



## **IEC 61508 Overview Report**

### **A Summary of the IEC 61508 Standard for Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems**

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## 1 Overall Document Summary

IEC 61508 is an international standard for the “functional safety” of electrical, electronic, and programmable electronic equipment. This standard started in the mid 1980s when the International Electrotechnical Committee Advisory Committee of Safety (IEC ACOS) set up a task force to consider standardization issues raised by the use of programmable electronic systems (PES). At that time, many regulatory bodies forbade the use of any software-based equipment in safety critical applications. Work began within IEC SC65A/Working Group 10 on a standard for PES used in safety-related systems. This group merged with Working Group 9 where a standard on software safety was in progress. The combined group treated safety as a system issue.

The total IEC 61508 standard is divided into seven parts.

Part 1: General requirements (required for compliance);

Part 2: Requirements for electrical/electronic/programmable electronic safety-related systems (required for compliance);

Part 3: Software requirements (required for compliance);

Part 4: Definitions and abbreviations (supporting information)

Part 5: Examples of methods for the determination of safety integrity levels (supporting information)

Part 6: Guidelines on the application of parts 2 and 3 (supporting information)

Part 7: Overview of techniques and measures (supporting information).

Parts 1, 3, 4, and 5 were approved in 1998. Parts 2, 6, and 7 were approved in February 2000.

The relationship between the technical requirements presented in parts 1, 2, and 3 and the supporting information in parts 4 through 7 is shown in Figure 1.

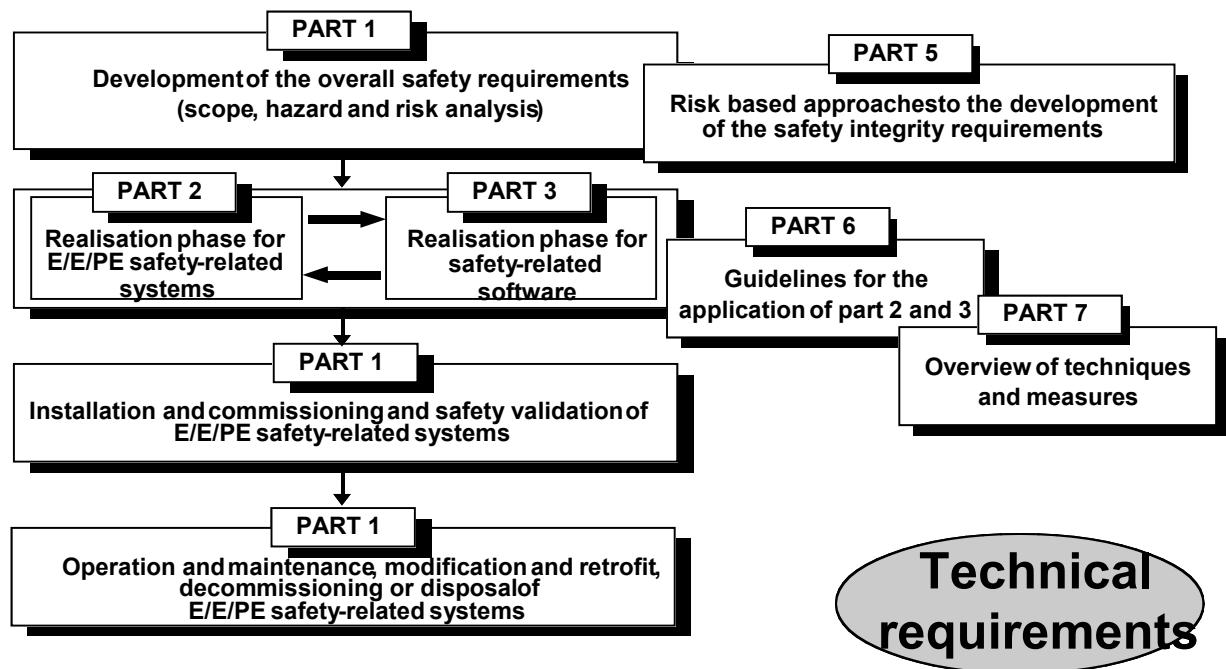


Figure 1: Technical requirements of IEC 61508.

Although the standard was initially criticized for its “extensive” documentation requirements and use of unproven “statistical” techniques for hardware failures, in many industries it represents a great step forward. The standard focuses attention on risk-based safety-related system design, which should result in far more cost-effective implementation. The standard also requires the attention to detail that is vital to any safe system design. Because of these features and the large degree of international acceptance for a single set of documents, many consider the standard to be major advance for the technical world.

#### OBJECTIVES OF THE STANDARD

IEC 61508 is a basic safety publication of the International Electrotechnical Commission (IEC). As such, it is an “umbrella” document covering multiple industries and applications. A primary objective of the standard is to help individual industries develop supplemental standards, tailored specifically to those industries based on the original 61508 standard. A secondary goal of the standard is to enable the development of E/E/PE safety-related systems where specific application sector standards do not already exist.

Several such industry specific standards have now been developed with more on the way. IEC 61511 has been written for the process industries. IEC 62061 has been written to address machinery safety. IEC 61513 has been written for the nuclear industry. All of these standards build directly on IEC 61508 and reference it accordingly.

#### SCOPE

The 61508 standard covers safety-related systems when one or more of such systems incorporates mechanical/electrical/electronic/programmable electronic devices. These devices can include anything from ball valves, solenoid valves, electrical relays and switches through to complex Programmable Logic Controllers (PLCs). The standard specifically covers possible hazards created when failures of the safety functions performed by E/E/PE safety-related

systems occur. The overall program to insure that the safety-related E/E/PE system brings about a safe state when called upon to do so is defined as “functional safety.”

IEC 61508 does not cover safety issues like electric shock, hazardous falls, long-term exposure to a toxic substance, etc.; these issues are covered by other standards. IEC 61508 also does not cover low safety E/E/PE systems where a single E/E/PE system is capable of providing the necessary risk reduction and the required safety integrity of the E/E/PE system is less than safety integrity level 1, i.e., the E/E/PE system is only available 90 percent of the time or less.

IEC 61508 is concerned with the E/E/PE safety-related systems whose failure could affect the safety of persons and/or the environment. However, it is recognized that the methods of IEC 61508 also may be applied to business loss and asset protection cases.

### FUNDAMENTAL CONCEPTS

The standard is based on two fundamental concepts: the safety life cycle and safety integrity levels. The safety life cycle is defined as an engineering process that includes all of the steps necessary to achieve required functional safety. The safety life cycle from IEC 61508 is shown in Figure 2.

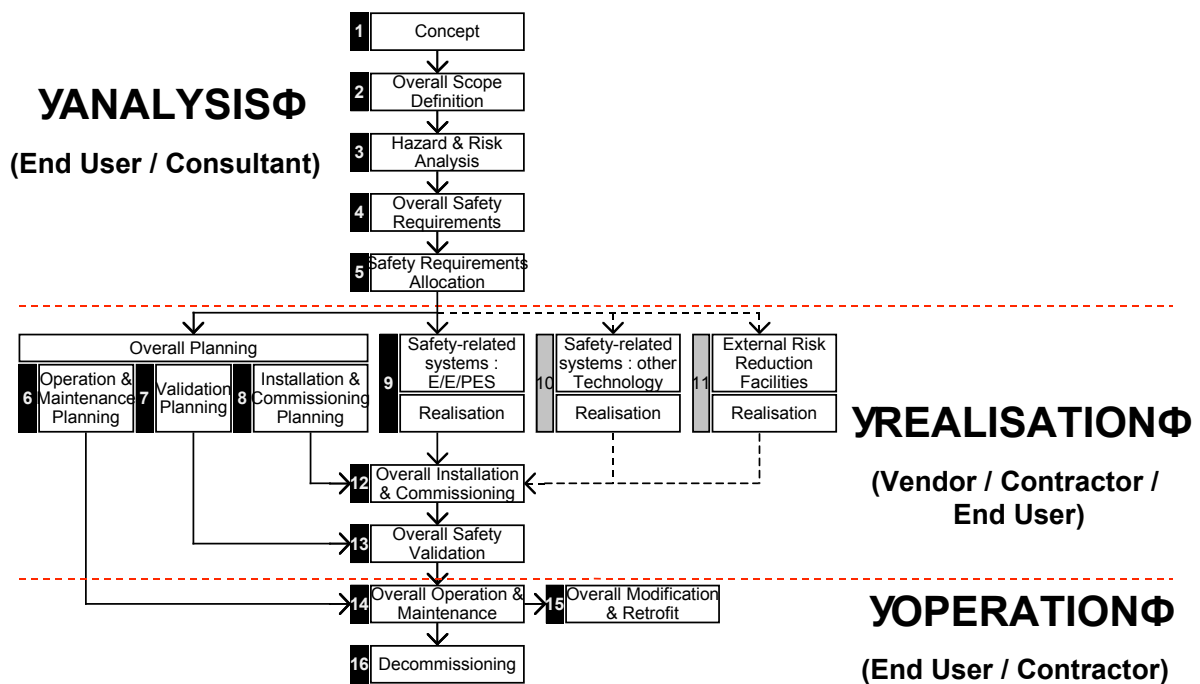


Figure 2: Safety life cycle from IEC 61508.

It should be noted that the safety life cycle as drawn in the ISA84.01 standard (Figure 3) looks different from that in IEC 61508. However, they convey the same intent and both should be viewed as similarly acceptable processes.

The basic philosophy behind the safety life cycle is to develop and document a safety plan, execute that plan, document its execution (to show that the plan has been met) and continue to follow that safety plan through to decommissioning with further appropriate documentation throughout the life of the system. Changes along the way must similarly follow the pattern of planning, execution, validation, and documentation.

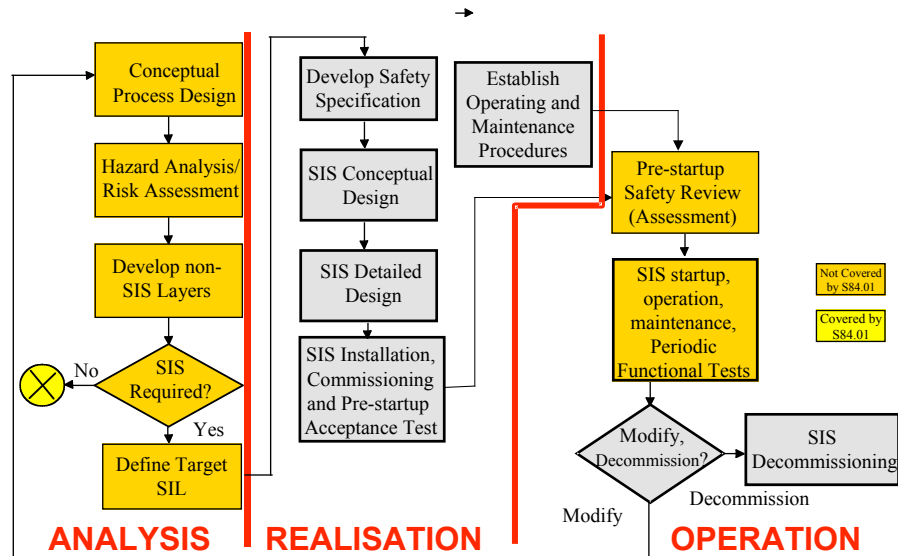


Figure 3: Safety life cycle from ISA84.01.

Safety integrity levels (SILs) are order of magnitude levels of risk reduction. There are four SILs defined in IEC 61508. SIL1 has the lowest level of risk reduction. SIL4 has the highest level of risk reduction. The SIL table for “demand mode” is shown in Figure 4. The SIL table for the continuous mode is shown in Figure 5.

Safety Integrity Level	Probability of failure on demand, average (Low Demand mode of operation)	Risk Reduction Factor
SIL 4	$\geq 10^{-5}$ to $< 10^{-4}$	100000 to 10000
SIL 3	$\geq 10^{-4}$ to $< 10^{-3}$	10000 to 1000
SIL 2	$\geq 10^{-3}$ to $< 10^{-2}$	1000 to 100
SIL 1	$\geq 10^{-2}$ to $< 10^{-1}$	100 to 10

Figure 4: Safety integrity levels – demand mode.

Safety Integrity Level	Probability of dangerous failure per hour (Continuous mode of operation)
SIL 4	$\geq 10^{-9}$ to $< 10^{-8}$
SIL 3	$\geq 10^{-8}$ to $< 10^{-7}$
SIL 2	$\geq 10^{-7}$ to $< 10^{-6}$
SIL 1	$\geq 10^{-6}$ to $< 10^{-5}$

Figure 5: Safety integrity levels – continuous mode

The mode differences are:

Low demand mode – where the frequency of demands for operation made on a safety-related system is no greater than twice the proof test frequency;

High demand or continuous mode – where the frequency of demands for operation made on a safety-related system is greater than twice the proof check frequency.

Note that the proof test frequency refers to how often the safety system is completely tested and insured to be fully operational.

NOTE: The definitions in Part 4 of the IEC 61508 standard include an arbitrary one year time interval to distinguish between low demand and high/continuous demand. This is arbitrary and has no relevance to probability calculation.

While the continuous mode appears to be far more stringent than the demand mode, it should be remembered that the units for the continuous mode are *per hour*. The demand mode units assume a time interval of roughly one year per the definition. Considering the fact that there are about 10,000 hours in a year (actual 8,760), the modes are approximately the same in terms of safety metrics.

Basically speaking, functional safety is achieved by properly designing a Safety Instrumented System (SIS) to carry out a Safety Instrumented Function (SIF) at a reliability indicated by the Safety Integrity Level (SIL). The concepts of risk and safety integrity are further discussed in Part 5 of the standard.

## COMPLIANCE

The IEC 61508 standard states: “To conform to this standard it shall be demonstrated that the requirements have been satisfied to the required criteria specified (for example safety integrity level) and therefore, for each clause or sub-clause, all the objectives have been met.”

In practice, demonstration of compliance often involves listing all of the IEC 61508 requirements with an explanation of how each requirement has been met. This applies to both products developed to meet IEC 61508 and specific application projects wishing to claim compliance.



Because IEC 61508 is technically only a standard and not a law, compliance is not always legally required. However, in many instances, compliance is identified as best practice and thus can be cited in liability cases. Also, many countries have incorporated IEC 61508 or large parts of the standard directly into their safety codes, so in those instances it indeed has the force of law. Finally, many industry and government contracts for safety equipment, systems, and services specifically require compliance with IEC 61508. So although IEC 61508 originated as a standard, its wide acceptance has led to legally required compliance in many cases.

## PARTS OF THE STANDARD

Part 1 covers the basic requirements of the standard and provides a detailed presentation of the safety life cycle. This section is considered to be the most important, as it provides overall requirements for documentation, compliance, management of functional safety, and functional safety assessment. Three annexes provide examples of documentation structure (Annex A), a personnel competency evaluation (Annex B), and a bibliography (Annex C).

Part 2 covers the hardware requirements for safety-related systems. Many consider this part, along with part 3, to be the key area for those developing products for the safety market. Part 2 is written with respect to the entire system but many of the requirements are directly applicable to safety-related hardware product development. Part 2 covers a detailed safety life cycle for hardware as well as specific aspects of assessing functional safety for the hardware. Part 2 also has detailed requirements for techniques to deal with “control of failures during operation” in Annex A (required for compliance). This annex covers hardware fault tolerance, diagnostic capability requirements and limitations, and systematic safety integrity issues for hardware. Annex B of Part 2 (required for compliance) contains listings of “techniques and measures” for “avoidance of systematic failures during different phases of the life cycle.” This covers design, analysis, and review procedures required by the standard. Annex C of Part 2 (required for compliance) discusses the calculation of diagnostic coverage factor (what fraction of failures are identified by the hardware) and safe failure fraction (what fraction of failures lead to a safe rather than a hazardous state). (Note: see exida technical papers for more detailed information on these topics.)

Part 3 covers the software requirements for IEC 61508. It applies to any software used in a safety-related system or software used to develop a safety-related system. This software is specifically referred to as safety-related software. This part provides details of the software safety life cycle, a process to be used when developing software. Annex A (required for compliance) provides a listing of “techniques and measures” used for software development where different development techniques are chosen depending on the SIL level of the software. Annex B (required for compliance) has nine detailed tables of design and coding standards and analysis and testing techniques that are to be used in the safety-related software development, depending on SIL level of the software and in some cases the choice of the development team.

Part 4 contains the definitions and abbreviations used throughout all parts of the standard. This section is extremely useful both to those new to the standard and to those already familiar with it as a reference to the precise meanings of terms in the standard.

Part 5 includes informative Annexes A through E which contain discussion and example methods for risk, safety integrity, tolerable risk, and SIL selection. It presents several techniques of SIL selection including both quantitative and qualitative methods. The quantitative method in Annex C is based on calculating the frequency of the hazardous event from failure rate data or



appropriate predictive methods combined with an assessment of the magnitude of the consequence compared to the level of risk that can be tolerated in the given situation. The qualitative risk graph and severity matrixes essentially address the same frequency and magnitude components, only with general categories rather than numbers before comparing the situation with the tolerable risk level.

Part 6 provides guidelines on the application of Parts 2 and 3 via informative Annexes A through E. Annex A gives a brief overview of Parts 2 and 3 as well as example flowcharts of detailed procedures to help with implementation. Annex B provides example techniques for calculating probabilities of failure for the safety-related system with tables of calculation results. Equations that approximate various example architectures are presented, although reliability block diagrams are used and these can be confusing in multiple failure mode situations. Annex C shows detailed calculation of diagnostic coverage factor based on FMEDA techniques. (Note: more information on the FMEDA technique (Failure Modes, Effects, and Diagnostics Analysis) is available in [exida.com](http://exida.com) courses and papers.) Annex D shows a method for estimating the effect of common cause modes of failure (beta factors) in a redundant hardware architecture. This method lists relevant parameters and provides a method of calculation. Annex E shows examples applying the software integrity level tables of Part 3 for two different safety software cases.

Part 7 contains important information for those doing product development work on equipment to be certified per IEC 61508. Annex A addresses control of random hardware failures. It contains a reasonable level of detail on various methods and techniques useful for preventing or maintaining safety in the presence of component failures. Annex B covers the avoidance of systematic failures through the different phases of the safety life cycle. Annex C provides a reasonably detailed overview of techniques for achieving high software safety integrity. Annex D covers a probabilities-based approach for SIL determination of already proven software.

## 2 Part 1: General Requirements

### SCOPE

The IEC 61508 standard covers safety-related systems when one or more of such systems incorporate electrical/electronic/programmable electronic devices. This includes mechanical devices used in such systems, relay-based systems, inherently safe solid-state logic based systems, and, perhaps most importantly, programmable systems based on microcomputer technology. The standard specifically covers possible hazards created when failures of the safety functions performed by E/E/PE safety-related systems occur: This is known as “functional safety.” Functional safety is the overall program to insure that a safety-related E/E/PE system brings about a safe state when it is called upon to do so and is different from other safety issues. For example, IEC 61508 does not cover safety issues like electric shock, long-term exposure to toxic substances, etc. These safety issues are covered by other standards.

IEC 61508 also does not cover low safety E/E/PE systems where a single E/E/PE system is capable of providing the necessary risk reduction and the required safety integrity of the E/E/PE system is less than safety integrity level 1, i.e., the E/E/PE system is only reliable 90 percent of the time or less. IEC 61508 is concerned with the E/E/PE safety-related systems whose failure could affect the safety of persons and/or the environment. However, it is recognized that the methods of IEC 61508 may apply to business loss and asset protection as well. Human beings may be considered part of a safety-related system, although specific human factor requirements are not considered in detail in the standard. The standard also specifically avoids the concept of “fail safe” because of the high level of complexity involved with the E/E/PE systems considered.

### CONFORMANCE

Part 1 of the standard contains the general conformance requirements. It states, “To conform to this standard it shall be demonstrated that the requirements have been satisfied to the required criteria specified (for example: safety integrity level) and therefore, for each clause or sub-clause, all the objectives have been met.” There is a statement that acknowledges that the “degree of rigor” (which determines if a requirement has been met) depends on a number of factors, including the nature of the potential hazard, degree of risk, etc.

Often, demonstrating compliance involves listing all IEC 61508 requirements with an explanation of how the requirement has been met. This applies to products developed to meet IEC 61508 and specific application projects wishing to claim compliance. The high level of documentation for compliance is consistent with the importance of keeping detailed records stressed throughout the standard. (Note: exida.com has a suite of products, including a full IEC 61508 requirements database, and documentation templates that can be used to form a system of compliance meeting IEC 61508.)

The language of conformance in the standard is quite precise. If an item is listed as “shall be...” or “must...”, it is required for compliance. If an item is listed as “may be...” it is not specifically required for compliance but clear reasoning must be shown to justify its omission.

### DOCUMENTATION (Clause 5)

The documentation used in safety-related systems must specify the necessary information such that safety life cycle activities can be performed. The documentation must also provide enough

information so that the management of functional safety verification and assessment activities can effectively be accomplished. The overall reasoning is to provide proper support for the plan, do, and verify theme present throughout the safety life cycle.

This translates into specific requirements for the documentation.

It must:

1. have sufficient information to effectively perform each phase of the safety life cycle as well as the associated verification activities;
2. have sufficient information to properly manage functional safety and support functional safety assessment;
3. be accurate and precise;
4. be easy to understand;
5. suit the purpose for which it was intended;
6. be accessible and maintainable;
7. have titles or names indicating the scope of the contents;
8. have a good table of contents and index;
9. have a good version control system sufficient to identify different versions of each document and indicate revisions, amendments, reviews, and approvals.

#### MANAGEMENT OF FUNCTIONAL SAFETY (Clause 6)

Managing functional safety includes taking on various activities and responsibilities to insure that the functional safety objectives are achieved and maintained. These activities must be documented, typically in a document called the functional safety management (FSM) plan. The FSM plan should consider:

1. the overall strategy and methods for achieving functional safety, including evaluation methods and the way in which the process is communicated within the organization;
2. the identification of the people, departments, and organizations that are responsible for carrying out and reviewing the applicable overall, E/E/PES, or software safety life cycle phases (including, where relevant, licensing authorities or safety regulatory bodies);
3. the safety life cycle phases to be used;
4. the documentation structure;
5. the measures and techniques used to meet requirements;
6. the functional safety assessment activities to be performed and the safety life cycle phases where they will be performed;
7. the procedures for follow-up and resolution of recommendations arising from hazard and risk analysis, functional safety assessment, verification and validation activities, etc.;
8. the procedures for ensuring that personnel are competent;
9. the procedures for ensuring that hazardous incidents (or near misses) are analyzed, and that actions are taken to avoid repetition;
10. the procedures for analyzing operations and maintenance performance, including periodic functional safety inspections and audits; the inspection frequency and level of independence of personnel to perform the inspection/audit should be documented;
11. the procedures for management of change.

All those responsible for managing functional safety activities must be informed and aware of their responsibilities. Suppliers providing products or services in support of any safety life cycle

phase, shall deliver products or services as specified by those responsible for that phase. These suppliers also shall have an appropriate quality management system.

#### SAFETY LIFE CYCLE REQUIREMENTS (Clause 7)

The safety life cycle can be viewed as a logical “identify-assess-design-verify” closed loop (Figure 6). The intended result is the optimum design where the risk reduction provided by the safety-related system matches the risk reduction needed by the process.

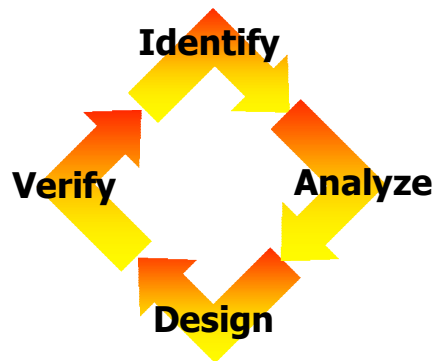


Figure 6: Closed loop view of the safety life cycle.

The safety life cycle concept came from studies done by the Health Safety Executive (HSE) in the United Kingdom. The HSE studied accidents involving industrial control systems and classified accident causes as shown in Figure 7.

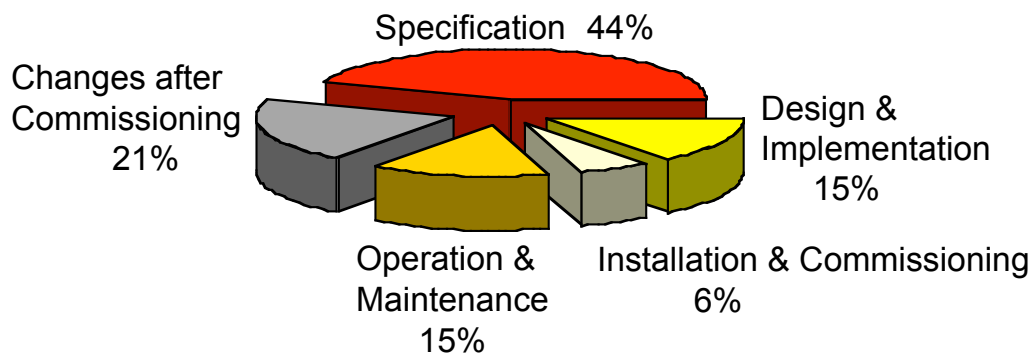
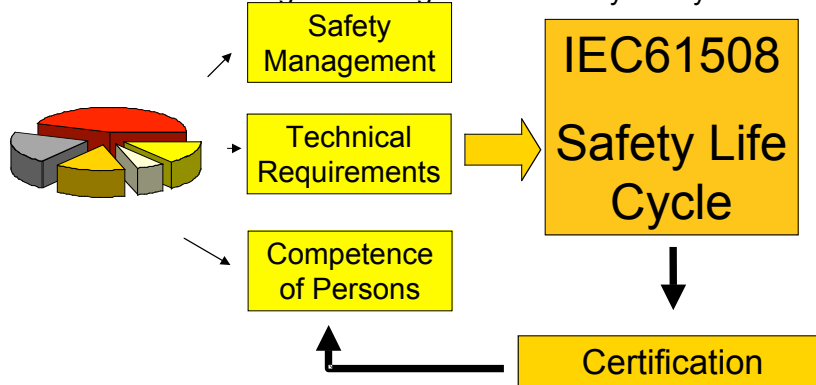


Figure 7: Results of system failure cause study: HSE “Out of Control.”

The basic aspects of the safety life cycle (shown in Figure 8) were created to address all of the causes identified in the HSE study.

Figure 8: Origin of the safety life cycle.



The first part of the safety life cycle, known as the analysis portion, covers:

- Concept and scope of the system or equipment under control (EUC);
- Hazard and Risk Analysis to identify both hazards and the events that can lead to them, including

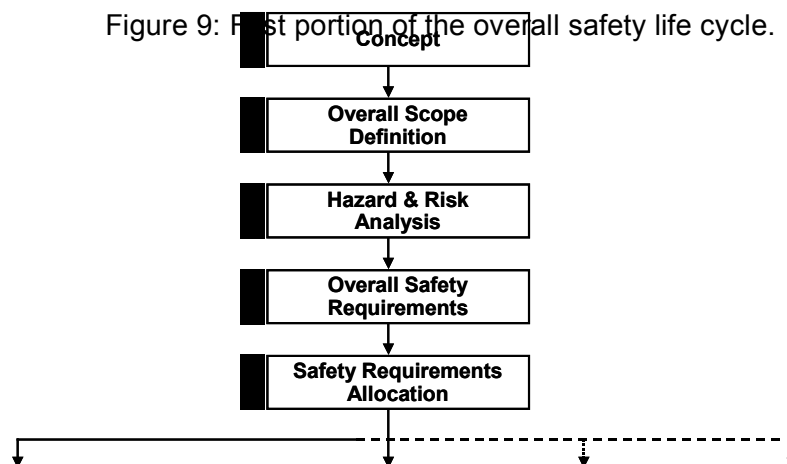
- Preliminary Hazards and Operability (HAZOP) study,
  - Layers of Protection Analysis (LOPA),
  - Criticality Analysis;

- Creation of overall safety requirements and identification of specific safety functions to prevent the identified hazards;

- Safety requirements allocation, i.e., assigning the safety function to an E/E/PE safety-related system, an external risk reduction facility, or a safety-related system of different technology. This also includes assigning a safety integrity level (SIL) or risk reduction factor required for each safety function.

These first phases are shown in Figure 9.

Figure 9: First portion of the overall safety life cycle.



The safety life cycle continues with the realization activities as shown in Figure 10.

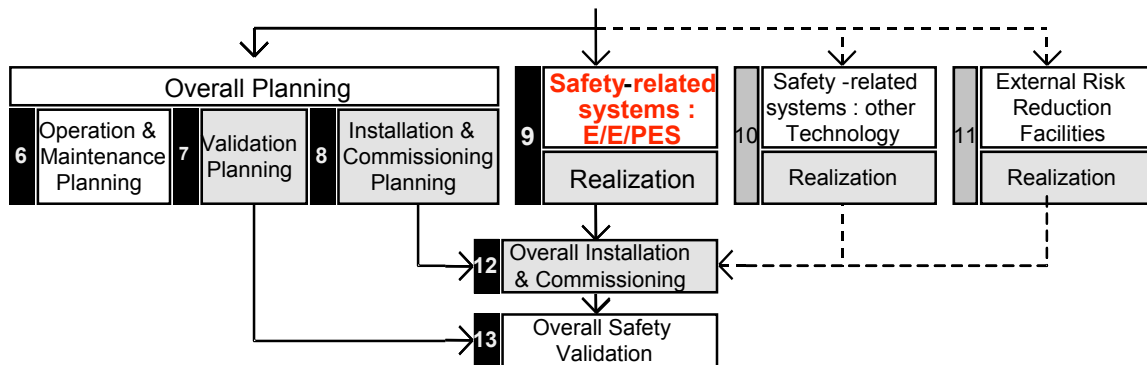


Figure 10: Realization activities in the overall safety life cycle.

The safety systems must be designed to meet the target safety integrity levels as defined in the risk analysis phase. This requires that a probabilistic calculation be done to verify that the design can meet the SIL (either in demand mode or continuous mode). The system must also

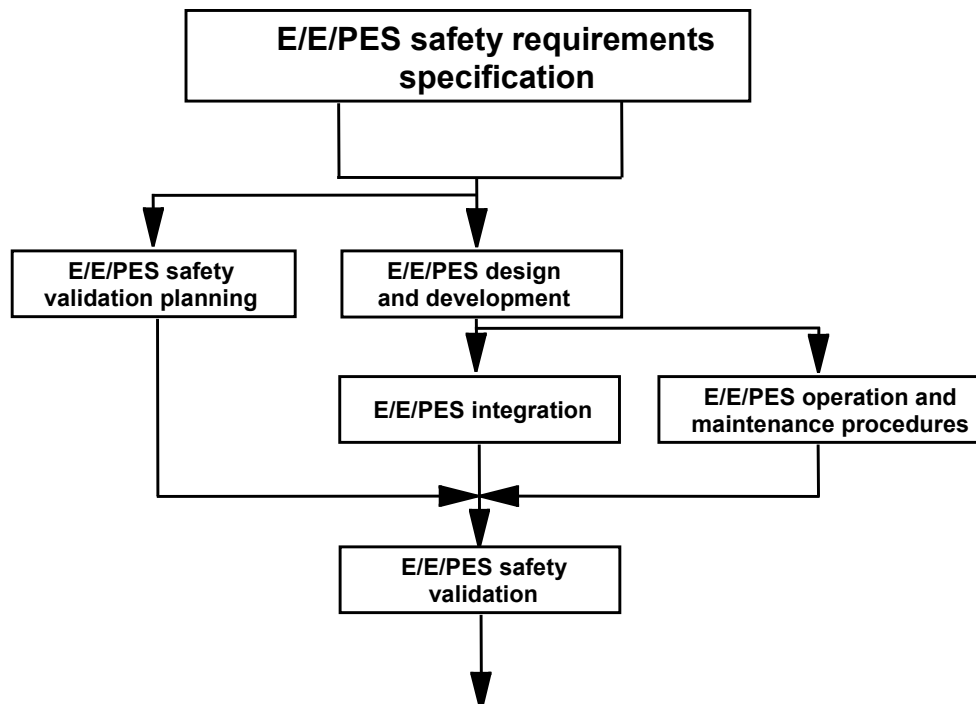


Figure 11: E/E/PES safety life cycle (IEC 61508, Part 2).

The final operation phases of the overall safety life cycle are shown in Figure 12.

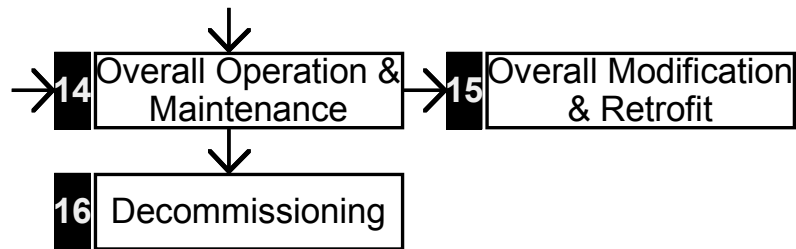


Figure 12: Operation and Maintenance phases of the overall safety life cycle.

In summary, the safety life cycle generally lays out the different activities required to achieve functional safety and compliance with the standard. It also should be noted that if all of the “shall be...” and “must...” conditions are met, other safety life cycle variations also are fully compliant with the standard.

#### FUNCTIONAL SAFETY ASSESSMENT (Clause 8)

Part 1 also describes the functional safety assessment activities required by IEC 61508. The objective of the assessment is to investigate and arrive at a conclusion regarding the level of safety achieved by the safety-related system. The process requires that one or more competent persons be appointed to carry out a functional safety assessment. These individuals must be suitably independent of those responsible for the functional safety being assessed, depending on the SIL and consequences involved. These requirements are shown in Tables 1 and 2.

Minimum level of Independence	Consequence			
	A	B	C	D
Independent person	HR	HR <sup>1</sup>	NR	NR
Independent department	-	HR <sup>2</sup>	HR <sup>1</sup>	NR
Independent organization (see note 2 of 8.2.12)	-	-	HR <sup>2</sup>	HR
Typical consequences could be: Consequence A - minor injury (for example temporary loss of function); Consequence B - serious permanent injury to one or more persons, death to one person; Consequence C - death to several people; Consequence D - very many people killed.				
Abbreviations – HR - highly recommended, NR – not recommended				

Table 1: Assessment independence level as a function of consequence.

Minimum level of Independence	Safety integrity level			
	1	2	3	4
Independent person	HR	HR <sup>1</sup>	NR	NR
Independent department	-	HR <sup>2</sup>	HR <sup>1</sup>	NR
Independent organization	-	-	HR <sup>2</sup>	HR

Table 2: Assessment independence level for E/E/PE and software life cycle activities.

The functional safety assessment shall include all phases of the safety life cycles. The assessment must consider the life cycle activities carried out and the outputs obtained. The assessment may be done in parts after each activity or group of activities. The main requirement is that the assessment be done before the safety-related system is needed to protect against a hazard.

The functional safety assessment must consider:

1. All work done since the previous functional safety assessment;
2. The plans for implementing further functional safety assessments;
3. The recommendations of the previous assessments including a check to verify that the changes have been made.

The functional safety assessment activities shall be consistent and planned. The plan must specify the personnel who will perform the assessment, their level of independence, and the competency required. The assessment plan must also state the scope of the assessment, outputs of the assessment, any safety bodies involved, and the resources required. At the conclusion of the functional safety assessment, recommendations shall indicate acceptance, qualified acceptance, or rejection.

#### Sample Documentation Structure (Annex A)

The documentation has to contain enough information to effectively perform each phase of the safety life cycle (Clause 7), manage functional safety (Clause 6), and allow functional safety assessments (Clause 8). However, IEC 61508 does not specify a particular documentation structure. Users have flexibility in choosing their own documentation structure as long as it meets the criteria described earlier. . An example set of documents for a safety life cycle project is shown in Table 3.

Safety Lifecycle phase	Information
Safety requirements	Safety Requirements Specification (safety functions and safety integrity)
E/E/PES validation planning	Validation Plan
E/E/PES design and development E/E/PES architecture  Hardware architecture Hardware module design Component construction and/or procurement	Architecture Design Description (hardware and software); Specification (integration tests) Hardware Architecture Design Description; Detail Design Specification(s) Hardware modules; Report (hardware modules test)
Programmable electronic integration	Integration Report
E/E/PES operation and maintenance procedures	Operation and Maintenance Instructions
E/E/PES safety validation	Validation Report
E/E/PES modification	E/E/PES modification procedures; Modification Request; Modification Report; Modification Log
Concerning all phases	Safety Plan; Verification Plan and Report; Functional Safety Assessment Plan and Report

Table 3: Documentation examples.

#### Personnel Competency (Annex B)

IEC 61508 specifically states, “All persons involved in any overall, E/E/PES or software safety life cycle activity, including management activities, should have the appropriate training, technical knowledge, experience and qualifications relevant to the specific duties they have to perform.” It is suggested that a number of things be considered in the evaluation of personnel. These are:

1. engineering knowledge in the application;
2. engineering knowledge appropriate to the technology;
3. safety engineering knowledge appropriate to the technology;
4. knowledge of the legal and safety regulatory framework;
5. the consequences of safety-related system failure;
6. the assigned safety integrity levels of safety functions in a project;
7. experience and its relevance to the job.

The training, experience, and qualifications of all persons should be documented. The Certified Functional Safety Expert (CFSE) program was designed to help companies show personnel competency in several different safety specialties.

#### Bibliography (Annex C)

A list of many related IEC standards, ISO standards, and other relevant references is provided.

### 3 Part 2: Hardware Requirements

IEC 61508 Part 2 covers specific requirements for safety-related hardware. As in other parts of the standard, a safety life cycle is to be used as the basis of requirement compliance. (Figure 9 shows the general safety life cycle model.) The hardware safety life cycle is an expanded plan for Phase 9 of the overall safety life cycle from Part 1 that is focused on the design of the control hardware for safety systems. As for the overall safety life cycle, there are requirements for a functional safety management plan and safety requirements specification including all verification and assessment activities.

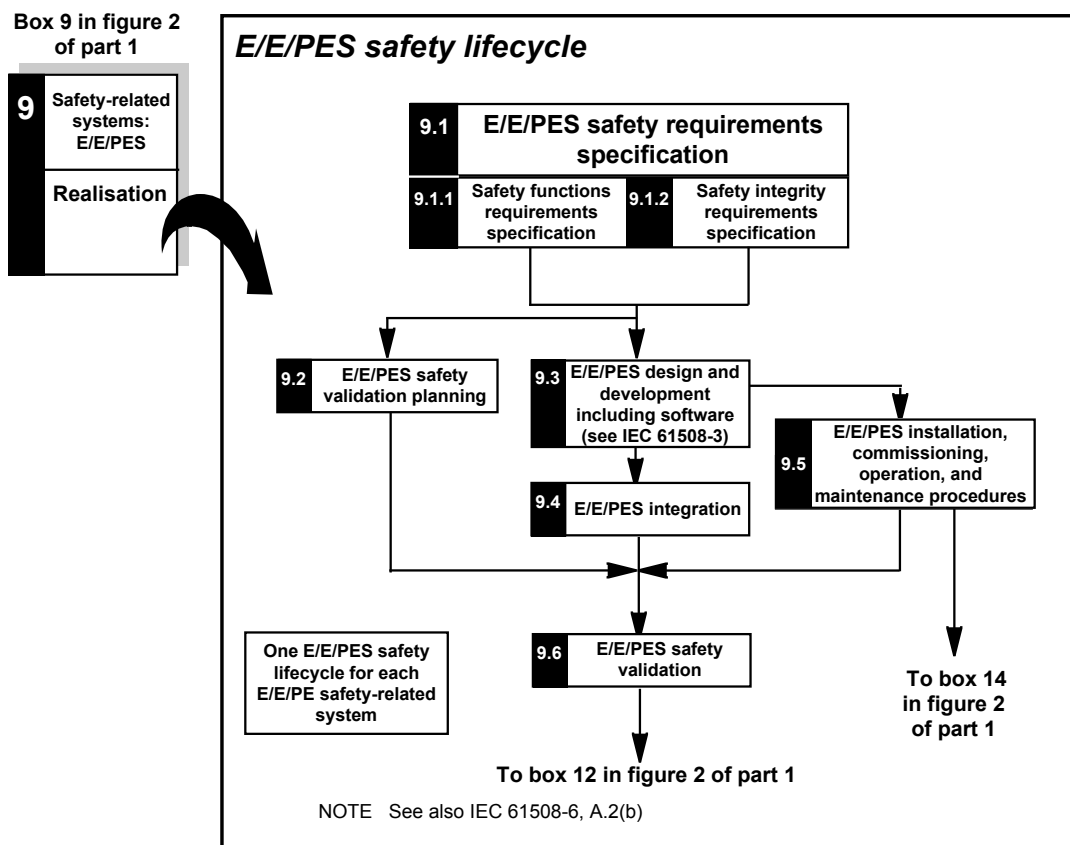


Figure 13: Hardware safety life cycle.

The safety requirements specification (described in Clause 7.2) shall include details on both the safety function and the safety integrity level of that function. Some of these safety function details are:

- how safe state is achieved
- operator interfaces
- required E/E/PES behavior modes
- response time
- operating modes of equipment under control
- start-up requirements

Some of the safety integrity level details are:

- SIL for each function
- environmental extremes
- high or low demand class for each function
- electromagnetic immunity limits

One particular aspect of the hardware design and development requirements (Clause 7.4) is the limit on the safety integrity level achievable by any particular level of fault tolerant safety

redundancy. These are shown in Tables 4 and 5 for various fractions of failures leading to a safe state.

Table 4: Type A safe failure fraction chart.

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

NOTE 1 A hardware fault tolerance of N means that N+1 faults could cause a loss of the safety function.

Table 5: Type B safe failure fraction chart.

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

NOTE 1 A hardware fault tolerance of N means that N+1 faults could cause a loss of the safety function.

Type A components are described as simple devices with well-known failure modes and a solid history of operation. Type B devices are complex components with potentially unknown failure modes, i.e., microprocessors, ASICs, etc.

Tables 4 and 5 represent limits on the use of single or even dual architectures in higher SIL levels. This is appropriate based on the level of uncertainty present in the failure data as well as in the SIL calculations themselves.

Note the separate phase specifically devoted to integrating the software and hardware before validating the safety of the combined system (described in Clause 7.5). Operation and maintenance procedures and documentation are described in Clause 7.6 while validation, modification, and verification phase details are provided in the remaining parts of Clause 7.

#### Control of Failures during Operation (Annex A)

This annex limits claims that can be made for self diagnostic capabilities and also recommends methods of failure control. Numerous types of failures are addressed including random, systematic, environmental, and operational failures. It should be noted that following these methods does not guarantee that a given system will meet a specific SIL.

#### Avoidance of Systematic Failures during Different Phases of the Life Cycle (Annex B)

Here, numerous tables present recommended techniques for different life cycle phases to achieve different SILs. Again, simply using these techniques does not guarantee a system will achieve a specific SIL.

#### Diagnostic Coverage and Safe Failure Fraction (Annex C)

Here, a basic procedure is described for calculating the fraction of failures that can be self-diagnosed and the fraction that result in a safe state.

## 4 Part 3: Software Requirements

IEC 61508 Part 3 covers specific requirements for safety-related software. As in other parts of the standard, a safety life cycle is to be used as the basis of requirement compliance. (Figure 9 shows the general safety life cycle model.) The software safety life cycle is an expanded plan for Phase 9 of the overall safety life cycle from Part 1 and is closely linked with the hardware life cycle. As for the overall safety life cycle, there are requirements for a functional safety management plan and safety requirements specification, including all verification and assessment activities.

Here the functional safety is addressed in the context of a software quality management system (QMS) in Clause 6. A detailed functional safety plan is presented as part of this QMS. As in other parts of the standard, the same key features of change management, demonstration, and documentation are present.

#### SOFTWARE FUNCTIONAL SAFETY PLAN (Clause 6)

A software functional safety plan (either as a part of other documentation or as a separate document) shall define the strategy for the software procurement, development, integration, verification, validation, and modification as required for the SIL level of the safety-related system. The plan must specify a configuration management system.

This software configuration management system must:

1. manage software changes to ensure that the specified requirements for software safety are satisfied;
2. guarantee that all necessary activities have been carried out to demonstrate that the required software safety integrity has been achieved;

3. accurately maintain all documentation and source code including the safety analysis and requirements; software specification and design documents; software source code modules; test plans and results; commercial off the shelf (COTS) and pre-existing software components which are to be incorporated into the E/E/PE safety-related system; all tools and development environments which are used to create or test, or carry out any action on, the software of the E/E/PE safety-related system;
4. prevent unauthorized modifications;
5. document modification/change requests;
6. analyze the impact of a proposed modification;
7. approve or reject the modification request;
8. establish baseline software and document the (partial) integration testing that justifies the baseline;
9. formally document the release of safety-related software.

Master copies of the software and all documentation should be maintained throughout the operational lifetime of the released software.

#### SOFTWARE SAFETY LIFE CYCLE (Clause 7)

IEC 61508 has a considerable but appropriate number of requirements for safety critical software put forth in the details of the software safety life cycle framework. The major phases of the software safety life cycle are shown in Figure 14.

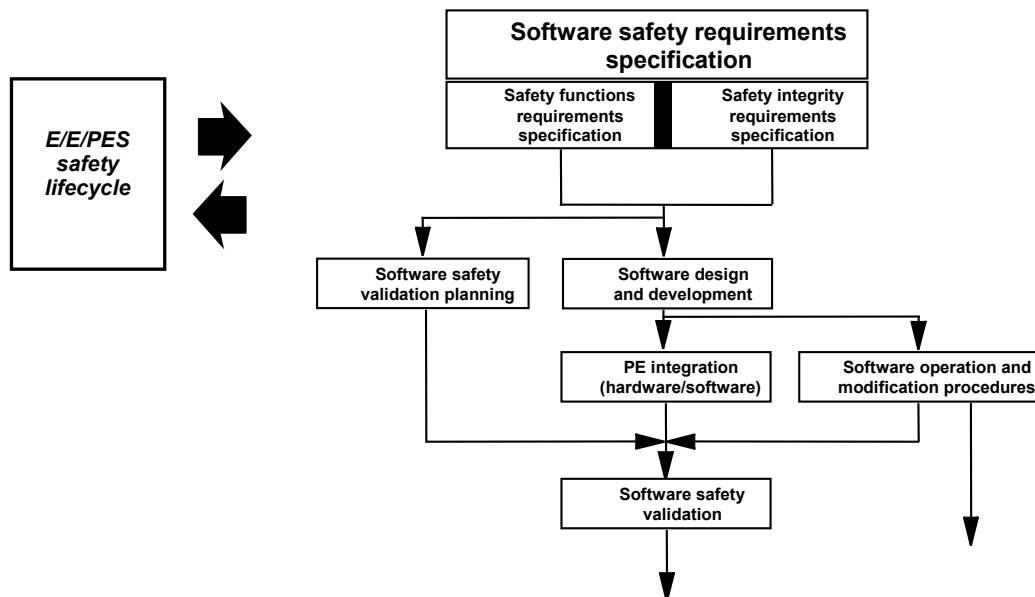


Figure 14: Software safety life cycle.

Part 3 requires that a process (such as the safety life cycle) for the development of software shall be selected and specified during safety planning. Note that the exact process is not specified, it may be customized according to company preference. Appropriate quality and safety assurance procedures must be included. Each step of the software safety life cycle must be divided into elementary activities with the functions, inputs, and outputs specified for each phase.

The standard has complete details of an example software safety life cycle. Many practitioners use a version of the V-model. The exida.com iterative V-model is shown in Figure 15.

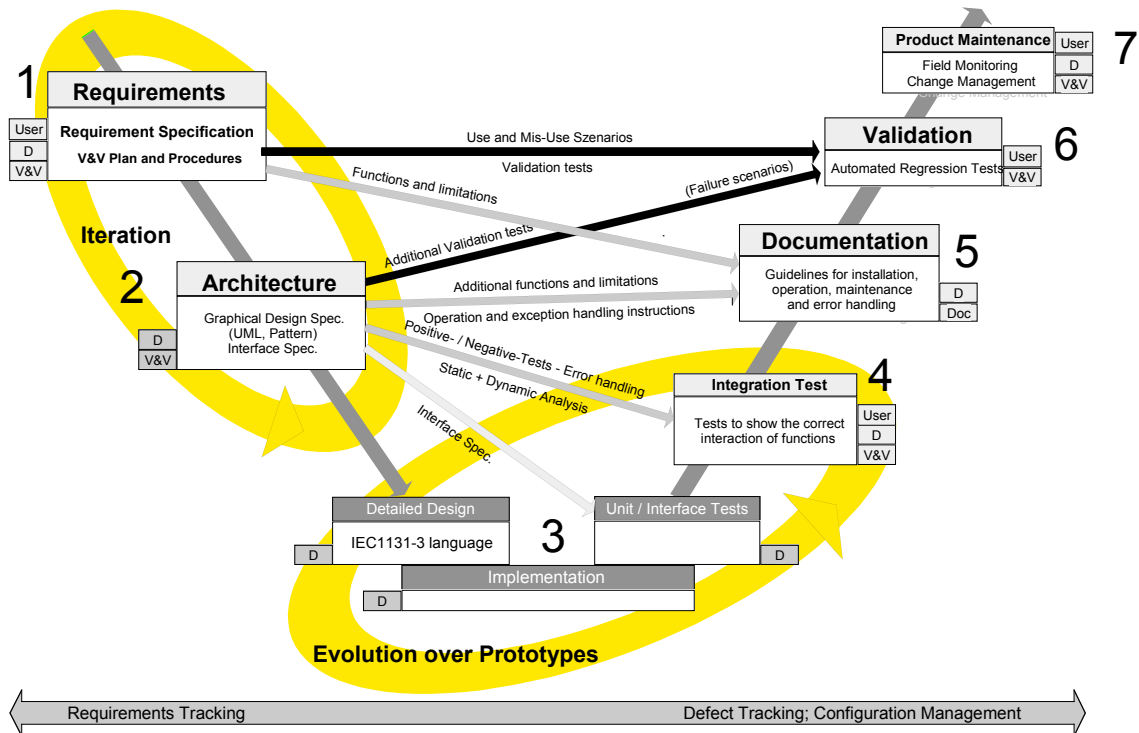


Figure 15: exida iterative V-model for software development.

During each step of process, appropriate “techniques and measures” must be used.

Part 3 Annexes A and B give recommendations from a list of software techniques.

The standard says, “If at any stage of the software safety life cycle, a change is required pertaining to an earlier life cycle phase, then that earlier safety life cycle phase and the following phases shall be repeated”. This natural iterative process is best done in two major loops per Figure 15.

### SOFTWARE SAFETY REQUIREMENTS SPECIFICATION (Clause 7.2)

The functional safety requirements for software must be specified. This can be done in a separate document or as part of another document. The specification of the requirements for software safety shall be derived from the specified safety requirements of the safety-related system and any requirements of safety planning.

The requirements for software safety shall be sufficiently detailed to allow design and implementation and to allow a functional safety assessment. The software developers should review the document to verify that it contains sufficient detail. It should be noted that this is often another iterative process.

The requirements must be clear, precise, verifiable, testable, maintainable, and feasible. The requirements must also be appropriate for the safety integrity level. and traceable back to the

specification of the safety requirements of the safety-related system. Terminology must be clear and understandable by those using the document. All modes of operation for the safety-related system must be listed. The requirements must detail any relevant constraints between the hardware and the software.

Since the software is often called upon to perform much of the online diagnostics, the requirements must detail all software self-monitoring, any diagnostic tests performed on the hardware, periodic testing of critical functions, and means for online testing of safety functions. If the software also performs non-safety functions, means to insure that the software safety is not compromised (non-interfering) must also be specified.

#### SOFTWARE SAFETY VALIDATION PLANNING (Clause 7.3)

A plan must be set up to demonstrate that the software satisfies the safety requirements set out in the specification. A combination of analysis and testing techniques is allowed and the chosen techniques must be specified in the plan. The plan must consider:

1. required equipment;
2. when validation will be done;
3. who will do the validation;
4. the modes of operation to be validated including start up, teach, automatic, manual, semi-automatic, steady state of operation, re-set, shut down, and maintenance;
5. reasonably foreseeable abnormal conditions;
6. identification of the safety-related software that needs to be validated;
7. specific reference to the specified requirements for software safety;
8. expected results and pass/fail criteria.

The plan must show how assessment will be done, who will review the plan, and the assessor's level of independence.

#### SOFTWARE DESIGN AND DEVELOPMENT (Clause 7.4)

Design methods shall be chosen that support abstraction, modularity, information hiding, and other good software engineering practices. The design method shall allow clear and unambiguous expression of functionality, data flow, sequencing, and time-dependent data, timing constraints, concurrency, data structures, design assumptions, and their dependencies.

During design, the overall complexity of the design, its testability, and the ability to make safe modifications shall be considered. The entire design is considered safety-related even if non-safety functions are included unless sufficient independence between safety and non-safety can be demonstrated. If different safety integrity levels are part of the design, the overall design is only valid for the least stringent SIL of the component parts.

The design must include software functions to execute proof tests and all online diagnostic tests as specified in the requirements. Software diagnostics shall include monitoring of control flow and data flow.

The architectural design defines the major components and subsystems of the software. The architectural design description must include:

1. interconnections of these components;
- 2 the "techniques and measures" necessary during the software safety life cycle phases to satisfy requirements for software safety at the required safety integrity level including software design strategies for fault tolerance and/or fault avoidance (redundancy/diversity);

3. the software safety integrity level of the subsystem/component;
4. all software/hardware interactions and their significance;
5. the design features for maintaining the safety integrity of all data;
6. software architecture integration tests to ensure that the software architecture satisfies the requirements for software.

It is assumed and permitted that iteration occurs between the design and the requirements phases. Any resulting changes in requirements must be documented and approved.

Support tools and programming languages must meet the safety integrity needs of the software. A set of integrated tools, including languages, compilers, configuration management tools, and, when applicable, automatic testing tools, shall be selected for the required safety integrity level.

Detailed design and coding shall follow the software safety life cycle. Coding standards shall be employed and must specify good programming practice, prohibit unsafe language features, and specify procedures for source code documentation including:

1. legal entity;
2. description;
3. inputs and outputs;
4. configuration management history.

The software code must be :

1. readable, understandable, and testable;
2. able to satisfy the specified requirements;
3. reviewed;
4. tested as specified during software design.

#### INTEGRATION AND TESTING (Clause 7.5)

Tests of the integration between the hardware and software are created during the design and development phases and specify the following:

1. test cases and test data in manageable integration sets;
2. test environment, tools, and configuration;
3. test criteria;
4. procedures for corrective action on failure of test.

The integration testing results shall state each test and the pass/fail results.

#### SOFTWARE SAFETY VALIDATION (Clause 7.7)

Software validation is done as an overall check to insure that the software design meets the software safety requirements and must include the appropriate documentation. The validation may be done as part of overall system validation or it may be done separately for the software. Testing must be the primary method of validation with analysis used only to supplement. All tools used in the validation must be calibrated and an approved quality system must be in place. If validation is done separately for the software, the validation must follow the software safety validation plan. For each safety function, the validation effort shall document:

1. a record of the validation activities;
2. the version of the software safety validation plan;

3. the safety function being validated with reference to planned test;
4. test environment (tools and equipment);
5. the results of the validation activity with discrepancies, if any.

If discrepancies occur, a change request must be created and an analysis must be done to determine if the validation may continue.

#### OPERATION AND MODIFICATION (Clauses 7.6 and 7.8)

Software modification requires authorization under the procedures specified during safety planning and must insure that the required safety integrity level is maintained. This authorization must address:

1. the hazards that may be affected;
2. the proposed change;
3. the reasons for change.

The modification process starts with an analysis on the impact of the proposed software modification on functional safety. The analysis will determine how much of the safety life cycle must be repeated.

#### SOFTWARE VERIFICATION (Clause 7.9)

The software verification process tests and evaluates the results of the software safety life cycle phases to insure they are correct and consistent with the input information to those phases. Verification of the steps used in the software safety life cycle must be performed according to the plan and must be done concurrently with design and development. The verification plan must indicate the activities performed and the items to be verified (documents, reviews, etc.). A verification report must include an explanation of all activities and results. Verification must be performed on:

1. software safety requirements;
2. software architecture design;
3. software system design;
4. software module design;
5. software source code;
6. data;
7. software module testing;
8. software integration testing;
9. hardware integration testing;
10. software safety requirements testing (software validation).

#### SOFTWARE FUNCTIONAL SAFETY ASSESSMENT (Clause 9)

The software assessment process is similar to the other assessment processes in the standard. Techniques and measures relevant to this assessment are listed in Annexes A and B as well as in Part 1 of the standard.

## GUIDE TO THE SELECTION OF TECHNIQUES AND MEASURES (Annex A)

Annex A provides ten tables of different techniques relevant to the software safety requirements, software design and development, architecture design, support tools and programming languages, detailed design, software module testing, integration testing, safety validation, modification and functional safety assessment. Different techniques are “recommended” or “highly recommended” as a function of safety integrity level required. Some techniques are used alone or in combination with other techniques to show compliance with the standard.

## DETAILED TABLES (Annex B)

Annex B provides nine tables of detailed techniques for design and coding standards, dynamic analysis and testing, functional and black box testing, failure analysis, modeling, performance testing, semi-formal methods, static analysis, and modular approaches. These tables are also referenced in the tables from Annex A.

## 5 Part 4: Abbreviations and Definitions

Part 4 of the standard contains the abbreviations and definitions used throughout the entire document. Some selected key definitions are:

diversity - different means of performing a required function

equipment under control (EUC) - equipment, machinery, apparatus, or plant used for manufacturing, process, transportation, medical, or other activities

functional safety - part of the overall safety relating to the EUC and the EUC control system which depends on the correct functioning of the E/E/PE safety-related systems, other technology safety-related systems, and external risk reduction facilities

harm - physical injury or damage to the health of people either directly or indirectly as a result of damage to property or to the environment

hazard - potential source of harm

limited variability language - software programming language, either textual or graphical, for commercial and industrial programmable electronic controllers with a range of capabilities limited to their application

redundancy - means, in addition to the means which would be sufficient, for a functional unit to perform a required function or for data to represent information

risk - combination of the probability of occurrence of harm and the severity of that harm

safety - freedom from unacceptable risk

safety function - function to be implemented by an E/E/PE safety-related system, other technology safety-related system, or external risk reduction facilities which is intended to achieve or maintain a safe state for the EUC, with respect to a specific hazardous event

safety integrity - probability of a safety-related system satisfactorily performing the required safety functions under all the stated conditions within a stated period of time

safety integrity level (SIL) - discrete level (one out of a possible four) for specifying the safety integrity requirements of the safety functions to be allocated to the E/E/PE safety-related systems, where safety integrity level 4 has the highest level of safety integrity and safety integrity level 1 has the lowest

safety life cycle - necessary activities involved in the implementation of safety-related systems, occurring during a period of time that starts at the concept phase of a project and finishes when

all of the E/E/PE safety-related systems, other technology safety-related systems, and external risk reduction facilities are no longer available for use

safety-related system - designated system that both:

- implements the required safety functions necessary to achieve or maintain a safe state for the EUC; 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

systematic failure - failure related in a deterministic way to a certain cause, which can only be eliminated by a modification of the design or of the manufacturing process, operational procedures, documentation, or other relevant factors

tolerable risk - risk which is accepted in a given context based on the current values of society

## **6 Part 5: Examples of Methods for the Determination of Safety Integrity Levels (Informative)**

Part 5 is primarily composed of Annexes A through E which describe key concepts as well as various methods of SIL selection and verification.

### **RISK AND SAFETY INTEGRITY – GENERAL CONCEPTS (Annex A)**

This annex describes the required safety actions to bridge the gap between the current level of risk present in the system and the level that can be tolerated in the given situation. This necessary risk reduction is noted to include contributions from E/E/PE safety-related systems, other safety-related systems, and external risk reduction methods. Elements of safety integrity relating to both the hardware and the overall systematic safety integrity are sometimes difficult to assess. This is part of the basis for SIL only referring to the order of magnitude of risk reduction for a safety-related system.

### **ALARP AND TOLERABLE RISK CONCEPTS (Annex B)**

Annex B describes the concept of a finite level of tolerable risk based on the benefits derived from undertaking that risk in the context of the norms of society. It further describes the reduction of existing risk to a level “As Low As Reasonably Practicable” or ALARP. This level again takes into account the benefits derived from the risk as well as the costs to reduce the risk even further.

### **DETERMINATION OF SAFETY INTEGRITY LEVELS – A QUANTITATIVE METHOD (Annex C)**

This quantitative method presented is based on calculating a frequency of a hazard and the magnitude of its consequences to determine the difference between the existing risk and the tolerable risk. First the frequency of the initiating event is determined based on either local operating experience, failure rate database references for similar equipment in similar environments, or detailed analytical estimation. Then the probabilities that the initiating event will actually lead to the hazard are determined and combined with the initiating event to determine a hazard frequency. In parallel, the consequence of the hazard is calculated. Finally, the frequency and consequence of the hazard are assessed relative to the tolerable risk and a SIL is selected to bridge any gap.



Exida provides training, software, and services in support of this vital safety process. Training includes hazards analysis to identify hazards and Layer of Protection Analysis (LOPA) quantify the risk. Software includes PROBE™ to quantify the hazard probability and FurnEX and PhysEX to quantify the consequences. In addition to providing structure and computational support for the analyses, the software also provides easy standardized documentation of the process and results to support compliance with the standards.

#### DETERMINATION OF SAFETY INTEGRITY LEVELS – A QUALITATIVE METHOD: RISK GRAPH (Annex D)

This method assigns a category to both the frequency and severity of a hazard to assess the risk relative to the tolerable level. Some allowance is made for the likelihood that a given initiating event will not always lead to the potential hazard.

#### DETERMINATION OF SAFETY INTEGRITY LEVELS – A QUALITATIVE METHOD: HAZARDOUS EVENT SEVERITY MATRIX (Annex E)

This method is similar to the risk graph except that the form follows a matrix rather than a sequential graph.

## **7 Part 6: Guidelines in the Application of Parts 2 and 3 (Informative)**

Part 6 provides more detailed explanations and examples on how to comply with Parts 2 and 3 and also is made up almost entirely of Annexes.

#### APPLICATION OF PARTS 2 AND 3 (Annex A)

This annex shows flow charts of the expected implementation of both Part 2 (Hardware) and Part 3 (Software) and provides an overview of the requirements.

#### EXAMPLE TECHNIQUE FOR EVALUATING PROBABILITIES OF FAILURE (Annex B)

This annex provides an example of evaluating probabilities of failure with many tables showing results for particular architectures for selected values of diagnostic coverage and common cause beta factors (factors assessing the likelihood of a common cause failure). The methods used for these calculations are approximation formulas based on reliability block diagrams. These methods consider the hardware train of field sensor, logic box, and final control element and address various architecture configurations.

#### CALCULATION OF DIAGNOSTIC COVERAGE: WORKED EXAMPLE (Annex C)

This annex covers the Failure Modes, Effects, and Diagnostics Analysis (FMEDA) technique for calculating diagnostic coverage factor. This method is similar to the method in ISA TR84.02 and the exida.com FMEDA template tool. All methods use identical techniques.

#### A METHODOLOGY FOR QUANTIFYING THE EFFECT OF HARDWARE-RELATED COMMON CAUSE FAILURES IN MULTI-CHANNEL PROGRAMMABLE ELECTRONIC SYSTEMS (Annex D)

This annex explains the important phenomenon of common cause failures in redundant systems. A chart is provided along with a method of estimating the beta factor (factor assessing the likelihood of a common cause failure) to be used in subsequent calculations.



## EXAMPLE APPLICATION OF SOFTWARE SAFETY INTEGRITY TABLES OF PART 3 (Annex E)

This annex provides an example of how to use the software safety integrity level tables of Part 3. Twenty tables are provided with detailed examples of a SIL2 ladder logic program with PLC hardware and a SIL3 full pre-coded complex plant system.

## 8 Part 7: Overview of Techniques and Measures (Informative)

Part 7 provides descriptions and an explanation of the many engineering techniques presented earlier in the standard.

### OVERVIEW OF TECHNIQUES AND MEASURES FOR E/E/PES: CONTROL OF RANDOM HARDWARE FAILURES (Annex A)

This annex addresses random hardware failures. It contains methods and techniques useful to prevent or maintain safety in the presence of component failures. The explanations provided here support many of the recommended techniques listed in the hardware tables in Part 2.

### OVERVIEW OF TECHNIQUES AND MEASURES FOR E/E/PES: AVOIDANCE OF SYSTEMATIC FAILURES(Annex B)

This annex covers the avoidance of systematic failures in both hardware and software systems and is referenced by Parts 2 and 3. It is structured according to the safety life cycle and addresses numerous points relevant to the key phases as noted in the annex.

### OVERVIEW OF TECHNIQUES AND MEASURES FOR ACHIEVING SOFTWARE SAFETY INTEGRITY (Annex C)

This annex provides an overview of techniques for achieving high software safety integrity. Many of these techniques fall into the detailed design phase of the life cycle. Architectural design issues are also addressed as well as development tools and programming languages. The annex also addresses the verification, modification, and functional safety assessment phase of the life cycle.

### PROBABILISTIC APPROACH TO DETERMINING SOFTWARE SAFETY INTEGRITY FOR PRE-DEVELOPED SOFTWARE (Annex D)

The annex covers a probabilistic approach for SIL determination of proven software. With many systems seeking to employ previously written software, this annex can be valuable. It lists several tests to determine the integrity level of the software based on statistical analysis.

## 9 Additional IEC 61508 Information

exida offers a two-day course that provides an “Introduction to IEC 61508.” This course covers the IEC 61508 standard from the perspective of a user (project orientation) or a product manufacturer (product orientation). All of the basic principles are covered with exercises to



reinforce the material. The training manual is available separately from the exida.com online store for those wishing to investigate this further.

There is of course no substitute to the purchase and study of the actual standard for those wanting more in-depth knowledge. The entire seven sections total over 400 pages and are available from the International Electrotechnical Commission, Geneva, Switzerland, or from many national standards bodies.

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