.1 – Decomposition of the safety function.....	101
Figure B.2 – Overview of design of the subsystems of the SCS .....	101
Figure F.1 – Plant sketch .....	117
Figure F.2 – Principal module architecture design.....	120
Figure F.3 – Principal design approach of logical evaluation .....	121
Figure F.4 – Example of logical representation (program sketch) .....	122
Figure H.1 – Basic subsystem architecture A logical representation.....	128
Figure H.2 – Basic subsystem architecture B logical representation.....	129
Figure H.3 – Basic subsystem architecture C logical representation.....	129
Figure H.4 – Correlation of basic subsystem architecture C and the pertinent fault handling function .....	130
Figure H.5 – Basic subsystem architecture C with external fault handling function .....	131
Figure H.6 – Basic subsystem architecture C with external fault diagnostics .....	132
Figure H.7 – Basic subsystem architecture C with external fault reaction .....	132
Figure H.8 – Basic subsystem architecture C with internal fault diagnostics and internal fault reaction.....	133
Figure H.9 – Basic subsystem architecture D logical representation.....	135
Figure I.1 – Example of a machine design plan including a safety plan .....	137
Figure I.2 – Example of activities, documents and roles (1 of 2).....	139
Table 1 – Terms used in IEC 62061 .....	13
Table 2 – Abbreviations used in IEC 62061.....	28
Table 3 – SIL and limits of <i>PFH</i> values.....	36
Table 4 – Required SIL and <i>PFH</i> of pre-designed subsystem .....	40
Table 5 – Relevant information for each subsystem .....	47

Table 6 – Architectural constraints on a subsystem: maximum SIL that can be claimed for an SCS using the subsystem .....	56
Table 7 – Overview of basic requirements and interrelation to basic subsystem architectures .....	62
Table 8 – Different levels of application software .....	63
Table 9 – Documentation of an SCS .....	89
Table A.1 – Severity (Se) classification .....	94
Table A.2 – Frequency and duration of exposure (Fr) classification .....	95
Table A.3 – Probability (Pr) classification .....	96
Table A.4 – Probability of avoiding or limiting harm (Av) classification .....	97
Table A.5 – Parameters used to determine class of probability of harm (Cl) .....	97
Table A.6 – Matrix assignment for determining the required SIL (or $PL_r$ ) for a safety function .....	98
Table B.1 – Safety requirements specification – example of overview .....	100
Table B.2 – Systematic integrity – example of overview .....	105
Table B.3 – Verification by tests .....	106
Table C.1 – Standards references and $MTTF_D$ or $B_{10D}$ values for components .....	108
Table D.1 – Estimates for diagnostic coverage (DC) (1 of 2) .....	110
Table E.1 – <del>Criteria for estimation of CCF</del> Estimation of CCF factor ( $\beta$ ) .....	113
Table E.2 – Criteria for estimation of CCF .....	114
Table F.1 – Example of relevant documents related to the simplified V-model .....	115
Table F.2 – Examples of coding guidelines .....	116
Table F.3 – Specified safety functions .....	118
Table F.4 – Relevant list of input and output signals .....	119
Table F.5 – Example of simplified cause and effect matrix .....	122
Table F.6 – Verification of software system design specification .....	123
Table F.7 – Software code review .....	123
Table F.8 – Software validation .....	124
Table G.1 – Examples of typical safety functions .....	125
Table H.1 – Allocation of $PFH$ value of a subsystem .....	127
Table H.2 – Relationship between $B_{10D}$ , operations and $MTTF_D$ .....	128
Table H.3 – Minimum value of $1/\lambda_D F_H$ for the applicability of $PFH$ equation (H.43) .....	133
Table J.1 – Minimum levels of independence for review, testing and verification activities .....	141
Table J.2 – Minimum levels of independence for validation activities .....	141

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

---

**SAFETY OF MACHINERY –  
FUNCTIONAL SAFETY OF SAFETY-RELATED CONTROL SYSTEMS****FOREWORD**

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <https://patents.iec.ch>. IEC shall not be held responsible for identifying any or all such patent rights.

**This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.**

**IEC 62061 edition 2.1 contains the second edition (2021-03) [documents 44/885/FDIS and 44/888/RVD] and its amendment 1 (2024-03) [documents 44/1020/FDIS and 44/1024/RVD].**

**In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.**



IEC 62061 has been prepared by IEC technical committee 44: Safety of machinery – Electrotechnical aspects. It is an International Standard.

This second constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- structure has been changed and contents have been updated to reflect the design process of the safety function,
- standard extended to non-electrical technologies,
- definitions updated to be aligned with IEC 61508-4,
- functional safety plan introduced and configuration management updated (Clause 4),
- requirements on parametrization expanded (Clause 6),
- reference to requirements on security added (Subclause 6.8),
- requirements on periodic testing added (Subclause 6.9),
- various improvements and clarification on architectures and reliability calculations (Clause 6 and Clause 7),
- shift from "SILCL" to "maximum SIL" of a subsystem (Clause 7),
- use cases for software described including requirements (Clause 8),
- requirements on independence for software verification (Clause 8) and validation activities (Clause 9) added,
- new informative annex with examples (Annex G),
- new informative annexes on typical  $MTTF_D$  values, diagnostics and calculation methods for the architectures (Annex C, Annex D and Annex H).

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications](http://www.iec.ch/standardsdev/publications).

The committee has decided that the contents of this document and its amendment will remain unchanged until the stability date indicated on the IEC website under [webstore.iec.ch](http://webstore.iec.ch) in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

**IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.**

## INTRODUCTION

As a result of automation, demand for increased production and reduced operator physical effort, Safety-related Control Systems (referred to as SCS) of machines play an increasing role in the achievement of overall machine safety. Furthermore, the SCS themselves increasingly employ complex electronic technology.

IEC 62061 specifies requirements for the design and implementation of safety-related control systems of machinery. This document is machine sector specific within the framework of IEC 61508.

NOTE While IEC 62061 and ISO 13849-1 are using different methodologies for the design of safety related control systems, they intend to achieve the same risk reduction.

This International Standard is intended for use by machinery designers, control system manufacturers and integrators, and others involved in the specification, design and validation of an SCS. It sets out an approach and provides requirements to achieve the necessary performance and facilitates the specification of the safety functions intended to achieve the risk reduction.

This document provides a machine sector specific framework for functional safety of an SCS of machines. It only covers those aspects of the safety lifecycle that are related to safety requirements allocation through to safety validation. Requirements are provided for information for safe use of SCS of machines that can also be relevant to later phases of the lifecycle of an SCS.

There are many situations on machines where SCS are employed as part of safety measures that have been provided to achieve risk reduction. A typical case is the use of an interlocking guard that, when it is opened to allow access to the danger zone, signals the safety related parts of the machine control system to stop hazardous machine operation. In automation, the machine control system that is used to achieve correct operation of the machine process often contributes to safety by mitigating risks associated with hazards arising directly from control system failures. This document gives a methodology and requirements to:

- assign the required safety integrity for each safety function to be implemented by SCS;
- enable the design of the SCS appropriate to the assigned safety (control) function(s);
- integrate safety-related subsystems designed in accordance with other applicable functional safety-related standards (see 6.3.4);
- validate the SCS.

This document is intended to be used within the framework of systematic risk reduction, in conjunction with risk assessment described in ISO 12100. Suggested methodologies for a safety integrity assignment are given in informative Annex A.

## SAFETY OF MACHINERY – FUNCTIONAL SAFETY OF SAFETY-RELATED CONTROL SYSTEMS

### 1 Scope

This International Standard specifies requirements and makes recommendations for the design, integration and validation of safety-related control systems (SCS) for machines. It is applicable to control systems used, either singly or in combination, to carry out safety functions on machines that are not portable by hand while working, including a group of machines working together in a co-ordinated manner.

This document is a machinery sector specific standard within the framework of IEC 61508 (all parts).

The design of complex programmable electronic subsystems or subsystem elements is not within the scope of this document. This is in the scope of IEC 61508 or standards linked to it; see Figure 1.

NOTE 1 Elements such as systems on chip or microcontroller boards are considered complex programmable electronic subsystems.

The main body of this sector standard specifies general requirements for the design, and verification of a safety-related control system intended to be used in high/continuous demand mode.

This document:

- is concerned only with functional safety requirements intended to reduce the risk of hazardous situations;
- is restricted to risks arising directly from the hazards of the machine itself or from a group of machines working together in a co-ordinated manner;

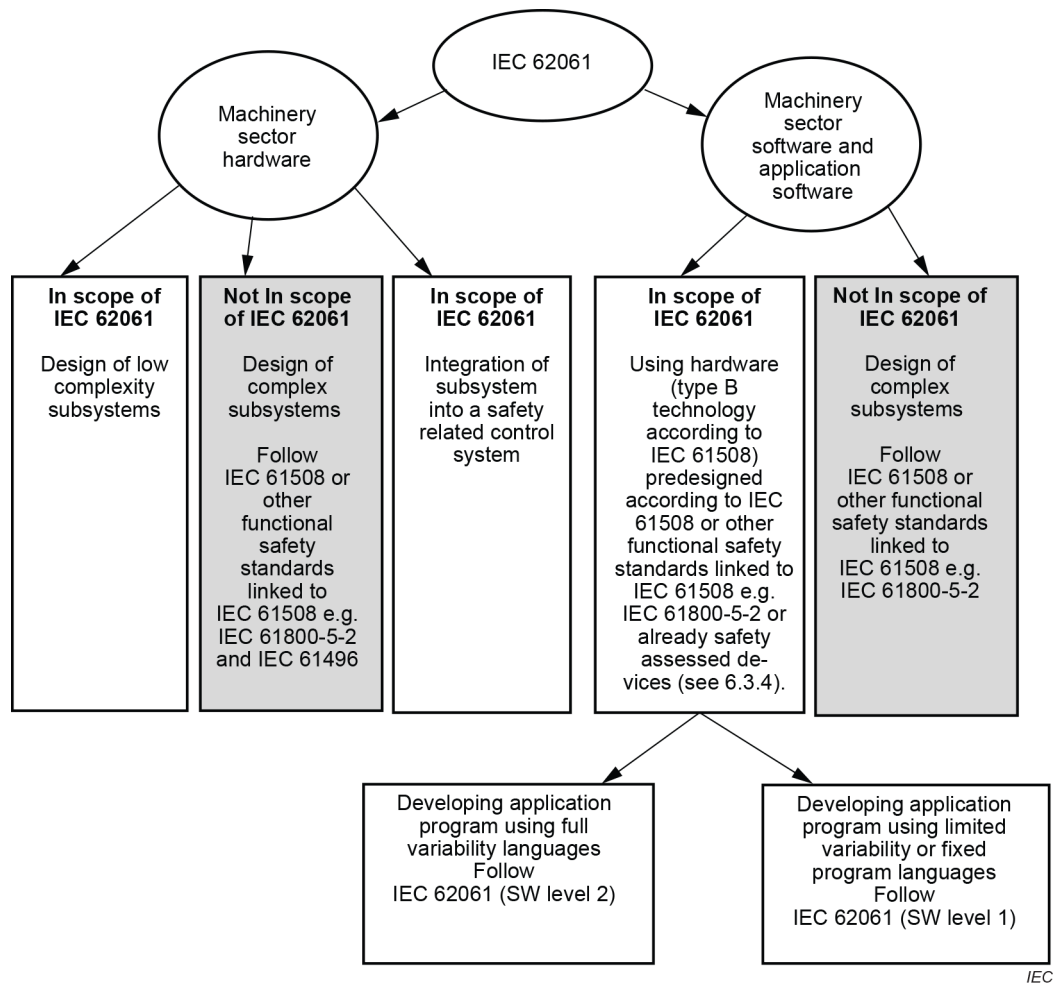
NOTE 2 Requirements to mitigate risks arising from other hazards are provided in relevant sector standards. For example, where a machine(s) is part of a process activity, additional information is available in IEC 61511.

This document does not cover

- electrical hazards arising from the electrical control equipment itself (e.g. electric shock – see IEC 60204-1);
- other safety requirements necessary at the machine level such as safeguarding;
- specific measures for security aspects – see IEC-TR TS 63074.

This document is not intended to limit or inhibit technological advancement.

Figure 1 illustrates the scope of this document.



**Figure 1 – Scope of this document**

## 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.

IEC 60204-1:2016, *Safety of machinery – Electrical equipment of machines – Part 1: General requirements*

IEC 61000-1-2:2016, *Electromagnetic compatibility (EMC) – Part 1-2: General – Methodology for the achievement of functional safety of electrical and electronic systems including equipment with regard to electromagnetic phenomena*

IEC 61508 (all parts), *Functional safety of electrical/electronic/programmable electronic safety-related systems*

IEC 61508-2:2010, *Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 2: Requirements for electrical/electronic/programmable electronic safety-related systems*

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

© IEC 2024

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

ISO 13849 (all parts), *Safety of machinery – Safety-related parts of control systems*

ISO 13849-1:2015, *Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design*

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

## CONTENTS

FOREWORD.....	8
INTRODUCTION.....	10
1 Scope.....	11
2 Normative references .....	12
3 Terms, definitions and abbreviations .....	13
3.1 Alphabetical list of definitions.....	13
3.2 Terms and definitions.....	15
3.3 Abbreviations.....	28
4 Design process of an SCS and management of functional safety.....	28
4.1 Objective .....	28
4.2 Design process .....	29
4.3 Management of functional safety using a functional safety plan .....	31
4.4 Configuration management .....	33
4.5 Modification .....	33
5 Specification of a safety function .....	34
5.1 Objective .....	34
5.2 Safety requirements specification (SRS).....	34
5.2.1 General .....	34
5.2.2 Information to be available.....	34
5.2.3 Functional requirements specification .....	35
5.2.4 Estimation of demand mode of operation .....	35
5.2.5 Safety integrity requirements specification.....	36
6 Design of an SCS .....	37
6.1 General.....	37
6.2 Subsystem architecture based on top down decomposition .....	37
6.3 Basic methodology – Use of subsystem .....	37
6.3.1 General .....	37
6.3.2 SCS decomposition .....	38
6.3.3 Sub-function allocation .....	39
6.3.4 Use of a pre-designed subsystem.....	39
6.4 Determination of safety integrity of the SCS.....	40
6.4.1 General .....	40
6.4.2 PFH.....	40
6.5 Requirements for systematic safety integrity of the SCS .....	41
6.5.1 Requirements for the avoidance of systematic hardware failures .....	41
6.5.2 Requirements for the control of systematic faults.....	42
6.6 Electromagnetic immunity .....	43
6.7 Software based manual parameterization.....	43
6.7.1 General .....	43
6.7.2 Influences on safety-related parameters .....	43
6.7.3 Requirements for software based manual parameterization .....	44
6.7.4 Verification of the parameterization tool.....	45
6.7.5 Performance of software based manual parameterization .....	45
6.8 Security aspects .....	45
6.9 Aspects of periodic testing .....	46
7 Design and development of a subsystem.....	46

7.1	General.....	46
7.2	Subsystem architecture design .....	47
7.3	Requirements for the selection and design of subsystem and subsystem elements .....	48
7.3.1	General .....	48
7.3.2	Systematic integrity .....	48
7.3.3	Fault consideration and fault exclusion .....	51
7.3.4	Failure rate of subsystem element .....	52
7.4	Architectural constraints of a subsystem .....	55
7.4.1	General .....	55
7.4.2	Estimation of safe failure fraction ( <i>SFF</i> ) .....	56
7.4.3	Behaviour (of the SCS) on detection of a fault in a subsystem .....	58
7.4.4	Realization of diagnostic functions .....	59
7.5	Subsystem design architectures.....	59
7.5.1	General .....	59
7.5.2	Basic subsystem architectures.....	60
7.5.3	Basic requirements .....	61
7.6	<i>PFH</i> of subsystems .....	62
7.6.1	General .....	62
7.6.2	Methods to estimate the <i>PFH</i> of a subsystem .....	62
7.6.3	Simplified approach to estimation of contribution of common cause failure ( <i>CCF</i> ).....	62
8	Software.....	62
8.1	General.....	62
8.2	Definition of software levels .....	63
8.3	Software – Level 1 .....	64
8.3.1	Software safety lifecycle – SW level 1 .....	64
8.3.2	Software design – SW level 1 .....	65
8.3.3	Module design – SW level 1.....	67
8.3.4	Coding – SW level 1 .....	67
8.3.5	Module test – SW level 1 .....	68
8.3.6	Software testing – SW level 1 .....	68
8.3.7	Documentation – SW level 1.....	69
8.3.8	Configuration and modification management process – SW level 1.....	69
8.4	Software level 2 .....	70
8.4.1	Software safety lifecycle – SW level 2 .....	70
8.4.2	Software design – SW level 2 .....	71
8.4.3	Software system design – SW level 2 .....	73
8.4.4	Module design – SW level 2.....	73
8.4.5	Coding – SW level 2 .....	74
8.4.6	Module test – SW level 2 .....	75
8.4.7	Software integration testing SW level 2.....	75
8.4.8	Software testing SW level 2.....	75
8.4.9	Documentation – SW level 2.....	76
8.4.10	Configuration and modification management process – SW level 2.....	77
9	Validation .....	77
9.1	Validation principles.....	77
9.1.1	Validation plan.....	80
9.1.2	Use of generic fault lists .....	80

9.1.3	Specific fault lists .....	80
9.1.4	Information for validation .....	81
9.1.5	Validation record .....	81
9.2	Analysis as part of validation .....	82
9.2.1	General .....	82
9.2.2	Analysis techniques .....	82
9.2.3	Verification of safety requirements specification (SRS) .....	82
9.3	Testing as part of validation .....	83
9.3.1	General .....	83
9.3.2	Measurement accuracy .....	83
9.3.3	More stringent requirements .....	84
9.3.4	Test samples .....	84
9.4	Validation of the safety function .....	84
9.4.1	General .....	84
9.4.2	Analysis and testing .....	85
9.5	Validation of the safety integrity of the SCS .....	85
9.5.1	General .....	85
9.5.2	Validation of subsystem(s) .....	85
9.5.3	Validation of measures against systematic failures .....	86
9.5.4	Validation of safety-related software .....	86
9.5.5	Validation of combination of subsystems .....	87
10	Documentation .....	87
10.1	General .....	87
10.2	Technical documentation .....	87
10.3	Information for use of the SCS .....	89
10.3.1	General .....	89
10.3.2	Information for use given by the manufacturer of subsystems .....	89
10.3.3	Information for use given by the SCS integrator .....	90
Annex A (informative)	Determination of required safety integrity .....	92
A.1	General .....	92
A.2	Matrix assignment for the required SIL .....	92
A.2.1	Hazard identification/indication .....	92
A.2.2	Risk estimation .....	92
A.2.3	Severity (Se) .....	93
A.2.4	Probability of occurrence of harm .....	93
A.2.5	Class of probability of harm (Cl) .....	96
A.2.6	SIL assignment .....	96
A.3	Overlapping hazards .....	98
Annex B (informative)	Example of SCS design methodology .....	99
B.1	General .....	99
B.2	Safety requirements specification .....	99
B.3	Decomposition of the safety function .....	99
B.4	Design of the SCS by using subsystems .....	100
B.4.1	General .....	100
B.4.2	Subsystem 1 design – “guard door monitoring” .....	100
B.4.3	Subsystem 2 design – “evaluation logic” .....	102
B.4.4	Subsystem 3 design – “motor control” .....	103
B.4.5	Evaluation of the SCS .....	103
B.4.6	PFH .....	104



B.5	Verification.....	104
B.5.1	General .....	104
B.5.2	Analysis.....	104
B.5.3	Tests .....	105
Annex C (informative)	Examples of $MTTF_D$ values for single components .....	106
C.1	General.....	106
C.2	Good engineering practices method .....	106
C.3	Hydraulic components.....	106
C.4	$MTTF_D$ of pneumatic, mechanical and electromechanical components .....	107
Annex D (informative)	Examples for diagnostic coverage ( $DC$ ).....	109
Annex E (informative)	Methodology for the estimation of susceptibility to common cause failures (CCF).....	111
E.1	General.....	111
E.2	Methodology .....	111
E.2.1	Requirements for CCF .....	111
E.2.2	Estimation of effect of CCF .....	111
Annex F (informative)	Guideline for software level 1 .....	114
F.1	Software safety requirements.....	114
F.2	Coding guidelines .....	115
F.3	Specification of safety functions.....	116
F.4	Specification of hardware design .....	117
F.5	Software system design specification.....	119
F.6	Protocols .....	121
Annex G (informative)	Examples of safety functions.....	124
Annex H (informative)	Simplified approaches to evaluate the $PFH$ value of a subsystem .....	125
H.1	Table allocation approach .....	125
H.2	Simplified formulas for the estimation of $PFH$ .....	127
H.2.1	General .....	127
H.2.2	Basic subsystem architecture A: single channel without a diagnostic function .....	127
H.2.3	Basic subsystem architecture B: dual channel without a diagnostic function .....	128
H.2.4	Basic subsystem architecture C: single channel with a diagnostic function .....	128
H.2.5	Basic subsystem architecture D: dual channel with a diagnostic function(s).....	133
H.3	Parts count method.....	134
Annex I (informative)	The functional safety plan and design activities .....	135
I.1	General.....	135
I.2	Example of a machine design plan including a safety plan .....	135
I.3	Example of activities, documents and roles.....	135
Annex J (informative)	Independence for reviews and testing/verification/validation activities .....	138
J.1	Software design .....	138
J.2	Validation.....	138
Bibliography	.....	140
Figure 1 – Scope of this document	.....	12

Figure 2 – Integration within the risk reduction process of ISO 12100 (extract) .....	29
Figure 3 – Iterative process for design of the safety-related control system .....	30
Figure 4 – Example of a combination of subsystems as one SCS.....	31
Figure 5 – By activating a low demand safety function at least once per year it can be assumed to be high demand .....	36
Figure 6 – Examples of typical decomposition of a safety function into sub-functions and its allocation to subsystems .....	39
Figure 7 – Example of safety integrity of a safety function based on allocated subsystems as one SCS .....	40
Figure 8 – Basic subsystem architecture A logical representation .....	60
Figure 9 – Basic subsystem architecture B logical representation .....	60
Figure 10 – Basic subsystem architecture C logical representation .....	60
Figure 11 – Basic subsystem architecture D logical representation .....	61
Figure 12 – V-model for SW level 1.....	64
Figure 13 – V-model for software modules customized by the designer for SW level 1.....	64
Figure 14 – V-model of software safety lifecycle for SW level 2.....	70
Figure 15 – Overview of the validation process .....	79
Figure A.1 – Parameters used in risk estimation .....	92
Figure A.2 – Example proforma for SIL assignment process .....	98
Figure B.1 – Decomposition of the safety function.....	100
Figure B.2 – Overview of design of the subsystems of the SCS .....	100
Figure F.1 – Plant sketch .....	116
Figure F.2 – Principal module architecture design.....	119
Figure F.3 – Principal design approach of logical evaluation .....	120
Figure F.4 – Example of logical representation (program sketch) .....	121
Figure H.1 – Basic subsystem architecture A logical representation.....	127
Figure H.2 – Basic subsystem architecture B logical representation.....	128
Figure H.3 – Basic subsystem architecture C logical representation.....	128
Figure H.4 – Correlation of basic subsystem architecture C and the pertinent fault handling function .....	129
Figure H.5 – Basic subsystem architecture C with external fault handling function .....	130
Figure H.6 – Basic subsystem architecture C with external fault diagnostics .....	131
Figure H.7 – Basic subsystem architecture C with external fault reaction .....	131
Figure H.8 – Basic subsystem architecture C with internal fault diagnostics and internal fault reaction.....	131
Figure H.9 – Basic subsystem architecture D logical representation.....	133
Figure I.1 – Example of a machine design plan including a safety plan .....	135
Figure I.2 – Example of activities, documents and roles (1 of 2).....	136
Table 1 – Terms used in IEC 62061 .....	13
Table 2 – Abbreviations used in IEC 62061.....	28
Table 3 – SIL and limits of <i>PFH</i> values.....	36
Table 4 – Required SIL and <i>PFH</i> of pre-designed subsystem .....	40
Table 5 – Relevant information for each subsystem .....	47

Table 6 – Architectural constraints on a subsystem: maximum SIL that can be claimed for an SCS using the subsystem .....	56
Table 7 – Overview of basic requirements and interrelation to basic subsystem architectures .....	61
Table 8 – Different levels of application software .....	63
Table 9 – Documentation of an SCS .....	88
Table A.1 – Severity (Se) classification .....	93
Table A.2 – Frequency and duration of exposure (Fr) classification .....	94
Table A.3 – Probability (Pr) classification .....	95
Table A.4 – Probability of avoiding or limiting harm (Av) classification .....	96
Table A.5 – Parameters used to determine class of probability of harm (Cl) .....	96
Table A.6 – Matrix assignment for determining the required SIL (or PL <sub>r</sub> ) for a safety function .....	97
Table B.1 – Safety requirements specification – example of overview .....	99
Table B.2 – Systematic integrity – example of overview .....	104
Table B.3 – Verification by tests .....	105
Table C.1 – Standards references and $MTTF_D$ or $B_{10D}$ values for components .....	107
Table D.1 – Estimates for diagnostic coverage (DC) (1 of 2) .....	109
Table E.1 – Estimation of CCF factor ( $\beta$ ) .....	112
Table E.2 – Criteria for estimation of CCF .....	113
Table F.1 – Example of relevant documents related to the simplified V-model .....	114
Table F.2 – Examples of coding guidelines .....	115
Table F.3 – Specified safety functions .....	117
Table F.4 – Relevant list of input and output signals .....	118
Table F.5 – Example of simplified cause and effect matrix .....	121
Table F.6 – Verification of software system design specification .....	122
Table F.7 – Software code review .....	122
Table F.8 – Software validation .....	123
Table G.1 – Examples of typical safety functions .....	124
Table H.1 – Allocation of $PFH$ value of a subsystem .....	126
Table H.2 – Relationship between $B_{10D}$ , operations and $MTTF_D$ .....	127
Table H.3 – Minimum value of $1/\lambda_D F_H$ for the applicability of $PFH$ equation (H.3) .....	132
Table J.1 – Minimum levels of independence for review, testing and verification activities .....	138
Table J.2 – Minimum levels of independence for validation activities .....	138

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

---

**SAFETY OF MACHINERY –  
FUNCTIONAL SAFETY OF SAFETY-RELATED CONTROL SYSTEMS****FOREWORD**

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <https://patents.iec.ch>. IEC shall not be held responsible for identifying any or all such patent rights.

**This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.**

**IEC 62061 edition 2.1 contains the second edition (2021-03) [documents 44/885/FDIS and 44/888/RVD] and its amendment 1 (2024-03) [documents 44/1020/FDIS and 44/1024/RVD].**

**This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.**

IEC 62061 has been prepared by IEC technical committee 44: Safety of machinery – Electrotechnical aspects. It is an International Standard.

This second constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- structure has been changed and contents have been updated to reflect the design process of the safety function,
- standard extended to non-electrical technologies,
- definitions updated to be aligned with IEC 61508-4,
- functional safety plan introduced and configuration management updated (Clause 4),
- requirements on parametrization expanded (Clause 6),
- reference to requirements on security added (Subclause 6.8),
- requirements on periodic testing added (Subclause 6.9),
- various improvements and clarification on architectures and reliability calculations (Clause 6 and Clause 7),
- shift from "SILCL" to "maximum SIL" of a subsystem (Clause 7),
- use cases for software described including requirements (Clause 8),
- requirements on independence for software verification (Clause 8) and validation activities (Clause 9) added,
- new informative annex with examples (Annex G),
- new informative annexes on typical  $MTTF_D$  values, diagnostics and calculation methods for the architectures (Annex C, Annex D and Annex H).

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications](http://www.iec.ch/standardsdev/publications).

The committee has decided that the contents of this document and its amendment will remain unchanged until the stability date indicated on the IEC website under [webstore.iec.ch](http://webstore.iec.ch) in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

**IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.**

## INTRODUCTION

As a result of automation, demand for increased production and reduced operator physical effort, Safety-related Control Systems (referred to as SCS) of machines play an increasing role in the achievement of overall machine safety. Furthermore, the SCS themselves increasingly employ complex electronic technology.

IEC 62061 specifies requirements for the design and implementation of safety-related control systems of machinery. This document is machine sector specific within the framework of IEC 61508.

NOTE While IEC 62061 and ISO 13849-1 are using different methodologies for the design of safety related control systems, they intend to achieve the same risk reduction.

This International Standard is intended for use by machinery designers, control system manufacturers and integrators, and others involved in the specification, design and validation of an SCS. It sets out an approach and provides requirements to achieve the necessary performance and facilitates the specification of the safety functions intended to achieve the risk reduction.

This document provides a machine sector specific framework for functional safety of an SCS of machines. It only covers those aspects of the safety lifecycle that are related to safety requirements allocation through to safety validation. Requirements are provided for information for safe use of SCS of machines that can also be relevant to later phases of the lifecycle of an SCS.

There are many situations on machines where SCS are employed as part of safety measures that have been provided to achieve risk reduction. A typical case is the use of an interlocking guard that, when it is opened to allow access to the danger zone, signals the safety related parts of the machine control system to stop hazardous machine operation. In automation, the machine control system that is used to achieve correct operation of the machine process often contributes to safety by mitigating risks associated with hazards arising directly from control system failures. This document gives a methodology and requirements to:

- assign the required safety integrity for each safety function to be implemented by SCS;
- enable the design of the SCS appropriate to the assigned safety (control) function(s);
- integrate safety-related subsystems designed in accordance with other applicable functional safety-related standards (see 6.3.4);
- validate the SCS.

This document is intended to be used within the framework of systematic risk reduction, in conjunction with risk assessment described in ISO 12100. Suggested methodologies for a safety integrity assignment are given in informative Annex A.

## **SAFETY OF MACHINERY – FUNCTIONAL SAFETY OF SAFETY-RELATED CONTROL SYSTEMS**

### **1 Scope**

This International Standard specifies requirements and makes recommendations for the design, integration and validation of safety-related control systems (SCS) for machines. It is applicable to control systems used, either singly or in combination, to carry out safety functions on machines that are not portable by hand while working, including a group of machines working together in a co-ordinated manner.

This document is a machinery sector specific standard within the framework of IEC 61508 (all parts).

The design of complex programmable electronic subsystems or subsystem elements is not within the scope of this document. This is in the scope of IEC 61508 or standards linked to it; see Figure 1.

NOTE 1 Elements such as systems on chip or microcontroller boards are considered complex programmable electronic subsystems.

The main body of this sector standard specifies general requirements for the design, and verification of a safety-related control system intended to be used in high/continuous demand mode.

This document:

- is concerned only with functional safety requirements intended to reduce the risk of hazardous situations;
- is restricted to risks arising directly from the hazards of the machine itself or from a group of machines working together in a co-ordinated manner;

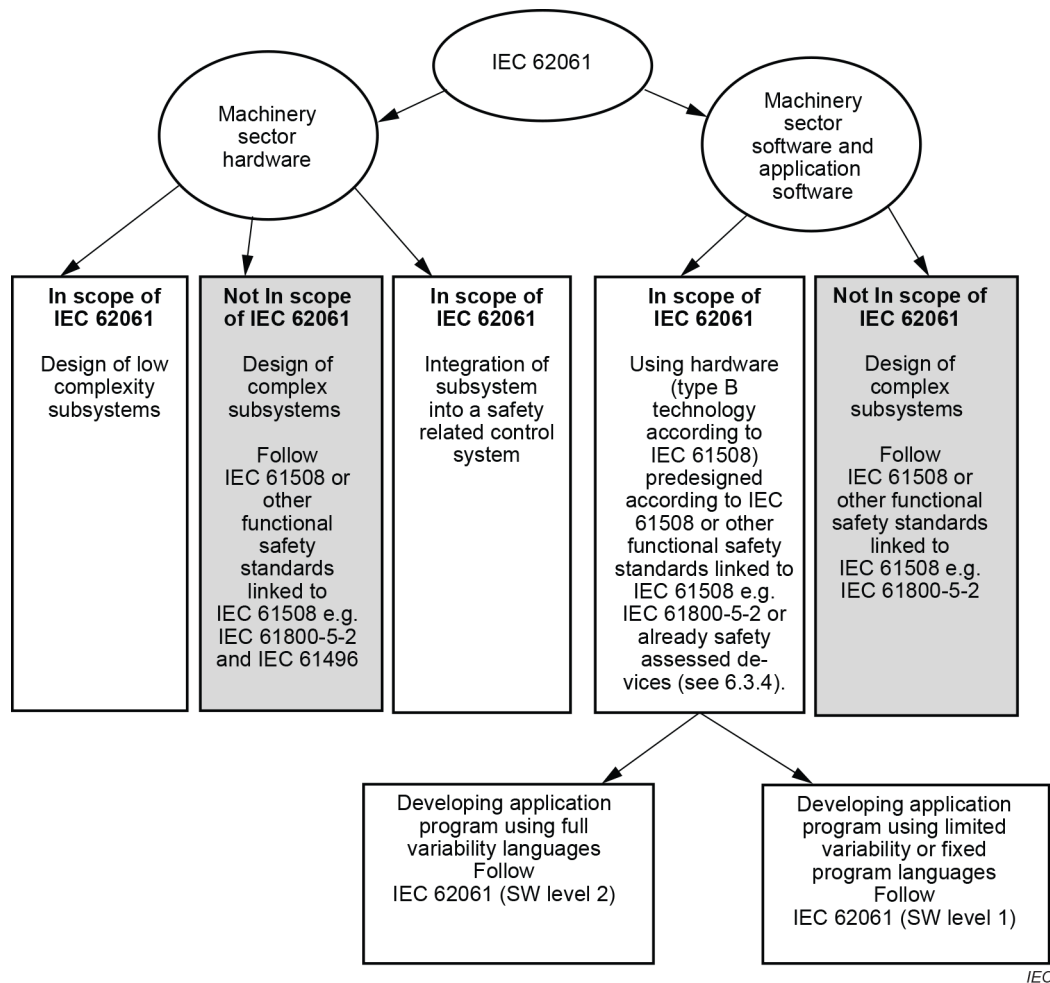
NOTE 2 Requirements to mitigate risks arising from other hazards are provided in relevant sector standards. For example, where a machine(s) is part of a process activity, additional information is available in IEC 61511.

This document does not cover

- electrical hazards arising from the electrical control equipment itself (e.g. electric shock – see IEC 60204-1);
- other safety requirements necessary at the machine level such as safeguarding;
- specific measures for security aspects – see IEC TS 63074.

This document is not intended to limit or inhibit technological advancement.

Figure 1 illustrates the scope of this document.



**Figure 1 – Scope of this document**

## 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.

IEC 60204-1:2016, *Safety of machinery – Electrical equipment of machines – Part 1: General requirements*

IEC 61000-1-2:2016, *Electromagnetic compatibility (EMC) – Part 1-2: General – Methodology for the achievement of functional safety of electrical and electronic systems including equipment with regard to electromagnetic phenomena*

IEC 61508 (all parts), *Functional safety of electrical/electronic/programmable electronic safety-related systems*

IEC 61508-2:2010, *Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 2: Requirements for electrical/electronic/programmable electronic safety-related systems*

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



© IEC 2024

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

ISO 13849 (all parts), *Safety of machinery – Safety-related parts of control systems*

ISO 13849-1:2015, *Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design*

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