COMMISSION ELECTROTECHNIQUE INTERNATIONALE **CEI IEC 61508-5**

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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

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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

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 cooperation 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, prepared by technical committees on which all the national committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the national committees in that sense.

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5) Attention is drawn to the possibility that some of the elements of IEC 61508 may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

6) The IEC has not laid down any procedure concerning marking as an indication of approval and has no responsibility when an item of equipment is declared to comply with one of its standards.

IEC 61508-5 has been prepared by sub-committee 65A: System aspects, of IEC technical committee FORMTEXT65: Industrial process measurement and controlFORMTEXT.

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

FDIS	Report on voting
65A/xxx	65A/xxx

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

Annexes A, B, C, D and E are for information only.

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.

This part 5 is to be used in conjunction with part 1.

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 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 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 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 exact prescription of safety measures will be dependent on many factors specific to the application. This standard, by being generic, will enable such a prescription to be formulated in future application sector international standards.

This 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 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 use 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.

AUTOTEXTMERGEFORMATFUNCTIONAL SAFETY OF ELECTRICAL/ELECTRONIC/PROGRAMMABLE ELECTRONIC SAFETY-RELATED SYSTEMSAUTOTEXTMERGEFORMAT

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

1 Scope

1.1 This part provides information on:

— the underlying concepts of risk and the relationship of risk to safety integrity (annex A);

— a number of methods that will enable the safety integrity levels for the E/E/PE safety-related systems, other technology safety-related systems and external risk reduction facilities to be determined (annexes B, C, D and E).

1.2 The method selected will depend upon the application sector and the specific circumstances under consideration. Annexes B, C, D and E 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, D and E, see references [51], [47] and [48] respectively in annex C of part 1. See also reference [52] in annex C of part 1 for a description of an additional approach.

1.3 Parts 1, 2, 3 and 4 of this standard 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 part 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 ISO/IEC Guide 104 and ISO/IEC Guide 51. One of the responsibilities of a Technical Committee is, wherever applicable, to make use of basic safety publications in the preparation of its own publications. IEC 61508 is also intended for use as a stand-alone standard.

1.4 Figure 1 shows the overall framework for parts 1 to 7 of this standard and indicates the role that part 5 plays in the achievement of functional safety for E/E/PE safety-related systems.

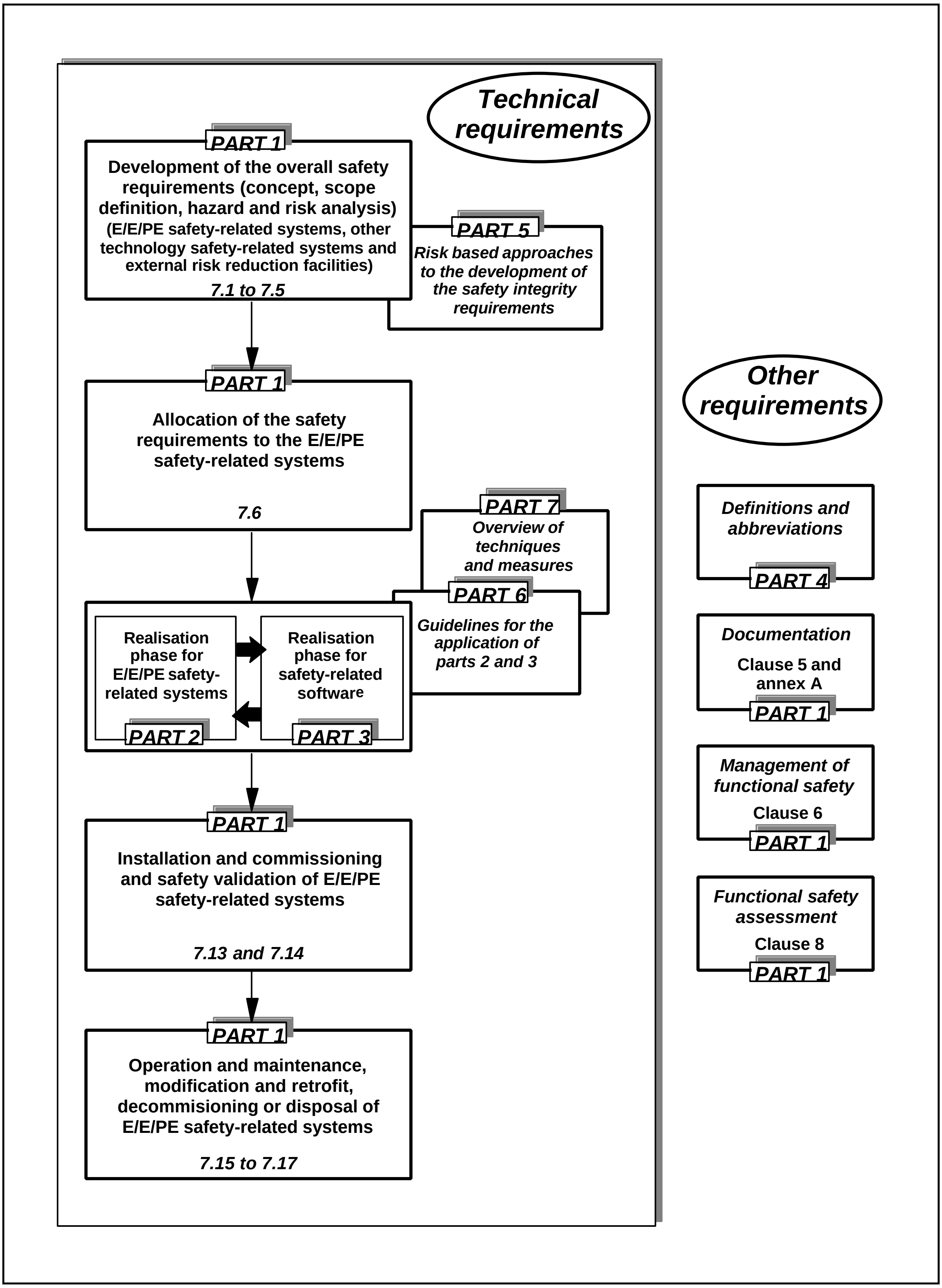

Figure 1 — Overall framework of this standard

2 Definitions and abbreviations

For the purposes of this standard, the definitions and abbreviations given in part 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 3.5.14 of part 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:

— 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 are becoming increasingly important in arriving at tolerable risk criteria for specific applications;

— the best independent industrial, expert and scientific advice from advisory bodies;

— legal requirements – both general and those directly relevant to the specific application.

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1 In determining the tolerable risk, the necessary risk reduction will need to be established. Annexes D and E of part 5 outline qualitative methods, although in the examples quoted the necessary risk reduction is incorporated implicitly rather than stated explicitly.

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

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

E/E/PE safety-related systems contribute towards meeting 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, other technology safety-related systems or external risk reduction facilities, the necessary safety integrity for the required safety functions (3.4.1 of part 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 3.5.12 of part 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 (3.5.2 of part 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 3.5.5 of part 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 3.5.4 of part 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). A judgement therefore has to be made on the selection of the best techniques to minimise this uncertainty. Note that it is not necessarily 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.

The required safety integrity of the E/E/PE safety-related systems, other technology safety-related systems and external risk reduction facilities, must be of such a level so as to ensure that:

— the failure frequency 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 an EUC control system;

— there are associated human factor issues;

— the safety protective features comprise:

  — external risk reduction facilities,

  — E/E/PE safety-related systems,

  — other technology safety-related systems.

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 technology safety-related systems and/or external risk reduction facilities. The resulting risk model may therefore differ from that shown in figure A.1.

The various risks indicated in figure A.1 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 3.2.4 of part 4);

— tolerable risk – the risk which is accepted in a given context based on the current values of society (see 3.1.6 of part 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 external risk reduction facilities, E/E/PE safety-related systems and other technology safety-related systems (see also 3.1.7 of part 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 part 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 point of the EUC risk, is shown in figure A.1.

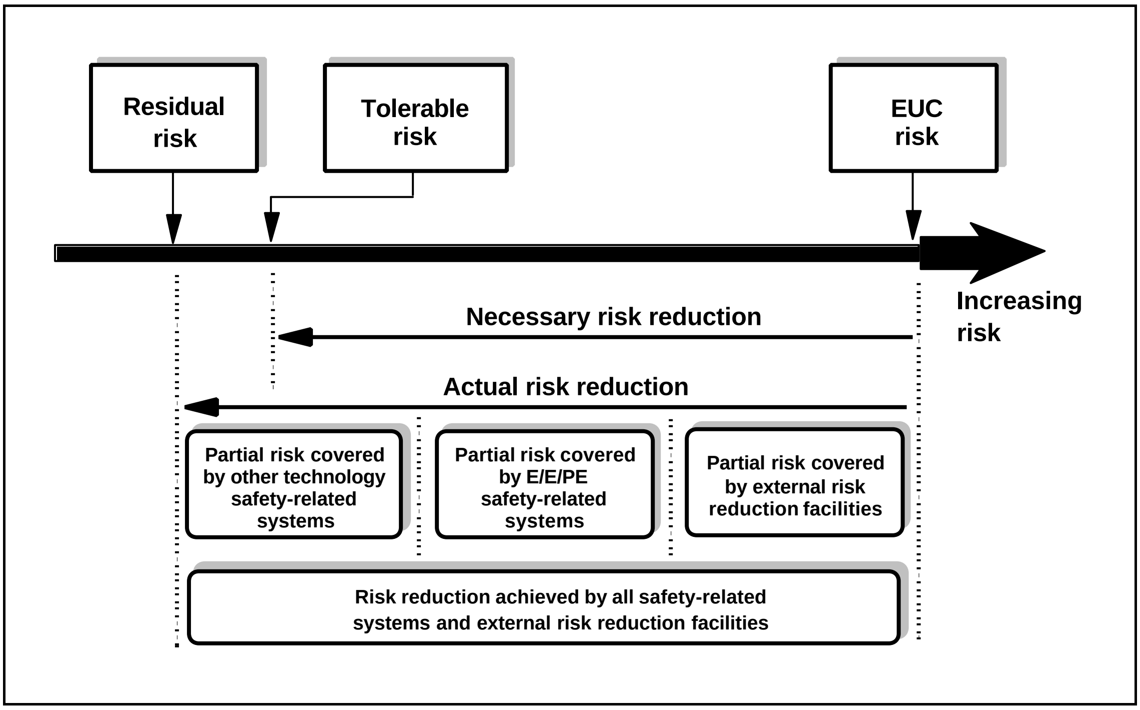


Figure A.1 — Risk reduction: general concepts

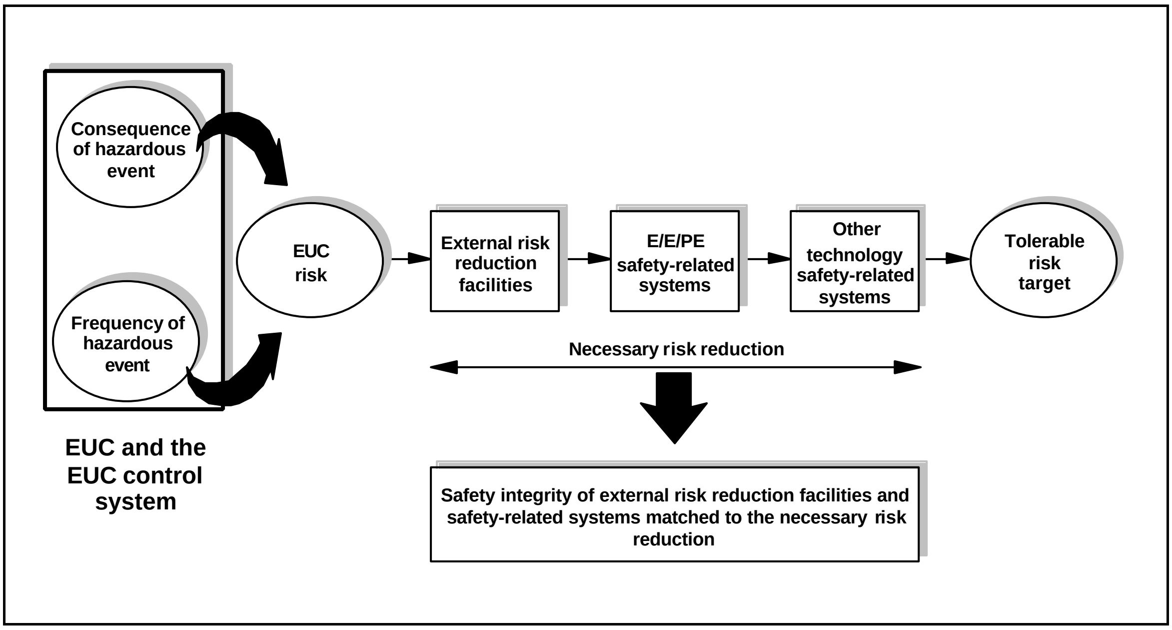


Figure A.2 — Risk and safety integrity concepts

A.5 Risk and safety integrity

It is important that the distinction between risk and safety integrity be fully appreciated. Risk is a measure of the probability and consequence of a specified hazardous event occurring. This can be evaluated for different situations (EUC risk, risk required to meet the tolerable risk, actual risk (see figure A.1)). The tolerable risk is determined on a societal basis and involves consideration of societal and political factors. Safety integrity applies solely to the E/E/PE safety-related systems, other technology safety related-systems and external risk reduction facilities and is a measure of the likelihood of those systems/facilities satisfactorily achieving the necessary risk reduction in respect of the specified safety functions. Once the tolerable risk has been set, and the necessary risk reduction estimated, the safety integrity requirements for the safety-related systems can be allocated (see 7.4, 7.5 and 7.6 of part 1).

NOTE The allocation is necessarily iterative in order to optimize the design to meet the various requirements.

The role that safety-related systems play in achieving the necessary risk reduction is illustrated in figures A.1 and A.2.

A.6 Safety integrity levels and software safety integrity levels

To cater for the wide range of necessary risk reductions that the safety-related systems have to achieve, it is useful to have available a number of safety integrity levels as a means of satisfying the safety integrity requirements of the safety functions allocated to the safety-related systems. Software safety integrity levels are used as the basis of specifying the safety integrity requirements of the safety functions implemented by safety-related software. The safety integrity requirements specification will specify the safety integrity levels for the E/E/PE safety-related systems.

In this standard, four safety integrity levels are specified, with safety integrity level 4 being the highest level and safety integrity level 1 being the lowest.

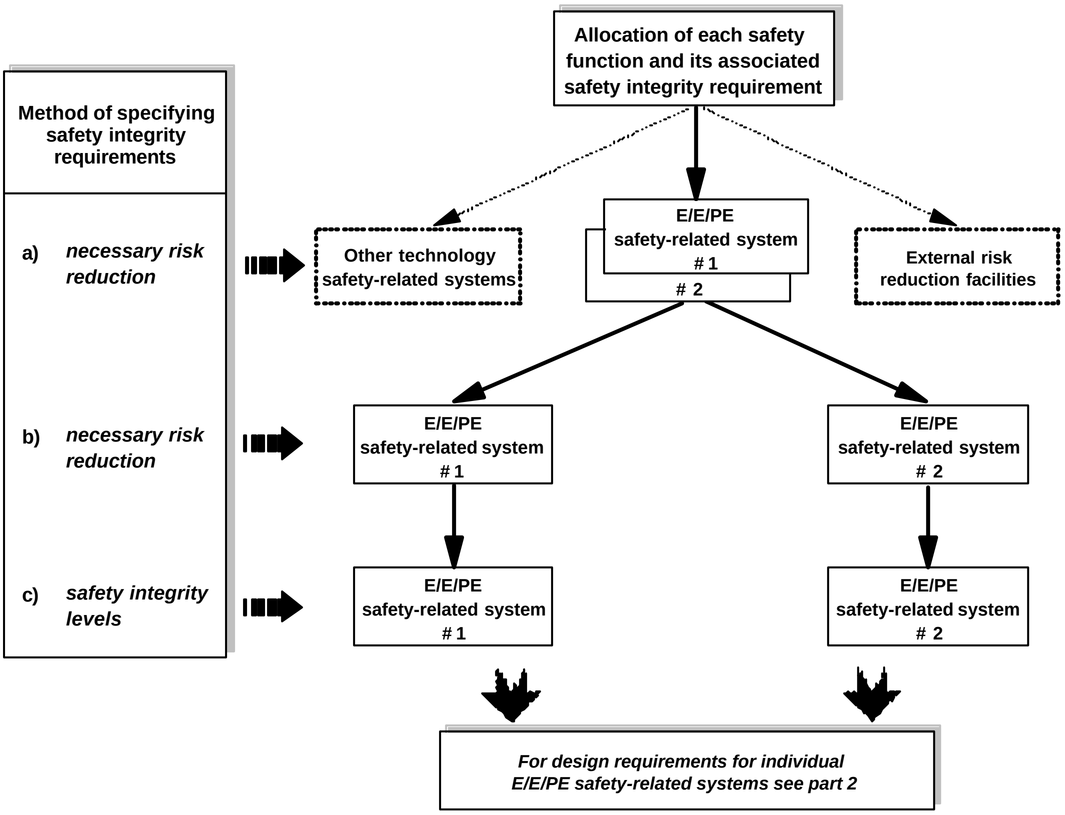
The safety integrity level target failure measures for the four safety integrity levels are specified in tables 2 and 3 of part 1. Two parameters are specified, one for safety-related systems operating in a low demand mode of operation and one for safety-related systems operating in a high demand or continuous mode of operation.

NOTE For safety-related systems operating in a low demand mode of operation, the safety integrity measure of interest is the probability of failure to perform its design function on demand. For safety-related systems operating in a high demand or continuous mode of operation, the safety integrity measure of interest is the average probability of a dangerous failure per hour (see 3.5.12 and 3.5.13 of part 4).

A.7 Allocation of safety requirements

The allocation of safety requirements (both the safety functions and the safety integrity requirements) to the E/E/PE safety-related systems, other technology safety-related systems and external risk reduction facilities is shown in figure A.3 (this is identical to figure 6 of part 1). The requirements for the safety requirements allocation phase are given in 7.6 of part 1.

The methods used to allocate the safety integrity requirements to the E/E/PE safety-related systems, other technology safety-related systems and external risk reduction facilities depend, primarily, upon whether the necessary risk reduction is specified explicitly in a numerical manner or in a qualitative manner. These approaches are termed quantitative and qualitative methods respectively (see annexes B, C, D and E).



NOTE 1 Safety integrity requirements are associated with each safety function before allocation (see 7.5.2.6 of part 1).

NOTE 2 A safety function may be allocated across more than one safety-related system.

Figure A.3 — Allocation of safety requirements to the E/E/PE safety-related systems, other technology safety-related systems and external risk reduction facilities

Annex B
(informative)

ALARP and tolerable risk concepts

B.1 General

This annex considers one particular approach to the achievement of a tolerable risk. The intention is not to provide a definitive account of the method but rather an illustration of the general principles. Those intending to apply the methods indicated in this annex should consult the source material referenced.

B.2 ALARP model

B.2.1 Introduction

Subclause A.2 outlines the main tests that are applied in regulating industrial risks and indicates that the activities involve determining whether:

a) the risk is so great that it must be refused altogether; or

b) the risk is, or has been made, so small as to be insignificant; or

c) the risk falls between the two states specified in a) and b) above **and** has been reduced to the lowest practicable level, bearing in mind the benefits resulting from its acceptance and taking into account the costs of any further reduction.

With respect to c), the ALARP principle requires that any risk must be reduced so far as is reasonably practicable, or to a level which is as low as reasonably practicable (these last 5 words form the abbreviation ALARP). If a risk falls between the two extremes (ie the unacceptable region and broadly acceptable region) and the ALARP principle has been applied, then the resulting risk is the tolerable risk for that specific application. This three zone approach is shown in figure B.1.

Above a certain level, a risk is regarded as intolerable and cannot be justified in any ordinary circumstance.

Below that level, there is the tolerability region where an activity is allowed to take place provided the associated risks have been made as low as reasonably practicable. Tolerable here is different from acceptable - it indicates a willingness to live with a risk so as to secure certain benefits, at the same time expecting it to be kept under review and reduced as and when this can be done. Here a cost benefit assessment is required either explicitly or implicitly to weigh the cost and the need or otherwise for additional safety measures. The higher the risk, the more proportionately would be expected to be spent to reduce it. At the limit of tolerability, expenditure in gross disproportion to the benefit would be justified. Here the risk will by definition be substantial, and equity requires that a considerable effort is justified even to achieve a marginal reduction.

Where the risks are less significant, the less proportionately, need be spent to reduce them and at the lower end of the tolerability region, a balance between costs and benefits will suffice.

Below the tolerability region, the levels of risk are regarded as so insignificant that the regulator need not ask for further improvements. This is the broadly acceptable region where the risks are small in comparison with the every day risks we all experience. While in the broadly acceptable region, there is no need for a detailed working to demonstrate ALARP; however, it is necessary to remain vigilant to ensure that the risk remains at this level.

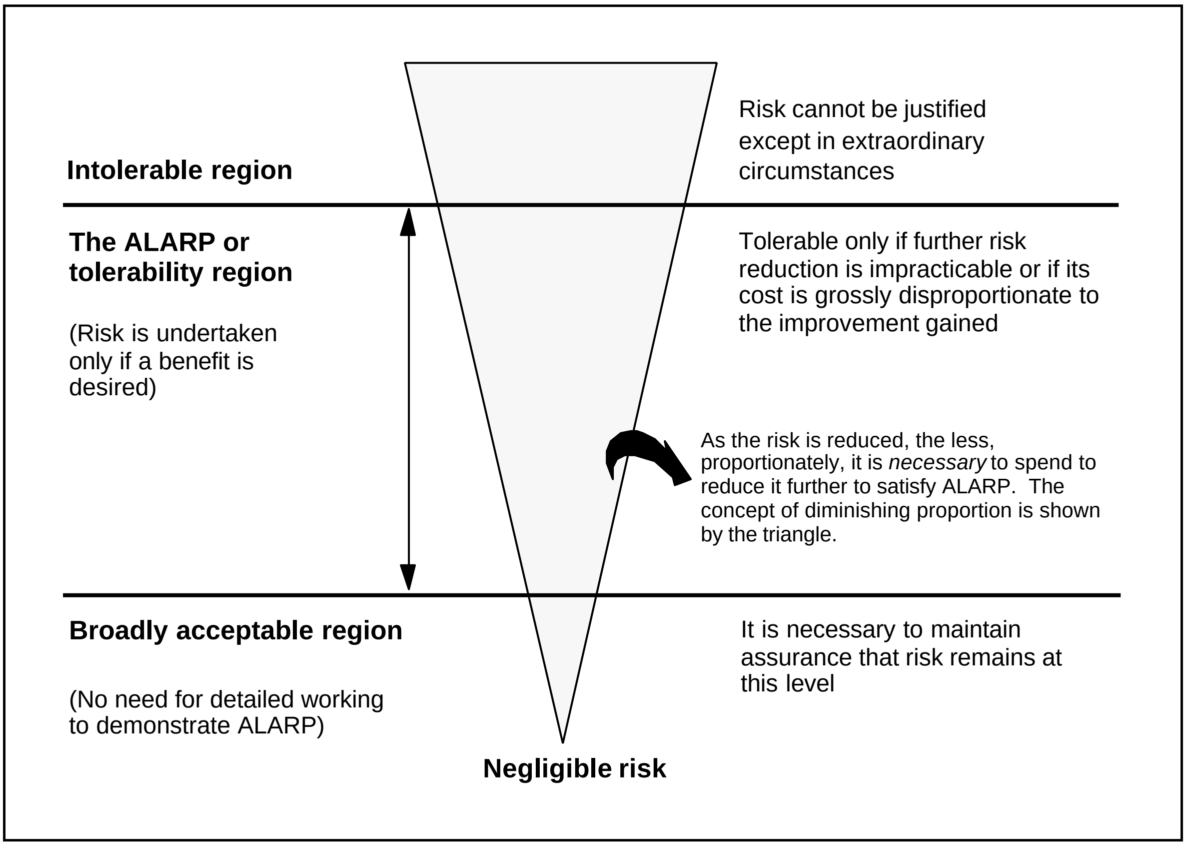


Figure B.1 — Tolerable risk and ALARP

The concept of ALARP can be used when qualitative or quantitative risk targets are adopted. Subclause B.2.2 outlines a method for quantitative risk targets. (Annex C outlines a quantitative method and annexes D and E outline qualitative methods for the determination of the necessary risk reduction for a specific hazard. The methods indicated could incorporate the concept of ALARP in the decision making).

NOTE Further information on ALARP is given in reference [51] in annex C of part 1.

B.2.2 Tolerable risk target

One way in which a tolerable risk target can be obtained is for a number of consequences to be determined and tolerable frequencies allocated to them. This matching of the consequences to the tolerable frequencies would take place by discussion and agreement between the interested parties (for example safety regulatory authorities, those producing the risks and those exposed to the risks).

To take into account ALARP concepts, the matching of a consequence with a tolerable frequency can be done through risk classes. Table B.1 is an example showing four risk classes (I, II, III, IV) for a number of consequences and frequencies. Table B.2 interprets each of the risk classes using the concept of ALARP. That is, the descriptions for each of the four risk classes are based on figure B.1. The risks within these risk class definitions are the risks that are present when risk reduction measures have been put in place. With respect to figure B.1, the risk classes are as follows:

— risk class I is in the unacceptable region;

— risk classes II and III are in the ALARP region, risk class II being just inside the ALARP region;

— risk class IV is in the broadly acceptable region.

For each specific situation, or sector comparable industries, a table similar to table B.1 would be developed taking into account a wide range of social, political and economic factors. Each consequence would be matched against a frequency and the table populated by the risk classes. For example, frequent in table B.1 could denote an event that is likely to be continually experienced, which could be specified as a frequency greater than 10 per year. A critical consequence could be a single death and/or multiple severe injuries or severe occupational illness.

Table B.1 — Risk classification of accidents

Frequency	**Consequence**			
	Catastrophic	Critical	Marginal	Negligible
Frequent	I	I	I	II
Probable	I	I	II	III
Occasional	I	II	III	III
Remote	II	III	III	IV
Improbable	III	III	IV	IV
Incredible	IV	IV	IV	IV

NOTE 1 The actual population with risk classes I, II, III and IV will be sector dependent and will also depend upon what the actual frequencies are for frequent; probable etc. Therefore, this table should be seen as an example of how such a table could be populated, rather than as a specification for future use.

NOTE 2 Determination of the safety integrity level from the frequencies in this table is outlined in annex C.

Table B.2 — Interpretation of risk classes

Risk class	**Interpretation**
Class I	Intolerable risk
Class II	Undesirable risk, and tolerable only if risk reduction is impracticable or if the costs are grossly disproportionate to the improvement gained
Class III	Tolerable risk if the cost of risk reduction would exceed the improvement gained
Class IV	Negligible risk

Annex C
(informative)

Determination of safety integrity levels: a quantitative method

C.1 General

This annex outlines how the safety integrity levels can be determined if a quantitative approach is adopted and illustrates how the information contained in tables such as table B.1 can be used. A quantitative approach is of particular value when:

— the tolerable risk is to be specified in a numerical manner (for example that a specified consequence should not occur with a greater frequency than 1 in 10^4 years); or

— numerical targets have been specified for the safety integrity levels for the safety-related systems. Such targets have been specified in this standard (see tables 2 and 3 of part 1).

This annex is not intended to be a definitive account of the method but is intended to illustrate the general principles. It is particularly applicable when the risk model is as indicated in figures A.1 and A.2.

C.2 General method

The model used to illustrate the general principles is that shown in figure A.1. The key steps in the method are as follows and will need to be done for each safety function to be implemented by the E/E/PE safety-related system:

— determine the tolerable risk from a table such as table B.1;

— determine the EUC risk;

— determine the necessary risk reduction to meet the tolerable risk;

— allocate the necessary risk reduction to the E/E/PE safety-related systems, other technology safety-related systems and external risk reduction facilities (see 7.6 of part 1).

Table B.1 is populated with risk frequencies and allows a numerical tolerable risk target (F_t) to be specified.

The frequency associated with the risk that exists for the EUC, including the EUC control system and human factor issues (the EUC risk), without any protective features, can be estimated using quantitative risk assessment methods. This frequency with which a hazardous event could occur without protective features present (F_{np}) is one of two components of the EUC risk; the other component is the consequence of the hazardous event. F_{np} may be determined by:

— analysis of failure rates from comparable situations;

— data from relevant databases;

— calculation using appropriate predictive methods.

This standard places constraints on the minimum failure rates that can be claimed for the EUC control system (see 7.5.2.5 of part 1). If it is to be claimed that the EUC control system has a failure rate less than these minimum failure rates, then the EUC control system shall be considered a safety-related system and shall be subject to all the requirements for safety-related systems in this standard.

C.3 Example calculation

Figure C.1 provides an example of how to calculate the target safety integrity for a single safety-related protection system. For such a situation:

$PFD_{avg} \le F_t / F_{np}$

where:

— PFD_{avg} is the average probability of failure on demand of the safety-related protection system, which is the safety integrity failure measure for safety-related protection systems operating in a low demand mode of operation (see table 2 of part 1 and 3.5.12 of part 4);

— F_t is the tolerable risk frequency;

— F_{np} is the demand rate on the safety-related protection system.

Also in figure C.1:

— C is the consequence of the hazardous event;

— F_p is the risk frequency with the protective features in place.

It can be seen that determination of F_{np} for the EUC is important because of its relationship to PFD_{avg} and hence to the safety integrity level of the safety-related protection system.

The necessary steps in obtaining the safety integrity level (when the consequence C remains constant) are given below (as in figure C.1), for the situation where the entire necessary risk reduction is achieved by a single safety-related protection system which must reduce the hazard rate, as a minimum, from F_{np} to F_t:

— determine the frequency element of the EUC risk without the addition of any protective features (F_{np});

— determine the consequence (C) without the addition of any protective features;

— determine, by use of table B.1, whether for frequency (F_{np}) and consequence (C) a tolerable risk level is achieved. If, through the use of table B.1, this leads to risk class I, then further risk reduction is required. Risk class IV or III would be tolerable risks. Risk class II would require further investigation;

NOTE Table B.1 is used to check whether or not further risk reduction measures are necessary, since it may be possible to achieve a tolerable risk without the addition of any protective features.

— determine the probability of failure on demand for the safety-related protection system (PFD_{avg}) to meet the necessary risk reduction (ΔR). For a constant consequence in the specific situation described, $PFD_{avg} = (F_t / F_{np}) = \Delta R$;

— for $PFD_{avg} = (F_t / F_{np})$, the safety integrity level can be obtained from table 2 of part 1 (for example, for $PFD_{avg} = 10^{-2} - 10^{-3}$, the safety integrity level = 2).

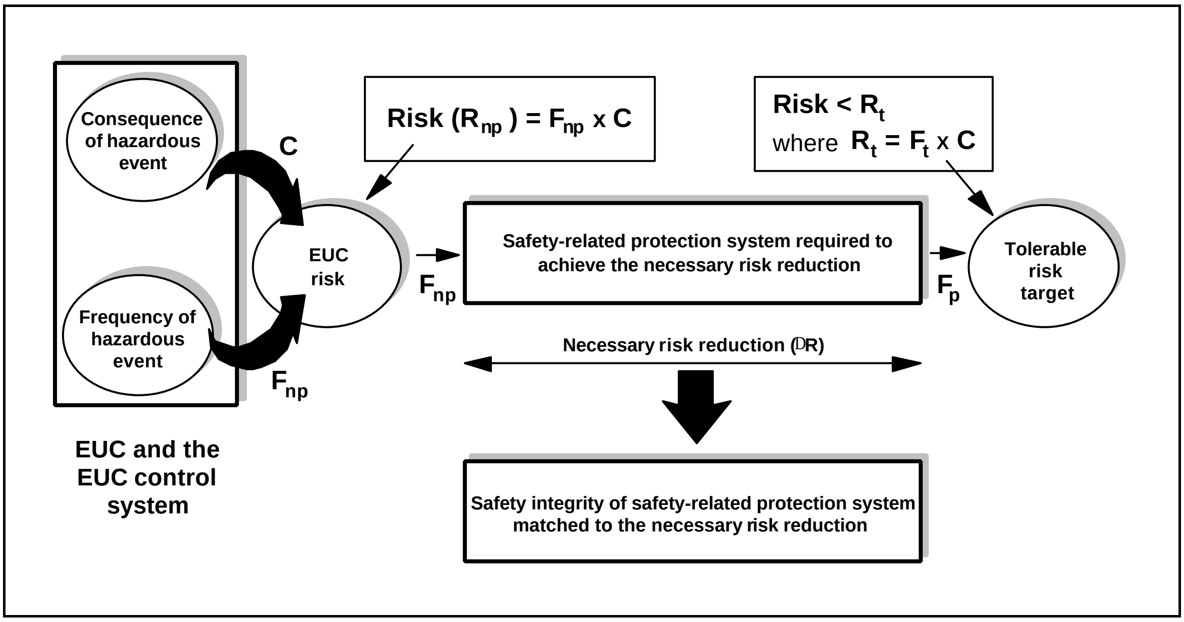


Figure C.1 — Safety integrity allocation: example for safety-related protection system

Annex D
(informative)

Determination of safety integrity levels - a qualitative method: risk graph

D.1 General

This annex describes the risk graph method, which is a qualitative method that enables the safety integrity level of a safety-related system to be determined from a knowledge of the risk factors associated with the EUC and the EUC control system. It is particularly applicable when the risk model is as indicated in figures A.1 and A.2.

Where a qualitative approach is adopted, in order to simplify matters a number of parameters are introduced which together describe the nature of the hazardous situation when safety-related systems fail or are not available. One parameter is chosen from each of four sets, and the selected parameters are then combined to decide the safety integrity level allocated to the safety-related systems. These parameters:

— allow a meaningful graduation of the risks to be made, and

— contain the key risk assessment factors.

This annex is not intended to be a definitive account of the method but is intended to illustrate the general principles. Those intending to apply the methods indicated in this annex should consult the source material referenced.

D.2 Risk graph synthesis

The following simplified procedure is based on the following equation:

$$R = f \times C$$

where:

— R is the risk with no safety-related systems in place;

— f is the frequency of the hazardous event with no safety-related systems in place;

— C is the consequence of the hazardous event (the consequences could be related to harm associated with health and safety or harm from environmental damage).

The frequency of the hazardous event (f) is, in this case, considered to be made up of three influencing factors:

— frequency of, and exposure time in, the hazardous zone;

— the possibility of avoiding the hazardous event; and

— the probability of the hazardous event taking place without the addition of any safety-related systems (but having in place external risk reduction facilities) – this is termed the probability of the unwanted occurrence.

This produces the following four risk parameters:

— consequence of the hazardous event (C);

— frequency of, and exposure time in, the hazardous zone (F);

— possibility of failing to avoid the hazardous event (P);

— probability of the unwanted occurrence (W).

D.3 Other possible risk parameters

The risk parameters specified above are considered to be sufficiently generic to deal with a wide range of applications. There may, however, be applications which have aspects which require the introduction of additional risk parameters. For example, the use of new technologies in the EUC. The purpose of the additional parameters would be to more accurately estimate the necessary risk reduction (see figure A.1).

D.4 Risk graph implementation: general scheme

The combination of the risk parameters described above enables a risk graph such as that shown in figure D.1 to be developed. With respect to figure D.1: $C_A < C_B < C_C < C_D$; $F_A < F_B$; $P_A < P_B$; $W_1 < W_2 < W_3$. An explanation of this risk graph is as follows.

— Use of risk parameters C, F and P leads to a number of outputs X_1, X_2, X_3 … X_n (the exact number being dependent upon the specific application area to be covered by the risk graph). Figure D.1 indicates the situation when no additional weighting is applied for the more serious consequences. Each one of these outputs is mapped onto one of three scales (W_1, W_2 and W_3). Each point on these scales is an indication of the necessary safety integrity that has to be met by the E/E/PE safety-related system under consideration. In practice, there will be situations when for specific consequences a single E/E/PE safety-related system is not sufficient to give the necessary risk reduction.

— The mapping onto W_1, W_2 or W_3 allows the contribution of other risk reduction measures to be made. The offset feature of the scales for W_1, W_2 and W_3 is to allow for three different levels of risk reduction from other measures. That is, scale W_3 provides the minimum risk reduction contributed by other measures (ie the highest probability of the unwanted occurrence taking place), scale W_2 a medium contribution and scale W_1 the maximum contribution. For a specific intermediate output of the risk graph (ie X_1, X_2 ... or X_6) and for a specific W scale (ie W_1, W_2 or W_3) the final output of the risk graph gives the safety integrity level of the E/E/PE safety-related system (ie 1, 2, 3 or 4) and is a measure of the required risk reduction for this system. This risk reduction, together with the risk reductions achieved by other measures (for example by other technology safety-related systems and external risk reduction facilities) which are taken into account by the W scale mechanism, gives the necessary risk reduction for the specific situation.

The parameters indicated in figure D.1 (C_A, C_B, C_C, C_D, F_A, F_B, P_A, P_B, W_1, W_2, W_3), and their weightings, would need to be accurately defined for each specific situation or sector comparable industries, and would also need to be defined in application sector international standards.

D.5 Risk graph example

An example of a risk graph implementation from the machinery sector, based on the example data in table D.1, is shown in figure D.2. Use of the risk parameters C, F, and P lead to one of eight outputs. Each one of these outputs is mapped onto one of three scales (W_1, W_2 and W_3). Each point on these scales (a, b, c, d, e, f, g and h) is an indication of the necessary risk reduction that has to be met by the safety-related system.

NOTE Further information on this risk graph implementation is given in reference [47] in annex C of part 1.

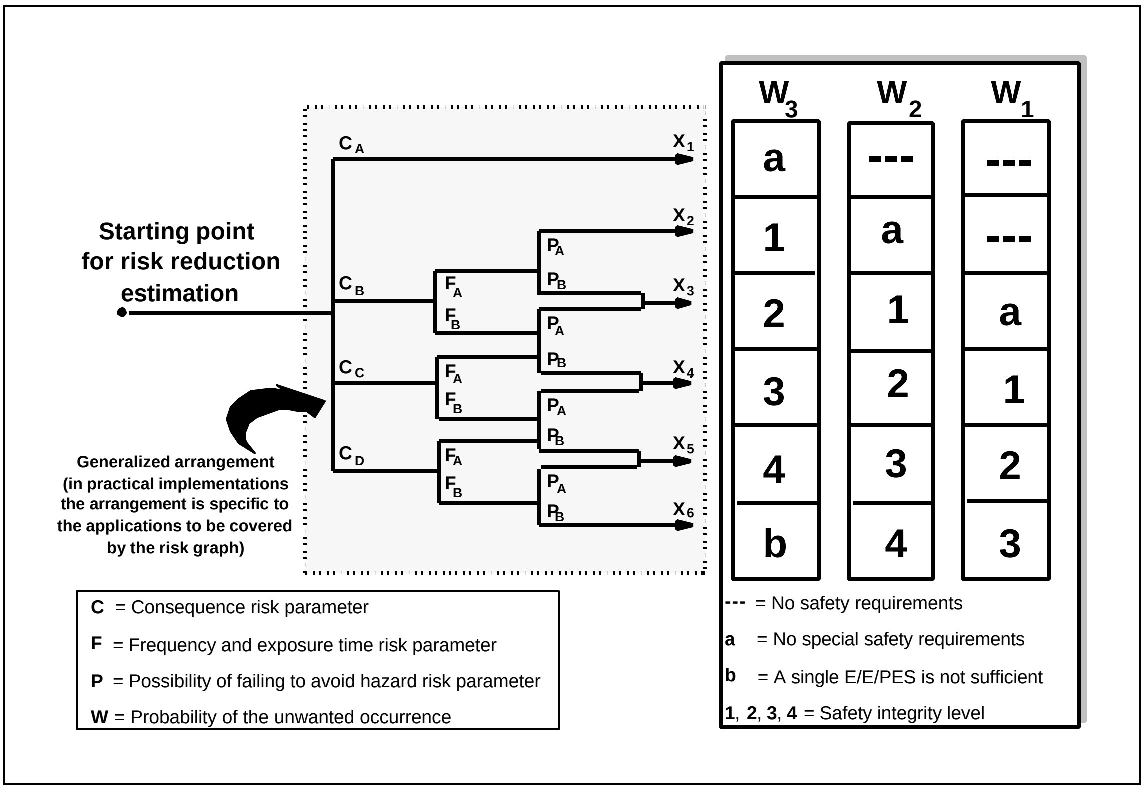


Figure D.1 — Risk graph: general scheme

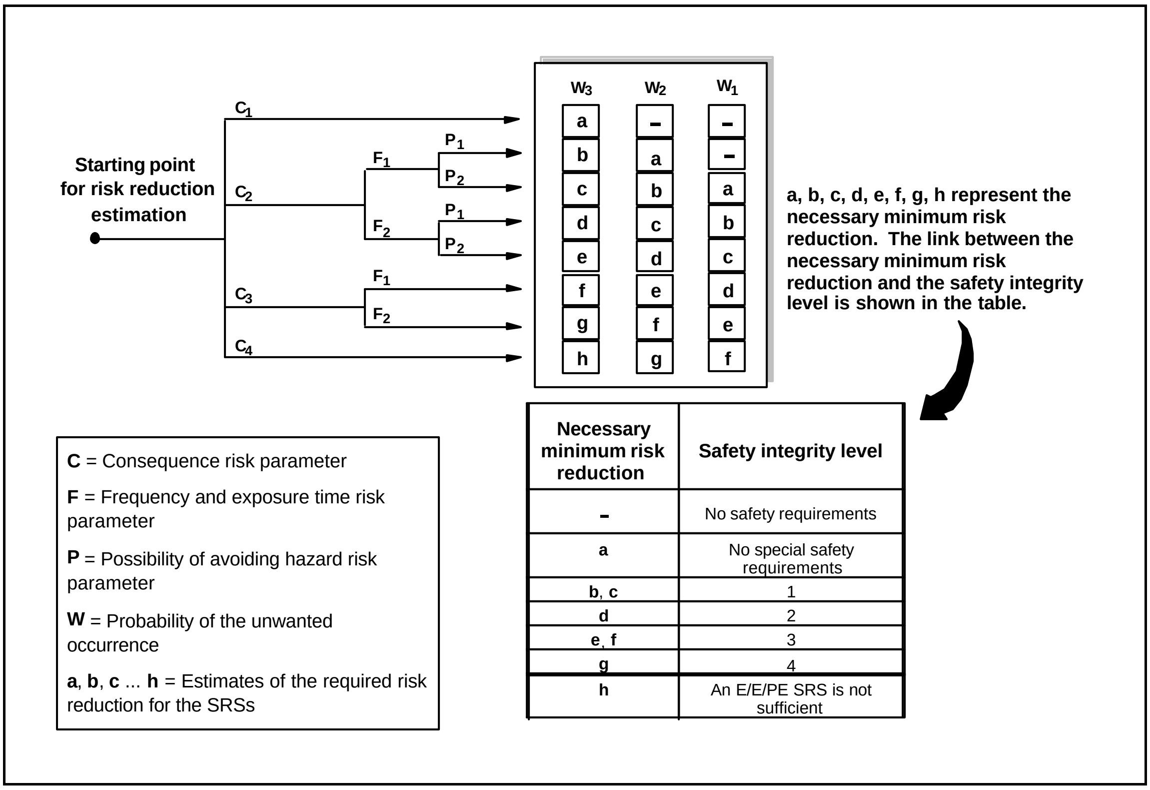


Figure D.2 — Risk graph: example (illustrates general principles only)

Table D.1 — Example data relating to example risk graph (figure D.2)

Risk parameter		Classification	Comments
Consequence (C)	C_1	Minor injury	1 The classification system has been developed to deal with injury and death to people. Other classification schemes would need to be developed for environmental or material damage.
	C_2	Serious permanent injury to one or more persons; death to one person	2 For the interpretation of C_1, C_2, C_3 and C_4, the consequences of the accident and normal healing shall be taken into account.
	C_3	Death to several people	
	C_4	Very many people killed	
Frequency of, and exposure time in, the hazardous zone (F)	F_1	Rare to more often exposure in the hazardous zone	3 See comment 1 above.
	F_2	Frequent to permanent exposure in the hazardous zone	
Possibility of avoiding the hazardous event (P)	P_1	Possible under certain conditions	4 This parameter takes into account: — operation of a process (supervised (ie operated by skilled or unskilled persons) or unsupervised); — rate of development of the hazardous event (for example suddenly, quickly or slowly); — ease of recognition of danger (for example seen immediately, detected by technical measures or detected without technical measures); — avoidance of hazardous event (for example escape routes possible, not possible or possible under certain conditions); — actual safety experience (such experience may exist with an identical EUC or a similar EUC or may not exist).
	P_2	Almost impossible	
Probability of the unwanted occurrence (W)	W_1	A very slight probability that the unwanted occurrences will come to pass and only a few unwanted occurrences are likely	5 The purpose of the W factor is to estimate the frequency of the unwanted occurrence taking place without the addition of any safety-related systems (E/E/PE or other technology) but including any external risk reduction facilities.
	W_2	A slight probability that the unwanted occurrences will come to pass and few unwanted occurrences are likely	6 If little or no experience exists of the EUC, or the EUC control system, or of a similar EUC and EUC control system, the estimation of the W factor may be made by calculation. In such an event a worst case prediction shall be made.
	W_3	A relatively high probability that the unwanted occurrences will come to pass and frequent unwanted occurrences are likely	

Annex E
(informative)

Determination of safety integrity levels - a qualitative method: hazardous event severity matrix

E.1 General

The numeric method described in annex C is not applicable where the risk (or the frequency portion of it) cannot be quantified. This annex describes the hazardous event severity matrix method, which is a qualitative method that enables the safety integrity level of an E/E/PE safety-related system to be determined from a knowledge of the risk factors associated with the EUC and the EUC control system. It is particularly applicable when the risk model is as indicated in figures A.1 and A.2.

The scheme outlined in this annex assumes that each safety-related system and external reduction facility is independent.

This annex is not intended to be a definitive account of the method but is intended to illustrate the general principles of how such a matrix could be developed by those having a detailed knowledge of the specific parameters that are relevant to its construction. Those intending to apply the methods indicated in this annex should consult the source material referenced.

NOTE Further information on the hazardous event matrix is given in reference [48] in annex C of part 1.

E.2 Hazardous event severity matrix

The following requirements underpin the matrix and each one is necessary for the method to be valid:

a) the safety-related systems (E/E/PE and other technology) together with the external risk reduction facilities are independent;

b) each safety-related system (E/E/PE and other technology) and external risk reduction facilities are considered as protection layers which provide, in their own right, partial risk reductions as indicated in figure A.1;

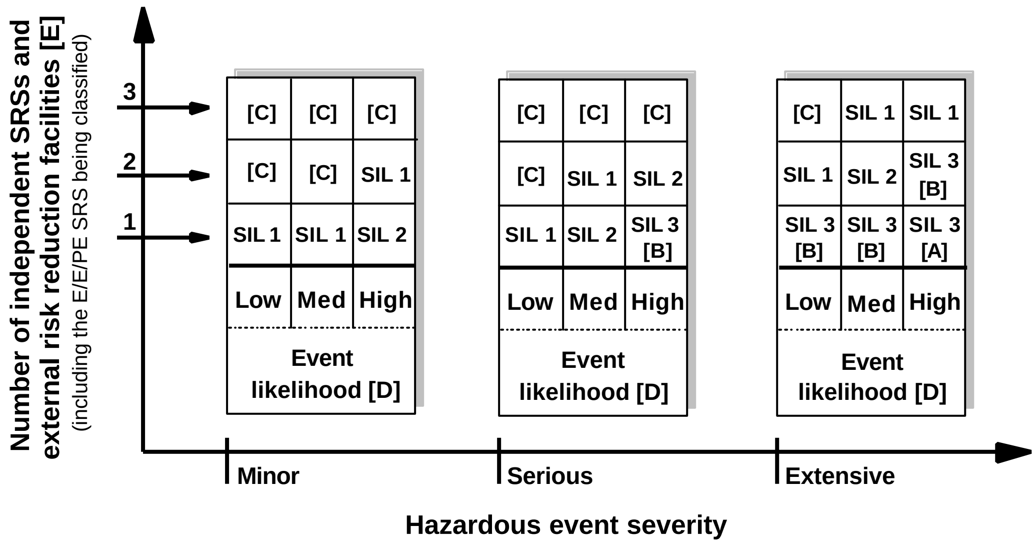
NOTE 1 This assumption is valid only if regular proof tests of the protection layers are carried out.

c) when one protection layer (see b) above) is added to the next one then one order of magnitude improvement in safety integrity is achieved;

NOTE 2 This assumption is valid only if the safety-related systems and external risk reduction facilities achieve an adequate level of independence.

d) only one E/E/PE safety-related system is used (but this may be in combination with an other technology safety-related system and/or external risk reduction facilities), for which this method establishes the necessary safety integrity level.

The above considerations lead to the hazardous event severity matrix shown in figure E.1. It should be noted that the matrix has been populated with example data to illustrate the general principles. For each specific situation, or sector comparable industries, a matrix similar to figure E.1 would be developed.



[A] One SIL 3 E/E/PE safety-related system does not provide sufficient risk reduction at this risk level. Additional risk reduction measures are required.

[B] One SIL 3 E/E/PE safety-related system may not provide sufficient risk reduction at this risk level. Hazard and risk analysis is required to determine whether additional risk reduction measures are necessary.

[C] An independent E/E/PE safety-related system is probably not required.

[D] Event likelihood is the likelihood that the hazardous event occurs without any safety related systems or external risk redution facilities.

[E] SRS = safety-related system. Event likelihood and the total number of independent protection layers are defined in relation to the specific application.

Figure E.1 — Hazardous event severity matrix: example (illustrates general principles only)