INTERNATIONAL STANDARD

IEC 61511-2

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Functional safety –
Safety instrumented systems
for the process industry sector –

Part 2:
Guidelines for the application of IEC 61511-1

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International Electrotechnical Commission, 3, rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: inmail@iec.ch Web: www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

FUNCTIONAL SAFETY – SAFETY INSTRUMENTED SYSTEMS FOR THE PROCESS INDUSTRY SECTOR –

Part 2: Guidelines for the application of IEC 61511-1

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 61511-2 has been prepared by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement and control.

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

FDIS	Report on voting
65A/387A/FDIS	65A/390/RVD

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

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

IEC 61511 series has been developed as a process sector implementation of IEC 61508 series.

IEC 61511 consists of the following parts, under the general title *Functional safety – Safety Instrumented Systems for the process industry sector* (see Figure 1):

Part 1: Framework, definitions, system, hardware and software requirements

Part 2: Guidelines for the application of IEC 61511-1

Part 3: Guidance for the determination of the required safety integrity levels

The committee has decided that the contents of this publication will remain unchanged until 2007. At this date, the publication will be

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

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

Safety instrumented systems have been used for many years to perform safety instrumented functions in the process industries. If instrumentation is to be effectively used for safety instrumented functions, it is essential that this instrumentation achieves certain minimum standards.

This International Standard addresses the application of safety instrumented systems for the Process Industries. It also deals with the interface between safety instrumented systems and other safety systems in requiring that a process hazard and risk assessment be carried out. The safety instrumented system includes sensors, logic solvers and final elements.

This International Standard has two concepts, which are fundamental to its application; safety lifecycle and safety integrity levels. The safety lifecycle forms the central framework which links together most of the concepts in this International Standard.

The safety instrumented system logic solvers addressed include Electrical (E)/Electronic (E)/ and Programmable Electronic (PE) technology. Where other technologies are used for logic solvers, the basic principles of this standard may also be applied. This standard also addresses the safety instrumented system sensors and final elements regardless of the technology used. This International Standard is process industry specific within the framework of the IEC 61508 series.

This International Standard sets out an approach for safety lifecycle activities to achieve these minimum standards. This approach has been adopted in order that a rational and consistent technical policy is used. The objective of this standard is to provide guidance on how to comply with IEC 61511-1.

To facilitate use of this standard, the clause and subclause numbers provided are identical to the corresponding normative text in 61511-1 (excluding the annexes).

In most situations, safety is best achieved by an inherently safe process design whenever practicable, combined, if necessary, with a number of protective systems which rely on different technologies (for example, chemical, mechanical, hydraulic, pneumatic, electrical, electronic, thermodynamic (for example, flame arrestors), programmable electronic) which manage any residual identified risk. Any safety strategy considers each individual safety instrumented system in the context of the other protective systems. To facilitate this approach, this standard

- 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 functions and related safety systems, such as 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.

This International Standard on safety instrumented systems for the process industry:

- addresses relevant safety lifecycle stages from initial concept, through design, implementation, operation and maintenance and decommissioning;
- enables existing or new country specific process industry standards to be harmonized with this standard.

This standard is intended to lead to a high level of consistency (for example, of underlying principles, terminology, information) within the process industries. This should have both safety and economic benefits.

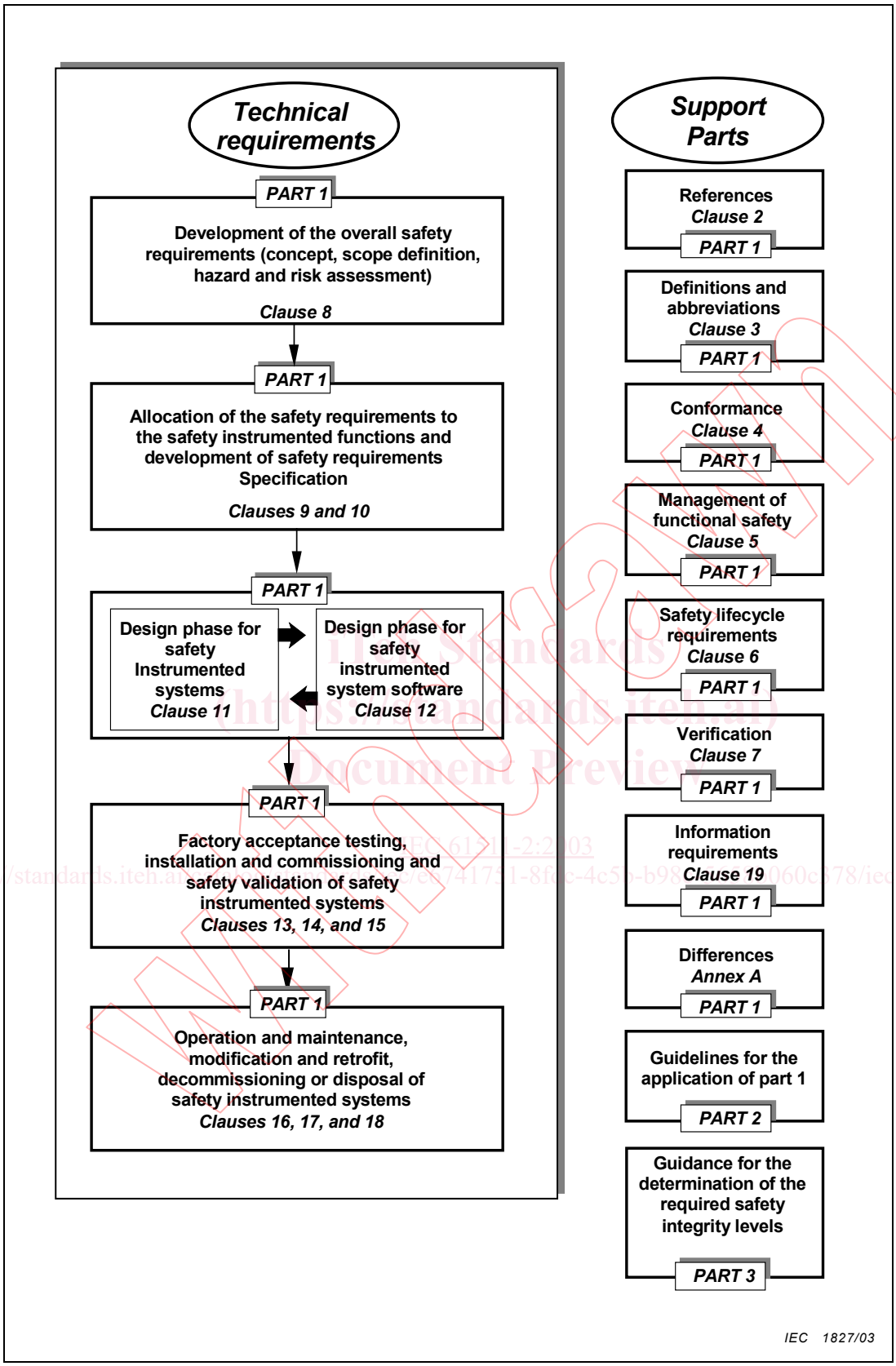

Figure 1 – Overall framework of this standard

FUNCTIONAL SAFETY – SAFETY INSTRUMENTED SYSTEMS FOR THE PROCESS INDUSTRY SECTOR –

Part 2: Guidelines for the application of IEC 61511-1

1 Scope

IEC 61511-2 provides guidance on the specification, design, installation, operation and maintenance of Safety Instrumented Functions and related safety instrumented system as defined in IEC 61511-1. This standard has been organized so that each clause and subclause number herein addresses the same clause number in IEC 61511-1 (with the exception of the annexes).

2 Normative references

No further guidance provided.

3 Terms, definitions and abbreviations

No further guidance provided except for 3.2.68 and 3.2.71 of IEC 61511-1.

3.2.68 A safety function should prevent a specified hazardous event. For example, “prevent the pressure in vessel #ABC456 exceeding 100 bar.” A safety function may be achieved by

a) a single safety instrumented system (SIS), or

b) one or more safety instrumented systems and/or other layers of protection.

In case b), each safety instrumented system or other layer of protection has to be capable of achieving the safety function and the overall combination has to achieve the required risk reduction (process safety target).

3.2.71 Safety instrumented functions are derived from the safety function, have an associated safety integrity level (SIL) and are carried out by a specific safety instrumented system (SIS). For example, “close valve #XY123 within 5 s when pressure in vessel #ABC456 reaches 100 bar”. Note that components of a safety instrumented system may be used by more than one safety instrumented function.

4 Conformance to this International Standard

No further guidance provided.

5 Management of functional safety

5.1 Objective

The objective of Clause 5 of IEC 61511-1 is to provide requirements for implementing the management activities that are necessary to ensure that the functional safety objectives are met.

5.2 Requirements

5.2.1 General

5.2.1.1 No further guidance provided.

5.2.1.2 When an organization has responsibility for one or more activities necessary for functional safety and that organization works according to quality assurance procedures, then many of these activities described in this clause will already be carried out for the purposes of quality. Where this is the case, it may be unnecessary to repeat these activities for the purposes of functional safety. In such cases, the quality assurance procedures should be reviewed to establish that they are suitable so that the objectives of functional safety will be achieved.

5.2.2 Organization and resources

5.2.2.1 The organizational structure associated with safety instrumented systems within a Company/Site/Plant/Project should be defined and the roles and responsibilities of each element clearly understood and communicated. Within the structure, individual roles, including their description and purpose should be identified. For each role, unambiguous accountabilities should be identified; and specific responsibilities should be recognised. In addition, whom the individual reports to and who makes the appointment should be identified. The intent is to ensure that everyone in an organization understands their role and responsibilities for safety instrumented systems.

5.2.2.2 The skills and knowledge required to implement any of the activities of the safety life cycle relating to the safety instrumented systems should be identified; and for each skill, the required competency levels should be defined. Resources should be assessed against each skill for competency and also the number of people per skill required. When differences are identified, development plans should be established to enable the required competency levels to be achieved in a timely manner. When shortages of skills arise, suitably qualified and experienced personnel may be recruited or contracted.

5.2.3 Risk evaluation and risk management

The requirement stated in 5.2.3 of IEC 61511 is that hazards are identified, risks evaluated and the necessary risk reduction is determined. It is recognized that there are numerous different methodologies available for conducting these evaluations. IEC 61511-1 does not endorse any particular methodology. Instead, the reader is encouraged to review a number of methodologies on this issue in IEC 61511-3. See 8.2.1 for further guidance.

5.2.4 Planning

The intent of this subclause is to ensure that, within the overall project, adequate safety planning is conducted so that all of the required activities during each phase of the lifecycle (for example, engineering design, plant operation) are addressed. The standard does not require any particular structure for these planning activities, but it does require periodic update or review of them.

5.2.5 Implementing and monitoring

5.2.5.1 The intent of this subclause is to ensure that effective management procedures are in place to

- ensure that all recommendations resulting from hazard analysis, risk assessment, other assessment and auditing activities, verification and validation activities are satisfactorily resolved.
- determine that the SIS is performing in accordance with its safety requirements specification throughout its operational lifetime.

5.2.5.2 Note that, in this context, suppliers could include design contractors and maintenance contractors as well as suppliers of components.

5.2.5.3 A review of the SIS performance should be periodically undertaken to ensure the original assumptions made during the development of the safety requirements specification (SRS) are still adhered to. For example, a periodic review of the assumed failure rate of different components in a SIS should be carried out to ensure that it remains as originally defined. If the failure rates are worse than originally anticipated, a design modification may be necessary. Likewise, the demand rate on the SIS should be reviewed. If the rate is more than that which was originally assumed, then an adjustment in the SIL may be needed.

5.2.6 Assessment, auditing and revision

Assessments and audits are tools targeted at the detection and elimination of errors. The paragraphs below make clear the distinction between these activities

Functional safety assessment aims to evaluate whether provisions made during the assessed lifecycle phases are adequate for the achievement of safety. Judgements are made by assessors on the decisions taken by those responsible for the realisation of functional safety. An assessment would for example be made prior to commissioning as to whether procedures for maintenance are adequate.

Functional safety auditors will determine from project or plant records whether the necessary procedures have been applied at the specified frequency by persons with the necessary competence. Auditors are not required to make judgements on the adequacy of the work they are considering. However, if they became aware that there would be benefits in making changes, then an observation should be included in the report.

It should be noted that in many cases there can be an overlap between the work of the assessor and the auditor. For example an auditor may need to determine not only whether an operator has been given the necessary training but in addition make judgements as to whether the training has resulted in the required competency.

5.2.6.1 Functional safety assessment

5.2.6.1.1 The use of Functional Safety Assessment (FSA) is fundamental in demonstrating that a Safety Instrumented System (SIS) fulfils its requirements regarding safety instrumented function(s) and Safety Integrity Level (SIL). The basic objective of this assessment is to demonstrate compliance with agreed standards and practices through independent assessment of the system's development process. An assessment of a SIS may be needed at different lifecycle stages. In order to conduct an effective assessment, a procedure should be developed that defines the scope of this assessment along with some guidance on the makeup of the assessment team.

The following attributes are considered good practice for Functional Safety Assessment:

- A plan should be generated for each FSA identifying such arrangements as the scope of the assessment, the assessors, the competencies of the assessors and the information to be generated by the assessment.

- The FSA should take into account other standards and practices, which may be contained within external or internal corporate standards, guides, procedures or codes of practice. The FSA plan should define what is to be assessed for the particular assessment/ system/application area.
- The frequency of FSAs may vary across different system developments but as a minimum should always take place before the potential hazards being presented to the system. Some companies also like to conduct an assessment prior to the construction/installation phase to prevent costly rework later in the lifecycle.
- FSA frequency and rigour should be defined taking into account system attributes such as:
  - complexity;
  - safety significance;
  - previous experience of similar systems;
  - standardization of design features.
- Sufficient evidence of design, installation, verification and validation activities should be available prior to the assessment. The availability of sufficient evidence could itself be an assessment criterion. The evidence should represent the current/approved state of system design or installation.
- The independence of the assessor(s) must be appropriate.
- The assessor(s) should have experience and knowledge appropriate to the technology and application area of the system being assessed.
- A systematic and consistent approach to FSA should be maintained throughout the lifecycle and across systems. FSA is a subjective activity therefore detailed guidance, possibly through the use of checklists, as to what is acceptable for an organisation should be defined to remove as much subjectivity as possible.

Records generated from the FSA should be complete and the conclusions agreed with those responsible for the management of functional safety for the SIS prior to commencement of the next lifecycle phase.

5.2.6.1.2 The need for someone independent to the project team is to increase objectivity in the assessment. The need for someone of senior stature (for example, experience, grade level, position) is to ensure their concerns are duly noted and addressed. As the note also suggests, on some large projects or assessment teams, it may be necessary to have more than one senior person on this team that is independent to the original project team.

Depending upon the company organisation and expertise within the company, the requirement for an independent assessor may have to be met by using an external organisation. Conversely, companies that have internal organisations skilled in risk assessment and the application of safety instrumented systems, which are independent to and separate (by ways of management and other resources) from those responsible for the project, may be able to use their own resources to meet the requirements for an independent organisation.

5.2.6.1.3 The amount of assessment depends on the size and complexity of a project. It may be possible to assess the results of different phases at the same time. This is particularly true in the case of small changes in a running plant.

5.2.6.1.4 In some countries, a functional safety assessment undertaken at stage 3 is often referred to as the Pre-Startup-Safety-Review (PSSR).

5.2.6.1.5 No further guidance provided.

5.2.6.1.6 No further guidance provided.

5.2.6.1.7 The assessment team should have access to any information they deem necessary for them to conduct the assessment. This should include information from the hazard and risk assessment, design phase through installation, commissioning and validation.

5.2.6.2 Auditing and revision

5.2.6.2.1 This subclause is intended to give guidance about auditing, using an example illustrating relevant activities.

a) Audit categories

Safety instrumented system audits provide beneficial information to plant management, instrument maintenance engineers and instrument design engineers. This enables management to be proactive and aware of the degree of implementation and effectiveness of their safety instrumented systems. Many types of audits, which can be carried out exist. The actual type, scope, and frequency of the audit of any specific activity should reflect the potential impact of the activity on the safety integrity.

Types of audit include:

1) audits, both independent and self-audit;
2) inspections;
3) safety visits (for example, plant walk about and incident review);
4) safety instrumented systems surveys (via questionnaires).

A distinction needs to be made between “surveillance and checking” and audit activities. Surveillance and checking focuses on evaluating the performance of specific lifecycle activities (for example, supervisor checking completion of maintenance activity prior to the component being returned to service.) In contrast, audit activities are more comprehensive and focus on overall implementation of safety instrumented systems concerning the safety lifecycle. An audit would include determination as to whether the surveillance and checking program is carried out.

Audits and inspections may be carried out by a company’s/site’s/plant’s/project’s own staff (for example, self-audit) or by independent persons (for example, corporate auditors, quality assurance department, regulators, customers or third parties).

Management at the various levels may want to apply the relevant type of audit to gain information on the effectiveness of the implementation of their safety instrumented systems. Information from audits could be used to identify the procedures that have not been properly applied, leading to improved implementation.

b) Audit strategy

Site/plant/project implementing audit programmes might consider rolling, independent or self-audit and inspection programmes.

Rolling programmes are updated regularly to reflect previous safety instrumented systems performance and audit results, and current concerns and priorities. These cover all site/plant/project related activities and aspects of the safety instrumented systems in an appropriate time period and to an appropriate depth.

The primary reason for, and the added value from audits comes from acting on the information they provide in a timely manner. The actions aim to strengthen the effectiveness of safety instrumented systems, for example, to help minimize the risk of employees or members of the public being injured or killed, contribute to improving safety culture, contribute to prevent any avoidable release of substance into the environment.

In summary, the audit strategy may have a mix of audits types, driven by management (the customer), and in order to feed back the relevant information up the management chain for timely action.

c) Audit process and protocols

The overall aim is to achieve maximum value from the performance of the audit, which can only be achieved when all parties (including auditors, contact nominee, plant managers and head of departments, etc.) understand the need for and can influence each audit. The following audit process and protocols might help to ensure some consistency in the approach to achieving these aims. They bear on the following five key stages of the audit process: