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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Sécurité fonctionnelle des systèmes électriques/électroniques/électroniques programmables relatifs à la sécurité –
Partie 5: Exemples de méthodes pour la détermination des niveaux d'intégrité de sécurité

IEC 61508-5:2010

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CONTENTS

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

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

FOREWORD

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International Standard IEC 61508-5 has been prepared by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement, control and automation.

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

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

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

FDIS	Report on voting
65A/552/FDIS	65A/576/RVD

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

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

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

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

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- withdrawn,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

INTRODUCTION

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

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

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

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

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

This International Standard

– considers all relevant overall, E/E/PE system and software safety lifecycle phases (for example, from initial concept, though design, implementation, operation and maintenance to decommissioning) when E/E/PE systems are used to perform safety functions;
– has been conceived with a rapidly developing technology in mind; the framework is sufficiently robust and comprehensive to cater for future developments;
– enables product and application sector international standards, dealing with E/E/PE safety-related systems, to be developed; the development of product and application sector international standards, within the framework of this standard, should lead to a high level of consistency (for example, of underlying principles, terminology etc.) both within application sectors and across application sectors; this will have both safety and economic benefits;
– provides a method for the development of the safety requirements specification necessary to achieve the required functional safety for E/E/PE safety-related systems;
– adopts a risk-based approach by which the safety integrity requirements can be determined;
– introduces safety integrity levels for specifying the target level of safety integrity for the safety functions to be implemented by the E/E/PE safety-related systems;

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

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

– sets a lower limit on the target failure measures for a safety function carried out by a single E/E/PE safety-related system. For E/E/PE safety-related systems operating in

  – a low demand mode of operation, the lower limit is set at an average probability of a dangerous failure on demand of 10^{-5};

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

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

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

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

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

– adopts a broad range of principles, techniques and measures to achieve functional safety for E/E/PE safety-related systems, but does not explicitly use the concept of fail safe However, the concepts of "fail safe" and "inherently safe" principles may be applicable and adoption of such concepts is acceptable providing the requirements of the relevant clauses in the standard are met.

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

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

1 Scope

1.1 This part of IEC 61508 provides information on

– the underlying concepts of risk and the relationship of risk to safety integrity (see Annex A);

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

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

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

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

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

1.4 Figure 1 shows the overall framework of the IEC 61508 series and indicates the role that IEC 61508-5 plays in the achievement of functional safety for E/E/PE safety-related systems.

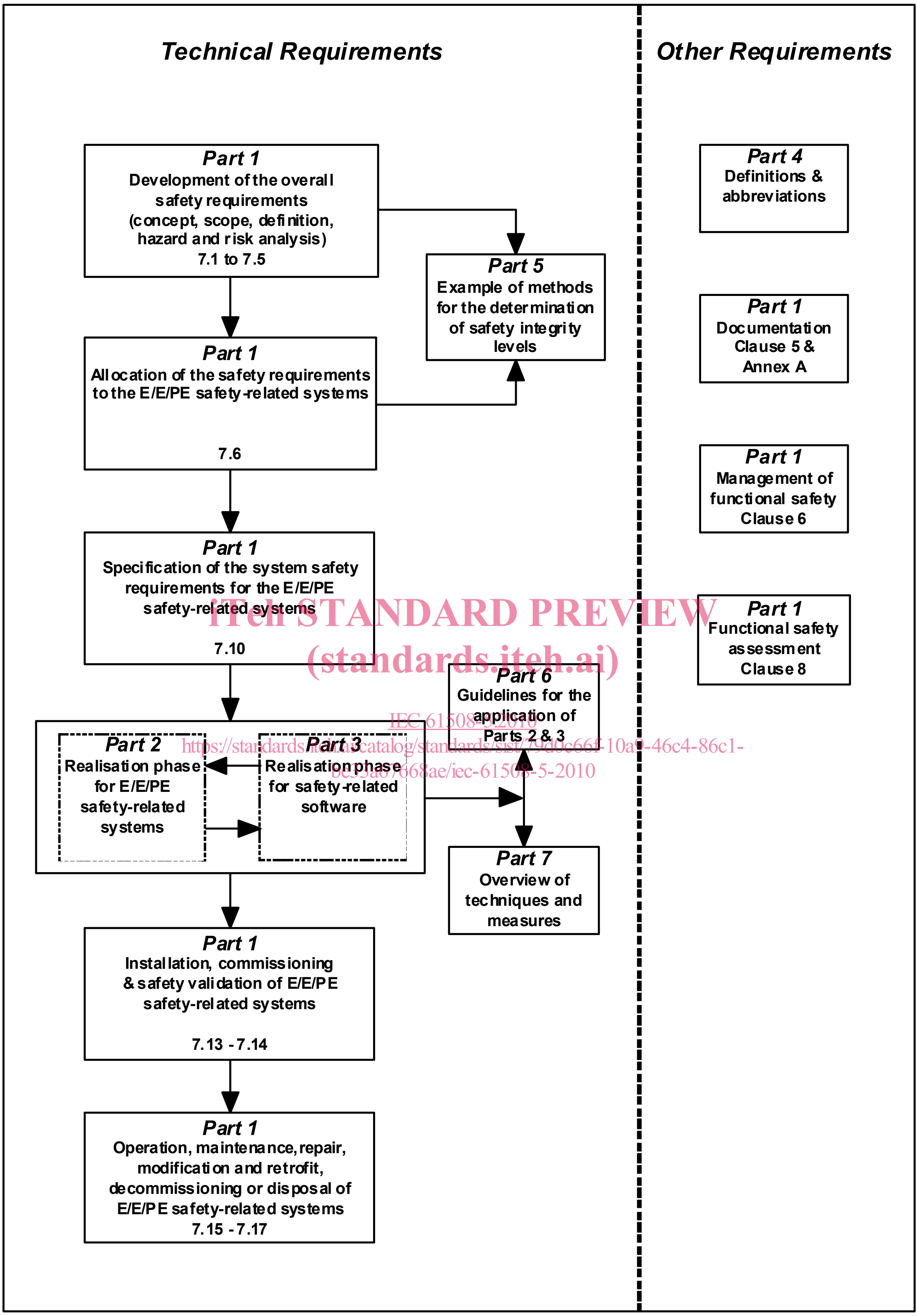

Figure 1 – Overall framework of the IEC 61508 series

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

3 Definitions and abbreviations

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

Annex A
(informative)

Risk and safety integrity – General concepts

A.1 General

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

A.2 Necessary risk reduction

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

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

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

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

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

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

A.2.1 Individual risk

Different targets are usually defined for employees and members of the public. The target for individual risk for employees is applied to the most exposed individual and may be expressed as the total risk per year arising from all work activities. The target is applied to a hypothetical person and therefore needs to take into account the percentage of time that the individual spends at work. The target applies to all risks to the exposed person and the tolerable risk for an individual safety function will need to take account of other risks.

Assurance that the total risk is reduced below a specified target can be done in a number of ways. One method is to consider and sum all risks to the most exposed individual. This may be difficult in cases where a person is exposed to many risks and early decisions are needed for system development. An alternative approach is to allocate a percentage of the overall individual risk target to each safety function under consideration. The percentage allocated can usually be decided from previous experience of the type of facility under consideration.

The target applied to an individual safety function should also take into account the conservatism of the method of risk analysis used. All qualitative methods such as risk graphs involve some evaluation of the critical parameters that contribute to risk. The factors that give rise to risk are the consequence of the hazardous event and its frequency. In determining these factors a number of risk parameters may need to be taken into account such as a vulnerability to the hazardous event, number of people who may be affected by the hazardous event, the probability that a person is present when the hazardous event occurs (i.e. occupancy) and probability of avoiding the hazardous event.

Qualitative methods generally involve deciding if a parameter lies within a certain range. The descriptions of the criteria when using such methods will need to be such that there can be a high level of confidence that the target for risks is not exceeded. This can involve setting range boundaries for all parameters so applications with all parameters at the boundary condition will meet the specified risk criteria for safety. This approach to setting the range boundaries is very conservative because there will be very few applications where all parameters will be at the worst case of the range. If members of the public are to be exposed to risk from failure of a E/E/PE safety-related system then a lower target will normally apply.

A.2.2 Societal risk

This arises where multiple fatalities are likely to arise from single events. Such events are called societal because they are likely to provoke a socio-political response. There can be significant public and organisational aversion to high consequence events and this will need to be taken into consideration in some cases. The criterion for societal risk is often expressed as a maximum accumulated frequency for fatal injuries to a specified number of persons. The criterion is normally specified in the form of one or more lines on an F/N plot where F is the cumulative frequency of hazards and N the number of fatalities arising from the hazards. The relationship is normally a straight line when plotted on logarithmic scales. The slope of the line will depend on the extent to which the organisation is risk averse to higher levels of consequence. The requirement will be to ensure the accumulated frequency for a specified number of fatalities is lower than the accumulated frequency expressed in the F/N plot. (see reference [7] in the Bibliography)

A.2.3 Continuous improvement

The principles of reducing risk to as low as reasonably practicable are discussed in Annex C.

A.2.4 Risk profile

In deciding risk criteria to be applied for a specific hazard, the risk profile over the life of the asset may need to be considered. Residual risk will vary from low just after a proof test or a repair has been performed to a maximum just prior to proof testing. This may need to be taken into consideration by organisations that specify the risk criteria to be applied. If proof test intervals are significant, then it may be appropriate to specify the maximum hazard probability that can be accepted just prior to proof testing or that the PFD(t) or PFH(t) is lower than the upper SIL boundary more than a specified percentage of the time (e.g. 90 %).

A.3 Role of E/E/PE safety-related systems

E/E/PE safety-related systems contribute towards providing the necessary risk reduction in order to meet the tolerable risk.

A safety-related system both

– implements the required safety functions necessary to achieve a safe state for the equipment under control or to maintain a safe state for the equipment under control; and
– is intended to achieve, on its own or with other E/E/PE safety-related systems or other risk reduction measures, the necessary safety integrity for the required safety functions (3.5.1 of IEC 61508-4).

NOTE 1 The first part of the definition specifies that the safety-related system must perform the safety functions which would be specified in the safety functions requirements specification. For example, the safety functions requirements specification may state that when the temperature reaches x, valve y shall open to allow water to enter the vessel.

NOTE 2 The second part of the definition specifies that the safety functions must be performed by the safety-related systems with the degree of confidence appropriate to the application, in order that the tolerable risk will be achieved.

A person could be an integral part of an E/E/PE safety-related system. For example, a person could receive information, on the state of the EUC, from a display screen and perform a safety action based on this information.

E/E/PE safety-related systems can operate in a low demand mode of operation or high demand or continuous mode of operation (see 3.5.16 of IEC 61508-4).

A.4 Safety integrity

Safety integrity is defined as the probability of a safety-related system satisfactorily performing the required safety functions under all the stated conditions within a stated period of time (3.5.4 of IEC 61508-4). Safety integrity relates to the performance of the safety-related systems in carrying out the safety functions (the safety functions to be performed will be specified in the safety functions requirements specification).

Safety integrity is considered to be composed of the following two elements.

– Hardware safety integrity; that part of safety integrity relating to random hardware failures in a dangerous mode of failure (see 3.5.7 of IEC 61508-4). The achievement of the specified level of safety-related hardware safety integrity can be estimated to a reasonable level of accuracy, and the requirements can therefore be apportioned between subsystems using the normal rules for the combination of probabilities. It may be necessary to use redundant architectures to achieve adequate hardware safety integrity.
– Systematic safety integrity; that part of safety integrity relating to systematic failures in a dangerous mode of failure (see 3.5.6 of IEC 61508-4). Although the mean failure rate due to systematic failures may be capable of estimation, the failure data obtained from design faults and common cause failures means that the distribution of failures can be hard to predict. This has the effect of increasing the uncertainty in the failure probability calculations for a specific situation (for example the probability of failure of a safety-related protection system). Therefore a judgement has to be made on the selection of the best techniques to minimise this uncertainty. Note that it is not the case that measures to reduce the probability of random hardware failure will have a corresponding effect on the probability of systematic failure. Techniques such as redundant channels of identical hardware, which are very effective at controlling random hardware failures, are of little use in reducing systematic failures such as software errors.

A.5 Modes of operation and SIL determination

The mode of operation relates to the way in which a safety function is intended to be used with respect to the frequency of demands made upon it which may be either:

– **low demand mode:** where frequency of demands for operation made on the safety function is no greater than one per year; or
– **high demand mode:** where frequency of demands for operation made on the safety function is greater than one per year; or
– **continuous mode:** where demand for operation of the safety function is continuous.

Tables 2 and 3 of IEC 61508-1 detail the target failure measures associated with the four safety integrity levels for each of the modes of operation. The modes of operation are explained further in the following paragraphs.

A.5.1 Safety integrity and risk reduction for low demand mode applications

The required safety integrity of the E/E/PE safety-related systems and other risk reduction measures shall be of such a level so as to ensure that:

– the average probability of failure on demand of the safety-related systems is sufficiently low to prevent the hazardous event frequency exceeding that required to meet the tolerable risk; and/or
– the safety-related systems modify the consequences of failure to the extent required to meet the tolerable risk.

Figure A.1 illustrates the general concepts of risk reduction. The general model assumes that:

– there is an EUC and a control system;
– there are associated human factor issues;
– the safety protective features comprise:
  – E/E/PE safety-related systems;
  – other risk reduction measures.

NOTE Figure A.1 is a generalised risk model to illustrate the general principles. The risk model for a specific application will need to be developed taking into account the specific manner in which the necessary risk reduction is actually being achieved by the E/E/PE safety-related systems and/or other risk reduction measures. The resulting risk model may therefore differ from that shown in Figure A.1.

The various risks indicated in Figure A.1 and A.2 are as follows:

– EUC risk: the risk existing for the specified hazardous events for the EUC, the EUC control system and associated human factor issues: no designated safety protective features are considered in the determination of this risk (see 3.1.9 of IEC 61508-4);
– tolerable risk; the risk which is accepted in a given context based on the current values of society (see 3.1.7 of IEC 61508-4);
– residual risk: in the context of this standard, the residual risk is that remaining for the specified hazardous events for the EUC, the EUC control system, human factor issues but with the addition of, E/E/PE safety-related systems and other risk reduction measures (see also 3.1.7 of IEC 61508-4).

The EUC risk is a function of the risk associated with the EUC itself but taking into account the risk reduction brought about by the EUC control system. To prevent unreasonable claims for the safety integrity of the EUC control system, this standard places constraints on the claims that can be made (see 7.5.2.5 of IEC 61508-1).

The necessary risk reduction is achieved by a combination of all the safety protective features. The necessary risk reduction to achieve the specified tolerable risk, from a starting