

I requisiti delle Norme IEC EN 61508 Ed 2: 2010 e IEC EN 61511 Ed. 2: 2016

18 Febbraio 2016

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Associazione Italiana Strumentisti





Move Forward with Confidence



Agenda

- ► The Norm IEC EN 61508 Ed. 2: 2010 overview
 - Normative & informative requirements
- ► The *new* Norm IEC EN 61511 Ed. 2: 2016 overview
 - Normative & informative requirements
- Norms relevant clauses in safety-related system design and operation





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



- International standard and European standard EN 61508 Ed. 2: 2010
- ⇒ Basic Safety Standard
- Official issue in March 2010 Ed. 2 but already used since 10 years
- ⇒7 volumes
- ⇒ More than 1000 requirements



-"Functional Safety of Electrical/Electronic/Programmable

- Electronic Safety-related Systems"
- Part 1: General Requirements

Part2 : Requirements for Electrical/ Electronic/Programmable Electronic Safety-related Systems (E/E/PES)

- □ Part 3: Software Requirements
- Part 4: Definitions and Abbreviations
- □ Part 5: Examples of Methods for the Determination of SILs
- □ Part 6: Guidelines on the Application of Parts 2 and 3
- □ Part 7: Overview of Techniques and Measures



- Part 1 Clause 4
- To conform to the std it shall be demonstrated that the requirements have been satisfied to the required critieria specified (for example safety integrity level) and therefore, for each clause or subclause, all the objectives are met
- Parts 1, 2, 3 & 4 are normative
- Parts 5, 6 & 7 are informative



SAFETY SYSTEMS FOR UNFIRED PRESSURE VESSELS

- § Accessories
- ARTT. 9, 13: DLGS 329: commissioning and periodic tests

(HIPPS VS PSV, RD)



► § 5: DOCUMENTATION

▶ § 6: FUNCTIONAL SAFETY MANAGEMENT

▶ § 7: LIFE CYCLE SAFETY REQUIREMENT

§ 8:FUNCTIONAL SAFETY ASSESSMENT

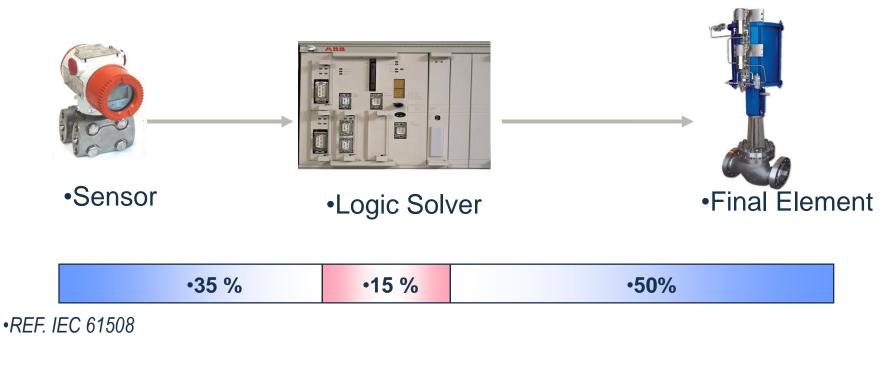




A SAFETY-RELATED ELEMENT IS A PART OF A SAFETY -INSTRUMENTED SYSTEM

Basic SIS structure and subsystem PFDavg/PFH allocation ratio

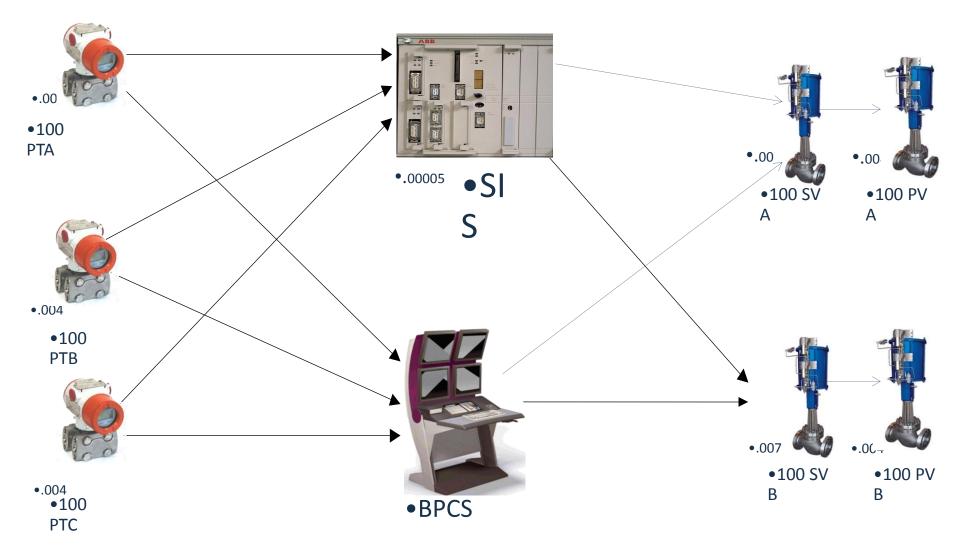




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Bubble Diagram showing the PFDavg of each SIS device





The Norm IEC EN 61508 Ed. 2: 2010 overview: Normative & informative requirements

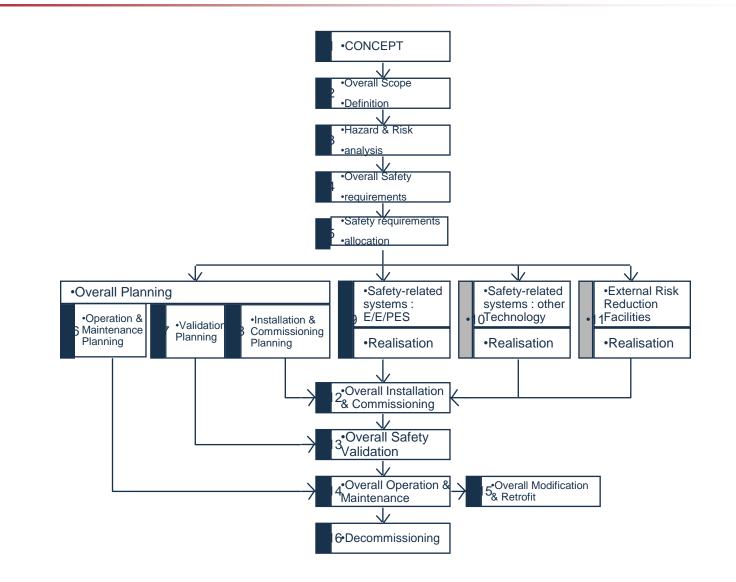


The Life Cycle

► SIL

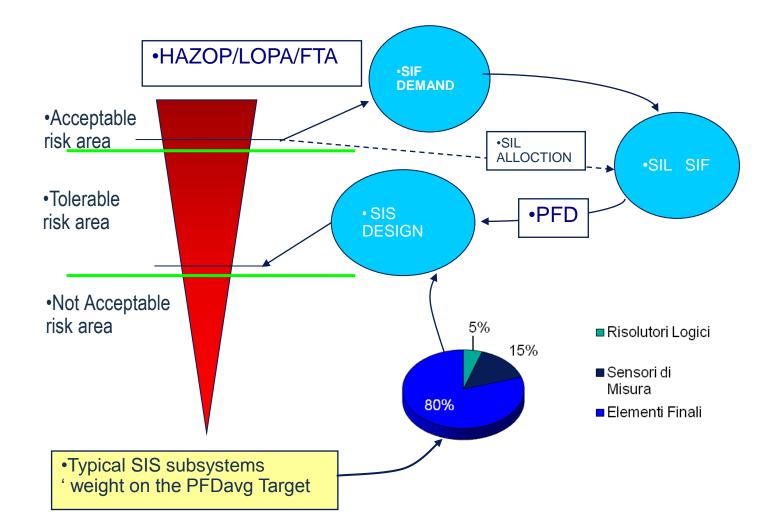
The Life Cycle





SIS Assessment Process (SIS)







Definition

- Characterization
- Functional safety
 - Failure rates
 - Safety Integrity hardware
 - Capability (systematic integrity)



Probability of an E/E/PE safety-related system satisfactorily performing the specified safety functions under all the stated conditions within a stated period of time



Function to be implemented by an E/E/PE safety-related system or other risk reduction measures, that is intended to achieve or maintain a safe state for the EUC, in respect of a specific hazardous event.



Probability of an E/E/PE safety-related system satisfactorily performing the specified safety functions under all the stated conditions within a stated period of time



Safety Integrity Level (SIL)	Low Demand Mode of Operation (Average probability of failure to perform its design function on demand: PFDavg)	High Demand or continuous Mode of Operation (Probability of <i>dangerous</i> failure per hour: PFH)
SIL 4	>=10 ⁻⁵ to <10 ⁻⁴	>=10 ⁻⁹ to <10 ⁻⁸
SIL 3	>=10 ⁻⁴ to <10 ⁻³	>=10 ⁻⁸ to <10 ⁻⁷
•SIL 2	•>=10 ⁻³ to <10 ⁻²	•>=10 ⁻⁷ to <10 ⁻⁶

Safety Integrity



□In determining safety integrity, all causes of failures (both <u>random</u> hardware failures and <u>systematic</u> failures) that lead to an unsafe state should be included, for example hardware failures, software induced failures and failures due to electrical interference. Some of these types of failure, in particular random hardware failures, may be quantified using such measures as the average frequency of failure in the dangerous mode of failure or the probability of a safety-related protection system failing to operate on demand. However, safety integrity also depends on many factors that cannot be accurately quantified but can only be considered qualitatively.

□Safety integrity comprises *hardware* safety integrity and *systematic* safety integrity.

□This definition focuses on the *reliability* (dependability) of the safety-related systems to perform the safety functions .



- Systematic safety integrity
- •Part of the safety integrity of a safety-related system relating to <u>systematic</u> failures in a dangerous mode of failure
- •<u>NOTE:</u> Systematic safety integrity cannot usually be quantified (as distinct from hardware safety integrity which usually can).

Hardware safety integrity

•Part of the safety integrity of a safety-related system relating to <u>random</u> hardware failures in a dangerous mode of failure



•Dangerous failure

•failure of an element and/or subsystem and/or system that plays a part in implementing the safety function that:

•a) **prevents** a safety function from operating when required (demand mode) or causes a safety function to **fail** (continuous mode) such that the EUC is put into a hazardous or potentially hazardous state; or

•b) **decreases** the probability that the safety function operates correctly when required

Safe failure

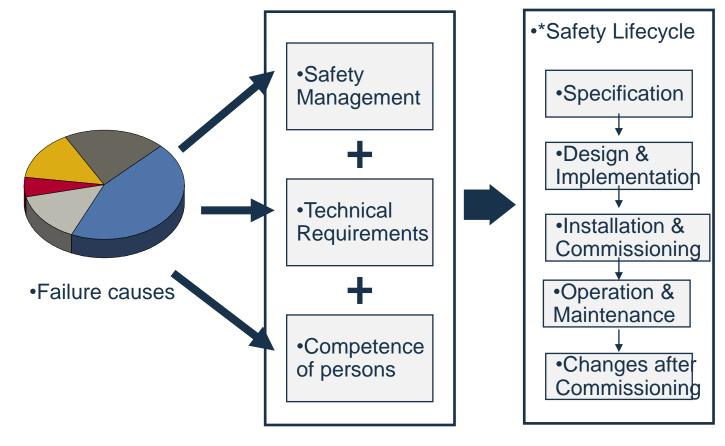
•failure of an element and/or subsystem and/or system that plays a part in implementing the safety function that:

•a) results in the **Spurious operation** of the safety function to put the EUC (or part thereof) into a safe state or maintain a safe state; or

•b) **increases** the probability of the spurious operation of the safety function to put the EUC (or part thereof) into a safe state or maintain a safe state

The Functional Safety Strategy





•* Simplified view



This annex limits the maximum diagnostic coverage that may be claimed for relevant techniques and measures. For each safety integrity level, the annex recommends techniques and measures for controlling random hardware, systematic, environmental and operational failures.

NOTE 2 The designations low, medium and high diagnostic coverage are quantified as 60 %, 90 % and 99 % respectively.

7.4.10 Requirements for proven in use elements (Manufacturer)



7.4.10.4 A proven in use safety justification shall be documented, using the information available from 7.4.10.2, that the element supports the required safety function with the required systematic safety integrity. This shall include:

a) the suitability analysis <u>and</u> testing of the element for the intended application;

•b) the demonstration of equivalence between the intended operation and the previous operation experience, including the impact analysis on the differences;

•c) the statistical evidence.

Overview of IEC EN 61508 Ed.2 & IEC EN 61511 Ed.1 Norms – Essential topics



IEC 61508 IS A BASIC STANDARD – IT APPLIES TO SAFETY-RELATED ELEMENTS AND PROVIDES INFORMATION FOR THE WHOLE SAFETY- RELATED SYSTEMS DESIGN AND OPERATION

IEC 61511 APPLIES SPECIFICALLY FOR THE DESIGN AND OPERATION OF SAFETY INSTRUMENTED SYSTEMS



- § 7.4.4.1.2 A SUBSYSTEM CAN BE REGARDED AS TYPE "A" IF, FOR THE COMPONENTS REQUIRED TO ACHIEVE THE SAFETY FUNCTION:
 - a) THE FAILURE MODE OF ALL CONSTITUENT COMPONENTS ARE WELL DEFINED, AND
 - b) THE BEHAVIOUR OF THE SUBSYSTEM UNDER FAULT CONDITIONS CAN BE COMPLETELY DETERMINED; AND
 - c) THERE IS SUFFICIENT DEPENDABLE FAILURE DATA FROM FIELD EXPERIENCE TO SHOW THAT CLAIMED RATES OF FAILURE FOR DETECTED AND UNDETECTED DANGEROUS FAILURES ARE MET (SEE 7.4.9.3 TO 7.4.9.5)





- Functional safety management
- Safety life cycle requirements
- Verification
- Validation



§ 7.4.4.1.3 - A SUBSYSTEM CAN BE REGARDED AS TYPE "B" IF, FOR THE COMPONENTS REQUIRED TO ACHIEVE THE SAFETY FUNCTION:

- a) THE FAILURE MODE OF ALL CONSTITUENT COMPONENTS ARE NOT WELL DEFINED, AND
- b) THE BEHAVIOUR OF THE SUBSYSTEM UNDER FAULT CONDITIONS CANNOT BE COMPLETELY DETERMINED; AND
- c) THERE IS NOT SUFFICIENT DEPENDABLE FAILURE DATA FROM FIELD EXPERIENCE TO SHOW THAT CLAIMED RATES OF FAILURE FOR DETECTED AND UNDETECTED DANGEROUS FAILURES ARE MET (SEE 7.4.9.3 TO 7.4.9.5)

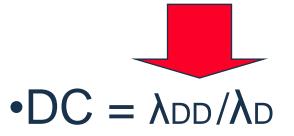


§ 7.4.4.1.2 - A SUBSYSTEM CAN BE REGARDED AS TYPE "A" IF, FOR THE COMPONENTS REQUIRED TO ACHIEVE THE SAFETY FUNCTION:

- a) THE FAILURE MODE OF ALL CONSTITUENT COMPONENTS ARE WELL DEFINED, AND
- b) THE BEHAVIOUR OF THE SUBSYSTEM UNDER FAULT CONDITIONS CAN BE COMPLETELY DETERMINED; AND
- c) THERE IS SUFFICIENT DEPENDABLE FAILURE DATA FROM FIELD EXPERIENCE TO SHOW THAT CLAIMED RATES OF FAILURE FOR DETECTED AND UNDETECTED DANGEROUS FAILURES ARE MET (SEE 7.4.9.3 TO 7.4.9.5)



$$\begin{split} \lambda &= \lambda S + \lambda U \\ \lambda S &= \lambda S D + \lambda S U \\ \lambda D &= \lambda DU + \lambda DD \end{split}$$



•DCpst, vi , cm = λ DD, PST, VI, cm / λ D

•SFF% = $(\lambda S + \lambda DD) / \lambda$

•MTTF = 1/ λ_t

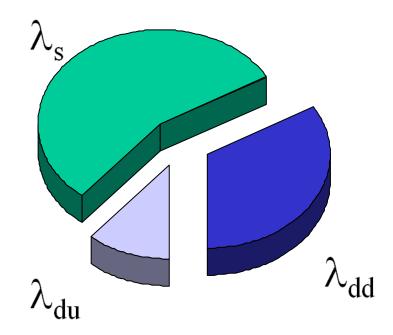
•MTTFs = 1/ λ_{SAFE}





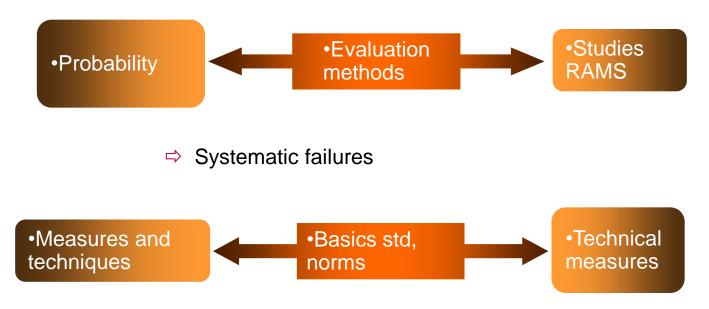


FAILURE RATES AND RELATED PARAMETERS (SFF, DC) ARE CONCERNING TO SAFETY REQUIREMENTS SPECIFICATIONS





⇒ Random failures





ARCHITECTURAL CONSTRAINTS ON TYPE A SAFETY-RELATED SUBSYSTEMS-HARDWARE FAULT TOLERANCE (EN 61508)

Safe Failure Fraction	0	1	2
< 60%	SIL 1	SIL 2	SIL 3
60%-<90%	SIL 2	SIL 3	SIL 4
90%- <99%	SIL 3	SIL4	SIL 4
>= 99%	SIL 3	SIL 4	SIL 4



§ 7.4.4.1.3 - A SUBSYSTEM CAN BE REGARDED AS TYPE "B" IF, FOR THE COMPONENTS REQUIRED TO ACHIEVE THE SAFETY FUNCTION:

a) THE FAILURE MODE OF ALL CONSTITUENT COMPONENTS ARE NOT WELL DEFINED, AND

b) THE BEHAVIOUR OF THE SUBSYSTEM UNDER FAULT CONDITIONS CANNOT BE COMPLETELY DETERMINED; AND

c) THERE IS NOT SUFFICIENT *DEPENDABLE* FAILURE DATA FROM FIELD EXPERIENCE TO SHOW THAT CLAIMED RATES OF FAILURE FOR DETECTED AND UNDETECTED DANGEROUS FAILURES ARE MET (SEE 7.4.9.3 TO 7.4.9.5)

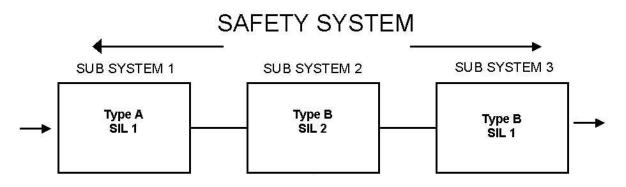


ARCHITECTURAL CONSTRAINTS ON TYPE B SAFETY-RELATED SUBSYSTEMS-HARDWARE FAULT TOLERANCE (EN 61508)

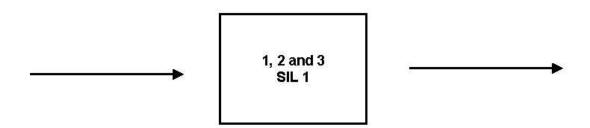
Safe Failure Fraction	0	1	2
•< 60%	•NOT ALLOWED	•SIL 1	•SIL 2
•60%- <90%	•SIL 1	•SIL 2	• SIL 3
•90%- <99%	• SIL 2	• SIL3	• SIL 4
•>= 99%	• SIL 3	• SIL 4	• SIL 4



 Ciascun blocco deve avere la classificazione SIL anche in termini di PFDavg /PFH

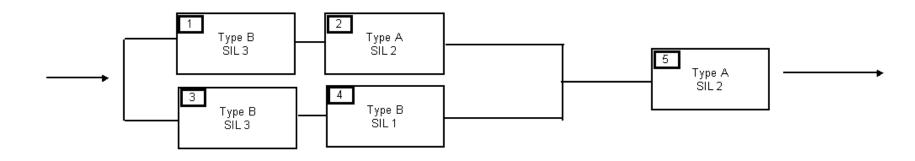


- Il blocco SIL 1 compromette la funzione di sicurezza dle blocco SIL 2
- Il blocco risultante è SIL 1



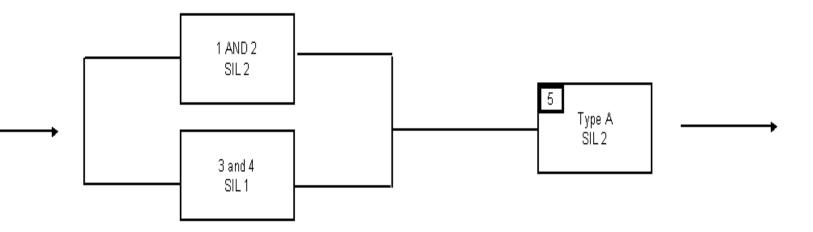


Consideriamo il seguente sistema

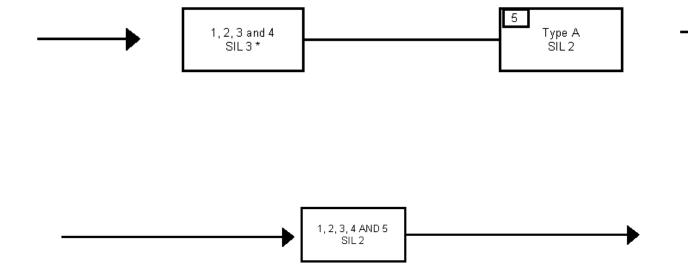




- I due blocchi serie possono essere semplificati in un blocco ciascuno
- Per i blocchi in parallelo dobbiamo considerare la tolleranza al guasto di ciascun blocco



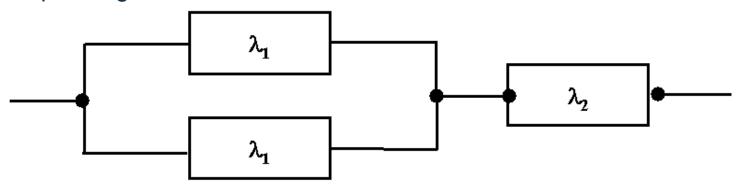




I Guasti di modo comune



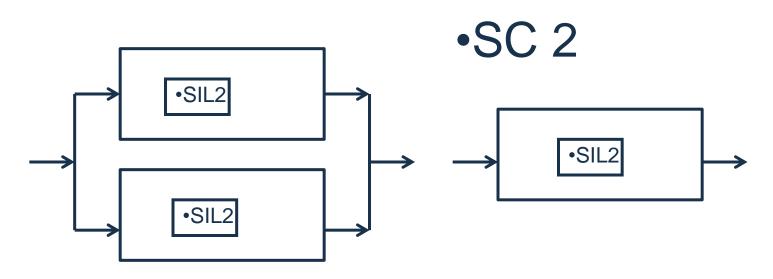
• E' possibile che uno o più canali ridondanti possano guastarsi per un guasto comune



- In questa situazione la ridondanza non è efficace
- Il fattore di guasto di modo comune, indicato con ß, è particolarmente critico per i canali ridondanti identici.

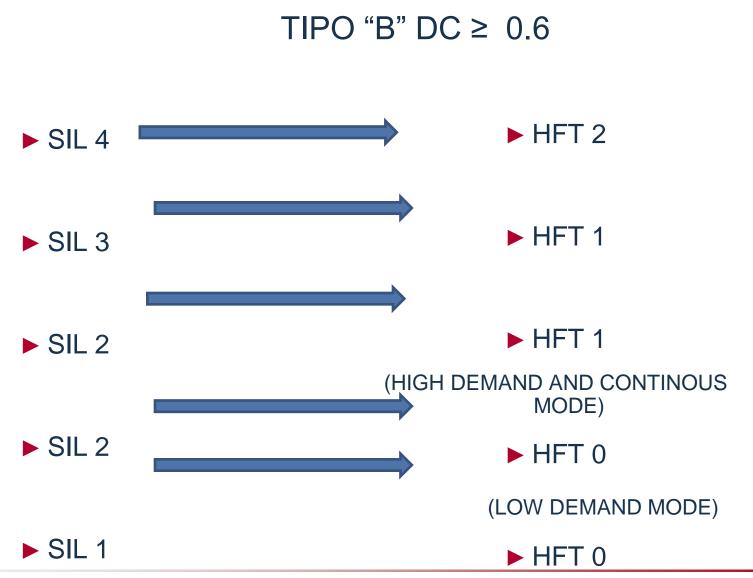
Systematic Capability (SC)





- La "Systematic capability" 2 vincola il livello SIL level nelle architetture di canali identici
- In questa situazione la ridondanza non è efficace





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PART 2, Hardware fault TOLEERANCE: Route 2H § 7.4.4.3.2



For type A elements only, if it is determined that by following the HFT requirements specified in 7.4.4.3.1, for the situation where an HFT greater than 0 is required, it would introduce additional failures and lead to a decrease in the overall safety of the EUC, then a safer alternative architecture with reduced HFT may be implemented. In such a case this shall be justified and documented. The justification shall provide evidence that:

a) compliance with the HFT requirements specified in 7.4.4.3.1 would introduce additional

• failures and lead to a decrease in the overall safety of the EUC; and

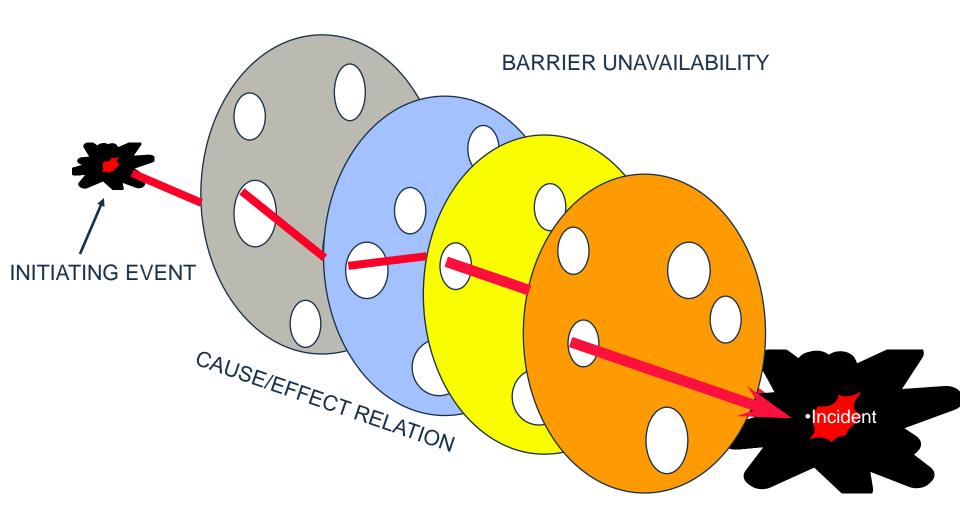
b) if the HFT is reduced to zero, the failure modes, identified in the element performing the

- safety function, can be excluded because the dangerous failure rate(s) of the identified
- failure mode(s) are very low compared to the target failure measure for the safety function
- under consideration (see 7.4.4.1.1 c)). That is, the sum of the dangerous failure
- Frequencies of all serial elements, on which fault exclusion is being claimed, should not
- exceed 1 % of the target failure measure. Furthermore the applicability of fault exclusions
- shall be justified considering the potential for systematic faults





INDEPENDENT PROTECTION LAYER CONCEPT



The Process Plant protection layers



	•Evacuation plan					
Protection	•Fire protection system					
	•Physical relief & protection					
	•Safety instrumented system					
Prevention	•Alarm system					
	•Control system					

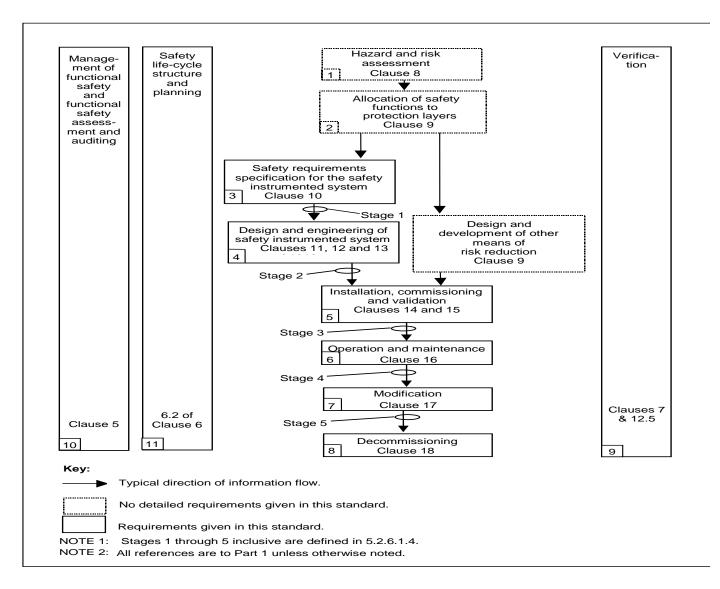


A.1 Application Differences:

- IEC61511 relates solely to the process sector, while IEC61508 relates to all industrial sectors (e.g., machinery, process, medical, rail).
- IEC61511 addresses the process sector owner/user applications, while IEC61508 addresses the manufacturers' design requirements for the E/E/PE elements and related equipment requirements necessary to achieve the SIL claim limit assigned to each E/E/PE element and related equipment.
- IEC61511 does not address software, while IEC61508 does address software (i.e., full variability programming) utilized in SIS elements and equipment.

IEC61511 addresses application programming (i.e., limited variability languages and fixed variability language) utilized in the process sector applications.

IEC 61511 LIFECYCLE





- ► DEFINITIONS
- ► SIL4
- ► HARDWARE FAULT TOLERANCE RULES
- BCPS/CONTROL SYSTEM
- ► APPLICATION SOFTWARE
- SAFETY MANUAL



SAFETY INTEGRITY = DEPENDABILITY (J. C, Laprie, 1989)

dependability is a measure of a system's availability, reliability, and its maintainability. This may also encompass mechanisms designed to increase and maintain the dependability of a system.

DIAGNOSTIC COVERAGE

- FRACTION OF DANGEROUS FAILURES
- ► FAULT EXCLUSION (REF. EN 13 849) ROUTE 2H, § 7.4.4.3.2
- PRIOR USE = PROVEN IN USE

Improvements



- ► APPLICATION PROGRAM SIS SAFETY LIFE CYCLE REQUIREMENTS
- SECURITY RISK ASSSESSMENT (SIS VULNERABILITY) OBLIGATION WITH OWNER
- ► SAFETY REQUIREMENTS SPECIFICATION EXTENSION
 - PROCESS OPERATING MODES
 - EXTREMES OF ENVIRONMENTAL CONDITIONS DURING SHPPING SORAGE, INSTALLTION AND EPERATION
- HARDWARE FAULT TOLERANCE
- ROUTE 2H
- ▶ § 11.4.6, § 11.4.7, § 11.4.8, § 11.4.9



	IEC 61511 – Minimum hardware fault tolerance							
	Table 5 – PE logic solvers				Table 6 – other devices			
SIL	Minimum hardware fault tolerance				SIL	Minimum hardware fault tolerance		
	SFF< 60%	SFF 60% to 90%	SFF >90%					
1	1	0	0		1	0		
2	2	1	0		2	1		
3	3	2	1		3	2		
4	see IEC 61508				4	see IEC 61508		

Table 3 from IEC 61508 – Architectural constraints on Type B							
Safe Failure Fraction	Hardware fault tolerance						
	0	1	2				
<60%	Not Allowed	SIL1	SIL2				
60% to <90%	SIL1	SIL2	SIL3				
90% to <99%	SIL2	SIL3	SIL4				
≥99%	SIL3	SIL4	SIL4				



SIL	Minimum required HFT			
1 (Any mode)	0			
2 (low demand mode)	0			
2 (high demand/continuous mode)	1			
3 (Any mode)	1			
4 (Any mode)	2			

11.4.6 If the minimum HFT as specified in Table 6, would result in decreased overall process safety then the HFT may be reduced. This shall be justified and documented. The justification shall provide evidence that the proposed architecture is suitable for its intended purpose and meets the safety integrity requirements.



General requirements

11.5.2.1 Components and subsystems selected for use as part of a safety instrumented system for SIL 1 to SIL 4 applications shall either be in accordance with IEC 61508-2 and IEC 61508-3, as appropriate, or else they shall be in accordance with 11.4 and 11.5.3 to 11.5.6, as appropriate.

11.5.2.2

For an SIS implementing a SIL 4 functions then the following shall apply:

- a) All system elements shall be proven by prior use in safety applications
- b) hard wired non programmable elements shall be used

The Safety Manual (IEC 761508-2, ANNEX D)



- D1. The purpose of the safety manual for compliant items is to document all the information, relating to a compliant item, which is required to enable the integration of the compliant item into a safety-related system, or a subsystem or element, in compliance with the requirements of this standard.
- ► D.2.2 For every function, the safety manual shall contain:

.

- d) the failure modes of the diagnostics, internal to the compliant item (in terms of the behaviour of its outputs), due to random hardware failures, that result in a failure of the diagnostics to detect failures of the function;
- i) for those failure modes, in respect of a specified function, that are capable of being detected by external diagnostics, sufficient information shall be provided to facilitate the development of an external diagnostics capability. The information shall include details of failure modes and for those failure modes the failure rates.

What is stated in IEC 61511-1



3.2.73 safety manual functional safety manual

information that defines how a SIS device, subsystem or system can be safely applied

NOTE 1: The safety manual may include inputs from the manufacturer as well as from the user.

NOTE 2: For IEC 61508 compliant devices, the manufacturer's input is the safety manual,

NOTE 3: This could be a generic stand-alone document, or a collection of documents.

NOTE 4: This definition deviates from the definition in IEC 61508-4:2010 to reflect differences in process sector terminology.

11.2.13 A safety manual covering operation, maintenance, fault detection and constraints associated with the SIS shall be available covering the intended configurations of the devices and the intended operating environment.



- is the responsibility of end user
- Is not made generic, but for a specific installation/application
- comprises input from SMs per IEC 61508 (for IEC 61508 compliant items) plus other input needed to document safe use of prior use components and/or logic solvers and SIS loops.

What is stated in IEC 61511-1



3.2.73 safety manual functional safety manual information that defines how a SIS device, subsystem or system can be safely applied NOTE 1: The safety manual may include inputs from the manufacturer as well as from the user.

NOTE 2: For IEC 61508 compliant devices, the manufacturer's input is the safety manual,

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11.2.13 A safety manual covering operation, maintenance, fault detection and constraints associated with the SIS shall be available covering the intended configurations of the devices and the intended operating environment.



But is not this type of information already provided in other documents provided by many manufacturers and system integrators?



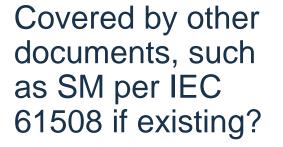
IEC 61511-2 says:

The purpose of the safety manual is to document all the necessary information related to how a device, SIS subsystem, or system can be **safely applied**.[A.11.2.13] Proposed content (A.11.2.13):

- Description and topology
- Revision and constraints (AP, HW, FW)
- Operational description, incl. fail-safe operation
- Assumptions related to operation, maintenance, and testing
- Restrictions safety functions (e.g. configuration settings)
- ► Failure modes and rates
- Other reliability data (DC, MTTR, test intervals)



Some of this information is beyond "can be safely applied"?



Proposed content (A.11.2.13):

- Description and topology
- Revision and constraints (AP, HW, FW)
- Operational description, incl. fail-safe operation
- Assumptions related to operation, maintenance, and testing
- Restrictions safety functions (e.g. configuration settings)
- ► Failure modes and rates
- Other reliability data (DC, MTTR, test intervals)

Points for discussion

Produced by whom?

End users involvement and responsibility. Allocated to system integrator/engineering during project execution, but what about operational phase?

Produced when:

- During design phase
- Must be provided for non-compliant items
- Must be provided for plant-specific considerations: application program, proof testing of subsystems and whole loop

Purpose?

- What is necessary to demonstrate "can be safety applied"?
- Focus on compliance to safe design requirements, or the application (operation, maintenance and modifications)?
- Example: How to carry out proof tests (beyond function testing)

Relation to other documents:

Manufacturer & system integrators input is SM per IEC 61508 and "Operation and maintenance manual+"



Points for discussion



"Device". Lowcomplexity, non E/E/PE

IEC 61508 SM only

Or IEC 61511 SM for prior use

"Logic solver with application program"



IEC 61508 SM

IEC 61511 SM to cover application program & interface

What type of

safety manual?

"VSD drive"

IEC 61508 SM (if existing)

IEC 61511 SM to cover installation-specific issues

"Device": E/E/PE



IEC 61508 SM only

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Safety manual for device (field devices):

- ▶ Per 61508 OR
- Per IEC 61511

Safety manual a subsystem (e.g. logic solver):

- Safety manual per 61508 for generic typicals
- Safety manual per IEC 61511 for application program and plant specific considerations
- Can be covered by "updating" the operation and maintenance manual?

Safety manual for a whole SIS system:

- Non-existing
- SRS gives references to all SMs and compliance reports

Safety manual in GL070



- Called "Safety analysis report" (SAR)
- Introduced as a concept in 2004
- SAR shall document the SIL capability of the various SIS equipment and components. These reports may include a number of assumptions that have relevance for operation:
 - Requirements and recommendations related to operation, maintenance and proof testing (e.g. tools, methods and test intervals)
 - Constraints related to response times, closure times, demand rates and other parameters relevant for the SIS performance



- Main purpose is to demonstrate compliance of a delivery ("specific application")
- To be produced by each equipment supplier
- Can be more simple and generic for devices
- More extensive for subsystems (logic solvers) and systems (fire detection system, fire pump system) – and may comprise generic as well as application specific information

Same as SM per IEC 61511?

Extensive version:

SAR Table of content - example

I Abbreviations II References III Summary

- 1. Introduction
- 2. System Description
- 3. System Topology and Block Diagram
- 4. Operational description of the system (including modes of operation)
- 5. Assumptions
- 6. Failure rate of the components
- 7. Common Cause failures (CCF)
- 8. Diagnostic Coverage & Safe Failure Fraction
- 9. Behaviour of system/components on detection of a fault
- 10. Factory testing
- 11. Proof testing
- 12. Architectural Constraints
- 13. Avoidance and Control of Systematic Failures
- 14. Effective time to repair
- 15. Software documentation
- 16. Results
- Appendices

Concluding remarks and basis for further discussions



- It is not very clear what the safety manual should contain
 - Modify/align existing operation and maintenance manual
- Collection of information/document that is not covered elsewhere or where the information would be difficult to subtract from a high number of document, e.g. proof/function test strategy and constraints/restrictions to consider in case of modifications.
- For whom should the manual be prepared?
 - Hardware designers
 - Assessors and reliability analysts
 - Application program developers
 - Engineers in end user organization ("equipment responsible")?
 - Operators and maintenance personnel in plant?



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