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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Functional safety of electrical/electronic/programmable electronic safety-related systems –
Part 6: Guidelines on the application of IEC 61508-2 and IEC 61508-3

Sécurité fonctionnelle des systèmes électriques/électroniques/électroniques programmables relatifs à la sécurité –
Partie 6: Lignes directrices pour l'application de la CEI 61508-2 et de la CEI 61508-3

IEC 61508-6:2010

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

Part 6: Guidelines on the application of IEC 61508-2 and IEC 61508-3

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 61508-6 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 2000. 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/553/FDIS	65A/577/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.

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 6: Guidelines on the application of IEC 61508-2 and IEC 61508-3

1 Scope

1.1 This part of IEC 61508 contains information and guidelines on IEC 61508-2 and IEC 61508-3.

– Annex A gives a brief overview of the requirements of IEC 61508-2 and IEC 61508-3 and sets out the functional steps in their application.

– Annex B gives an example technique for calculating the probabilities of hardware failure and should be read in conjunction with 7.4.3 and Annex C of IEC 61508-2 and Annex D.

– Annex C gives a worked example of calculating diagnostic coverage and should be read in conjunction with Annex C of IEC 61508-2.

– Annex D gives a methodology for quantifying the effect of hardware-related common cause failures on the probability of failure.

– Annex E gives worked examples of the application of the software safety integrity tables specified in Annex A of IEC 61508-3 for safety integrity levels 2 and 3.

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 61508-6 plays in the achievement of functional safety for E/E/PE safety-related systems.

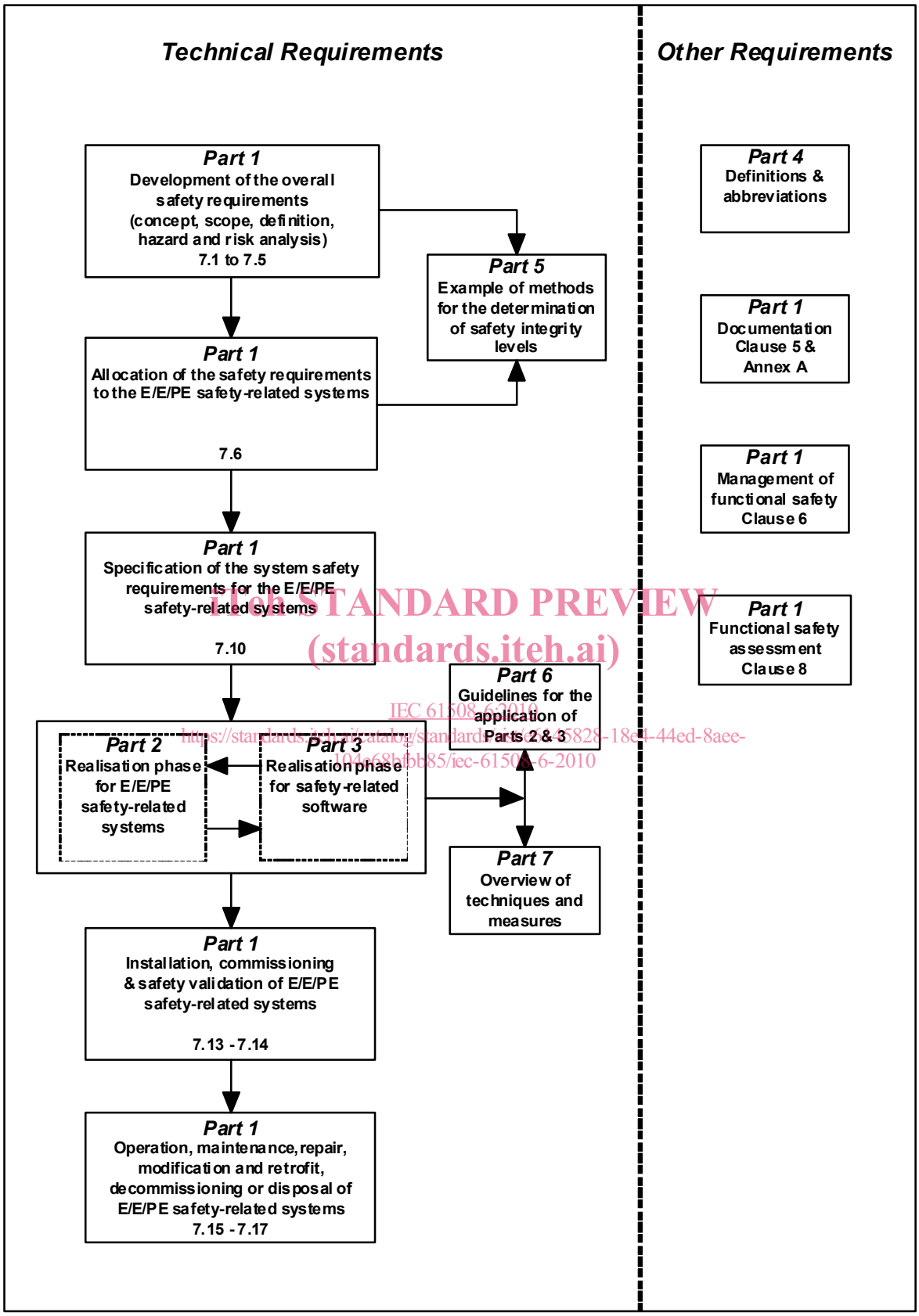

Figure 1 – Overall framework of the IEC 61508 series

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 61508-2:2010, *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 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)

Application of IEC 61508-2 and of IEC 61508-3

A.1 General

Machinery, process plant and other equipment may, in the case of malfunction (for example by failures of electrical, electronic and/or programmable electronic devices), present risks to people and the environment from hazardous events such as fires, explosions, radiation overdoses, machinery traps, etc. Failures can arise from either physical faults in the device (for example causing random hardware failures), or from systematic faults (for example human errors made in the specification and design of a system cause systematic failure under some particular combination of inputs), or from some environmental condition.

IEC 61508-1 provides an overall framework based on a risk approach for the prevention and/or control of failures in electro-mechanical, electronic, or programmable electronic devices.

The overall goal is to ensure that plant and equipment can be safely automated. A key objective of this standard is to prevent:

- failures of control systems triggering other events, which in turn could lead to danger (for example fire, release of toxic materials, repeat stroke of a machine, etc.); and
- undetected failures in protection systems (for example in an emergency shut-down system), making the systems unavailable when needed for a safety action.

IEC 61508-1 requires that a hazard and risk analysis at the process/machine level is carried out to determine the amount of risk reduction necessary to meet the risk criteria for the application. Risk is based on the assessment of both the consequence (or severity) and the frequency (or probability) of the hazardous event.

IEC 61508-1 further requires that the amount of risk reduction established by the risk analysis is used to determine if one or more safety-related systems[1] are required and what safety functions (each with a specified safety integrity)[2] they are needed for.

IEC 61508-2 and IEC 61508-3 take the safety functions and safety integrity requirements allocated to any system, designated as a E/E/PE safety-related system, by the application of IEC 61508-1 and establish requirements for safety lifecycle activities which:

- are to be applied during the specification, design and modification of the hardware and software; and
- focus on means for preventing and/or controlling random hardware and systematic failures (the E/E/PE system and software safety lifecycles)[3].

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1 Systems necessary for functional safety and containing one or more electrical (electro-mechanical), electronic or programmable electronic (E/E/PE) devices are *designated* as E/E/PE safety-related systems and include all equipment necessary to carry out the required safety function (see 3.5.1 of IEC 61508-4).

2 Safety integrity is specified as one of four discrete levels. Safety integrity level 4 is the highest and safety integrity level 1 the lowest (see 3.5.4 and 3.5.8 of IEC 61508-4).

3 To enable the requirements of this standard to be clearly structured, a decision was made to order the requirements using a development process model in which each stage follows in a defined order with little iteration (sometimes referred to as a waterfall model). However, it is stressed that any lifecycle approach can be used provided a statement of equivalence is given in the safety plan for the project (see Clause 7 of IEC 61508-1).