

# IEC 61511 – an aid to COMAH and Safety Case Regulations compliance

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## INTRODUCTION

There are specific safety related regulations for the UK offshore and onshore processing sectors. Safety Case Regulations (SCR)<sup>(1)</sup> apply to the offshore sector for oil and gas related processing, whilst the onshore process sector comes under the Control of Major Accident Hazards Regulations 1999 (COMAH)<sup>(2)</sup> regulations which are applicable to the chemical industry, some storage facilities, explosives and nuclear sites and any other industries where threshold quantities (as defined by the Regulations) of dangerous substances are kept or used.

SCR came into existence for the UK Offshore oil and gas processing sector in 1992 to implement the findings of the Lord Cullen Enquiry<sup>(3)</sup> following the 1988 Piper Alpha disaster, which took 167 lives.

SCR are underpinned by the Offshore Installation (Prevention of Fire and Explosion, and Emergency Response) Regulations 1995 (SI 1995/743) (PFEER)<sup>(4)</sup>, and the Offshore Installations and Wells (Design and Construction, etc) Regulations (SI 1996/913) (DCR)<sup>(5)</sup>. PFEER is focussed on identifying and preventing fire and explosion hazards, protecting persons from the effects, and securing effective response to emergencies, whilst DCR seek to 'ensure that the level of the integrity of the installation is as high as reasonably practicable at all times, and that risks to people on an installation arising from matters of integrity, are kept as low as reasonably practicable'. This includes the design, modifications, operation and maintenance.

DCR also amend the SCR to 'require an installation duty holder to ensure that a verification scheme is drawn up covering the safety-critical elements of the installation'.

COMAH replaced the Control of Major Accident Hazards Regulations (CMAH), which had been around since 1984, in order to provide a degree of uniformity with SCR. Thus there are many similarities between the two regulations, and both require operators to demonstrate that they have a Safety Management System (SMS) in place as part of the overall management system. SCR require a Safety Case to be submitted to the UK Health and Safety Executive for every offshore installation, whilst Upper and Lower Tier COMAH sites are required to submit a Safety Report. These have to address hazards with the potential to cause a major accident and demonstration of the adequacy of the Safety Management System.

It is accepted that the management of safety, like most other business management, is now a risk based approach and that is the basis of the SMS within COMAH and SCR. This is also the approach of the IEC 61511<sup>(6)</sup> (Functional Safety: Safety Instrumented Systems for the Process Industry Sector) standard and this paper will outline the synergy between the two Regulations and IEC 61511.

The essence of a Safety Management System is to demonstrate: (IEC 61511<sup>(6)</sup> is outlined in the next section but key words that dovetail with this standard have been highlighted below)

- a) the organisation of personnel involved in **major hazard management** and provision of **training**;
- b) **identification of major hazards, likelihood and severity**;
- c) **operational control** including **maintenance of plant, processes and equipment**;
- d) **management of change** including **design** of new installations and processes;
- e) **planning** for emergencies;
- f) **monitoring performance**;
- g) **audit and review** of the SMS.

The minimum information to be included in a Safety Report can be summarised as follows:

1. Information on the management system with a view to major accident prevention.
2. Presentation of the environment of the establishment:
  - site description, environment, geographical location etc.;
  - **identification** of installations and activities presenting a major accident **hazard**;
  - description of areas where a major accident may occur.
3. Description of the installation:
  - main activities and products from the **major accident risks** perspective with proposed **preventative measures**;
  - description and inventory of dangerous substances;
4. Identification of **accidental risks and prevention** methods:
  - details of possible **major accident scenarios, triggers and probability**;
  - **assessment of the severity of the consequences** of identified major accidents;
  - description of technical parameters and **equipment used for the safety of installations**.
5. Measures of **protection and intervention to limit the consequences** of a major accident:
  - description of the **equipment installed in the plant to limit the consequences** of major accidents;
  - organisation of **alert** and intervention;
  - description of mobilised resources, internal and external;
  - summary of the elements necessary for the on-site emergency plan.

The paper focuses on the relationship between hazards and Safety Instrumented Systems (SIS) that automatically shut down processes operations, when an abnormal situation is encountered, to prevent a hazardous event or mitigate the consequences of a hazardous event if it occurs (see section - Safety Instrumented Systems). Thus a SIS will represent an integral part of an SMS to reduce the risk of major accident hazards or mitigate the consequences.

It is unfortunate that the terminology used in the two Regulations is often different (e.g. Safety Case and Safety Report) and throughout the rest of this paper it will not be possible to use specific references to both SCR and COMH Regulations, so the requirements that are stated have often been made in a generic sense for both Regulations.

If the ‘key’ words from the SMS and Safety Case/Report framework are examined and compared to the requirements of IEC 61508 <sup>(7)</sup> and IEC 61511, it can be seen that there is a very good fit with the following aspects that need to be addressed:

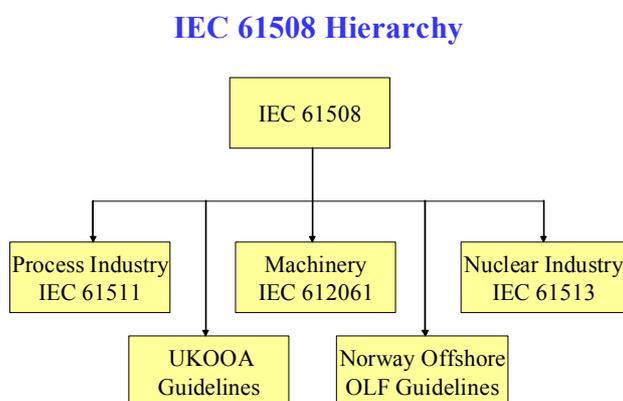
- Hazards are identified;
- The likelihood of occurrence is determined;
- Consequences are assessed;
- Safety critical elements protecting persons from hazards are identified;
- Risks are kept as low as reasonably practicable (ALARP);
- Design is appropriate;
- There is an audit trail for the decision making process;
- Modifications/changes are properly designed and controlled;
- Operations do not compromise integrity;
- Performance standards are set;
- Operation against performance standards are verified;
- The integrity of the facility is maintained throughout its lifecycle;
- Performance is reviewed and modifications made where necessary;
- Safety critical roles are identified;
- People in safety critical roles are assessed as competent to perform those roles.
- Emergency planning

Developing a Safety Case or a Safety Report is quite an onerous task, and it makes a great deal of sense to adopt established ‘best practice’ standards, providing they can be shown to have the appropriate mapping and synergy.

The COMAH and SCR requirements cover safety critical elements and activities over the entire spectrum of disciplines and roles from management, designers, through construction, operations and maintenance. When they are viewed from an SIS perspective there is a distinct synergy with IEC 61511, and this will now be examined in more detail.

## IEC 61511 – Functional Safety: Safety Instrumented Systems for the Process Industry Sector

IEC 61511 is a process sector standard of IEC 61508 and is applicable to a wide range of industries including chemical, oil refining, oil and gas production, pulp and paper, non nuclear power generation, etc. Figure 1 shows the relationship between IEC 61508 and IEC 61511.



IEC 61511 is a three-part standard that focuses on Safety Instrumented Systems (SIS):

Part 1: General framework, definitions system software and hardware requirements;

**Figure 1 - Relationship between IEC 61508 & IEC 61511**

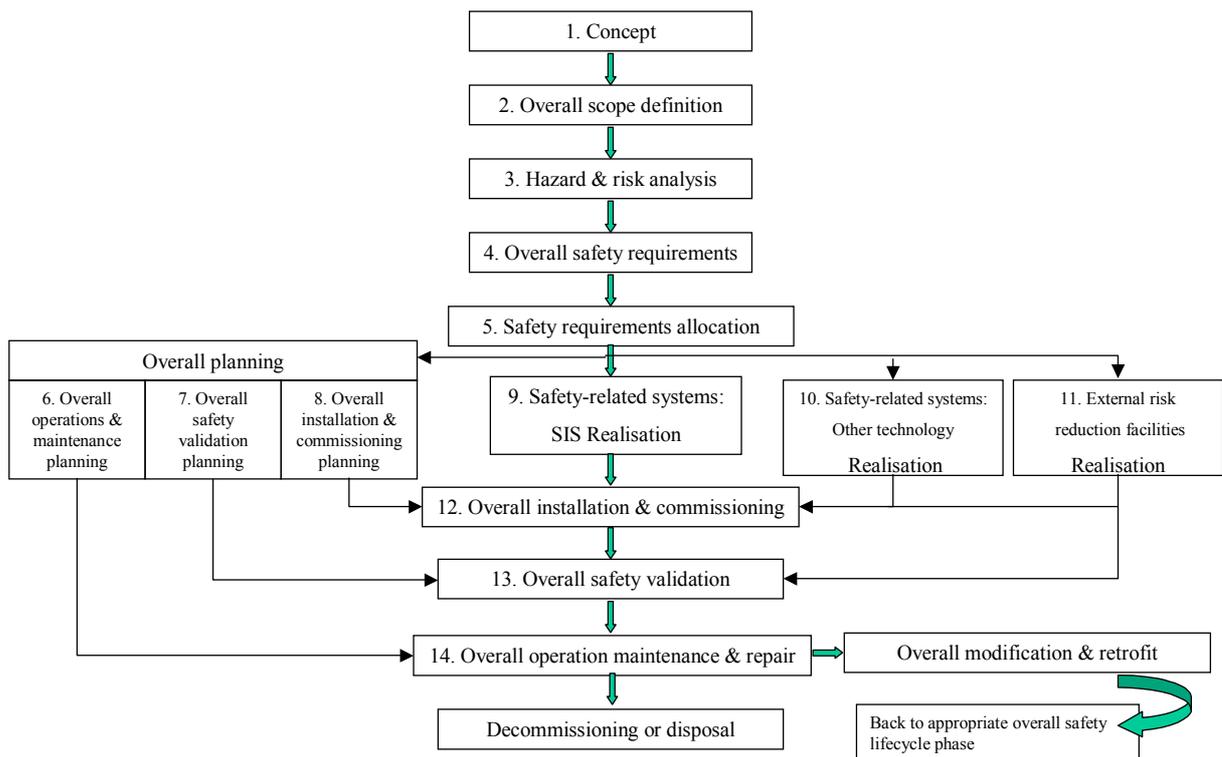
- Part 2: Guidelines on the application of Part 1;
- Part 3: Guidelines on the application of hazard and risk analysis.

IEC 61511 is concerned with the functional safety of safety instrumented systems and:

- Requires that a hazard and risk assessment is carried out to identify the overall safety requirements;
- Requires that an allocation of the safety requirements to the safety-instrumented system(s) is carried out;
- Works within a framework which is applicable to all instrumented methods of achieving functional safety;
- Details the use of certain activities, such as safety management, which may be applicable to all methods of achieving functional safety.

It is not simply concerned with the aspects of design but it addresses all the relevant safety lifecycle stages including the initial concept, design, implementation, operation and maintenance through to decommissioning as shown in Figure 2.

## Overall Safety Lifecycle



**Figure 2 – Overall safety lifecycle**

Since IEC 61511 is so comprehensive, it also provides a framework for harmonising with country specific process sector standards and legislation such as the UK COMAH and SCR Regulations.

This paper now examines the way in which IEC 61511 interfaces with each of the COMAH and SCR key aspects.

## Hazard Analysis

The Operator must identify all major accident hazards where,

- **A hazard is:**

**The potential source of harm, damage to property, production or the environment, production losses or increased liabilities.**

Hazard identification is often undertaken by a technique known as Hazard and Operability (HAZOP) analysis that was first developed by ICI in the United Kingdom but became more generally adopted following the Flixborough (Nypro UK) chemical disaster that killed 28 people in June 1974.

The screenshot shows a software window titled "Cause/Consequence: More Pressure". It has a "Save" button in the top right corner. Below the title bar, there are tabs for "Cause/Consequence", "Safeguards", "Actions", and "Documents". The main area contains four sections: "Cause" with the text "Blocked outlet of V101"; "Consequence" with "Overpressure and possible loss of containment"; "Cause frequency" with a detailed paragraph about waxy deposits in a feed from the Signit field; and "Notes" with a note about waxy deposits falling off as lighter crude is extracted.

The Hazop process systematically questions every part of a process by node and line to establish how deviations from design intent can occur. The causes and consequences of each deviation are then analysed using worksheets (Figure 3) to determine if they would have an adverse effect upon the safe operation of the process.

**Figure 3 – Hazop worksheet**

Existing protective devices that prevent or safeguard against the adverse consequences of hazards are considered and actions are raised where the protection is considered inadequate.

These actions are either:

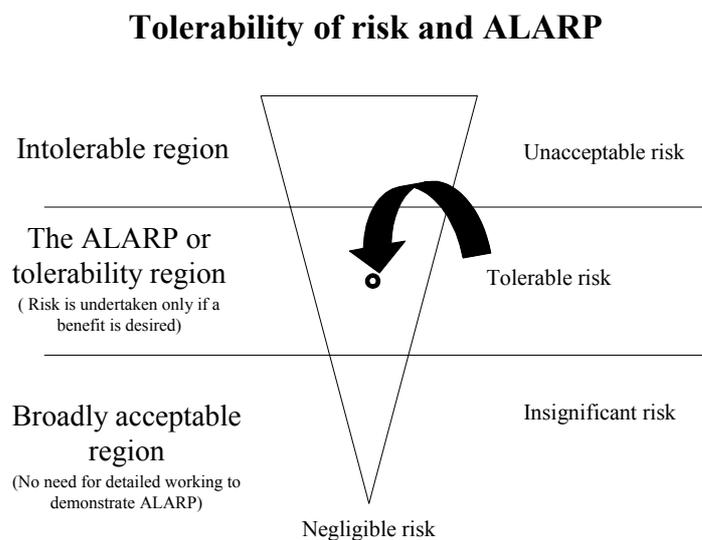
- To remove the cause
- To mitigate or eliminate the consequences.

Where it is not possible to remove the cause additional safeguarding is required and Safety Instrumented Systems (SIS) play a significant role in preventing or mitigating major hazardous accidents.

The Hazop process demands detailed recording and reporting to demonstrate that the rigour of process has been thoroughly carried out, and this is extremely time consuming, particularly if undertaken as a paper exercise. The effort can be greatly reduced with computer power and there are numerous packages available to make the process more efficient. Such packages offer the advantages of secure database records and comprehensive reporting for audit purposes. These packages often share a database with other safety assessment tools thus minimising data entry.

## Process Safety Target

The main emphasis of the IEC 61511 standard is concerned with the identification of hazards and reducing the associated risks from a level that is intolerable to a residual risk that is tolerable or 'as low as reasonably practicable' (ALARP) Figure 4. This concept is also fundamental to SCR and COMAH and has recently been supplemented by the HSE document "Reducing Risks Protecting People" (R2P2).



**Figure 4 – The ALARP principal**

- **What is risk?**

$$\text{Risk} = \text{Consequence (severity)} \times \text{Probability (likelihood)}$$

Risk is the combination of the consequence severity or harm that can result from a hazardous event and the probability/likelihood of that event actually occurring.

Operators need to define their corporate safety targets for individual risk (i.e. risks per year of the most exposed individual) and societal risk (i.e. the total risk per year of all exposed individuals). They then have to demonstrate ALARP by ensuring that the residual risk is tolerable only if further risk reduction is impracticable, or the cost and time involved is grossly disproportionate to the any further risk reduction achieved.

## Risk Reduction

Having identified the potential hazards, measures must be taken to reduce residual risk to the 'tolerability region' (Figure 4), and total risk reduction is usually achieved by using a combination of protective systems that may cover a number of technologies. These can include mechanical, pneumatic, hydraulic, electrical, electronic, programmable electronic, etc.

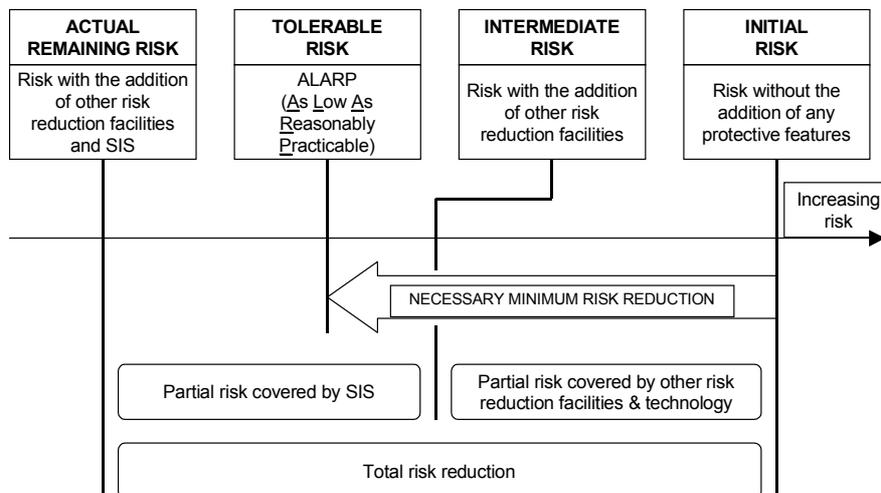
IEC 61511 requires all technologies to be considered before establishing the need for a Safety Instrumented System (SIS) as process is design, the chosen materials and their strength form

an essential part of process safety and risk reduction, but these factors alone may not reduce the risk of averting a hazard to a level that is ALARP.

The usual model that represents the concepts of risk reduction (Figure 5) includes:

- Process design;
- A process control system;
- Associated human factor issues;
- Safety protective systems comprising:
  - External risk reduction facilities;
  - Safety Instrumented Systems;
  - Other technology safety-related systems.

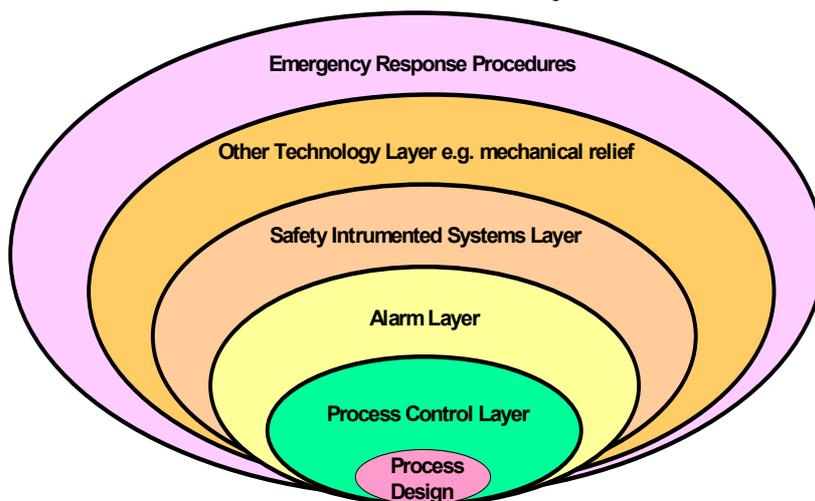
## Risk Reduction - General Concepts



**Figure 5 – Risk reduction concepts**

The different facets of risk reduction can be represented as separate layers (Figure 6).

## Risk Reduction Layers



Process design has been discussed above, and the objective of process control is to keep operation within the normal operating envelope, and properly configured alarms<sup>(8)</sup> will alert the operator to deviations from the normal so that corrective action can be taken if there is time to react.

**Figure 6 – Risk reduction layers**

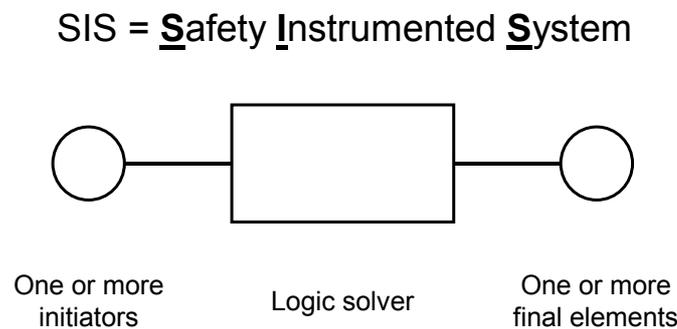
A process may also have a number of protective layers that work independently of each other, and examples include mechanical relief devices to protect against overpressure and over

speed protection for rotating equipment machinery. In addition, a responsible operator will ensure that the SMS has properly implemented emergency response procedures to mitigate the consequences of a hazardous event.

However, all of these measures may still not achieve the total risk reduction necessary for the target safety level and safety instrumented systems often form an essential and integral part of the overall risk reduction.

## Safety Instrumented Systems

A SIS may contain a number of specific safety instrumented functions (SIF) to sense abnormal conditions and automatically return the process to a safe condition. This is usually achieved by performing a partial shutdown or complete shutdown of the process.



**Figure 7 – Safety Instrumented System**

A SIS may comprise one or more initiators (i.e. sensors and measurement devices), a logic solver (relay based, solid state, magnetic core, etc.) and one or more final elements (i.e. valves, dampers, motor drives, etc.) as shown in Figure 7. The initiators and final elements are connected through the logic of the logic solver to achieve specific functional safety protection within the process such as over/under pressure protection, high/low temperature protection, high/low flow protection, etc. These protective functions are known as Safety Instrumented Functions (SIF) and the criticality of each function must be determined so that it can be designed, tested and maintained to match the risk reduction attributed to it.

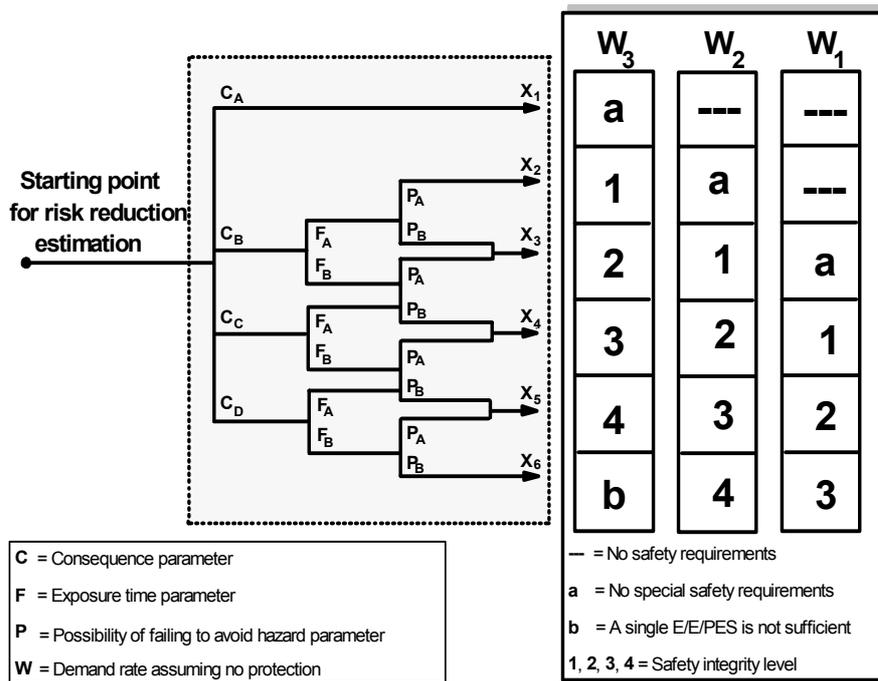
## Assessing the criticality of safety instrumented functions

SCR and COMAH recognise that a mixture of quantitative, semi-quantitative and qualitative methods can be used for risk assessment and that it is the responsibility of the operator to use the most appropriate method.

In IEC 61511 the risk assessment is known as SIL determination, and the standard also provides a scale the criticality as a Safety Integrity Level (SIL). This is given a range from SIL 1 to SIL 4, where SIL 1 represents the lowest integrity requirement and SIL 4 the highest integrity requirement.

IEC 61511 offers several methods of SIL determination with Quantitative Risk Assessment (QRA) is the most rigorous, which makes it ideal for assessing the very high consequence events but, being the most time consuming, it can be impractical to use it in assessing all potential accident hazards. The most popular alternative methods are Semi Quantitative such

as Risk Graphs (Figure 8), Risk Matrices (Figure 9) and Layers of Protection Analysis (LOPA) as shown in Figure 10.



**Figure 8 –General Risk graph**

COMAH requires the operator to consider the impact that a major accident could have on the environment as well a safety and, although not a requirement, it also makes sound economic sense to determine the potential impact an accident could have on the asset, in terms of equipment damage and/or lost production.

The general arrangement risk graph shown in Figure 8 can be adjusted to enable three risk assessments to be made covering personnel safety, asset loss and environmental risk. The required risk reduction is determined from a combination of the demand rate (W) on the SIF, i.e. the probability or likelihood, and the consequence severity (C) that would occur is the SIF failed on demand, i.e. the harm.

For the safety assessment the time that the hazardous location is occupied is assessed (F) along with alternatives to avert the hazard (P).

A risk matrix as shown in Figure 9 uses a simple Severity / Probability relationship, whilst the LOPA worksheet shown in Figure 10 provides a more detailed analysis of every hazard, the causes, consequences and all the layers of protection and mitigation that reduce the risk.

<b>Severity Probability</b>	Major	Serious	Minor	Incidental
Frequent	4	3	2	0
Occasional	3	2	1	0
Seldom	2	1	0	0
Unlikely	1	0	0	0

**Figure 9 –A typical risk matrix**

Whatever risk assessment method is chosen, it is essential to have the appropriate skills represented for the decision making process.

A multiple discipline team should undertake this activity with the following skills composition:

- A facilitator (skilled in the IEC 61508/61511 risk assessment process)
- Process Engineer
- Instrument Engineer
- Operations representative
- Safety specialist

**Figure 10 – Layers of Protection Analysis work sheet**

A SIL determination study requires considerable commitment of time and resource, and this must be recognised by management. However, it should not be an issue if management are genuinely committed to safety through the SMS.

Like Hazop, SIL determination will generate a significant amount of data this must be recorded to provide a complete audit trail to the background behind the decisions that are made during the process. If these are recorded on paper they will represent a snapshot in time and as the process changes, either through design modifications or process dynamics, it will become an onerous task to keep the records updated.

It should be stressed that the SIL determination sets the scene for the SIF performance standard, and it is important to maintain these records in a format that can be easily updated and maintained throughout the lifetime of the process to meet SCR and COMAH requirements.

Selecting a comprehensive software application and database tool will significantly reduce the time committed to the SIL analysis process, sorting and maintaining the records whilst providing the integrity afforded by databases. Some applications also offer a choice of SIL determination method from risk graphs, risk matrices or LOPA.

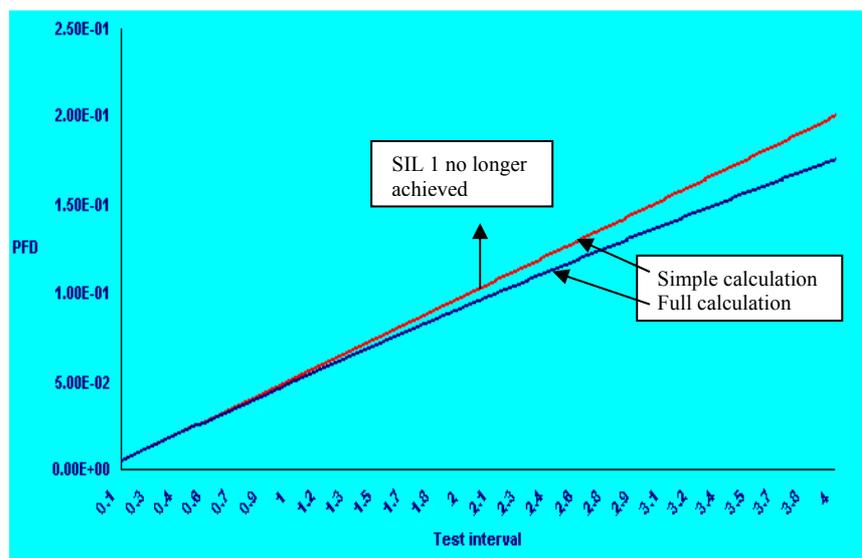
## Ensuring that the design, testing and maintenance are appropriate

Once the criticality has been established in the range SIL 1 to SIL 4, this corresponds to the level of integrity required for the SIF design. The standard sets a reliability requirement, or the Probability of Failure on Demand (PFD), for each SIL band and this represents the level of risk reduction to be achieved for each SIL as shown in Figure 11. The PFD requirements actually comprise the performance standard to be achieved, since the more critical the function the lower the failure probability that must be achieved.

Safety Integrity Level (SIL)	Probability of Failure on Demand (PFD)	Risk Reduction
4	$\leq 10^{-4} - \geq 10^{-5}$	10,000 – 100,000
3	$\leq 10^{-3} - \geq 10^{-4}$	1,000 – 10,000
2	$\leq 10^{-2} - \geq 10^{-3}$	100 – 1,000
1	$\leq 10^{-1} - \geq 10^{-2}$	10 - 100

**Figure 11 – Relationship between SIL, PFD & risk reduction**

The PFD is a dimensionless number, but it is based on a relationship between the failure rate and frequency at which tests are carried out to reveal any hidden or covert failures that would prevent the function working on a real demand, Figure 12. In this example if the SIF was intended to meet a SIL 1, the test interval must not exceed 2.1 years.



For a single device:

$$PFD = 1/2 \lambda_d T_i$$

Where:

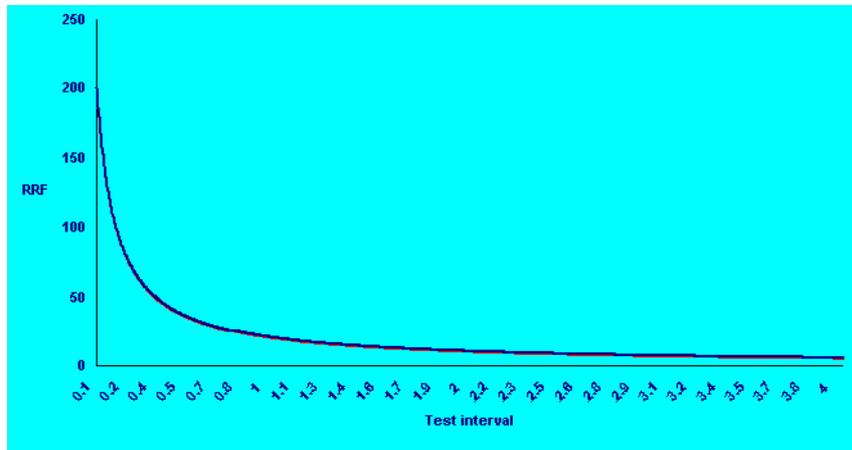
$\lambda_d$  = dangerous failure rate

$T_i$  = the testing interval

**Figure 12 – Relationship between PFD and testing (years)**

This basic relationship provides the foundations for calculating the most appropriate SIF architecture in terms of the initiators, logic devices and final elements.

If devices with a poor record of reliability are selected then they will require more frequent testing. If the test interval is extended then there is a higher probability that the device will fail. Similarly if the achieved risk reduction is plotted against test intervals (Figure 13) then it can be seen to decay rapidly as the test interval is extended.



In reality, the calculations are far more complex as factors such as the time taken to carry out the test, the coverage of the test (i.e. does the test cover every aspect that can cause failure), the period at which routine maintenance will

Figure 13 –Risk reduction and test interval (years) relationship

be undertaken and the time taken to repair or return the device to the ‘as new’ condition, all need to be considered. In addition, the architecture will often be far more complex than single devices for the initiators, logic and final elements, and there may also be common mode failure influences to be considered.

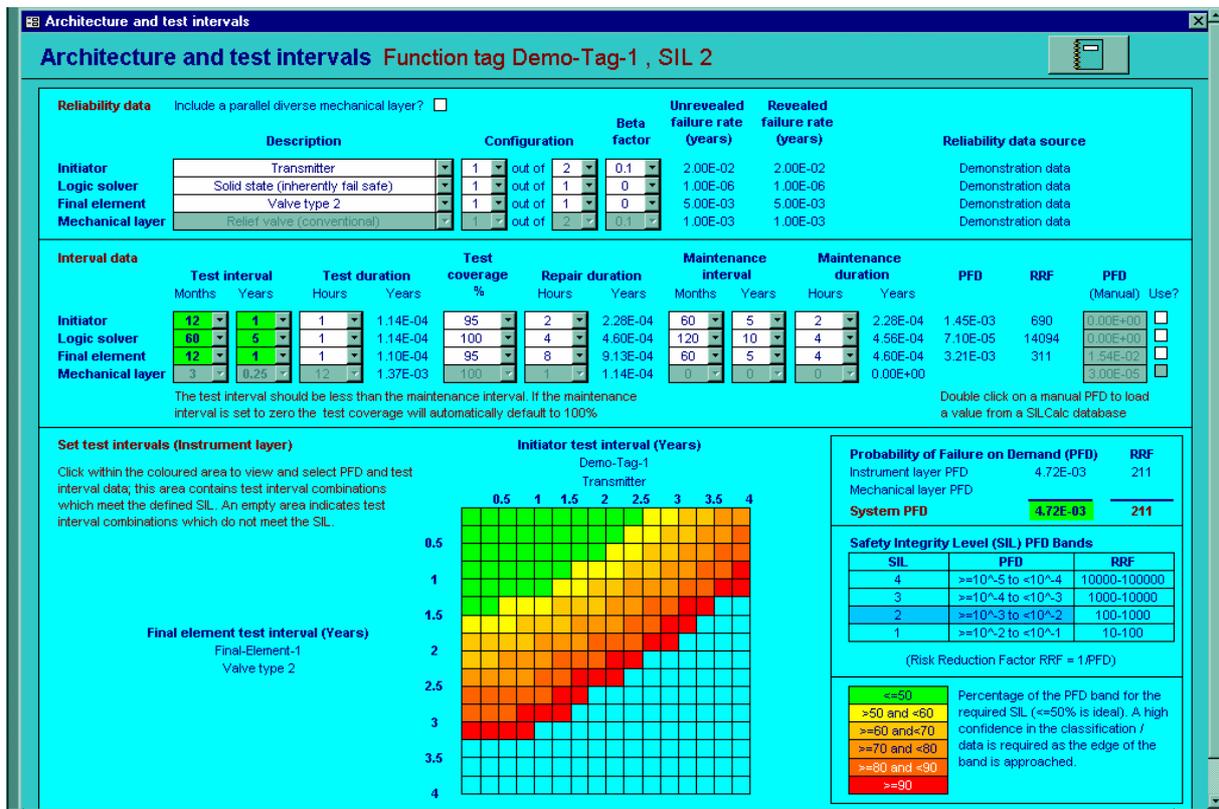


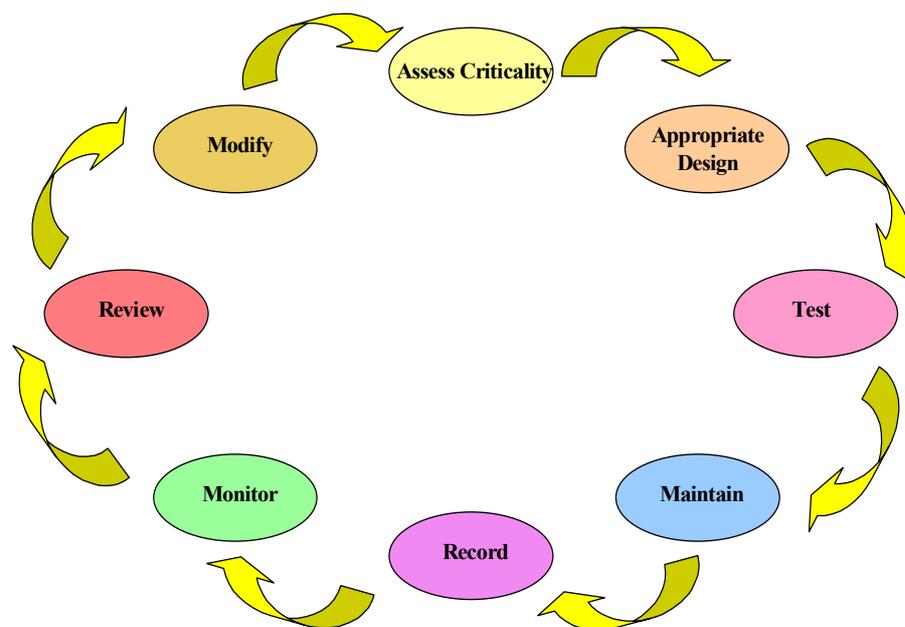
Figure 14 –Plotting the PFD for a range of test and maintenance intervals

Providing appropriate tools are used, these calculations are not an issue as discussed below.

There are many parameters and variables that can influence the probability that the protective function will actually operate on a demand, and they all need to be managed through the design stage and the operational lifetime. It is also essential to maintain the audit trail of how a particular design was selected and why a particular test and maintenance strategy has been adopted. Figure 12 shows how the PFD varies with test interval for a single device, but a SIF comprises initiator, logic solver and final element and all these devices have to be taken into account as the failure of any of them would lead to failure of the protective function. Figure 14 demonstrates how the power of design tools can pre-calculate the interaction of all the variables for the complete SIF, to help the selection of the most appropriate design and optimal test and maintenance requirements. This gives assurance that the design, testing and maintenance meet the required PFD criteria for the determined SIL and, since all the information resides in the database records, this actually completes the performance standard for each function.

### Performance Monitoring and Verification

Having assessed the criticality of the SIF, established an appropriate design and set the test and maintenance strategy, then IEC 61511 requires the actual performance to be monitored and verified throughout its operational lifetime.



**Figure 15 – Performance monitoring**

This will include all the activities shown in Figure 15. Records must be maintained of testing and maintenance so that deviations and failures can be reviewed and modifications made to ensure that performance meets the set standards and integrity is not compromised. If records show better or worse than

expected performance then the reliability data must be updated to take account of the operating experience. Poor performance may require additional test and maintenance or even modifications to design, whilst better than expected performance could indicate that the test and maintenance intervals can be extended, and experience shows that these can result in significant cost savings compared with previous design practices.

Proper scheduling of test and maintenance, and comprehensive reporting for these activities will ensure consistency for analysing the records and these will aid the verification process.

## **Modifications and Change control**

Any change to the process such as the process dynamics, the mode of operation or the design, may have an impact on the integrity of the process. Consequently the design and integrity of the protective functions, such as safety-instrumented functions, will also need to be reviewed. Thus, from a Safety Case or Safety Report and IEC 61511 perspective, all changes must be flagged and managed by a formalised change control process. This must have the mechanisms in place to make proper assessments of the changes and their impact upon integrity. The impact of change may result in plant modifications or changes in operating and maintenance strategy or all of these things.

Some of the common changes that can have an impact on a SIF include changes to the affecting the frequency of demand on the protective function, or the range characteristics of the measured parameters may vary and require different trip settings, or the mechanical strength of materials could be compromised if the pressures, temperatures or products are modified etc.

The SIL may need to be reviewed, the architecture modified and/or the test and maintenance frequency changed. This is a relatively straightforward process if everything has been recorded within a database mechanism and the audit trail will be readily maintained at the same time.

## **Competency**

Since Safety Instrumented Systems (SIS) are intended to protect against hazards which could cause serious injury or loss of life, it is necessary to have competent individuals involved in each of the different lifecycle phases indicated in Figure 2. The safety critical roles and activities need to be identified (IEC 61511-1, Clause 5.2.2.2.) and documented, and the people who perform such activities must be assessed as competent to undertake those activities.

The following organisations will have people with specific safety critical roles with respect to the specification, design, implementation, and operation of SIS:

- engineering design contractors;
- vendors;
- system integrators;
- installation contractors;
- maintenance contractors;
- operating organisation.

Assurance of competent people involved in all the lifecycle activities is of great importance, from the designer at the conceptual end of the lifecycle, to the technician who undertakes testing and calibration during the operational lifetime.

Competence assurance at all engineering, technical and operational levels plays a vital part in maintaining the safety integrity and suitable schemes are required to ensure that individuals involved in the lifecycle process are assessed as competent. The IEE publication, "Safety, Competency, and Commitment: Competency Guidelines for Safety-Related System Practitioners" <sup>(9)</sup> details a suitable competency scheme specifically developed for safety-related systems.

## Conclusions

Safety Instrumented Systems play a significant role in protecting people and the environment from hazards. They generally form part of an overall risk reduction framework, but they can often make a major contribution to the total risk reduction. They therefore represent a fundamental part of any SMS from either an SCR or COMAH perspective. We have seen that some of the main requirements of these Regulations are that:

- Hazards are identified;
- Safety critical elements protecting persons from hazards are identified;
- Risks are kept as low as reasonably practicable;
- Design is appropriate;
- There is an audit trail for the decision making process;
- Modifications are properly designed and controlled;
- Operations do not compromise integrity;
- Performance standards are set;
- Operation against performance standards are verified;
- The integrity of the facility is maintained throughout its lifecycle;
- Performance is reviewed and modifications made where necessary;
- Safety critical roles are identified;
- People in safety critical roles are assessed as competent to perform those roles.

These requirements form a lifecycle framework and, from the outset of Safety Case Regulations and COMAH Regulations, instrumentation engineers recognised that there was a very neat dovetail with the requirements of the IEC 61508 and, more recently, the IEC 61511 standards. Thus compliance with the IEC 61511 standard, for Safety Instrumented Systems, will provide assurance that the Safety Case requirements are also met for these systems.

The whole lifecycle needs careful controls and management, because it forms an integral part of a safety management system, and keeping records throughout the entire lifecycle is essential for maintaining and demonstrating integrity. All of these factors demand considerable time and effort, but there are specialised software applications available to aid compliance and reduce the effort involved.

But what about process operations that fall out with the categories required for the submission of Safety Cases or Safety Reports? Companies will still have to demonstrate authoritative good practice and IEC 61511 and IEC 61508 have now become the established good practice.

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## **Biography:**

### **Clive Timms**

Clive has over 38 years experience in the petrochemical industry with offshore and onshore plants experience. He recently retired from Shell UK Exploration and production where he was Head of Automation and Control. He is now a Director of C&C Technical Support Services Ltd, which specialises in the application of the IEC 61508 and IEC 61511 standards, and he was a founder Director of the CASS Scheme Ltd for conformity assessment to IEC 61508. He chaired the UKOOA working group that produced the UKOOA Guidelines for Instrument-based Protective Systems, as an offshore sector interpretation of IEC 61508. He has a BSc. and MPhil in Control Engineering, is a Member of the IEE and currently chairs the Institute of Measurement and Control Safety Panel.

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