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I.S. EN 61508-3:2010

Functional safety of electrical/electronic/programmable electronic safety-related systems -- Part 3: Software requirements (IEC 61508 -3:2010 (EQV))

I.S. EN 61508-3:2010

Incorporating amendments/corrigenda issued since publication:

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I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

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SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

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Supersedes EN 61508-3:2001

English version

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

Sécurité fonctionnelle des systèmes
électriques/électroniques/électroniques
programmables relatifs à la sécurité -
Partie 3: Exigences concernant
les logiciels
(CEI 61508-3:2010)

Funktionale Sicherheit sicherheitsbezogener
elektrischer/elektronischer/programmierbarer
elektronischer Systeme -
Teil 3: Anforderungen an Software
(IEC 61508-3:2010)

This European Standard was approved by CENELEC on 2010-05-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 65A/550/FDIS, future edition 2 of IEC 61508-3, prepared by SC 65A, System aspects, of IEC TC 65, Industrial-process measurement, control and automation, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61508-3 on 2010-05-01.

This European Standard supersedes EN 61508-3:2001.

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2011-02-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2013-05-01 |

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61508-3:2010 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

- | | |
|----------------------|---|
| [1] IEC 61511 series | NOTE Harmonized in EN 61511 series (not modified). |
| [2] IEC 62061 | NOTE Harmonized as EN 62061. |
| [3] IEC 61800-5-2 | NOTE Harmonized as EN 61800-5-2. |
| [4] IEC 61508-5:2010 | NOTE Harmonized as EN 61508-5:2010 (not modified). |
| [5] IEC 61508-6:2010 | NOTE Harmonized as EN 61508-6:2010 (not modified). |
| [6] IEC 61508-7:2010 | NOTE Harmonized as EN 61508-7:2010 (not modified). |
| [7] IEC 60601 series | NOTE Harmonized in 60601 series (partially modified). |
| [8] IEC 61131-3 | NOTE Harmonized as EN 61131-3. |
-

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 61508-1	2010	Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 1: General requirements	EN 61508-1	2010
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	EN 61508-2	2010
IEC 61508-4	2010	Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 4: Definitions and abbreviations	EN 61508-4	2010
IEC Guide 104	1997	The preparation of safety publications and the use of basic safety publications and group safety publications	-	-
ISO/IEC Guide 51	1999	Safety aspects - Guidelines for their inclusion in standards	-	-

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 3: Software requirements

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.
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International Standard IEC 61508-3 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/550/FDIS	65A/574/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 stability 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 elements have been used for many years to perform safety functions in most application sectors. Computer-based systems (generically referred to as programmable electronic systems) 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 (E/E/PE) elements 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 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 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 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 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 application sector international standards and in revisions of those that already exist.

This International Standard

- considers all relevant overall, E/E/PE system and software safety lifecycle phases (for example, from initial concept, through design, implementation, operation and maintenance to decommissioning) when E/E/PE systems 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 systems, to be developed; the development of product and 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 by which the safety integrity requirements can be determined;
- 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 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 for a safety function carried out by a single E/E/PE safety-related system. 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 a dangerous failure on demand of 10^{-5} ;
 - a high demand or a continuous mode of operation, the lower limit is set at an average frequency of a dangerous failure of 10^{-9} [h⁻¹];

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.

- 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;
- introduces systematic capability which applies to an element with respect to its confidence that the systematic safety integrity meets the requirements of the specified safety integrity level;
- 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. 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.

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

Part 3: Software requirements

1 Scope

1.1 This part of the IEC 61508 series

- a) is intended to be utilized only after a thorough understanding of IEC 61508-1 and IEC 61508-2;
- b) applies to any software forming part of a safety-related system or used to develop a safety-related system within the scope of IEC 61508-1 and IEC 61508-2. Such software is termed safety-related software (including operating systems, system software, software in communication networks, human-computer interface functions, and firmware as well as application software);
- c) provides specific requirements applicable to support tools used to develop and configure a safety-related system within the scope of IEC 61508-1 and IEC 61508-2;
- d) requires that the software safety functions and software systematic capability are specified;

NOTE 1 If this has already been done as part of the specification of the E/E/PE safety-related systems (see 7.2 of IEC 61508-2), then it does not have to be repeated in this part.

NOTE 2 Specifying the software safety functions and software systematic capability is an iterative procedure; see Figures 3 and 6.

NOTE 3 See Clause 5 and Annex A of IEC 61508-1 for documentation structure. The documentation structure may take account of company procedures, and of the working practices of specific application sectors.

NOTE 4 Note: See 3.5.9 of IEC 61508-4 for definition of the term "systematic capability".

- e) establishes requirements for safety lifecycle phases and activities which shall be applied during the design and development of the safety-related software (the software safety lifecycle model). These requirements include the application of measures and techniques, which are graded against the required systematic capability, for the avoidance of and control of faults and failures in the software;
- f) provides requirements for information relating to the software aspects of system safety validation to be passed to the organisation carrying out the E/E/PE system integration;
- g) provides requirements for the preparation of information and procedures concerning software needed by the user for the operation and maintenance of the E/E/PE safety-related system;
- h) provides requirements to be met by the organisation carrying out modifications to safety-related software;
- i) provides, in conjunction with IEC 61508-1 and IEC 61508-2, requirements for support tools such as development and design tools, language translators, testing and debugging tools, configuration management tools;

NOTE 4 Figure 5 shows the relationship between IEC 61508-2 and IEC 61508-3.

- j) Does not apply for medical equipment in compliance with the IEC 60601 series.

1.2 IEC 61508-1, IEC 61598-2, 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 3.4.3 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.

1.3 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.

1.4 Figure 1 shows the overall framework of the IEC 61508 series and indicates the role that IEC 61508-3 plays in the achievement of functional safety for E/E/PE safety-related systems.

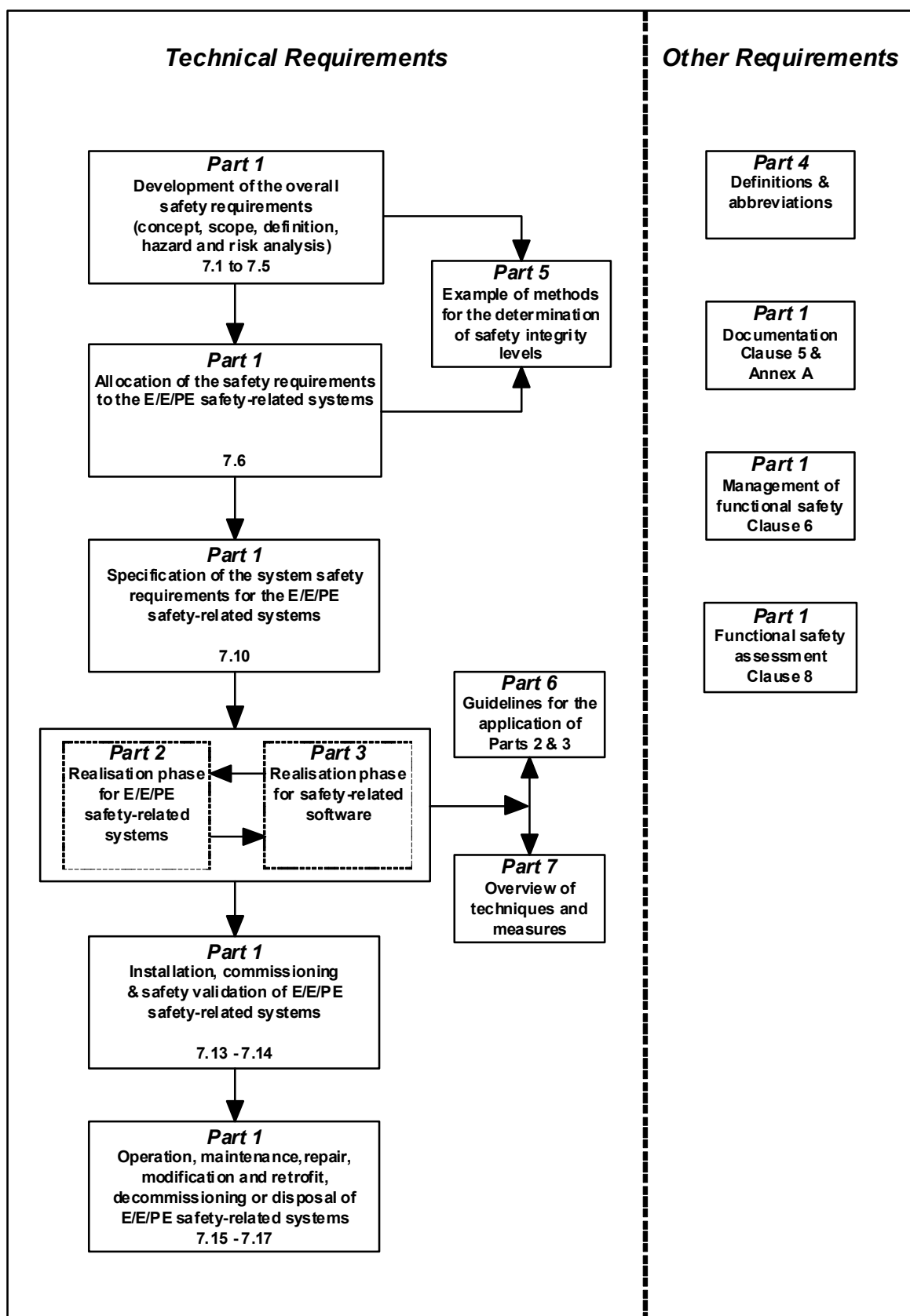


Figure 1 – Overall framework of the IEC 61508 series

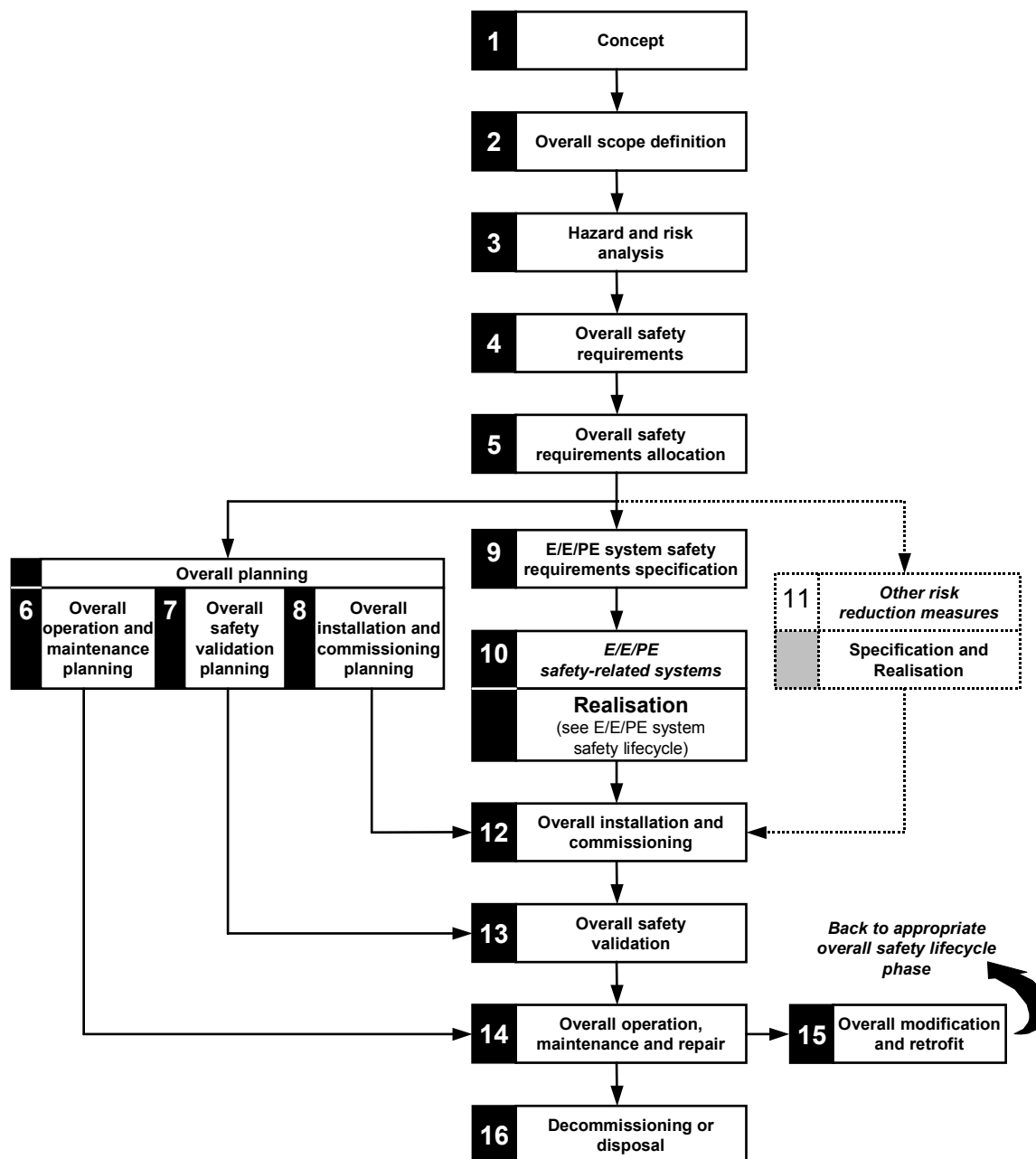


Figure 2 – Overall safety lifecycle

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 61508-1: 2010, *Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 1: General requirements*

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