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COMMENTED VERSION

Functional safety of electrical/electronic/programmable electronic safety-related systems –

Part 1: General requirements
Part 2: Requirements for electrical/electronic/programmable electronic safety-related systems
Part 3: Software requirements
Part 4: Definitions and abbreviations
Part 5: Examples of methods for the determination of safety integrity levels
Part 6: Guidelines on the application of IEC 61508-2 and IEC 61508-3
Part 7: Overview of techniques and measures

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

FUNCTIONAL SAFETY OF ELECTRICAL/ELECTRONIC/ PROGRAMMABLE ELECTRONIC SAFETY-RELATED SYSTEMS –

Part 1: General requirements

FOREWORD

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This Redline version provides you with a quick and easy way to compare all the changes between this standard and its previous edition. Additions and deletions are displayed in red, with deletions being struck through.

International Standard IEC 61508-1 has been prepared by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement, control and automation.

This second edition cancels and replaces the first edition published in 1998. This edition constitutes a technical revision.

This edition has been subject to a thorough review and incorporates many comments received at the various revision stages.

It has the status of a basic safety publication according to IEC Guide 104.

The text of this standard is based on the following documents:

FDIS	Report on voting
65A/548/FDIS	65A/572/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2

A list of all parts of the IEC 61508 series, published under the general title *Functional safety of electrical / electronic / programmable electronic safety-related systems*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

Systems comprised of electrical and/or electronic ~~components~~ elements (1) have been used for many years to perform safety functions in most application sectors. Computer-based systems (generically referred to as programmable electronic systems ~~(PESs)~~) are being used in all application sectors to perform non-safety functions and, increasingly, to perform safety functions. If computer system technology is to be effectively and safely exploited, it is essential that those responsible for making decisions have sufficient guidance on the safety aspects on which to make these decisions.

This International Standard sets out a generic approach for all safety lifecycle activities for systems comprised of electrical and/or electronic and/or programmable electronic ~~components (electrical/electronic/programmable electronic systems (E/E/PESs))~~ (E/E/PE) (2) elements (1) that are used to perform safety functions. This unified approach has been adopted in order that a rational and consistent technical policy be developed for all electrically-based safety-related systems. A major objective is to facilitate the development of product and application sector international standards based on the IEC 61508 series.

NOTE 1 Examples of product and application sector international standards based on the IEC 61508 series are given in the Bibliography (see references [1], [2] and [3]).

In most situations, safety is achieved by a number of ~~protective~~ systems which rely on many technologies (for example mechanical, hydraulic, pneumatic, electrical, electronic, programmable electronic). Any safety strategy must therefore consider not only all the elements (1) within an individual system (for example sensors, controlling devices and actuators) but also all the safety-related systems making up the total combination of safety-related systems. Therefore, while this International Standard is concerned with ~~electrical/electronic/programmable electronic (~~E/E/PE~~)~~ safety-related systems, it may also provide a framework within which safety-related systems based on other technologies may be considered.

It is recognized that there is a great variety of ~~E/E/PES~~ applications using E/E/PE safety-related systems in a variety of application sectors and covering a wide range of complexity, hazard and risk potentials. In any particular application, the required safety measures will be dependent on many factors specific to the application. This International Standard, by being generic, will enable such measures to be formulated in future product and (10) application sector international standards and in revisions of those that already exist.

This International Standard

– considers all relevant overall, E/E/PE~~S~~ system (2) and software safety lifecycle phases (for example, from initial concept, through design, implementation, operation and maintenance to decommissioning) when E/E/PE~~Ss~~ systems (2) are used to perform safety functions;

– has been conceived with a rapidly developing technology in mind; the framework is sufficiently robust and comprehensive to cater for future developments;

– enables product and application sector international standards, dealing with E/E/PE safety-related ~~E/E/PESs~~ systems (2), to be developed; the development of product and (10) application sector international standards, within the framework of this standard, should lead to a high level of consistency (for example, of underlying principles, terminology etc.) both within application sectors and across application sectors; this will have both safety and economic benefits;

– provides a method for the development of the safety requirements specification necessary to achieve the required functional safety for E/E/PE safety-related systems;

– adopts a risk-based approach ~~for the determination of~~ by which the safety integrity ~~level~~ requirements can be determined;

– ~~uses~~ introduces safety integrity levels for specifying the target level of safety integrity for the safety functions to be implemented by the E/E/PE safety-related systems;

NOTE 2 The standard does not specify the safety integrity level requirements for any safety function, nor does it mandate how the safety integrity level is determined. Instead it provides a risk-based conceptual framework and example techniques.

– sets ~~numerical~~ (3) target failure measures for safety functions carried out by E/E/PE safety-related systems, which are linked to the safety integrity levels;

– sets a lower limit on the target failure measures~~, in a dangerous mode of failure, that can be claimed~~ for a safety function carried out by a single E/E/PE safety-related system (4). For E/E/PE safety-related systems operating in

  – a low demand mode of operation, the lower limit is set at an average probability of ~~failure~~ a dangerous failure on demand of 10^{-5} ~~to perform its design function on demand~~;(4)

  – a high demand or a continuous mode of operation, the lower limit is set at ~~a probability~~ an average frequency of a dangerous failure of 10^{-9} ~~per hour~~ [h^{-1}];(4)

NOTE 3 A single E/E/PE safety-related system does not necessarily mean a single-channel architecture.

NOTE 4 It may be possible to achieve designs of safety-related systems with lower values for the target safety integrity for non-complex systems, but these limits are considered to represent what can be achieved for relatively complex systems (for example programmable electronic safety-related systems) at the present time.(6)

– sets requirements for the avoidance and control of systematic faults, which are based on experience and judgement from practical experience gained in industry. Even though the probability of occurrence of systematic failures cannot in general be quantified the standard does, however, allow a claim to be made, for a specified safety function, that the target failure measure associated with the safety function can be considered to be achieved if all the requirements in the standard have been met;(7)

– introduces systematic capability which applies to an element (1) with respect to its confidence that the systematic safety integrity meets the requirements of the specified safety integrity level;(8)

– adopts a broad range of principles, techniques and measures to achieve functional safety for E/E/PE safety-related systems, but does not explicitly use the concept of fail safe ~~which may be of value when the failure modes are well defined and the level of complexity is relatively low. The concept of fail safe was considered inappropriate because of the full range of complexity of E/E/PE safety-related systems that are within the scope of the standard.~~(5) However, the concepts of “fail safe” and “inherently safe” principles may be applicable and adoption of such concepts is acceptable providing the requirements of the relevant clauses in the standard are met.(9)

FUNCTIONAL SAFETY OF ELECTRICAL/ELECTRONIC/ PROGRAMMABLE ELECTRONIC SAFETY-RELATED SYSTEMS –

Part 1: General requirements

1 Scope

1.1 This International Standard covers those aspects to be considered when electrical/electronic/programmable electronic (E/E/PE) systems ~~(E/E/PESs)~~ (2) are used to carry out safety functions. A major objective of this standard is to facilitate the development of product and application sector international standards by the technical committees responsible for the product or application sector. This will allow all the relevant factors, associated with the product or application, to be fully taken into account and thereby meet the specific needs of users of the product and the application sector. A ~~dual~~ second objective of this standard is to enable the development of ~~electrical/electronic/programmable electronic~~ ~~(~~E/E/PE~~)~~ safety-related systems where product or application sector international standards ~~may~~ do not exist.(10)

1.2 In particular, this standard

a) applies to safety-related systems when one or more of such systems incorporates electrical/electronic/programmable electronic ~~devices~~ elements;(1)

NOTE 1 In the context of low complexity E/E/PE safety-related systems, certain requirements specified in this standard may be unnecessary, and exemption from compliance with such requirements is possible (see 4.2, and the definition of a low complexity E/E/PE safety-related system in ~~3.4.4~~ 3.4.3 of IEC 61508-4).

NOTE 2 Although a person can form part of a safety-related system (see 3.4.1 of IEC 61508-4), human factor requirements related to the design of E/E/PE safety-related systems are not considered in detail in this standard.

b) is generically-based and applicable to all E/E/PE safety-related systems irrespective of the application; ~~1)~~

c) ~~covers possible hazards caused by failures of the safety functions to be performed by E/E/PE safety-related systems, as distinct from hazards arising from the E/E/PE equipment itself (for example electric shock etc);~~ covers the achievement of a tolerable risk through the application of E/E/PE safety-related systems, but does not cover hazards (52) arising from the E/E/PE equipment itself (for example electric shock);(11)

d) applies to all types of E/E/PE safety-related systems, including protection systems and control systems;(12)

~~d~~e) does not cover E/E/PE systems where

- a single E/E/PE system is capable ~~of providing the necessary risk reduction~~ on its own of meeting the tolerable risk, and
- the required safety integrity of the safety functions of the single E/E/PE system is less than that specified for safety integrity level 1 (the lowest safety integrity level in this standard).(4)

~~e~~f) is mainly concerned with the E/E/PE safety-related systems whose failure could have an impact on the safety of persons and/or the environment; however, it is recognized that the consequences of failure could also have serious economic implications and in such cases this standard could be used to specify any E/E/PE system used for the protection of equipment or product;

NOTE 3 See 3.1.1 of IEC 61508-4.

~~1)~~ ~~Applies to French text only.~~

~~f~~g) considers E/E/PE safety-related systems and other ~~technology safety-related systems and external~~ risk reduction ~~facilities~~ measures, in order that the safety requirements specification for the E/E/PE safety-related systems can be determined in a systematic, risk-based manner;(13)

~~g~~h) uses an overall safety lifecycle model as the technical framework for dealing systematically with the activities necessary for ensuring the functional safety of the E/E/PE safety-related systems;

~~NOTE 3 – The early phases of the overall safety lifecycle include, of necessity, consideration of other technology (as well as the E/E/PE safety-related systems) and external risk reduction facilities, in order that the safety requirements specification for the E/E/PE safety-related systems can be developed in a systematic, risk-based manner.~~

NOTE 4 Although the overall safety lifecycle is primarily concerned with E/E/PE safety-related systems, it could also provide a technical framework for ~~the consideration of~~ considering any safety-related system irrespective of the technology of that system (for example mechanical, hydraulic or pneumatic).

~~h~~i) does not specify the safety integrity levels required for sector applications (which must be based on detailed information and knowledge of the sector application). The technical committees responsible for the specific application sectors shall specify, where appropriate, the safety integrity levels in the application sector standards;

~~i~~j) provides general requirements for E/E/PE safety-related systems where no product or application sector international standards exist;

k) requires malevolent and unauthorised actions to be considered during hazard and risk analysis. The scope of the analysis includes all relevant safety lifecycle phases;(14)

NOTE 5 Other IEC/ISO standards address this subject in depth; see ISO/IEC/TR 19791 and IEC 62443 series.

~~j~~l) does not cover the precautions that may be necessary to prevent unauthorized persons damaging, and/or otherwise adversely affecting, the functional safety of E/E/PE safety-related systems (see k) above);

m) does not specify the requirements for the development, implementation, maintenance and/or operation of security policies or security services needed to meet a security policy that may be required by the E/E/PE safety-related system;(15)

n) does not apply for medical equipment in compliance with the IEC 60601 series.(16)

1.3 This part of ~~IEC 61508 specifies~~ the IEC 61508 series of standards includes general requirements that are applicable to all parts. Other parts of the IEC 61508 series concentrate on more specific topics:

– parts 2 and 3 provide additional and specific requirements for E/E/PE safety-related systems (for hardware and software);

– part 4 gives definitions and abbreviations that are used throughout this standard;

– part 5 provides guidelines on the application of part 1 in determining safety integrity levels, by showing example methods;

– part 6 provides guidelines on the application of parts 2 and 3;

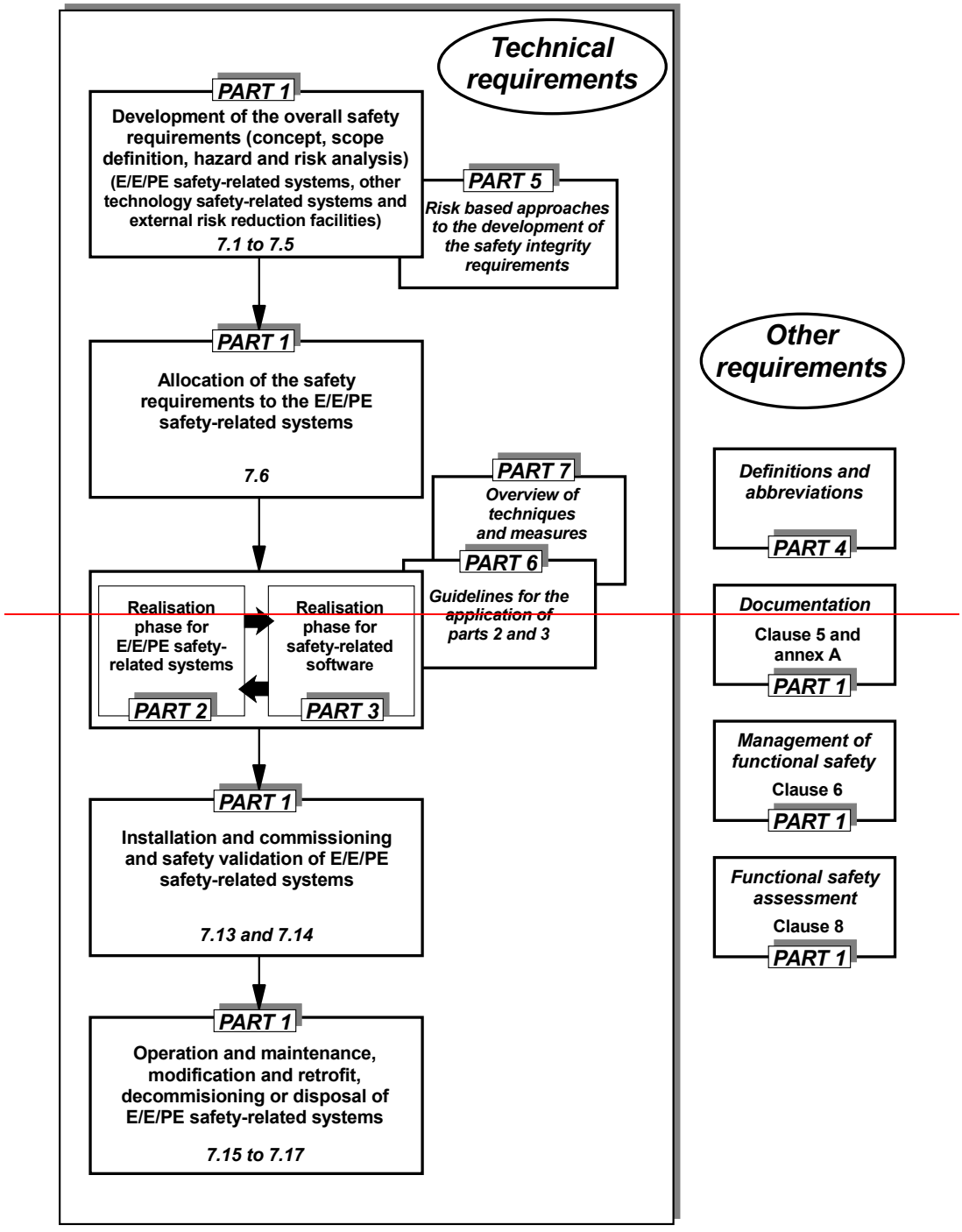
– part 7 contains an overview of techniques and measures.

1.4 IEC 61508-1, IEC 61508-2, IEC 61508-3 and IEC 61508-4 are basic safety publications, although this status does not apply in the context of low complexity E/E/PE safety-related systems (see ~~3.4.4~~ 3.4.3 of IEC 61508-4). As basic safety publications, they are intended for use by technical committees in the preparation of standards in accordance with the principles contained in IEC Guide 104 and ISO/IEC Guide 51. IEC 61508-1, IEC 61508-2, IEC 61508-3 and IEC 61508-4 are also intended for use as stand-alone publications. The horizontal safety function of this international standard does not apply to medical equipment in compliance with the IEC 60601 series.(16)

~~NOTE – In the USA and Canada, until the proposed process sector implementation of IEC 61508 is published as an international standard in the USA and Canada, existing national process safety standards based on IEC 61508 (i.e. ANSI/ISA S84.01-1996) (see reference [8] in annex C) can be applied to the process sector instead of IEC 61508.~~ (17)

NOTE One of the responsibilities of a technical committee is, wherever applicable, to make use of basic safety publications in the preparation of its publications. In this context, the requirements, test methods or test conditions of this basic safety publication will not apply unless specifically referred to or included in the publications prepared by those technical committees.

1.5 Figure 1 shows the overall framework of the IEC 61508 series and indicates the role that IEC 61508-1 plays in the achievement of functional safety for E/E/PE safety-related systems.



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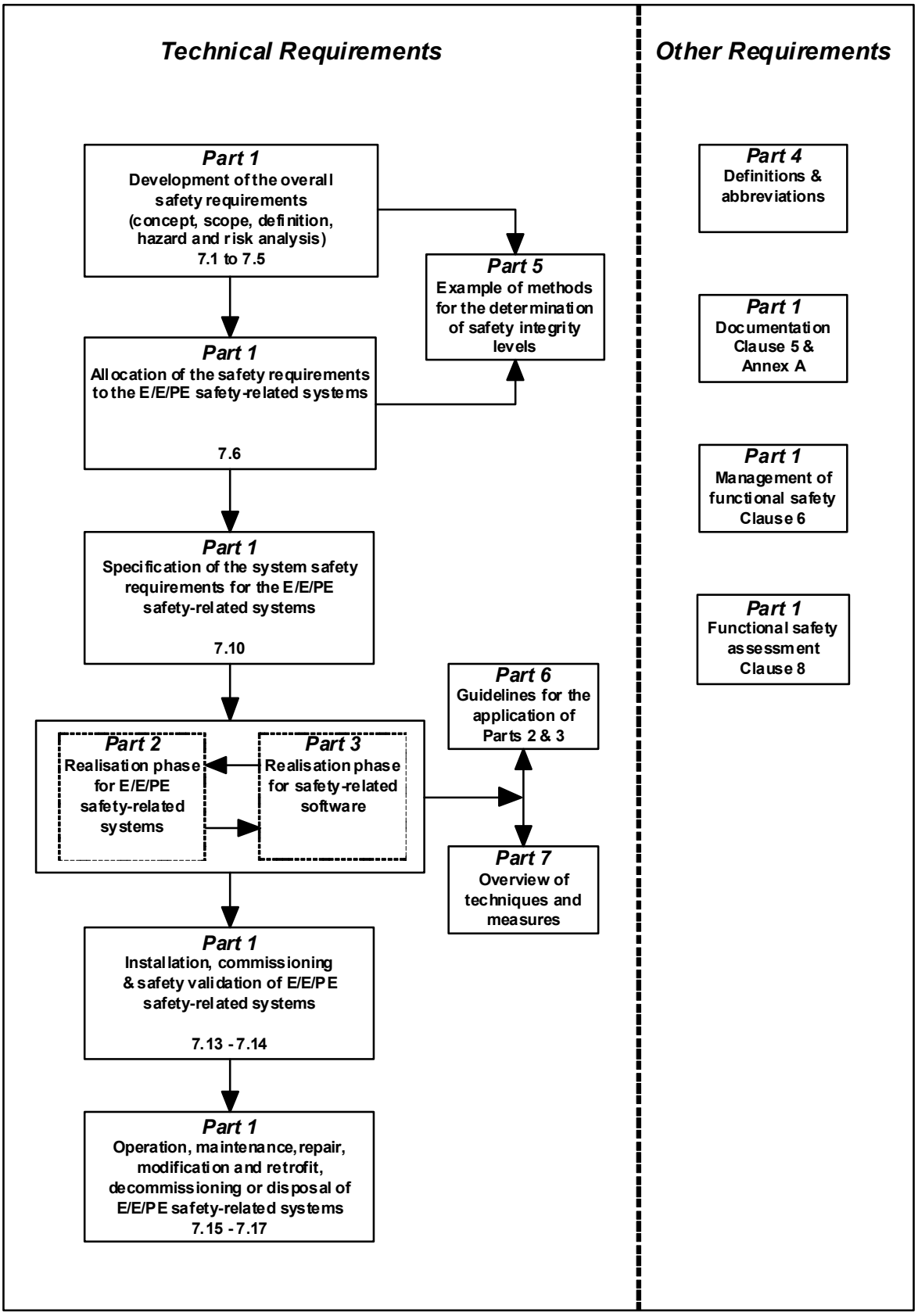

Figure 1 – Overall framework of the IEC 61508 series (1B)

2 Normative references

The following referenced documents are indispensable for the application 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 61508-2:2010, *Functional safety of electrical/electronic~~al~~/programmable electronic safety-related systems – Part 2: Requirements for electrical/electronical/programmable electronic safety-related systems* ~~1)~~

IEC 61508-3:~~1998~~ 2010, *Functional safety of electrical/electronic~~al~~/programmable electronic safety-related systems – Part 3: Software requirements*

IEC 61508-4:~~1998~~ 2010, *Functional safety of electrical/electronic~~al~~/programmable electronic safety-related systems – Part 4: Definitions and abbreviations*

~~IEC 61508-5:1998, *Functional safety of electrical/electronical/programmable electronic safety-related systems – Part 5: Examples of methods for the determination of safety integrity levels*~~

~~IEC 61508-6, — *Functional safety of electrical/electronical/programmable electronic safety-related systems – Part 6: Guidelines on the application of parts 2 and 3* 1)~~

~~IEC 61508-7, — *Functional safety of electrical/electronical/programmable electronic safety-related systems – Part 7: Overview of techniques and measures* 2)~~

IEC Guide 104:1997, ~~*Guide to the drafting of safety standards, and the role of Committees with safety pilot functions and safety group functions*~~ *The preparation of safety publications and the use of basic safety publications and group safety publications*

ISO/IEC Guide 51:~~1990~~ 1999, ~~*Guidelines for the inclusion of safety aspects in standards*~~ *Safety aspects – Guidelines for their inclusion in standards*

~~2) To be published.~~