NSAI Standards

Irish Standard
I.S. EN 61508-5:2010

Functional safety of electrical/electronic/programmable electronic safety-related systems -- Part 5: Examples of methods for the determination of safety integrity levels (IEC 61508-5:2010 (EQV))

I.S. EN 61508-5:2010

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NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie

W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

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EUROPEAN STANDARD
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EUROPÄISCHE NORM

EN 61508-5

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Supersedes EN 61508-5:2001

English version

Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 5: Examples of methods for the determination of safety integrity levels (IEC 61508-5:2010)

Sécurité fonctionnelle des systèmes électriques/électroniques/électroniques programmables relatifs à la sécurité - Partie 5: Exemples de méthodes pour la détermination des niveaux d'intégrité de sécurité (CEI 61508-5:2010)

Funktionale Sicherheit sicherheitsbezogener elektrischer/elektronischer/programmierbarer elektronischer Systeme - Teil 5: Beispiele zur Ermittlung der Stufe der Sicherheitsintegrität (safety integrety level) (IEC 61508-5:2010)

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 61508-5:2010 E

Foreword

The text of document 65A/552/FDIS, future edition 2 of IEC 61508-5, 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 61508-5 on 2010-05-01.

This European Standard supersedes EN 61508-5:2001.

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 61508-5:2010 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.
[9] ISO/IEC 31010	NOTE Harmonized as EN 31010.
[10] ISO 10418:2003	NOTE Harmonized as EN 10418:2003 (not modified).
[12] ISO 13849-1:2006	NOTE Harmonized as EN ISO 13849-1:2006 (not modified).
[13] IEC 60601 series	NOTE Harmonized in EN 60601 series (partially modified).
[14] IEC 61508-2	NOTE Harmonized as EN 61508-2.
[15] IEC 61508-3	NOTE Harmonized as EN 61508-3.
[16] IEC 61508-6	NOTE Harmonized as EN 61508-6.
[17] IEC 61508-7	NOTE Harmonized as EN 61508-7.
[18] IEC 61511-1	NOTE Harmonized as EN 61511-1.

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.

Publication	Year	Title	EN/HD	Year
IEC 61508-1	2010	Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 1: General requirements	EN 61508-1	2010
IEC 61508-4	2010	Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 4: Definitions and abbreviations	EN 61508-4	2010

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 5: Examples of methods for the determination of safety integrity levels

FOREWORD

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International Standard IEC 61508-5 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.

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

FDIS	Report on voting
65A/552/FDIS	65A/576/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, though 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 5: Examples of methods for the determination of safety integrity levels

1 Scope

1.1 This part of IEC 61508 provides information on

– the underlying concepts of risk and the relationship of risk to safety integrity (see Annex A);
– a number of methods that will enable the safety integrity levels for the E/E/PE safety-related systems to be determined (see Annexes C, D, E, F and G).

The method selected will depend upon the application sector and the specific circumstances under consideration. Annexes C, D, E, F and G illustrate quantitative and qualitative approaches and have been simplified in order to illustrate the underlying principles. These annexes have been included to illustrate the general principles of a number of methods but do not provide a definitive account. Those intending to apply the methods indicated in these annexes should consult the source material referenced.

NOTE For more information on the approaches illustrated in Annexes B, and E, see references [5] and [8] in the Bibliography. See also reference [6] in the Bibliography for a description of an additional approach.

1.2 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 3.4.3 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 61508-5 plays in the achievement of functional safety for E/E/PE safety-related systems.

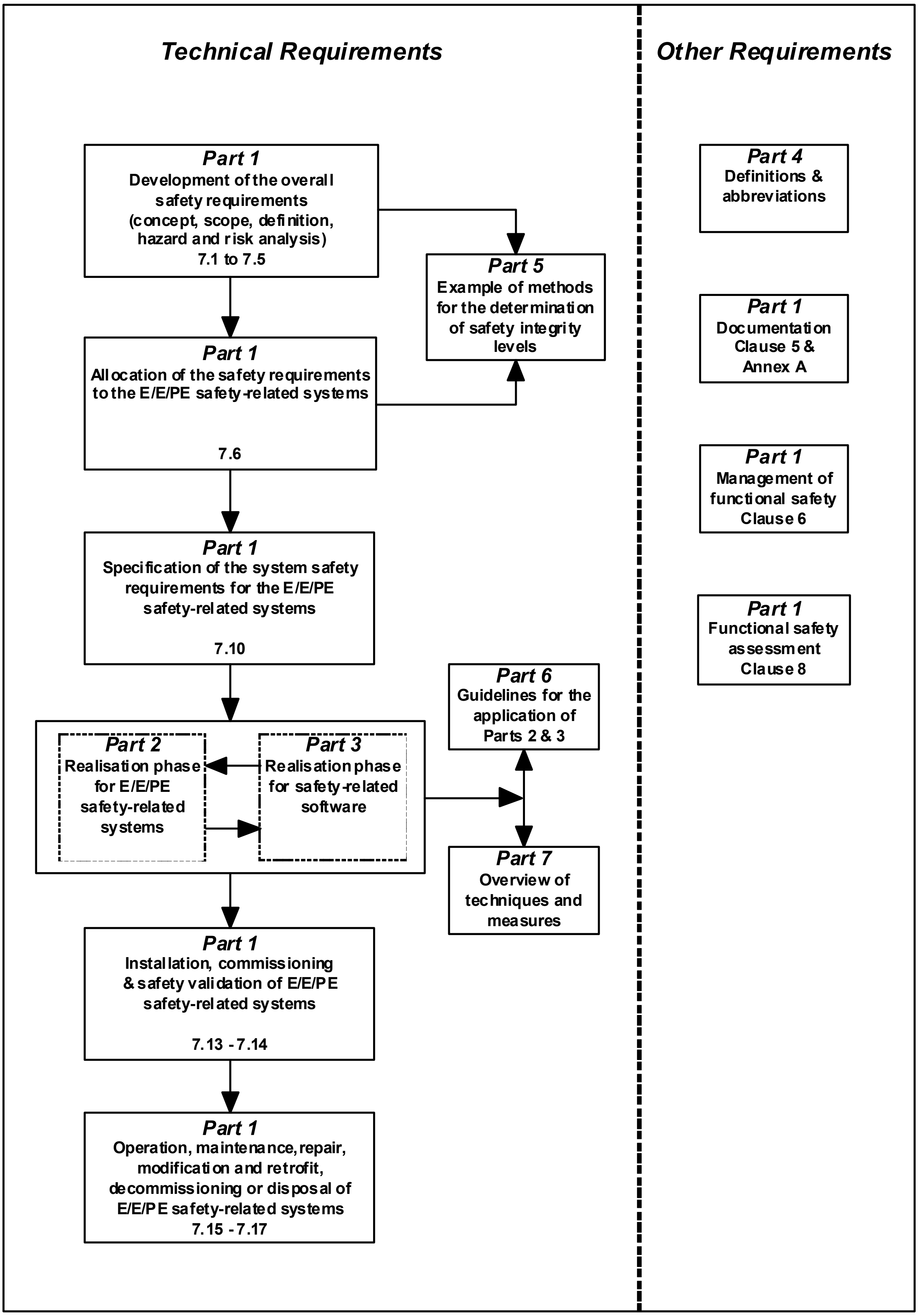

Figure 1 – Overall framework of the IEC 61508 series

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*

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

3 Definitions and abbreviations

For the purposes of this document, the definitions and abbreviations given in IEC 61508-4 apply.

Annex A
(informative)

Risk and safety integrity – General concepts

A.1 General

This annex provides information on the underlying concepts of risk and the relationship of risk to safety integrity.

A.2 Necessary risk reduction

The necessary risk reduction (see 3.5.18 of IEC 61508-4) is the reduction in risk that has to be achieved to meet the tolerable risk for a specific situation (which may be stated either qualitatively[1] or quantitatively[2]). The concept of necessary risk reduction is of fundamental importance in the development of the safety requirements specification for the E/E/PE safety-related systems (in particular, the safety integrity requirements part of the safety requirements specification). The purpose of determining the tolerable risk for a specific hazardous event is to state what is deemed reasonable with respect to both the frequency (or probability) of the hazardous event and its specific consequences. Safety-related systems are designed to reduce the frequency (or probability) of the hazardous event and/or the consequences of the hazardous event.

The tolerable risk will depend on many factors (for example, severity of injury, the number of people exposed to danger, the frequency at which a person or people are exposed to danger and the duration of the exposure). Important factors will be the perception and views of those exposed to the hazardous event. In arriving at what constitutes a tolerable risk for a specific application, a number of inputs are considered. These include:

– legal requirements, both general and those directly relevant to the specific application;
– guidelines from the appropriate safety regulatory authority;
– discussions and agreements with the different parties involved in the application;
– industry standards and guidelines;
– international discussions and agreements; the role of national and international standards is becoming increasingly important in arriving at tolerable risk criteria for specific applications;
– the best independent industrial, expert and scientific advice from advisory bodies.

In determining the safety integrity requirements of the E/E/PE safety-related system(s) and other risk reduction measures, in order to meet the tolerable frequency of a hazardous event, account needs to be taken of the characteristics of the risk that are relevant to the application. The tolerable frequency will depend on the legal requirements in the country of application and on the criteria specified by the user organisation. Issues that may need to be considered together with how they can be applied to E/E/PE safety-related systems are discussed below.

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1 In achieving the tolerable risk, the necessary risk reduction will need to be established. Annexes E and G of this document outline qualitative methods, although in the examples quoted the necessary risk reduction is incorporated implicitly by specification of the SIL requirement rather than stated explicitly by a numeric value of risk reduction required.

2 For example, that the hazardous event, leading to a specific consequence, shall not occur with a frequency greater than one in 10^8 h.