

INTERNATIONAL STANDARD

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BASIC SAFETY PUBLICATION

PUBLICATION FONDAMENTALE DE SÉCURITÉ

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

**Part 2: Requirements for electrical/electronic/programmable electronic
safety-related systems**

**Sécurité fonctionnelle des systèmes électriques/électroniques/électroniques
programmables relatifs à la sécurité –**

**Partie 2: Prescriptions pour les systèmes électriques/électroniques/
électroniques programmables relatifs à la sécurité**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 2: Requirements for electrical/electronic/programmable electronic safety-related systems

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 the 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 National Committees.
- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
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- 6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61508-2 has been prepared by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement and control.

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/294/FDIS	65A/303/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 3.

Annexes A, B, and C form an integral part of this standard.

IEC 61508 consists of the following parts, under the general title *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 parts 2 and 3
- Part 7: Overview of techniques and measures

The committee has decided that the contents of this publication will remain unchanged until 2006. At this date, the publication will be

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

Withdrawn

INTRODUCTION

Systems comprised of electrical and/or electronic components 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 those 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)) 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 application sector standards.

In most situations, safety is achieved by a number of protective systems which may 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 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 recognised that there is a great variety of E/E/PES applications 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 application sector International Standards.

This International Standard

- considers all relevant overall, E/E/PES and software safety lifecycle phases (for example, from initial concept, through design, implementation, operation and maintenance to decommissioning) when E/E/PESs 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 application sector International Standards, dealing with safety-related E/E/PESs, to be developed; the development of application sector International Standards, within the framework of this International 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;
- uses 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;

- adopts a risk-based approach for the determination of the safety integrity level requirements;
- sets numerical target failure measures for 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 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 failure of 10^{-5} to perform its design function on demand,
 - a high demand or continuous mode of operation, the lower limit is set at a probability of a dangerous failure of 10^{-9} per hour;

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

- adopts a broad range of principles, techniques and measures to achieve functional safety for E/E/PE safety-related systems, but does not rely on 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.

Withdrawn

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

Part 2: Requirements for electrical/electronic/programmable electronic safety-related systems

1 Scope

1.1 This part of IEC 61508

- a) is intended to be used only after a thorough understanding of IEC 61508-1, which provides the overall framework for the achievement of functional safety;
- b) applies to any safety-related system, as defined by IEC 61508-1, which contains at least one electrical, electronic or programmable electronic based component;
- c) applies to all subsystems and their components within an E/E/PE safety-related system (including sensors, actuators and the operator interface);
- d) specifies how to refine the information developed in accordance with IEC 61508-1, concerning the overall safety requirements and their allocation to E/E/PE safety-related systems, and specifies how the overall safety requirements are refined into E/E/PE safety functions requirements and E/E/PE safety integrity requirements;
- e) specifies requirements for activities that are to be applied during the design and manufacture of the E/E/PE safety-related systems (i.e. establishes the E/E/PE safety lifecycle model), except for software, which is dealt with by IEC 61508-3 (see figures 2 and 3) – these requirements include the application of techniques and measures, which are graded against the safety integrity level, for the avoidance of, and control of, faults and failures;
- f) specifies the information necessary for carrying out the installation, commissioning and final safety validation of the E/E/PE safety-related systems;
- g) does not apply to the operation and maintenance phase of the E/E/PE safety-related systems – this is dealt with in IEC 61508-1 – however, IEC 61508-2 does provide requirements for the preparation of information and procedures needed by the user for the operation and maintenance of the E/E/PE safety-related systems;
- h) specifies requirements to be met by the organisation carrying out any modification of the E/E/PE safety-related systems.

NOTE 1 This part of IEC 61508 is mainly directed at suppliers and/or in-company engineering departments, hence the inclusion of requirements for modification.

NOTE 2 The relationship between IEC 61508-2 and IEC 61508-3 is illustrated in figure 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 3.4.4 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 is also intended for use as a stand-alone standard.

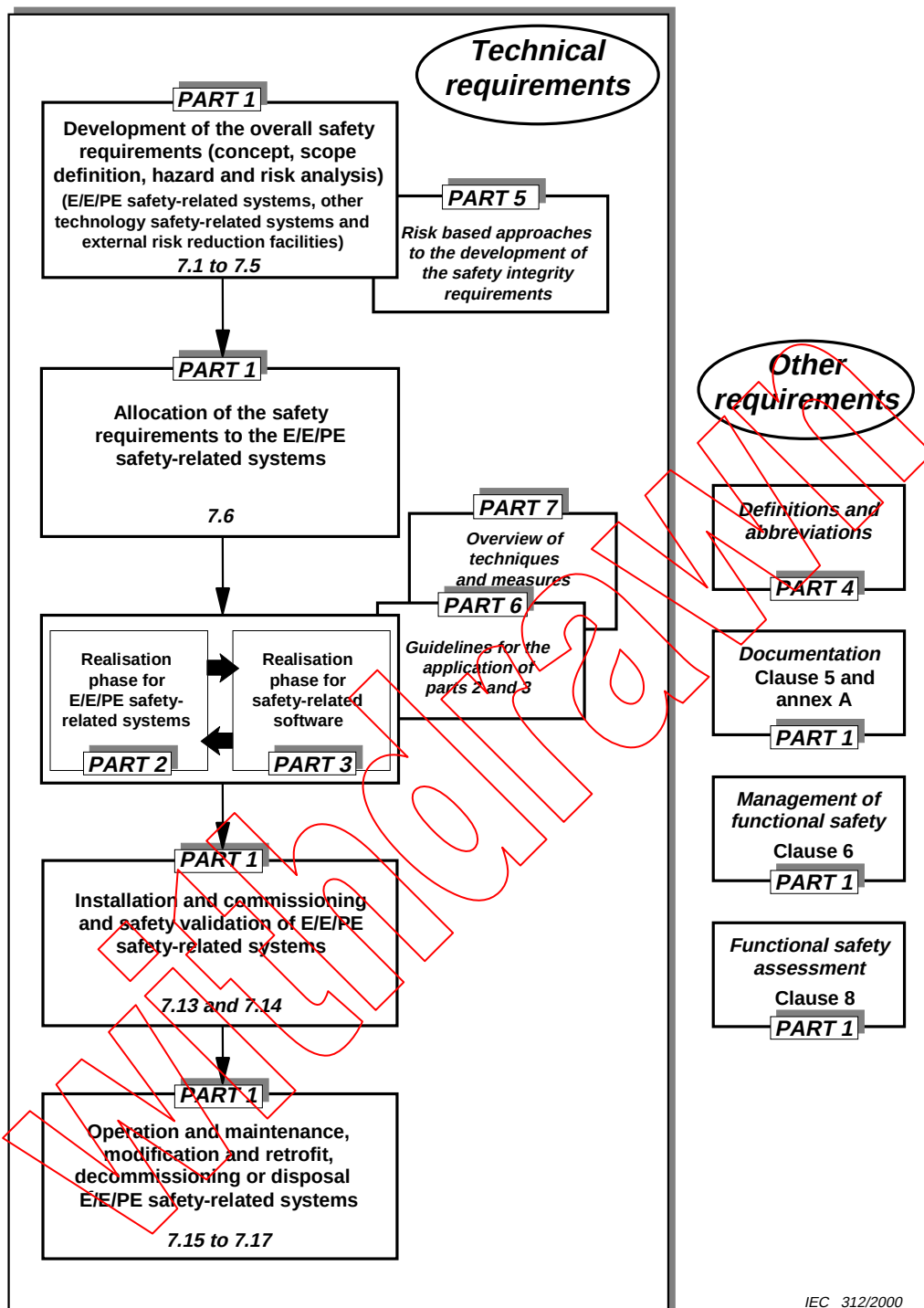
One of the responsibilities of a technical committee is, wherever applicable, to make use of basic safety publications in the preparation of its publications. In this context, the requirements, test methods or test conditions of this basic safety publication will not apply unless specifically referred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

NOTE 1 The functional safety of an E/E/PE safety-related system can only be achieved when all related requirements are met. Therefore, it is important that all related requirements are carefully considered and adequately referenced.

NOTE 2 In the USA and Canada, until the proposed sector implementation of IEC 61508 (i.e. IEC 61511) 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) can be applied to the process sector instead of IEC 61508.

1.3 Figure 1 shows the overall framework for parts 1 to 7 of IEC 61508 and indicates the role that IEC 61508-2 plays in the achievement of functional safety for E/E/PE safety-related systems. Annex A of IEC 61508-6 describes the application of IEC 61508-2 and IEC 61508-3.

Withdrawn



IEC 312/2000

Figure 1 – Overall framework of IEC 61508

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 61508. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of IEC 61508 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60050(371):1984, *International Electrotechnical Vocabulary – Chapter 371: Telecontrol*

IEC 60300-3-2:1993, *Dependability management – Part 3: Application guide – Section 2: Collection of dependability data from the field*

IEC 61000-1-1:1992, *Electromagnetic compatibility (EMC) – Part 1: General – Section 1: Application and interpretation of fundamental definitions and terms*

IEC 61000-2-5:1995, *Electromagnetic compatibility (EMC) – Part 2: Environment – Section 5: Classification of electromagnetic environments – Basic EMC publication*

IEC 61508-1:1998, *Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 1: General requirements*

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

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

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

IEC 61508-6, *Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 6: Guidelines on the application of parts 2 and 3¹⁾*

IEC 61508-7:2000, *Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 7: Overview of techniques and measures*

IEC Guide 104:1997, *The preparation of safety publications and the use of basic safety publications and group safety publications*

ISO/IEC Guide 51:1990, *Guidelines for the inclusion of safety aspects in standards*

IEEE 352:1987, *IEEE guide for general principles of reliability analysis of nuclear power generating station safety systems*

¹⁾ To be published.

3 Definitions and abbreviations

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

4 Conformance to this standard

The requirements for conformance to this standard are as detailed in clause 4 of IEC 61508-1.

5 Documentation

The requirements for documentation are as detailed in clause 5 of IEC 61508-1.

6 Management of functional safety

The requirements for management of functional safety are as detailed in clause 6 of IEC 61508-1.

7 E/E/PES safety lifecycle requirements

7.1 General

7.1.1 Objectives and requirements: General

7.1.1.1 This subclause sets out the objectives and requirements for the E/E/PES safety lifecycle phases.

NOTE The objectives and requirements for the overall safety lifecycle, together with a general introduction to the structure of the standard, are given in IEC 61508-1.

7.1.1.2 For all phases of the E/E/PES safety lifecycle, table 1 indicates

- the objectives to be achieved;
- the scope of the phase;
- a reference to the subclause containing the requirements;
- the required inputs to the phase;
- the outputs required to comply with the subclause.

7.1.2 Objectives

7.1.2.1 The first objective of the requirements of this subclause is to structure, in a systematic manner, the phases in the E/E/PES safety lifecycle that shall be considered in order to achieve the required functional safety of the E/E/PE safety-related systems.

7.1.2.2 The second objective of the requirements of this subclause is to document all information relevant to the functional safety of the E/E/PE safety-related systems throughout the E/E/PES safety lifecycle.

7.1.3 Requirements

7.1.3.1 The E/E/PES safety lifecycle that shall be used in claiming conformance with this standard is that specified in figure 2. If another E/E/PES safety lifecycle is used, it shall be specified during functional safety planning (see clause 6 of IEC 61508-1), and all the objectives and requirements of each subclause of IEC 61508-2 shall be met.

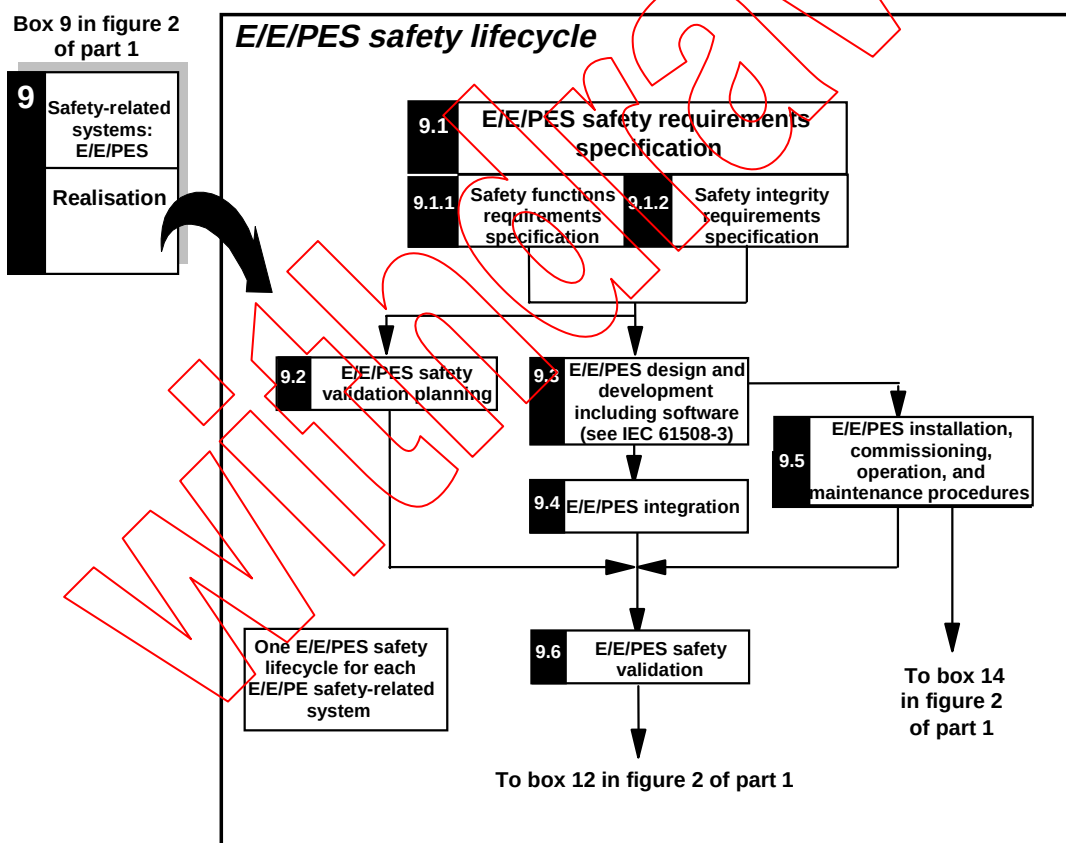
NOTE The relationship and scope for IEC 61508-2 and IEC 61508-3 are shown in figure 3.

7.1.3.2 The procedures for management of functional safety (see clause 6 of IEC 61508-1) shall run in parallel with the E/E/PES safety lifecycle phases.

7.1.3.3 Each phase of the E/E/PES safety lifecycle shall be divided into elementary activities, with the scope, inputs and outputs specified for each phase (see table 1).

7.1.3.4 Unless justified during functional safety planning, the outputs of each phase of the E/E/PES safety lifecycle shall be documented (see clause 5 of IEC 61508-1).

7.1.3.5 The outputs for each E/E/PES safety lifecycle phase shall meet the objectives and requirements specified for each phase (see 7.2 to 7.9).



NOTE See also IEC 61508-6, A.2(b).

Figure 2 – E/E/PES safety lifecycle (in realisation phase)

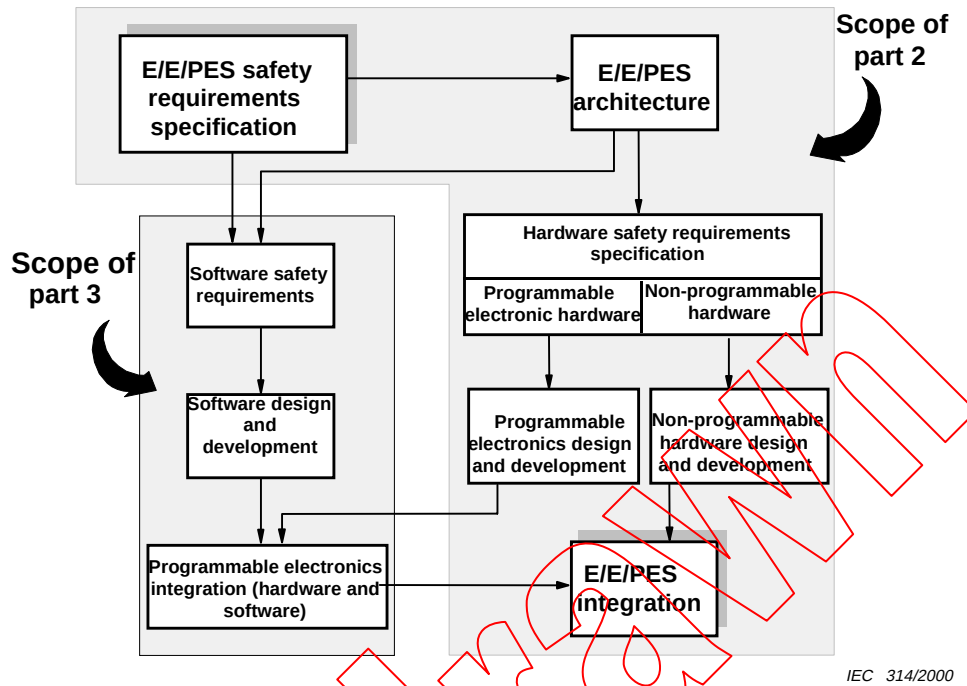


Figure 3 – Relationship and scope for IEC 61508-2 and IEC 61508-3

Table 1 – Overview – Realisation phase of the E/E/PES safety lifecycle

Safety lifecycle phase or activity		Objectives	Scope	Requirements subclause	Inputs	Outputs
Figure 2 box number	Title					
9.1	E/E/PES safety requirements specification	To specify the requirements for each E/E/PE safety-related system, in terms of the required safety functions and the required safety integrity, in order to achieve the required functional safety	E/E/PE safety-related systems	7.2.2	Description of allocation of safety requirements (see 7.6 of IEC 61508-1)	E/E/PES safety requirements Requirements for software safety as an input to the software safety requirements specification
9.2	E/E/PES safety validation planning	To plan the validation of the safety of the E/E/PE safety-related systems	E/E/PE safety-related systems	7.3.2	E/E/PES safety requirements	Plan for the safety validation of the E/E/PE safety-related systems
9.3	E/E/PES design and development	To design the E/E/PE safety-related systems to meet the requirements for safety functions and safety integrity	E/E/PE safety-related systems	7.4.2 to 7.4.9	E/E/PES safety requirements	Design of the E/E/PE safety related systems in conformance with the E/E/PES safety requirements Plan for the E/E/PES integration test PES architectural information as an input to the software requirements specification
9.4	E/E/PES integration	To integrate and test the E/E/PE safety-related systems	E/E/PE safety-related systems	7.5.2	E/E/PES design E/E/PES integration test plan Programmable electronics hardware and software	Fully functioning E/E/PE safety-related systems in conformance with the E/E/PES design Results of E/E/PES integration tests
9.5	E/E/PES installation, commissioning, operation, and maintenance procedures	To develop procedures to ensure that the functional safety of the E/E/PE safety-related systems is maintained during operation and maintenance	E/E/PE safety-related systems EUC	7.6.2	E/E/PES safety requirements E/E/PES design	E/E/PES installation, commissioning, operation and maintenance procedures for each individual E/E/PES
9.6	E/E/PES safety validation	To validate that the E/E/PE safety-related systems meet, in all respects, the requirements for safety in terms of the required safety functions and the required safety integrity	E/E/PE safety-related systems	7.7.2	E/E/PES safety requirements Plan for the safety validation of the E/E/PE safety-related systems	Fully safety validated E/E/PE safety-related systems Results of E/E/PES safety validation
–	E/E/PES modification	To make corrections, enhancements or adaptations to the E/E/PE safety-related systems, ensuring that the required safety integrity level is achieved and maintained	E/E/PE safety-related systems	7.8.2	E/E/PES safety requirements	Results of E/E/PES modification
–	E/E/PES verification	To test and evaluate the outputs of a given phase to ensure correctness and consistency with respect to the products and standards provided as input to that phase	E/E/PE safety-related systems	7.9.2	As above – depends on the phase Plan for the verification of the E/E/PE safety-related systems for each phase	As above – depends on the phase Results of the verification of the E/E/PE safety-related systems for each phase
–	E/E/PES functional safety assessment	To investigate and arrive at a judgement on the functional safety achieved by the E/E/PE safety-related systems	E/E/PE safety-related systems	8	Plan for E/E/PES functional safety assessment	Results of E/E/PES functional safety assessment

7.2 E/E/PES safety requirements specification

NOTE This phase is box 9.1 of figure 2.

7.2.1 Objective

The objective of the requirements of this subclause is to specify the requirements for each E/E/PE safety-related system, in terms of the required safety functions and the required safety integrity, in order to achieve the required functional safety.

NOTE The safety functions may, for example, be required to put the EUC into a safe state or to maintain a safe state.

7.2.2 General requirements

7.2.2.1 The specification of the E/E/PES safety requirements shall be derived from the allocation of safety requirements, specified in 7.6 of IEC 61508-1, and from those requirements specified during functional safety planning (see clause 6 of IEC 61508-1). This information shall be made available to the E/E/PES developer.

NOTE Caution should be exercised if non-safety functions and safety functions are implemented in the same E/E/PE safety-related system. While this is allowed in the standard, it may lead to greater complexity and increase the difficulty in carrying out E/E/PE safety lifecycle activities (for example design, validation, functional safety assessment and maintenance).

7.2.2.2 The E/E/PES safety requirements shall be expressed and structured in such a way that they are

- a) clear, precise, unambiguous, verifiable, testable, maintainable and feasible; and
- b) written to aid comprehension by those who are likely to utilise the information at any stage of the E/E/PES safety lifecycle.

7.2.2.3 The specification of the E/E/PES safety requirements shall contain the requirements for the E/E/PES safety functions (see 7.2.3.1) and the requirements for E/E/PES safety integrity (see 7.2.3.2).

7.2.3 E/E/PES safety requirements

7.2.3.1 The E/E/PES safety functions requirements specification shall contain

- a) a description of all the safety functions necessary to achieve the required functional safety, which shall, for each safety function,
 - provide comprehensive detailed requirements sufficient for the design and development of the E/E/PE safety-related systems,
 - include the manner in which the E/E/PE safety-related systems are intended to achieve or maintain a safe state for the EUC,
 - specify whether or not continuous control is required, and for what periods, in achieving or maintaining a safe state of the EUC, and
 - specify whether the safety function is applicable to E/E/PE safety-related systems operating in low demand or high demand/continuous modes of operation;
- b) throughput and response time performance;
- c) E/E/PE safety-related system and operator interfaces which are necessary to achieve the required functional safety;
- d) all information relevant to functional safety which may have an influence on the E/E/PE safety-related system design;
- e) all interfaces between the E/E/PE safety-related systems and any other systems (either directly associated within, or outside, the EUC);

- f) all relevant modes of operation of the EUC, including
- preparation for use including setting and adjustment,
 - start-up, teach, automatic, manual, semi-automatic, steady state of operation,
 - steady state of non-operation, re-setting, shut-down, maintenance,
 - reasonably foreseeable abnormal conditions;

NOTE 1 Reasonably foreseeable abnormal conditions are those reasonably foreseeable to either the developers or users.

NOTE 2 Additional safety functions may be required for particular modes of operation (for example setting, adjustment or maintenance), to enable these operations to be carried out safely.

- g) all required modes of behaviour of the E/E/PE safety-related systems – in particular, failure behaviour and the required response (for example alarms, automatic shut-down, etc.) of the E/E/PE safety-related systems shall be detailed;
- h) the significance of all hardware/software interactions – where relevant, any required constraints between the hardware and the software shall be identified and documented;
- NOTE 3 Where these interactions are not known before finishing the design, only general constraints can be stated.
- i) limiting and constraint conditions for the E/E/PE safety-related systems and their associated subsystems, for example timing constraints;
- j) any specific requirements related to the procedures for starting-up and restarting the E/E/PE safety-related systems.

7.2.3.2 The E/E/PES safety integrity requirements specification shall contain

- a) the safety integrity level for each safety function and, when required (see note 2), the required target failure measure for the safety function.

NOTE 1 The safety integrity level of a safety function determines the target failure measure for the safety function according to IEC 61508-1, tables 2 and 3.

NOTE 2 The target failure measure of a safety function will need to be specified when the required risk reduction for the safety function has been derived using a quantitative method (see IEC 61508-1, 7.5.2.2).

- b) the mode of operation (low demand or continuous/high demand) of each safety function;
- c) the requirements, constraints, functions and facilities to enable the proof testing of the E/E/PE hardware to be undertaken;
- d) the extremes of all environmental conditions that are likely to be encountered during the E/E/PES safety lifecycle including manufacture, storage, transport, testing, installation, commissioning, operation and maintenance;
- e) the electromagnetic immunity limits (see IEC 61000-1-1) which are required to achieve electromagnetic compatibility – the electromagnetic immunity limits should be derived taking into account both the electromagnetic environment (see IEC 61000-2-5) and the required safety integrity levels;

NOTE 1 It is important to recognise that the safety integrity level is a factor in determining electromagnetic immunity limits, especially since the level of electromagnetic disturbance in the environment is subject to a statistical distribution. In most practical situations, it is not possible to specify an absolute level of disturbance, only a level which it is expected will not be exceeded in practice (this is the electromagnetic compatibility level). Unfortunately, practical difficulties make the probability associated with this expectation very hard to define. Therefore, the immunity limit does not guarantee that the E/E/PE safety-related system will not fail due to electromagnetic disturbances, it only provides some level of confidence that such a failure will not occur. The actual level of confidence achieved is a function of the immunity limit in relation to the statistical distribution of the disturbance levels in the operating environment. For higher safety integrity levels it may be necessary to have a higher level of confidence, which means that the margin by which the immunity limit exceeds the compatibility level should be greater for higher safety integrity levels.

NOTE 2 Also, guidance may be found in EMC product standards, but it is important to recognise that higher immunity levels than those specified in such standards may be necessary for particular locations or when the equipment is intended for use in harsher electromagnetic environments.

NOTE 3 In developing the E/E/PES safety requirements specification, the application in which the E/E/PE safety-related systems are to be used should be taken into consideration. This is particularly important for maintenance, where the specified proof test interval should not be less than can be reasonably expected for the particular application. For example, the time between services that can be realistically attained for mass-produced items used by the public is likely to be greater than in a more controlled application.

7.2.3.3 For the avoidance of mistakes during the specification of the E/E/PES safety requirements, an appropriate group of techniques and measures according to table B.1 shall be used.

7.3 E/E/PES safety validation planning

NOTE This phase is box 9.2 of figure 2. It will normally be carried out in parallel with E/E/PE design and development (see 7.4).

7.3.1 Objective

The objective of the requirements of this subclause is to plan the validation of the safety of the E/E/PE safety-related systems.

7.3.2 Requirements

7.3.2.1 Planning shall be carried out to specify the steps (both procedural and technical) that are to be used to demonstrate that the E/E/PE safety-related systems satisfy the E/E/PES safety requirements specification (see 7.2).

NOTE See IEC 61508-3 for the validation plan for the software.

7.3.2.2 Planning for the validation of the E/E/PE safety-related systems shall consider the following:

- a) all of the requirements defined in the E/E/PES safety requirements specification;
- b) the procedures to be applied to validate that each safety function is correctly implemented, and the pass/fail criteria for accomplishing the tests;
- c) the procedures to be applied to validate that each safety function is of the required safety integrity, and the pass/fail criteria for accomplishing the tests;
- d) the required environment in which the testing is to take place including all necessary tools and equipment (also plan which tools and equipment should be calibrated);
- e) test evaluation procedures (with justifications);
- f) the test procedures and performance criteria to be applied to validate the specified electromagnetic immunity limits;

NOTE Guidance on the specification of immunity test limits is given in IEC 61000-2-5 and IEC 61000-4.

- g) policies for resolving validation failure.

7.4 E/E/PES design and development

NOTE This phase is box 9.3 of figure 2. It will normally be carried out in parallel with E/E/PES safety validation planning (see 7.3).

7.4.1 Objective

The objective of the requirements of this subclause is to ensure that the design and implementation of the E/E/PE safety-related systems meets the specified safety functions and safety integrity requirements (see 7.2).

7.4.2 General requirements

7.4.2.1 The design of the E/E/PE safety-related system shall be created in accordance with the E/E/PES safety requirements specification (see 7.2), taking into account all the requirements of 7.4.

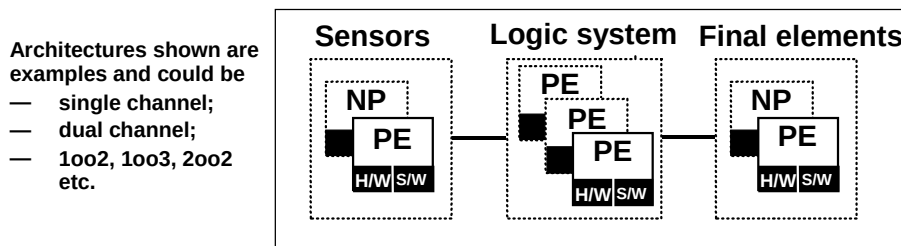
7.4.2.2 The design of the E/E/PE safety-related system (including the overall hardware and software architecture, sensors, actuators, programmable electronics, embedded software, application software, etc.), see figure 4, shall be such as to meet all of the requirements a) to c) as follows:

- a) the requirements for hardware safety integrity comprising
 - the architectural constraints on hardware safety integrity (see 7.4.3.1), and
 - the requirements for the probability of dangerous random hardware failures (see 7.4.3.2);
- b) the requirements for systematic safety integrity comprising
 - the requirements for the avoidance of failures (see 7.4.4), and the requirements for the control of systematic faults (see 7.4.5), or
 - evidence that the equipment is "proven in use" (see 7.4.7.6 to 7.4.7.12);
- c) the requirements for system behaviour on detection of a fault (see 7.4.6).

NOTE 1 Overall E/E/PES safety integrity framework: the overall method for selecting a design approach to demonstrate achievement of a safety integrity level (for both hardware and systematic safety integrity) in E/E/PE safety-related systems is as follows:

- determine the required safety integrity level (SIL) of the safety functions (see IEC 61508-1 and IEC 61508-5);
- set: hardware safety integrity = systematic safety integrity = SIL (see 7.4.3.2.1);
- for hardware safety integrity, determine the architecture to meet the architectural constraints (see 7.4.3.1) and demonstrate that the probabilities of failure of the safety functions due to random hardware failures meet the required target failure measures (see 7.4.3.2);
- for systematic safety integrity, select design features that control (tolerate) systematic faults in actual operation (see 7.4.5) or confirm that the 'proven-in-use' requirements have been met (see 7.4.7.6 to 7.4.7.12); and
- for systematic safety integrity, select techniques and measures that avoid (prevent the introduction of) systematic faults during design and development (see 7.4.4) or confirm that the 'proven-in-use' requirements have been met (see 7.4.7.6 to 7.4.7.12).

NOTE 2 IEC 61508-3 contains the requirements for the software architecture (see 7.4.2.2); the requirements to produce a programmable electronics and software integration test specification (see 7.5); and the requirements to integrate the programmable electronics and software according to that specification (see 7.5). In all cases, close co-operation between the developer of the E/E/PE safety-related systems and the software developer will be necessary.



Programmable electronics architecture		
PE hardware architecture	PE software architecture (s/w architecture consists of embedded s/w and applications s/w)	
Generic and application specific features in PE hardware. Examples include	PE embedded software	PE applications software
— diagnostic tests; — redundant processors; — dual I/O cards.	Examples include — communications drivers; — fault handling; — executive software.	Examples include — input/output functions; — derived functions (for example sensor checking if not provided as a service of the embedded software).

IEC 315/2000

Key

PE programmable electronics
 NP non-programmable devices
 H/W hardware
 S/W software
 MooN M out of N (for example 1oo2 is 1 out of 2)

Figure 4 – Relationship between the hardware and software architectures of programmable electronics

7.4.2.3 Where an E/E/PE safety-related system is to implement both safety and non-safety functions, then all the hardware and software shall be treated as safety-related unless it can be shown that the implementation of the safety and non-safety functions is sufficiently independent (i.e. that the failure of any non-safety-related functions does not cause a dangerous failure of the safety-related functions). Wherever practicable, the safety-related functions should be separated from the non-safety-related functions.

NOTE 1 Sufficient independence of implementation is established by showing that the probability of a dependent failure between the non-safety and safety-related parts is sufficiently low in comparison with the highest safety integrity level associated with the safety functions involved.

NOTE 2 Caution should be exercised if non-safety functions and safety functions are implemented in the same E/E/PE safety-related system. While this is allowed in the standard, it may lead to greater complexity and increase the difficulty in carrying out E/E/PES safety lifecycle activities (for example design, validation, functional safety assessment and maintenance).

7.4.2.4 The requirements for hardware and software shall be determined by the safety integrity level of the safety function having the highest safety integrity level unless it can be shown that the implementation of the safety functions of the different safety integrity levels is sufficiently independent.

NOTE 1 Sufficient independence of implementation is established by showing that the probability of a dependent failure between the parts implementing safety functions of different integrity levels is sufficiently low in comparison with the highest safety integrity level associated with the safety functions involved.

NOTE 2 Where several safety functions are implemented in an E/E/PE safety-related system then it will be necessary to consider the possibility that a single fault could cause a failure of several safety functions. In such a situation, it may be appropriate to determine the requirements for hardware and software on the basis of a higher safety integrity level than is associated with any one of the safety functions, depending on the risk associated with such a failure.

7.4.2.5 When independence between safety functions is required (see 7.4.2.3 and 7.4.2.4) then the following shall be documented during the design:

- a) the method of achieving independence;
- b) the justification of the method.

7.4.2.6 The requirements for safety-related software (see IEC 61508-3) shall be made available to the developer of the E/E/PE safety-related system.

7.4.2.7 The developer of the E/E/PE safety-related system shall review the requirements for safety-related software and hardware to ensure that they are adequately specified. In particular, the E/E/PE developer shall consider the following:

- a) safety functions;
- b) E/E/PE safety-related system safety integrity requirements;
- c) equipment and operator interfaces.

7.4.2.8 The E/E/PE safety-related system design documentation shall specify those techniques and measures necessary during the E/E/PE safety lifecycle phases to achieve the safety integrity level.

7.4.2.9 The E/E/PE safety-related system design documentation shall justify the techniques and measures chosen to form an integrated set which satisfies the required safety integrity level.

NOTE The adoption of an overall approach employing independent type approval of the E/E/PE safety-related systems (including sensors, actuators, etc) for hardware and software, diagnostic tests and programming tools, and using appropriate languages for software wherever possible, has the potential to reduce the complexity of E/E/PE application engineering.

7.4.2.10 During the design and development activities, the significance (where relevant) of all hardware and software interactions shall be identified, evaluated and documented.

7.4.2.11 The design shall be based on a decomposition into subsystems with each subsystem having a specified design and set of integration tests (see 7.4.7).

NOTE 1 A subsystem may be considered to comprise a single component or any group of components. A complete E/E/PE safety-related system is made up from a number of identifiable and separate subsystems, which when put together implement the safety function under consideration. A subsystem can have more than one channel. See 7.4.7.3.

NOTE 2 Wherever practicable, existing verified subsystems should be used in the implementation. This statement is generally valid only if there is almost 100 % mapping of the existing subsystem functionality, capacity and performance on to the new requirement or the verified subsystem is structured in such a way that the user is able to select only the functions, capacity or performance required for the specific application. Excessive functionality, capacity or performance can be detrimental to system safety if the existing subsystem is overly complicated or has unused features and if protection against unintended functions cannot be obtained.

7.4.2.12 Where a subsystem has multiple outputs then it is necessary to determine whether some combination of output states, which may be caused by a failure of the E/E/PE safety-related system, can directly cause a hazardous event (as determined by the hazard and risk analysis, see IEC 61508-1, 7.4.2.10). Where this has been established, then the prevention of that combination of output states shall be regarded as a safety function operating in the high demand/continuous mode of operation (see 7.4.6.3 and 7.4.3.2.5).

7.4.2.13 De-rating (see IEC 61508-7, A.2.8) shall be used as far as possible for all components. Justification for operating any components at their limits shall be documented (see IEC 61508-1, clause 5).

NOTE Where de-rating is appropriate, a de-rating factor of at least 0,67 should be used.

7.4.3 Requirements for hardware safety integrity

NOTE Clause A.2 of IEC 61508-6 gives an overview of the necessary steps in achieving required hardware safety integrity, and shows how this subclause relates to other requirements of this standard.

7.4.3.1 Architectural constraints on hardware safety integrity

7.4.3.1.1 In the context of hardware safety integrity, the highest safety integrity level that can be claimed for a safety function is limited by the hardware fault tolerance and safe failure fraction of the subsystems that carry out that safety function (see annex C). Tables 2 and 3 specify the highest safety integrity level that can be claimed for a safety function which uses a subsystem taking into account the hardware fault tolerance and safe failure fraction of that subsystem (see annex C). The requirements of tables 2 and 3 shall be applied to each subsystem carrying out a safety function and hence every part of the E/E/PE safety-related system; 7.4.3.1.2 to 7.4.3.1.4 specify which one of tables 2 and 3 apply to any particular subsystem. Subclauses 7.4.3.1.5 and 7.4.3.1.6 specify how the highest safety integrity level that can be claimed for a safety function is derived. With respect to these requirements,

- a) a hardware fault tolerance of N means that N+1 faults could cause a loss of the safety function. In determining the hardware fault tolerance no account shall be taken of other measures that may control the effects of faults such as diagnostics, and
- b) where one fault directly leads to the occurrence of one or more subsequent faults, these are considered as a single fault;
- c) in determining hardware fault tolerance, certain faults may be excluded, provided that the likelihood of them occurring is very low in relation to the safety integrity requirements of the subsystem. Any such fault exclusions shall be justified and documented (see note 3);
- d) the safe failure fraction of a subsystem is defined as the ratio of the average rate of safe failures plus dangerous detected failures of the subsystem to the total average failure rate of the subsystem (see annex C).

NOTE 1 The architectural constraints have been included in order to achieve a sufficiently robust architecture, taking into account the level of subsystem complexity. The hardware safety integrity level for the E/E/PE safety-related system, derived through applying these requirements, is the maximum that is permitted to be claimed even though, in some cases, a higher safety integrity level could theoretically be derived if a solely mathematical approach had been adopted for the E/E/PE safety-related system.

NOTE 2 The architecture and subsystem derived to meet the hardware fault tolerance requirements is that used under normal operating conditions. The fault tolerance requirements may be relaxed while the E/E/PE safety-related system is being repaired on-line. However, the key parameters relating to any relaxation must have been previously evaluated (for example mean time to restoration compared to the probability of a demand).

NOTE 3 This is necessary because if a component clearly has a very low probability of failure by virtue of properties inherent to its design and construction (for example, a mechanical actuator linkage), then it would not normally be considered necessary to constrain (on the basis of hardware fault tolerance) the safety integrity of any safety function which uses the component.

7.4.3.1.2 A subsystem (see 7.4.2.11, note 1) can be regarded as type A if, for the components required to achieve the safety function

- a) the failure modes of all constituent components are well defined; and
- b) the behaviour of the subsystem under fault conditions can be completely determined; and
- c) there is sufficient dependable failure data from field experience to show that the claimed rates of failure for detected and undetected dangerous failures are met (see 7.4.7.3 and 7.4.7.4).

7.4.3.1.3 A subsystem (see 7.4.2.11, note 1) shall be regarded as type B if, for the components required to achieve the safety function,

- a) the failure mode of at least one constituent component is not well defined; or
- b) the behaviour of the subsystem under fault conditions cannot be completely determined; or
- c) there is insufficient dependable failure data from field experience to support claims for rates of failure for detected and undetected dangerous failures (see 7.4.7.3 and 7.4.7.4).

NOTE This means that if at least one of the components of a subsystem itself satisfies the conditions for a type B subsystem then that subsystem must be regarded as type B rather than type A. See also 7.4.2.11, note 1.

7.4.3.1.4 The architectural constraints of either table 2 or table 3 shall apply to each subsystem carrying out a safety function, so that

- a) the hardware fault tolerance requirements shall be achieved for the whole of the E/E/PE safety-related system;
- b) table 2 applies for every type A subsystem forming part of the E/E/PE safety-related systems;

NOTE 1 If the E/E/PE safety-related system contains only type A subsystems then the requirements in table 2 will apply to the entire E/E/PE safety-related system.

- c) table 3 applies for every type B subsystem forming part of the E/E/PE safety-related systems;

NOTE 2 If the E/E/PE safety-related system contains only type B subsystems then the requirements in table 3 will apply to the entire E/E/PE safety-related system.

- d) both tables 2 and 3 will be applicable to E/E/PE safety-related systems comprising both type A and type B subsystems, since the requirements in table 2 shall apply for the type A subsystems and the requirements in table 3 shall apply for the type B subsystems.

Table 2 – Hardware safety integrity: architectural constraints on type A safety-related subsystems

Safe failure fraction	Hardware fault tolerance (see note 2)		
	0	1	2
< 60 %	SIL1	SIL2	SIL3
60 % – < 90 %	SIL2	SIL3	SIL4
90 % – < 99 %	SIL3	SIL4	SIL4
≥ 99 %	SIL3	SIL4	SIL4

NOTE 1 See 7.4.3.1.1 to 7.4.3.1.4 for details on interpreting this table.
 NOTE 2 A hardware fault tolerance of N means that N + 1 faults could cause a loss of the safety function.
 NOTE 3 See annex C for details of how to calculate safe failure fraction.

Table 3 – Hardware safety integrity: architectural constraints on type B safety-related subsystems

Safe failure fraction	Hardware fault tolerance (see note 2)		
	0	1	2
< 60 %	Not allowed	SIL1	SIL2
60 % – < 90 %	SIL1	SIL2	SIL3
90 % – < 99 %	SIL2	SIL3	SIL4
≥ 99 %	SIL3	SIL4	SIL4

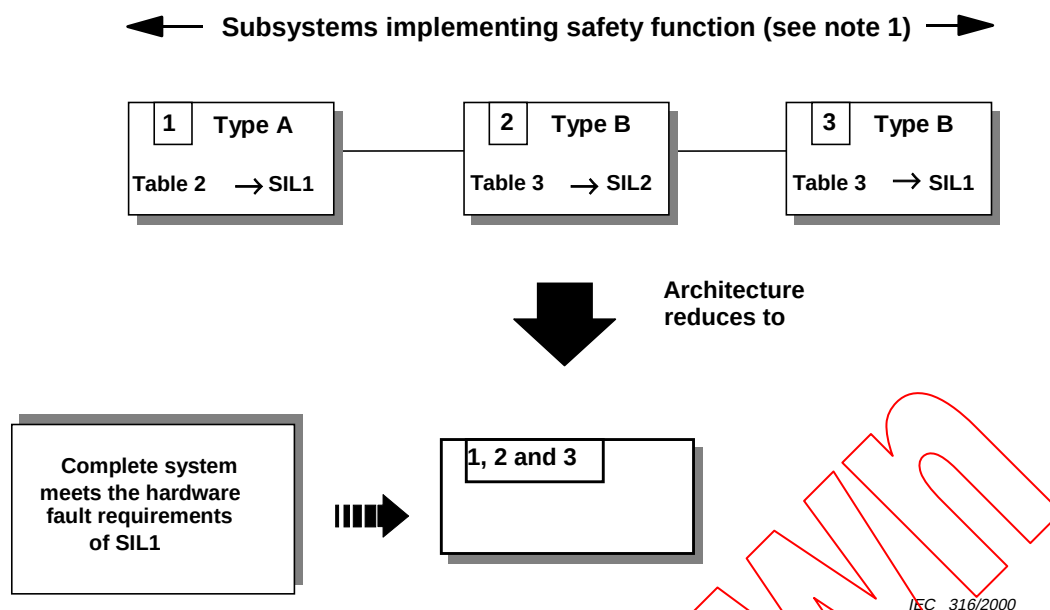
NOTE 1 See 7.4.3.1.1 to 7.4.3.1.4 for details on interpreting this table.
 NOTE 2 A hardware fault tolerance of N means that N + 1 faults could cause a loss of the safety function.
 NOTE 3 See annex C for details of how to calculate safe failure fraction.

7.4.3.1.5 In E/E/PE safety-related systems where a safety function is implemented through a single channel (such as in figure 5), the maximum hardware safety integrity level that can be claimed for the safety function under consideration shall be determined by the subsystem that has met the lowest hardware safety integrity level requirements (determined by consideration of tables 2 and 3).

EXAMPLE Assume an architecture in which a particular safety function is performed by a single channel of subsystems 1, 2 and 3 as in figure 5 and the subsystems meet the requirements of tables 2 and 3 as follows:

- subsystem 1 achieves the hardware fault tolerance requirements, for a specific safe failure fraction, of SIL1;
- subsystem 2 achieves the hardware fault tolerance requirements, for a specific safe failure fraction, of SIL2;
- subsystem 3 achieves the hardware fault tolerance requirements, for a specific safe failure fraction, of SIL1.

For this particular architecture, subsystems 1 and 3 are each only able to achieve the hardware fault tolerance requirements of SIL1, while subsystem 2 is able to achieve the hardware fault tolerance requirements of SIL2. Therefore, both subsystem 1 and subsystem 3 restrict the hardware safety integrity level that can be claimed, in respect of the hardware fault tolerance, for the safety function under consideration, to just SIL1.



NOTE 1 The subsystems implementing the safety function will be across the entire E/E/PE safety-related system in terms of ranging from the sensors to the actuators.

NOTE 2 For details on interpreting this figure, see the example to 7.4.3.1.5.

Figure 5 – Example limitation on hardware safety integrity for a single-channel safety function

7.4.3.1.6 In E/E/PE safety-related systems where a safety function is implemented through multiple channels of subsystems (such as in figure 6), the maximum hardware safety integrity level that can be claimed for the safety function under consideration shall be determined by

- a) assessing each subsystem against the requirements of table 2 or 3 (as specified in 7.4.3.1.2 to 7.4.3.1.4); and
- b) grouping the subsystems into combinations; and
- c) analysing those combinations to determine the overall hardware safety integrity level.

EXAMPLE The grouping and analysis of these combinations may be carried out in various ways. To illustrate one possible method, assume an architecture in which a particular safety function is performed by either a combination of subsystems 1, 2 and 3 or a combination of subsystems 4, 5 and 3, as in figure 6. In this case, the combination of subsystems 1 and 2 and the combination of subsystems 4 and 5 have the same functionality as regards the safety function, and provide separate inputs into subsystem 3. In this example, the combination of parallel subsystems is based on each subsystem implementing the required part of the safety function independent of the other (parallel) subsystem. The safety function will be performed

- in the event of a fault in either subsystem 1 or subsystem 2 (because the combination of subsystems 4 and 5 is able to perform the safety function); or
- in the event of a fault in either subsystem 4 or subsystem 5 (because the combination of subsystems 1 and 2 is able to perform the safety function).

Each subsystem meets the requirements of tables 2 and 3 as follows:

- subsystem 1 achieves the hardware fault tolerance requirements, for a specific safe failure fraction, of SIL3;
- subsystem 2 achieves the hardware fault tolerance requirements, for a specific safe failure fraction, of SIL2;
- subsystem 3 achieves the hardware fault tolerance requirements, for a specific safe failure fraction, of SIL2;
- subsystem 4 achieves the hardware fault tolerance requirements, for a specific safe failure fraction, of SIL2;
- subsystem 5 achieves the hardware fault tolerance requirements, for a specific safe failure fraction, of SIL1.

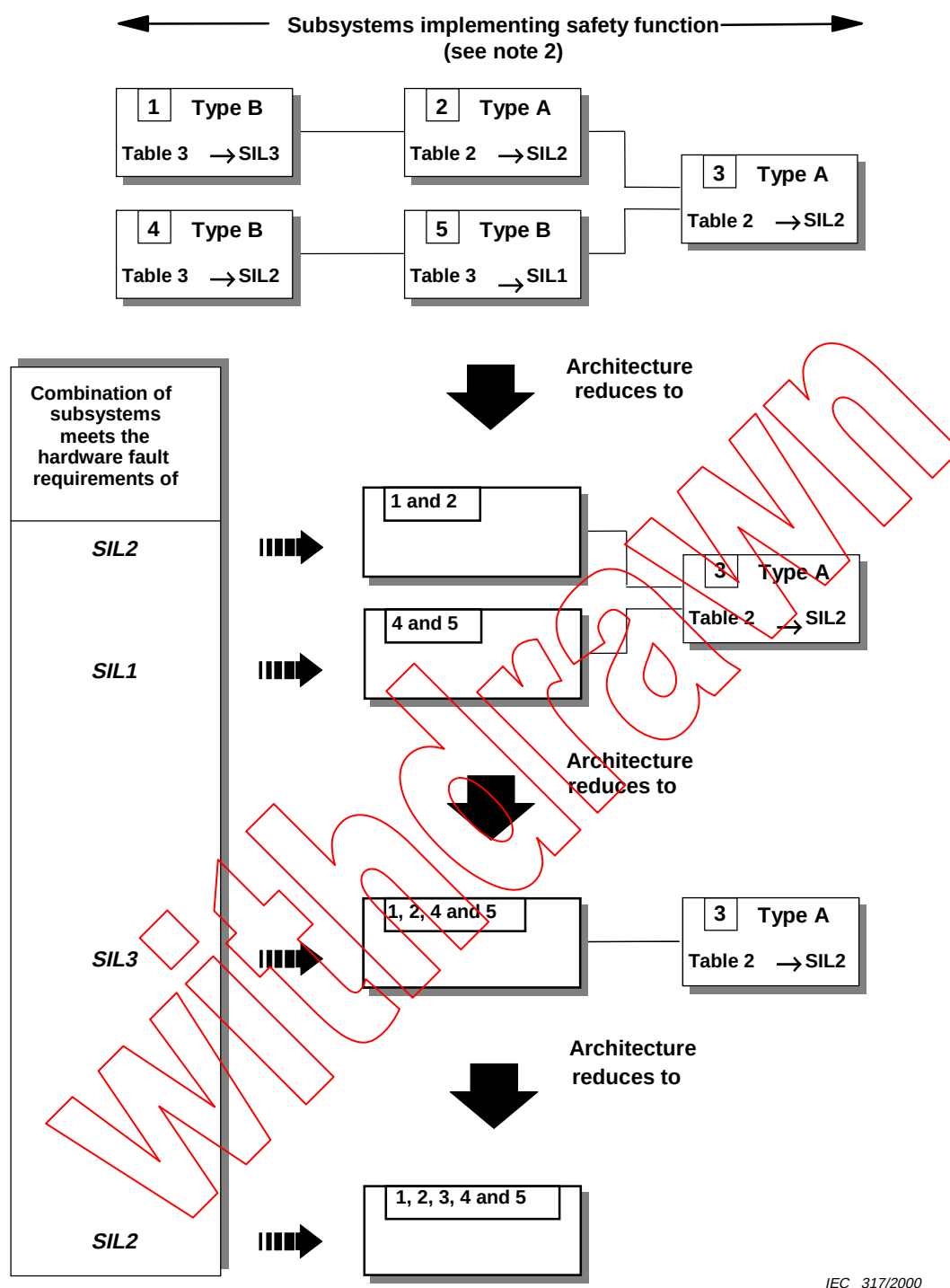
The determination of the maximum hardware safety integrity level that can be claimed, for the safety function under consideration, is detailed in the following steps.

- a) Combining subsystems 1 and 2: The hardware fault tolerance and safe failure fraction achieved by the combination of subsystems 1 and 2 (each separately meeting the requirements for SIL3 and SIL2 respectively) meets the requirements of SIL2 (determined by subsystem 2).
- b) Combining subsystems 4 and 5: The hardware fault tolerance and safe failure fraction achieved by the combination of subsystems 4 and 5 (each separately meeting the requirements for SIL2 and SIL1 respectively) meets the requirements of SIL1 (determined by subsystem 5).
- c) Further combining the combination of subsystems 1 and 2 with the combination of subsystems 4 and 5: The hardware safety integrity level, in respect of the hardware fault tolerance, of the combination of subsystems 1, 2, 4 and 5 is determined by
 - deciding which of the subsystem combinations (i.e. the combination of subsystems 1 and 2 or the combination of subsystems 4 and 5) has achieved the highest claimable hardware safety integrity level (in terms of meeting the hardware fault tolerance); and
 - analysing the effect the other subsystem combination has on the hardware fault tolerance for the combination of subsystems 1, 2, 4 and 5.

In this example, the combination of subsystems 1 and 2 has a maximum allowable claim of SIL2 (see a) above) while the combination of subsystems 4 and 5 has a maximum allowable claim of SIL1 (see b) above). However, in the event of a fault occurring in the combination of subsystems 1 and 2, the safety function could be performed by the combination of subsystems 4 and 5. To take account of this effect, the hardware fault tolerance achieved by the combination of subsystems 1 and 2 is increased by 1. Increasing the hardware fault tolerance by 1 has the effect of increasing the hardware safety integrity level that can be claimed by 1 (see tables 2 and 3). Therefore, the combination of subsystems 1, 2, 4 and 5 has a maximum claimable hardware safety integrity level, with respect to the hardware fault tolerance and safe failure fraction, of SIL3 (i.e. the hardware safety integrity level achieved by the combination of subsystems 1 and 2 (which was SIL2) plus 1).

- d) The complete E/E/PE safety-related system: The hardware safety integrity level, in respect of the hardware fault tolerance, that can be claimed for the safety function under consideration, is determined by analysing the combination of subsystems 1, 2, 4 and 5 (which achieved the fault tolerance requirements of SIL3 (see c)) and subsystem 3 (which achieved the fault tolerance requirements of SIL2). It is the subsystem that has achieved the lowest hardware safety integrity level requirements, in this case subsystem 3, which determines the maximum hardware safety integrity level for the complete E/E/PE safety-related system. Therefore, for this example, the maximum hardware safety integrity level, in respect of the hardware fault tolerance, that can be achieved for the safety function, is SIL2.

Withhold



NOTE 1 Subsystems 1 and 2 and subsystems 4 and 5 have the same functionality as regards implementing the safety function, and provide separate inputs into subsystem 3.

NOTE 2 The subsystems implementing the safety function will be across the entire E/E/PE safety-related system in terms of ranging from the sensors to the actuators.

NOTE 3 For details on interpreting this figure, see the example to 7.4.3.1.6.

Figure 6 – Example limitation on hardware safety integrity for a multiple-channel safety function

7.4.3.2 Requirements for estimating the probability of failure of safety functions due to random hardware failures

7.4.3.2.1 The probability of failure of each safety function due to random hardware failures, estimated according to 7.4.3.2.2 and 7.4.3.2.3, shall be equal to or less than the target failure measure as specified in the safety requirements specification (see 7.2.3.2).

NOTE 1 In the case of a safety function operating in the low demand mode of operation, the target failure measure will be expressed in terms of the average probability of failure to perform its design function on demand, as determined by the safety integrity level of the safety function (see IEC 61508-1, table 2), unless there is a requirement in the E/E/PES safety integrity requirements specification (see 7.2.3.2) for the safety function to meet a specific target failure measure, rather than a specific SIL. For example, when a target failure measure of $1,5 \times 10^{-6}$ (probability of failure on demand) is specified in order to meet the required risk reduction, then the probability of failure on demand of the safety function due to random hardware failures will need to be equal to or less than $1,5 \times 10^{-6}$.

NOTE 2 In the case of a safety function operating in the high demand/continuous mode of operation, the target failure measure will be expressed in terms of the average probability of a dangerous failure per hour, as determined by the safety integrity level of the safety function (see IEC 61508-1, table 3), unless there is a requirement in the E/E/PES safety integrity requirements specification (see 7.2.3.2) for the safety function to meet a specific target failure measure, rather than a specific SIL. For example, when a target failure measure of $1,5 \times 10^{-6}$ (probability of failure of dangerous failure per hour) is specified in order to meet the required risk reduction, then the probability of failure of the safety function due to random hardware failures will need to be equal to or less than $1,5 \times 10^{-6}$ dangerous failures per hour.

NOTE 3 In order to demonstrate that this has been achieved it is necessary to carry out a reliability prediction for the relevant safety function using an appropriate technique (see 7.4.3.2.2) and compare the result to the target failure measure of the safety integrity requirement for the relevant safety function (see IEC 61508-1, tables 2 and 3).

7.4.3.2.2 The probability of failure of each safety function, due to random hardware failures shall be estimated taking into account

- a) the architecture of the E/E/PE safety-related system as it relates to each safety function under consideration;

NOTE 1 This involves deciding which failure modes of the subsystems are in a series configuration (i.e. any failure causes failure of the relevant safety function to be carried out) and which are in a parallel configuration (i.e. co-incident failures are necessary for the relevant safety function to fail).

- b) the estimated rate of failure of each subsystem in any modes which would cause a dangerous failure of the E/E/PE safety-related system but which are detected by diagnostic tests (see 7.4.7.3 and 7.4.7.4);
- c) the estimated rate of failure of each subsystem in any modes which would cause a dangerous failure of the E/E/PE safety-related system which are undetected by the diagnostic tests (see 7.4.7.3 and 7.4.7.4);
- d) the susceptibility of the E/E/PE safety-related system to common cause failures (see notes 2 and 11);

NOTE 2 For example, see IEC 61508-6, annex D.

- e) the diagnostic coverage of the diagnostic tests (determined according to annex C) and the associated diagnostic test interval;

NOTE 3 The diagnostic test interval and the subsequent time for repair together constitute the mean time for restoration which will be considered in the reliability model. Also, for E/E/PE safety-related systems operating in high demand or continuous mode of operation where any dangerous failure of a channel results in a dangerous failure of the E/E/PE safety-related system, the diagnostic test interval will need to be considered directly (i.e. in addition to the mean time to restoration) in the reliability model if it is not at least a magnitude less than the expected demand rate (see 7.4.3.2.5).

NOTE 4 When establishing the diagnostic test interval, the intervals between all of the tests which contribute to the diagnostic coverage will need to be considered.

- f) the intervals at which proof tests are undertaken to reveal dangerous faults which are undetected by diagnostic tests;

g) the repair times for detected failures;

NOTE 5 The repair time will constitute one part of the mean time to restoration (see IEC 61508-1, 7.4.3.2.1), which will also include the time taken to detect a failure and any time period during which repair is not possible (see IEC 61508-1, annex B for an example of how the mean time to restoration can be used to calculate the probability of failure). For situations where the repair can only be carried out during a specific period of time, for example while the EUC is shut down and in a safe state, it is particularly important that full account is taken of the time period when no repair can be carried out, especially when this is relatively large.

h) the probability of undetected failure of any data communication process (see note 11 and 7.4.3.2.1).

NOTE 6 IEC 61508-1, annex B describes a simplified approach which may be used to estimate the probability of dangerous failure of a safety function due to random hardware failures in order to determine that an architecture meets the required target failure measure.

NOTE 7 IEC 61508-1, annex A, A.2 gives an overview of the necessary steps in achieving required hardware safety integrity, and shows how this subclause relates to other requirements of this standard.

NOTE 8 It is necessary to quantify separately for each safety function the reliability of the E/E/PE safety-related systems because different component failure modes will apply and the architecture of the E/E/PE safety-related systems (in terms of redundancy) may also vary.

NOTE 9 A number of modelling methods are available and the most appropriate method is a matter for the analyst and will depend on the circumstances. Available methods include:

- cause consequence analysis (see B.6.6.2 of IEC 61508-1);
- fault tree analysis (see B.6.6.5 of IEC 61508-1);
- Markov models (see C.6.4 of IEC 61508-1);
- reliability block diagrams (see C.6.5 of IEC 61508-1).

NOTE 10 The mean time to restoration (see IEC 61508-1, 7.4.3.2.1) which is considered in the reliability model will need to take into account the diagnostic test interval, the repair time and any other delays prior to restoration.

NOTE 11 Failures due to common cause effects and data communication processes may result from effects other than actual failures of hardware components (e.g. electromagnetic interference, decoding errors, etc). However, such failures are considered, for the purposes of this standard, as random hardware failures.

7.4.3.2.3 The diagnostic test interval of any subsystem having a hardware fault tolerance of more than zero shall be such as to enable the E/E/PE safety-related system to meet the requirement for the probability of random hardware failure (see 7.4.3.2.1).

7.4.3.2.4 The diagnostic test interval of any subsystem having a hardware fault tolerance of zero, on which a safety function is entirely dependent (see note 1), and which is only implementing safety function(s) operating in the low demand mode, shall be such as to enable the E/E/PE safety-related system to meet the requirement for the probability of random hardware failure (see 7.4.3.2.1).

NOTE 1 A safety function is considered to be entirely dependent on a subsystem if a failure of the subsystem causes a failure of the safety function in the E/E/PE safety-related system under consideration, and the safety function has not also been allocated to another safety-related system (see IEC 61508-1, 7.6).

NOTE 2 When there is a possibility that some combination of output states of a subsystem can directly cause a hazardous event (as determined by the hazard and risk analysis, see IEC 61508-1, 7.4.2.10) and when the combination of output states in the presence of a fault in the subsystem cannot be determined (for example, in the case of Type B subsystems), then it will be necessary to regard the detection of dangerous faults in the subsystem as a safety function operating in the high demand/continuous mode and the requirements of 7.4.6.3 and 7.4.3.2.5 will apply.

7.4.3.2.5 The diagnostic test interval of any subsystem having a hardware fault tolerance of zero, on which a safety function is entirely dependent (see note 1), and which is implementing any safety function operating in the high/continuous mode (see note 2), shall be such that the sum of the diagnostic test interval and the time to perform the specified action (fault reaction) to achieve or maintain a safe state (see 7.2.3.1 g)) is less than the process safety time. The process safety time is defined as the period of time between a failure occurring in the EUC or the EUC control system (with the potential to give rise to a hazardous event) and the occurrence of the hazardous event if the safety function is not performed.

NOTE 1 A safety function is considered to be entirely dependent on a subsystem if a failure of the subsystem causes a failure of the safety function in the E/E/PE safety-related system under consideration, and the safety function has not also been allocated to another safety-related system (see IEC 61508-1, 7.6).

NOTE 2 In the case of a subsystem implementing particular safety function where the ratio of the diagnostic test rate to the demand rate exceeds 100, then the subsystem can be treated as if it is implementing a safety function operating in the low demand mode (see 7.4.3.2.4), provided that the safety function is not preventing a combination of output states which could lead to a hazardous event (see note 3).

NOTE 3 If the safety function is to prevent a particular combination of output states which could directly cause a hazardous event, then it will always be necessary to regard such a safety function as operating in the high/continuous mode (see 7.4.2.12).

7.4.3.2.6 If, for a particular design, the target failure measure of the safety integrity requirement for the relevant safety function is not achieved then

- determine the critical components, subsystems and/or parameters;
- evaluate the effect of possible improvement measures on the critical components, subsystems or parameters (for example, more reliable components, additional defences against common mode failures, increased diagnostic coverage, increased redundancy, reduced proof test interval, etc);
- select and implement the applicable improvements;
- repeat the necessary steps to establish the new probability of a hardware failure.

7.4.4 Requirements for the avoidance of failures

NOTE Clauses 7.4.4.1 to 7.4.4.6 do not apply in the case of a subsystem which meets the requirements to be considered as "proven in use" (see 7.4.7.6 to 7.4.7.12).

7.4.4.1 An appropriate group of techniques and measures shall be used that are designed to prevent the introduction of faults during the design and development of the hardware of the E/E/PE safety-related system (see table B.2).

7.4.4.2 In accordance with the required safety integrity level the design method chosen shall possess features that facilitate

- a) transparency, modularity and other features which control complexity;
- b) clear and precise expression of
 - functionality,
 - subsystem interfaces,
 - sequencing and time-related information,
 - concurrency and synchronisation;
- c) clear and precise documentation and communication of information;
- d) verification and validation.

7.4.4.3 Maintenance requirements, to ensure the safety integrity of the E/E/PE safety-related systems is kept at the required level, shall be formalised at the design stage.

7.4.4.4 Where applicable, automatic testing tools and integrated development tools shall be used.

7.4.4.5 During the design, E/E/PE integration tests shall be planned. Documentation of the test planning shall include

- a) the types of tests to be performed and procedures to be followed;
- b) the test environment, tools, configuration and programs;
- c) the pass/fail criteria.

7.4.4.6 During the design, those activities which can be carried out on the developer's premises shall be distinguished from those that require access to the user's site.

7.4.5 Requirements for the control of systematic faults

NOTE Clauses 7.4.5.1 to 7.4.5.3 do not apply in the case of a subsystem which meets the requirements to be considered as "proven in use" (see 7.4.7.6 to 7.4.7.12).

7.4.5.1 For controlling systematic faults, the E/E/PE design shall possess design features that make the E/E/PE safety-related systems tolerant against

- a) any residual design faults in the hardware, unless the possibility of hardware design faults can be excluded (see table A.16);
- b) environmental stresses, including electromagnetic disturbances (see table A.17);
- c) mistakes made by the operator of the EUC (see table A.18);
- d) any residual design faults in the software (see 7.4.3 of IEC 61508-3 and associated table);
- e) errors and other effects arising from any data communication process (see 7.4.8).

7.4.5.2 Maintainability and testability shall be considered during the design and development activities in order to facilitate implementation of these properties in the final E/E/PE safety-related systems.

7.4.5.3 The design of the E/E/PE safety-related systems shall take into account human capabilities and limitations and be suitable for the actions assigned to operators and maintenance staff. The design of all interfaces shall follow good human-factor practice and shall accommodate the likely level of training or awareness of operators, for example in mass-produced E/E/PE safety-related systems where the operator is a member of the public.

NOTE 1 The design goal should be that foreseeable critical mistakes made by operators or maintenance staff are prevented or eliminated by design wherever possible, or that the action requires secondary confirmation before completion.

NOTE 2 Some mistakes made by operators or maintenance staff may not be recoverable by E/E/PE safety-related systems, for example if they are not detectable or realistically recoverable except by direct inspection, such as some mechanical failures in the EUC.

7.4.6 Requirements for system behaviour on detection of a fault

7.4.6.1 The detection of a dangerous fault (by diagnostic tests, proof tests or by any other means) in any subsystem which has a hardware fault tolerance of more than zero shall result in either

- a) a specified action to achieve or maintain a safe state (see note), or
- b) the isolation of the faulty part of the subsystem to allow continued safe operation of the EUC whilst the faulty part is repaired. If the repair is not completed within the mean time to restoration (MTTR) assumed in the calculation of the probability of random hardware failure (see 7.4.3.2.2), then a specified action shall take place to achieve or maintain a safe state (see note).

NOTE The specified action (fault reaction) required to achieve or maintain a safe state will be specified in the E/E/PES safety requirements (see 7.2.3.1). It may consist, for example, of the safe shut-down of the EUC, or that part of the EUC which relies, for risk reduction, on the faulty subsystem.

7.4.6.2 The detection of a dangerous fault (by diagnostic tests, proof tests or by any other means) in any subsystem having a hardware fault tolerance of zero and on which a safety function is entirely dependent (see note 1) shall, in the case that the subsystem is used only by safety function(s) operating in the low demand mode, result in either

- a) a specified action to achieve or maintain a safe state, or
- b) the repair of the faulty subsystem within the mean time to restoration (MTTR) period assumed in the calculation of the probability of random hardware failure (see 7.4.3.2.2). During this time the continuing safety of the EUC shall be ensured by additional measures and constraints. The risk reduction provided by these measures and constraints shall be at least equal to the risk reduction provided by the E/E/PE safety-related system in the absence of any faults. The additional measures and constraints shall be specified in the E/E/PES operation and maintenance procedures (see 7.6). If the repair is not undertaken within the specified mean time to restoration (MTTR), then a specified action shall be performed to achieve or maintain a safe state (see note 2).

NOTE 1 A safety function is considered to be entirely dependent on a subsystem if a failure of the subsystem causes a failure of the safety function in the E/E/PE safety-related system under consideration, and the safety function has not also been allocated to another safety-related system (see IEC 61508-1, 7.6).

NOTE 2 The specified action (fault reaction) required to achieve or maintain a safe state will be specified in the E/E/PES safety requirements (see 7.2.3.1). It may consist, for example, of the safe shut-down of the EUC, or that part of the EUC which relies, for risk reduction, on the faulty subsystem.

7.4.6.3 The detection of a dangerous fault (by diagnostic tests, proof tests or by any other means) in any subsystem having a hardware fault tolerance of zero, and on which a safety function is entirely dependent (see note 1) shall, in the case of a subsystem which is implementing any safety function(s) operating in the high/continuous demand mode (see notes 2, 3), result in a specified action to achieve or maintain a safe state (see note 3).

NOTE 1 A safety function is considered to be entirely dependent on a subsystem if a failure of the subsystem causes a failure of the safety function in the E/E/PE safety-related system under consideration, and the safety function has not also been allocated to another safety-related system (see IEC 61508-1, 7.6).

NOTE 2 When there is a possibility that some combination of output states of a subsystem can directly cause a hazardous event (as determined by the hazard and risk analysis, (see 7.4.2.12)) and when the combination of output states in the presence of a fault in the subsystem cannot be determined (for example, in the case of Type B subsystems), then it will be necessary to regard the detection of dangerous faults in the subsystem as a safety function operating in the high demand/continuous mode and the requirements of 7.4.6.3 and 7.4.3.2.5 will apply.

NOTE 3 The specified action (fault reaction) required to achieve or maintain a safe state will be specified in the E/E/PES safety requirements (see 7.2.3.1). It may consist, for example, of the safe shut-down of the EUC, or that part of the EUC which relies, for risk reduction, on the faulty subsystem.

7.4.7 Requirements for E/E/PES implementation

7.4.7.1 The E/E/PE safety-related system shall be implemented according to the E/E/PES design.

7.4.7.2 All subsystems which are used by one or more safety functions shall be identified and documented as safety-related subsystems.

7.4.7.3 The following information shall be available for each safety-related subsystem (see also 7.4.7.4):

- a) a functional specification of those functions and interfaces of the subsystem which can be used by safety functions;
- b) the estimated rates of failure (due to random hardware failures) in any modes which would cause a dangerous failure of the E/E/PE safety-related system, which are detected by diagnostic tests (see 7.4.7.4);
- c) the estimated rates of failure (due to random hardware failures) in any modes which would cause a dangerous failure of the E/E/PE safety-related system, which are undetected by diagnostic tests (see 7.4.7.4);
- d) any limits on the environment of the subsystem which should be observed in order to maintain the validity of the estimated rates of failure due to random hardware failures;
- e) any limit on the lifetime of the subsystem which should not be exceeded in order to maintain the validity of the estimated rates of failure due to random hardware failures;
- f) any periodic proof test and/or maintenance requirements;
- g) the diagnostic coverage derived according to annex C (when required, see note 1)
- h) the diagnostic test interval (when required, see note 1);

NOTE 1 Items g) and h) above relate to diagnostic tests which are internal to the subsystem. This information is only required when credit is claimed for the action of the diagnostic tests performed in the subsystem in the reliability model of the E/E/PE safety-related system (see 7.4.3.2.2).

- i) any additional information (for example repair times) which is necessary to allow the derivation of a mean time to restoration (MTTR) following detection of a fault by the diagnostics;

NOTE 2 Items b) to i) are needed to allow the probability of failure on demand, or the probability of failure per hour of the safety function to be estimated (see 7.4.3.2.2).

NOTE 3 Items b), c), g), h) and i) are only required as separate parameters for subsystems such as sensors and actuators which may be combined in redundant architectures to improve hardware safety integrity. For items such as logic solvers which will not themselves be combined in redundant architectures in the E/E/PE safety-related system, it is acceptable to specify performance in terms of probability of failure on demand, or probability of dangerous failure per hour taking into account items b), c), g), h) and i). For such items it will also be necessary to establish the proof test interval for failures which are undetected.

- j) all information which is necessary to enable the derivation of the safe failure fraction (SFF) of the subsystem as applied in the E/E/PE safety-related system, determined according to annex C;
- k) the hardware fault tolerance of the subsystem;

NOTE 4 Items j) and k) are needed to determine the highest safety integrity level that can be claimed for a safety function according to the architectural constraints (see 7.4.3.1).

- l) any limits on the application of the subsystem which should be observed in order to avoid systematic failures;
- m) the highest safety integrity level that can be claimed for a safety function which uses the subsystem on the basis of
 - measures and techniques used to prevent systematic faults being introduced during the design and implementation of the hardware and software of the subsystem (see 7.4.4.1 and 7.4 of IEC 61508-3),
 - the design features which make the subsystem tolerant against systematic faults (see 7.4.5.1);

NOTE 5 This is not required in the case of those subsystems which are considered to have been proven in use (see 7.4.7.5).

- n) any information which is required to identify the hardware and software configuration of the subsystem in order to enable the configuration management of the E/E/PE safety-related system in accordance with IEC 61508-1, 6.2.1.
- o) documentary evidence that the subsystem has been validated.

7.4.7.4 The estimated rates of failure, due to random hardware failures, for subsystems (see 7.4.7.3 b) and c)) can be determined either

- a) by a failure modes and effects analysis of the design using component failure data from a recognised industry source,

NOTE 1 Any failure rate data used should have a confidence level of at least 70 %. The statistical determination of confidence level is defined in IEEE 352. An equivalent term, significance level, is used in IEC 61164.

NOTE 2 If site-specific failure data are available then this is preferred. If this is not the case then generic data may have to be used.

NOTE 3 Although a constant failure rate is assumed by most probabilistic estimation methods this only applies provided that the useful lifetime of components is not exceeded. Beyond their useful lifetime (i.e. as the probability of failure significantly increases with time) the results of most probabilistic calculation methods are therefore meaningless. Thus any probabilistic estimation should include a specification of the components' useful lifetimes. The useful lifetime is highly dependent on the component itself and its operating conditions – temperature in particular (for example, electrolyte capacitors can be very sensitive). Experience has shown that the useful lifetime often lies within a range of 8 to 12 years. It can, however, be significantly less if components are operated near to their specification limits. Components with longer useful lifetimes tend to be considerably more expensive.

or

- b) from experience of the previous use of the subsystem in a similar environment (see 7.4.7.9).

7.4.7.5 In the case of a subsystem which is regarded as proven in use (see 7.4.7.6), then information regarding the measures and techniques for the prevention and control of systematic faults (see 7.4.7.3 m)) is not required.

7.4.7.6 A previously developed subsystem shall only be regarded as proven in use when it has a clearly restricted functionality and when there is adequate documentary evidence which is based on the previous use of a specific configuration of the subsystem (during which time all failures have been formally recorded, see 7.4.7.10), and which takes into account any additional analysis or testing, as required (see 7.4.7.8). The documentary evidence shall demonstrate that the likelihood of any failure of the subsystem (due to random hardware and systematic faults) in the E/E/PE safety-related system is low enough so that the required safety integrity level(s) of the safety function(s) which use the subsystem is achieved.

7.4.7.7 The documentary evidence required by 7.4.7.6 shall demonstrate that the previous conditions of use (see note) of the specific subsystem are the same as, or sufficiently close to, those which will be experienced by the subsystem in the E/E/PE safety-related system, in order to determine that the likelihood of any unrevealed systematic faults is low enough so that the required safety integrity level(s) of the safety function(s) which use the subsystem is achieved.

NOTE The conditions of use (operational profile) include all the factors which may influence the likelihood of systematic faults in the hardware and software of the subsystem. For example, environment, modes of use, functions performed, configuration, interfaces to other systems, operating system, translator, human factors.

7.4.7.8 When there is any difference between the previous conditions of use and those which will be experienced in the E/E/PE safety-related system, then any such difference(s) shall be identified and there shall be an explicit demonstration, using a combination of appropriate analytical methods and testing, in order to determine that the likelihood of any unrevealed systematic faults is low enough so that the required safety integrity level(s) of the safety function(s) which use the subsystem is achieved.

7.4.7.9 The documentary evidence required by 7.4.7.6 shall establish that the extent of previous use of the specific configuration of the subsystem (in terms of operational hours), is sufficient to support the claimed rates of failure on a statistical basis. As a minimum, sufficient operational time is required to establish the claimed failure rate data to a single-sided lower confidence limit of at least 70 % (see IEC 61508-7 annex D and IEEE 352). An operational time of any individual subsystem of less than one year shall not be considered as part of the total operational time in the statistical analysis (see note).

NOTE The necessary time, in terms of operational hours, required to establish the claimed rates of failure may result from the operation of a number of identical subsystems, provided that failures from all the subsystems have been effectively detected and reported (see 7.4.7.10). If, for example, 100 subsystems each work fault-free for 10,000 h, then the total time of fault-free operation may be considered as 1,000,000 h. In this case, each subsystem has been in use for over a year and the operation therefore counts towards the total number of operational hours considered.

7.4.7.10 Only previous operation where all failures of the subsystem have been effectively detected and reported (for example, when failure data has been collected in accordance with the recommendations of IEC 60300-3-2) shall be taken into account when determining whether the above requirements (7.4.7.6 to 7.4.7.9) have been met.

7.4.7.11 The following factors shall be taken into account when determining whether or not the above requirements (7.4.7.6 to 7.4.7.9) have been met, in terms of both the coverage and degree of detail of the available information (see also 4.1 of IEC 61508-1):

- a) the complexity of the subsystem;
- b) the contribution made by the subsystem to the risk reduction;
- c) the consequence associated with a failure of the subsystem;
- d) the novelty of design.

7.4.7.12 The application of a "proven-in-use" safety-related subsystem in the E/E/PE safety-related system should be restricted to those functions and interfaces of the subsystem which meet the relevant requirements (see 7.4.7.6 to 7.4.7.10).

NOTE The measures 7.4.7.4 to 7.4.7.12 are also applicable for subsystems which contain software. In this case it has to be assured that the subsystem performs in its safety related application only that function for which evidence of the required safety integrity is given. See also 7.4.2.11 of IEC 61508-3.

7.4.8 Requirements for data communications

7.4.8.1 When any form of data communication is used in the implementation of a safety function then the probability of undetected failure of the communication process shall be estimated taking into account transmission errors, repetitions, deletion, insertion, re-sequencing, corruption, delay and masquerade (see also 7.4.8.2). This probability shall be taken into account when estimating the probability of dangerous failure of the safety function due to random hardware failures (see 7.4.3.2.2).

NOTE The term masquerade means that the true contents of a message are not correctly identified. For example, a message from a non-safety component is incorrectly identified as a message from a safety component.

7.4.8.2 In particular, the following parameters shall be taken into account when estimating the probability of failure of the safety function due to the communication process:

- a) the residual error rate (see IEC 371-08-05);
- b) the rate of residual information loss (see IEC 371-08-09);
- c) the limits, and variability, of the rate of information transfer (bit rate);
- d) the limits, and variability, of the information propagation delay time.

NOTE 1 It can be shown that the probability of a dangerous failure per hour is equal to the quotient of the residual error probability and the message length (in bits) multiplied by the bus transmission rate for safety-related messages and a factor of 3600.

NOTE 2 Further information can be found in IEC 60870-5-1 and in EN 50159-1 and EN 50159-2.

7.5 E/E/PES integration

NOTE This phase is box 9.4 of figure 2.

7.5.1 Objective

The objective of the requirements of this subclause is to integrate and test the E/E/PE safety-related systems.

7.5.2 Requirements

7.5.2.1 The E/E/PE safety-related systems shall be integrated according to the specified E/E/PES design and shall be tested according to the specified E/E/PES integration tests (see 7.4.2.11).

7.5.2.2 As part of the integration of all modules into the E/E/PE safety-related systems, the E/E/PE safety-related systems shall be tested as specified (see 7.4). These tests shall show that all modules interact correctly to perform their intended function and are designed not to perform unintended functions.

NOTE 1 This does not imply testing of all input combinations. Testing all equivalence classes (see B.5.2 of IEC 61508-7) may suffice. Static analysis (see B.6.4 of IEC 61508-7), dynamic analysis (see B.6.5 of IEC 61508-7) or failure analysis (see B.6.6 of IEC 61508-7) may reduce the number of test cases to an acceptable level. In case of development according to the rules leading to structured design (see B.3.2 of 61508-7), or semi-formal methods (see B.2.3 of 61508-7), the requirements are easier to fulfil than if not.

NOTE 2 Where the development uses formal methods (see B.2.2 of IEC 61508-7) or formal proofs or assertions (see C.5.13 and C.3.3 of 61508-7), such tests may be reduced in scope.

NOTE 3 Statistical evidence may be used as well (see B.5.3 of IEC 61508-7).

7.5.2.3 The integration of safety-related software into the PES shall be carried out according to 7.5 of IEC 61508-3.

7.5.2.4 Appropriate documentation of the integration testing of the E/E/PE safety-related systems shall be produced, stating the test results and whether the objectives and criteria specified during the design and development phase have been met. If there is a failure, the reasons for the failure and its correction shall be documented.

7.5.2.5 During the integration and testing, any modifications or change to the E/E/PE safety-related systems shall be subject to an impact analysis which shall identify all components affected and the necessary re-verification activities.

7.5.2.6 The E/E/PES integration testing shall document the following information:

- a) the version of the test specification used;
- b) the criteria for acceptance of the integration tests;
- c) the version of the E/E/PE safety-related systems being tested;
- d) the tools and equipment used along with calibration data;
- e) the results of each test;
- f) any discrepancy between expected and actual results;
- g) the analysis made and the decisions taken on whether to continue the test or issue a change request, in the case when discrepancies occur.

7.5.2.7 For the avoidance of faults during the E/E/PES integration, an appropriate group of techniques and measures according to table B.3 shall be used.

7.6 E/E/PES operation and maintenance procedures

NOTE This phase is box 9.5 of figure 2.

7.6.1 Objective

The objective of the requirements of this subclause is to develop procedures to ensure that the required functional safety of the E/E/PE safety-related systems is maintained during operation and maintenance.

7.6.2 Requirements

7.6.2.1 E/E/PES operation and maintenance procedures shall be prepared which shall specify the following:

- a) the routine actions which need to be carried out to maintain the "as-designed" functional safety of the E/E/PE safety-related systems, including routine replacement of components with a pre-defined life, for example cooling fans, batteries, etc.;
- b) the actions and constraints that are necessary (for example, during installation, start-up, normal operation, routine testing, foreseeable disturbances, faults or failures, and shut-down) to prevent an unsafe state and/or reduce the consequences of a hazardous event;
- c) the documentation which needs to be maintained on system failure and demand rates on the E/E/PE safety-related systems;
- d) the documentation which needs to be maintained showing results of audits and tests on the E/E/PE safety-related systems;

- e) the maintenance procedures to be followed when faults or failures occur in the E/E/PE safety-related systems, including
 - procedures for fault diagnoses and repair,
 - procedures for revalidation,
 - maintenance reporting requirements;
- f) the procedures for reporting maintenance performance shall be specified. In particular:
 - procedures for reporting failures,
 - procedures for analysing failures;
- g) the tools necessary for maintenance and revalidation and procedures for maintaining the tools and equipment.

NOTE 1 It may be beneficial, for reasons of both safety and economics, to integrate the E/E/PES operation and maintenance procedures with the EUC overall operation and maintenance procedures.

NOTE 2 The E/E/PES operation and maintenance procedures should include the software modification procedures (see IEC 61508-3, 7.8).

7.6.2.2 The E/E/PE safety-related system operation and maintenance procedures shall be continuously upgraded from inputs such as (1) the results of functional safety audits and (2) tests on the E/E/PE safety-related systems.

7.6.2.3 The routine maintenance actions required to maintain the required functional safety (as designed) of the E/E/PE safety-related systems shall be determined by a systematic method. This method shall determine unrevealed failures of all safety-related components (from sensors through to final elements) which would cause a reduction in the safety integrity achieved. Suitable methods include

- examination of fault trees;
- failure mode and effect analysis;
- reliability centred maintenance.

NOTE 1 A consideration of human factors is a key element in determining the actions required and the appropriate interface(s) with the E/E/PE safety-related systems.

NOTE 2 Proof tests will be carried out with a frequency necessary to achieve the target failure measure.

NOTE 3 The frequency of the proof tests, the diagnostic test interval and the time for subsequent repair will be dependent upon several factors (see annex B of IEC 61508-6), including

- the target failure measure associated with the safety integrity level;
- the architecture;
- the diagnostic coverage of the diagnostic tests, and
- the expected demand rate.

NOTE 4 The frequency of the proof tests and the diagnostic test interval are likely to have a crucial bearing on the achievement of hardware safety integrity. One of the principal reasons for carrying out hardware reliability analysis (see 7.4.3.2.2) is to ensure that the frequencies of the two types of tests are appropriate for the target hardware safety integrity.

7.6.2.4 The E/E/PES operation and maintenance procedures shall be assessed for the impact they may have on the EUC.

7.6.2.5 For the avoidance of faults and failures during the E/E/PES operation and maintenance procedures, an appropriate group of techniques and measures according to table B.4 shall be used.

7.7 E/E/PES safety validation

NOTE This phase is box 9.6 of figure 2.

7.7.1 Objective

The objective of the requirements of this subclause is to validate that the E/E/PE safety-related systems meet, in all respects, the requirements for safety in terms of the required safety functions and the safety integrity (see 7.2).

7.7.2 Requirements

7.7.2.1 The validation of the E/E/PES safety shall be carried out in accordance with a prepared plan (see also 7.7 of IEC 61508-3).

NOTE 1 The E/E/PES safety validation is shown on the E/E/PES safety lifecycle as being carried out prior to installation but, in some cases, the E/E/PES safety validation cannot be carried out until after installation (for example, when the application software development is not finalised until after installation).

NOTE 2 Validation of a programmable electronic safety-related system comprises validation of both hardware and software. The requirements for validation of software are contained in IEC 61508-3.

7.7.2.2 All test measurement equipment used for validation shall be calibrated against a standard traceable to a national standard, if available, or to a well-recognised procedure. All test equipment shall be verified for correct operation.

7.7.2.3 Each safety function specified in the requirements for E/E/PES safety (see 7.2), and all the E/E/PES operation and maintenance procedures shall be validated by test and/or analysis.

7.7.2.4 Appropriate documentation of the E/E/PES safety validation testing shall be produced which shall state for each safety function

- a) the version of the E/E/PES safety validation plan being used;
- b) the safety function under test (or analysis), along with the specific reference to the requirement specified during E/E/PES safety validation planning;
- c) tools and equipment used, along with calibration data;
- d) the results of each test;
- e) discrepancies between expected and actual results.

NOTE Separate documentation is not needed for each safety function, but the information in a) to e) must apply to every safety function and where it differs by safety function the relationship must be stated.

7.7.2.5 When discrepancies occur (i.e. the actual results deviate from the expected results by more than the stated tolerances), the results of the E/E/PES safety validation testing shall be documented, including

- a) the analysis made; and
- b) the decision taken on whether to continue the test or issue a change request and return to an earlier part of the validation test.

7.7.2.6 The supplier or developer shall make available results of the E/E/PES safety validation testing to the developer of the EUC and the EUC control system so as to enable them to meet the requirements for overall safety validation in IEC 61508-1.

7.7.2.7 For the avoidance of faults during the E/E/PES safety validation, an appropriate group of techniques and measures according to table B.5 shall be used.

7.8 E/E/PES modification

7.8.1 Objective

The objective of the requirements of this subclause is to ensure that the required safety integrity is maintained after corrections, enhancements or adaptations to the E/E/PE safety-related systems.

7.8.2 Requirements

7.8.2.1 Appropriate documentation shall be established and maintained for each E/E/PES modification activity. The documentation shall include

- a) the detailed specification of the modification or change;
- b) an analysis of the impact of the modification activity on the overall system, including hardware, software (see IEC 61508-3), human interaction and the environment and possible interactions;
- c) all approvals for changes;
- d) progress of changes;
- e) test cases for components including revalidation data;
- f) E/E/PES configuration management history;
- g) deviation from normal operations and conditions;
- h) necessary changes to system procedures;
- i) necessary changes to documentation.

7.8.2.2 Manufacturers or system suppliers which claim compliance with all or part of this standard shall maintain a system to initiate changes as a result of defects being detected in hardware or software and to inform users of the need for modification in the event of the defect affecting safety.

7.8.2.3 Modifications shall be performed with at least the same level of expertise, automated tools (see 7.4.4.2 of IEC 61508-3), and planning and management as the initial development of the E/E/PE safety-related systems.

7.8.2.4 After modification, the E/E/PE safety-related systems shall be reverified and revalidated.

NOTE See also 7.16.2.6 of IEC 61508-1.

7.9 E/E/PES verification

7.9.1 Objective

The objective of the requirements of this subclause is to test and evaluate the outputs of a given phase to ensure correctness and consistency with respect to the products and standards provided as input to that phase.

NOTE For convenience all verification activities have been drawn together under 7.9, but they are actually performed across several phases.

7.9.2 Requirements

7.9.2.1 The verification of the E/E/PE safety-related systems shall be planned concurrently with the development (see 7.4), for each phase of the E/E/PES safety lifecycle, and shall be documented.

7.9.2.2 The E/E/PES verification planning shall refer to all the criteria, techniques and tools to be utilised in the verification for that phase.

7.9.2.3 The E/E/PES verification planning shall specify the activities to be performed to ensure correctness and consistency with respect to the products and standards provided as input to that phase.

7.9.2.4 The E/E/PES verification planning shall consider the following:

- a) the selection of verification strategies and techniques;
- b) the selection and utilisation of the test equipment;
- c) the selection and documentation of verification activities;
- d) the evaluation of verification results gained from verification equipment direct and from tests.

7.9.2.5 In each design and development phase it shall be shown that the functional and safety integrity requirements are met.

7.9.2.6 The result of each verification activity shall be documented, stating either that the E/E/PE safety-related systems have passed the verification, or the reasons for the failures. The following shall be considered:

- a) items which do not conform to one or more relevant requirements of the E/E/PES safety lifecycle (see 7.2);
- b) items which do not conform to one or more relevant design standards (see 7.4);
- c) items which do not conform to one or more relevant safety management requirements (see clause 6).

7.9.2.7 For E/E/PES safety requirements verification, after E/E/PES safety requirements have been established (see 7.2), and before the next phase (design and development) begins, verification shall

- a) determine whether the E/E/PES safety requirements are adequate to satisfy the requirements set out in the E/E/PES safety requirements allocation (see IEC 61508-1) for safety, functionality, and other requirements specified during safety planning, and
- b) check for incompatibilities between
 - the E/E/PES safety requirements (7.2),
 - the safety requirements allocation (IEC 61508-1),
 - the E/E/PES tests (see 7.4), and
 - the user documentation and all other system documentation.

7.9.2.8 For E/E/PES design and development verification, after E/E/PES design and development (see 7.4) has been completed and before the next phase (integration) begins, verification shall

- a) determine whether the E/E/PES tests (see 7.4) are adequate for the E/E/PES design and development (see 7.4);
- b) determine the consistency and completeness (down to and including module level) of the E/E/PES design and development (see 7.4) with respect to the E/E/PES safety requirements (see 7.2); and
- c) check for incompatibilities between
 - the E/E/PES safety requirements (7.2),
 - the E/E/PES design and development (7.4), and
 - the E/E/PES tests (see 7.4).

NOTE 1 Table B.5 recommends safety validation, failure analysis and testing techniques that are also applicable to verification.

NOTE 2 Verification that the diagnostic coverage has been achieved will take into account table A.1, which gives the faults and failures that must be detected.

7.9.2.9 For E/E/PES integration verification, the integration of the E/E/PE safety-related systems shall be verified to establish that the requirements of 7.5 have been achieved.

7.9.2.10 Test cases and their results shall be documented.

8 Functional safety assessment

The requirements for functional safety assessment are as detailed in clause 8 of IEC 61508-1.

Withdrawn

Annex A (normative)

Techniques and measures for E/E/PE safety-related systems: control of failures during operation

A.1 General

This annex shall be used in conjunction with 7.4. It limits the maximum diagnostic coverage that may be claimed for relevant techniques and measures. For each safety integrity level, the annex recommends techniques and measures for controlling random hardware, systematic, environmental and operational failures. More information about architectures and measures can be found in annex B of IEC 61508-6 and annex A of IEC 61508-7.

It is not possible to list every individual physical cause of a failure in complex hardware for two main reasons:

- the cause/effect relationship between faults and failures is often difficult to determine;
- the emphasis on failures changes from random to systematic when complex hardware and software is used.

Failures in E/E/PE safety-related systems may be categorised, according to the time of their origin, into

- failures caused by faults originating **before or during system installation** (for example, software faults include specification and program faults, hardware faults include manufacturing faults and incorrect selection of components); and
- failures caused by faults or human errors originating **after system installation** (for example random hardware failures, or failures caused by incorrect use).

In order to avoid or control such failures when they occur, a large number of measures are normally necessary. The structure of the requirements in annexes A and B results from dividing the measures into those used to **avoid failures** during the different phases of the E/E/PE safety lifecycle (annex B), and those used to **control failures** during operation (this annex). The measures to control failures are built-in features of the E/E/PE safety-related systems.

Diagnostic coverage and safe failure fraction is determined on the basis of table A.1 and according to procedures detailed in annex C. Tables A.2 to A.15 support the requirements of table A.1 by recommending techniques and measures for diagnostic tests and recommending maximum levels of diagnostic coverage that can be achieved using them. The tables do not replace any of the requirements of annex C. Tables A.2 to A.15 are not exhaustive. Other measures and techniques may be used, provided evidence is produced to support the claimed diagnostic coverage. If high diagnostic coverage is being claimed then, as a minimum, at least one technique of high diagnostic coverage should be applied from each of these tables.