T6A022

"Functional Safety Roles & Responsibilities:

End Users and Engineering Contractors"

1. Contents

2. Revision History

Version	Date	Author	Comments
3	10-Mar-16	T6A	First published version.
4	14-Sep-22	PB	Editorial and moved to updated T6A template.

Using This Document

Organisations can freely use this document to support procurement, project or contract activities.

Organisations using this document will need to review the applicability of each table to their individual situation and it is likely that some changes will need to be made each time the document is used. This is the reason that it is made available in an editable format.

It is expected that users of the document will reference the source of whatever material they use from the document, even if this is only part of the document (e.g., the tables) – wording along the following lines should be used whenever material from this document is used;

The following requirements are based upon a modified version of the 61508 Association's document "Functional Safety Roles and Responsibilities – End Users and Engineering Contractors". The original document can be downloaded from the 61508 Association's web site at http://www.61508.org/index.htm

3. Introduction

This document has been prepared by a Working Group of the 61508 Association to assist organisations contracting or partnering for provision that includes functional safety work as covered by the IEC 61508 (also published in the UK as BS EN 61508) and associated industry sector Standards.[1]

This document does not attempt to describe the work involved in undertaking functional safety – there are other guidelines documents for this purpose. The purpose of this document is to describe the various roles and responsibilities that generally need to be attributed and carried out. Hence, although they relate to and can be mapped to the IEC 61508 Safety Life Cycle, the activities in this document are different as they describe the activities in terms of executing an EPC (Engineer, Procure and Construct or "turnkey") project and/or contract.

This document will not remove the need to refer to the IEC 61508 and associated industry sector Standards and/or one of the relevant guidelines documents available. This latest revision of the IEC 61508 Standard emphasises the need to utilise competent staff with knowledge and experience in applying such Standards. Organisations need to have (or have appropriate access to) competent staff of the appropriate disciplines to carry out their roles and responsibilities for each activity.

This document has been prepared on the basis of the activities and the associated roles and responsibilities generally needing to be discharged during a project involving functional safety. It is possible that during some specific projects there might be additional activities and additional roles and responsibilities that need to be attributed – these can readily be added to the functional safety roles and responsibilities document created for the project. However, it is considered unlikely that any of the activities listed in this document would be irrelevant in any project involving functional safety – hence taking any out of the list should only be done after careful consideration and by people with knowledge and experience in applying the IEC 61508 and associated industry sector Standards.

Generally, all of the roles and responsibilities are relevant whatever the size of the project; it is merely the nature and extent of the role and responsibility that changes. Note that for non-EPC or in-house (eg smaller) projects the activities are still all relevant but the contents of each table will be different.

This document has been prepared on the basis of;

- The EPC contractor carrying the majority of the design roles and responsibilities for the project.
- The EPC contractor being responsible the majority of the functional safety work.
- The End User being responsible into the O&M phase for the plant and process being adequately safe and for being able to demonstrate that the plant is adequately safe.
- The End User being ultimately accountable for the majority of the functional safety decisions and outputs and therefore having a reviewing and/or approval role.

[1] The Association would welcome any comments on this publication, see http://www.61508.org/contact.htm. Whilst every effort has been made to ensure the accuracy of the information contained in this document, neither *The 61508 Association* nor any of its members will assume liability for any use made thereof.

- The End User having a responsibility to carry out due diligence on the adequacy, completeness and content of the functional safety work.

This document does suggest various attributions of the identified roles and responsibilities. Whilst these attributions have been made with consideration of the most appropriate placing in likely scenarios they are not fixed and should be re-considered by the user of the document each time a new project is being planned.

4. Executive Summary

4.1 End Users and Engineering Contractors

This document has been prepared around the model of an EPC (Engineer-Procure-Construct or "turnkey") type of project and contract strategy. The list of roles and responsibilities and the document format will suit many other types of similar relationship between organisations in projects involving functional safety.

It might well be that on some projects some of the organisations referred to in this document might not exist as separate entities (e.g., *End User's Owner's Engineer*, *EPC Contractor's functional safety consultant*, *sub-contractors to EPC contractor*) – in these circumstances any roles and responsibilities are presumed to be taken by the parent organisation.

5. Paper Detail

5.1 Terminology

End User: This term is intended to cover organisations which will own or operate the plant/equipment being designed including;

- Asset owners
- Project developers
- Those with operations and maintenance responsibilities

End User's Engineer: This term is intended to cover organisations providing project related advice and/or services to the end user – these can include plant, process and/or functional safety (specialist) advice and/or services. It is not a term commonly used in all industry sectors – alternatives with a similar meaning are "Owner's Engineer", "Design Co-ordinator", "Responsible Engineer" and "Engineering Consultant".

EPC (Engineer, Procure and Construct): This term is intended to cover a project or contract in which an engineering organisation other than the end user takes on all or nearly all of the design and provision of a plant or process. Such projects or contracts are often referred to as turnkey. It can also include

EPCM (Engineering Procurement Construction Management Services) and EPCC (Engineering Procurement Construction and Commissioning) projects and contracts where the contractor takes on all or nearly all of the design and provision of a plant or process.

EPC Contractor: This term is intended to cover organisations that are engineering a new plant or a plant modification or enhancement for an end user. This document presumes that the EPC contractor has a significant amount of plant or process design responsibility for the provision of the project. Some EPC contracts build a licensed plant design, with the licensor in contract with either the EPC contractor or End User – in these cases the tables below will need to be amended accordingly.

EPC contractor's plant/process subcontractors: This term is intended to include subcontractors appointed by and/or managed by the EPC contractor. These subcontractors provide plant and/or process design, systems, equipment and/or related services. This document presumes that the EPC contractor is reliant on some amount of plant and/or process information from these subcontractors to complete his design and (hence) functional safety roles and responsibilities.

EPC contractor's functional safety consultant: This term is intended to cover organisations that provide specialist functional safety advice and/or services to the EPC contractor.

EPC contractor's functional safety system subcontractor: This term is intended to cover organisations (such as systems integrators) that build functional safety equipment and systems to specifications or designs prepared by others – any design role is limited to the design of the E/E/PE systems within their scope. These organisations might provide safety related hardware and/or software. These organisations will be required to work to and to provide assurance of working to the requirements of the IEC 61508 and associated industry sector Standards.

5.2 Index to the Tables

#	Activity Title	IEC 61508:2010 Safety Life Cycle Box Number[2]	IEC 61508:2010 Clause references
1	Define and confirm functional safety strategy	-	Part 1 Clause 6.
2	Define and confirm scope	1, 2	Part 1 Clauses 7.2 and 7.3.2.1.
3	Identify functional safety teams	-	Part 1 Clauses 6.2.1, 6.2.3 and 6.2.13-6.2.15
4	Agree and define functional safety working methods	-	Part 1 Clauses 6.2.4-6.2.12.
5	Agree and define safety related software management	-	Part 1 Clause 6.2.10 and Part 3 Clause 6.
6	Agree and define tolerable risk issues	-	Part 1 Clause 7.4.2.10 and Part 5 Annex A2.
7	Prepare for Hazard Identification	-	Part 1 Clauses 7.3.2.2-7.3.2.6.
8	Hazard Identification	3	Part 1 Clause 7.4.
9	Prepare for initial functional safety quantification	3	Part 1 Clause 7.4.
10	Initial functional safety quantification	4, 5, 11[3]	Part 1 Clause 7.4-7.6 and Part 5 Annex B.
11	Safety Requirements Specification	9	Part 1 Clause 7.10 and Part 2 Clause 7.2.
12	Human Factors Issues	-	Part 1 Clauses 7.4.2.3 and 7.4.2.10 and Part 2 Clause 7.4.5.2 i).
13	Design factory-built scope	-	Part 2 Clause 7.4.
14	Design/Select field equipment scope	-	Part 2 Clause 7.4.
15	Second functional safety quantification	-	Part 2 Clause 7.4.
16	Fabricate factory-built Safety Related Systems	10	Part 2 Clauses 7.4.9.1-7.4.9.3 and Part 3 Clause 7.
17	Prepare for FAT (E/E/PE System Verification)	-	Part 2 Clauses 7.9.2.1-7.9.24.
18	Conduct and report FAT (E/E/PE System Verification)	-	Part 2 Clauses 7.9.2.5, 7.9.2.6 and 7.9.2.8.
19	Install factory-built and field equipment scopes on site	10	Part 2 Clause 7.5.
20	Prepare for E/E/PE System Validation	8	Part 2 Clause 7.3.
21	E/E/PE System Validation	12	Part 2 Clause 7.7.
22	Prepare for Overall safety Validation	7	Part 1 Clause 7.8.
23	Overall Safety Validation	13	Part 1 Clause 7.14.
24	Functional Safety Assessment Review	-	Part 1 Clause 8.
25	Handover	6	Part 2 Clause 7.6.
26	Operations & Maintenance (O&M) obligations	14, 15	Part 2 Clause 7.6.

[2] Where there is a blank in the Index of Tables against the IEC 61508 Safety Life Cycle this indicates that there is no direct mapping to a specific box in the Safety Life Cycle.
[3] Box 11 of the IEC 61508:2010 Safety Life Cycle has to be taken into account by those engaged in functional safety E/E/PE systems, but specification and realisation of it is generally carried out by others from those classically responsible for functional safety E/E/PE systems.

T6A022 – Functional Safety Roles & Responsibilities: End Users and Engineering Contractors

Legend	Definition
R (responsible)	The party responsible for completion of this activity and often involved in doing the work to accomplish this task.
A (approves or accountable)	Accountable for the contribution of the activity to the overall functional safety of the plant and/or process and, hence, the final decision taker on the completion and acceptability of the activity and its outputs and deliverables.
C (contributor)	People to seek input, guidance and feedback from prior to completion of this activity. Done under the leadership, direction, request, co-ordination and/or guidance of the responsible organisation.
I (inform)	People to inform about the activity, particularly about any decisions, outputs and deliverables, either during the activity or once it is complete.
Blank	No Involvement.
/	Divider for multiple roles; 1st letter is primary role; 2nd letter is secondary role.

5.3 Table 1 – Define and Confirm Functional Safety Strategy

TABLE 1	DEFINE AND CONFIRM FUNCTIONAL SAFETY STRATEGY			
Decide, define and confirm how the functional safety roles and responsibilities are to be allocated amongst the organisations involved (i.e., confirm or adapt this document for the project).				
See IEC 61508-1:2010 Clause 6.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
This document. End User's own Procedures. EPC Contractor's own Procedures.	End User	**R**	Decide upon the strategy for allocation of functional safety activities across the scope of plant and process works and between the organisations involved in the project. Define the allocation in the spec, contract or other suitable documentation, possibly through use of this document, amended as necessary.	Roles and responsibilities definition – a project specific (amended) version of this document. Inclusion in project specification and/or contract documentation.
	End User's Engineer	**C**	Provision of advice and recommendations.	
	EPC Contractor	**A**	Review the roles and responsibilities definition and confirm acceptance or otherwise. Create plan for allocation of roles and responsibilities and to manage the consolidation of individual contributions.	Confirmation of acceptance of roles and responsibilities definition. Outline plan for roles, responsibilities and consolidation.
	EPC contractor's Plant/process subcontractor(s)	**I**	Can be consulted if appointed at this phase of the project.	
	EPC contractor's functional safety consultant	**C**	Provision of advice and recommendations.	
	EPC contractor's safety system subcontractor	**I**	Can be consulted if appointed at this phase of the project.	

5.4 Table 2 – Define and Confirm Scope

TABLE 2	DEFINE AND CONFIRM SCOPE			
Define and confirm the scope of works and associated plant and process to be considered for having functional safety content or for affecting hazards, risks or risk reduction.				
See IEC 61508-1:2010 Clauses 7.2 and 7.3.2.1.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Project scope documentation. Project specification and/or contract documentation.	EPC Contractor	**R**	Define the scope of plant and process works to be covered by the functional safety activities. Define any split between organisations by plant or process area.	Functional Safety scope definition document(s).
	End User	**A**	Review and confirm acceptance of the scope definition and allocation.	Confirmation of acceptance
	End User's Engineer	**C**	Provision of advice and recommendations.	
	EPC contractor's Plant/process subcontractor(s)	**I**	Can be consulted if appointed at this phase of the project.	
	EPC contractor's functional safety consultant	**I**	Can be consulted if appointed at this phase of the project.	
	EPC contractor's safety system subcontractor	**I**	Can be consulted if appointed at this phase of the project.	

5.5 Table 3 – Identify Functional Safety Teams

TABLE 3	IDENTIFY FUNCTIONAL SAFETY TEAMS			
Identify those responsible for functional safety leadership and engineering within each organisation.				
See IEC 61508-1:2010 Clauses 6.2.1, 6.2.3 and 6.2.13-6.2.15				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Staff allocation processes and Procedures. Training and Competency records.	EPC Contractor	**R**	Identify the relevant people, confirming that they have the required competencies. Publish the information to the other organisations through a project organogram or similar.	Project organogram or similar showing functional safety leaders and engineers in all organisations.
	End User	**C/A /I**	Identify the relevant people, confirming that they have the required competencies. Publish the information to the other organisations through the EPC Contractor.	List of functional safety team.
	End User's Engineer	**C/I**	Identify the relevant people, confirming that they have the required competencies. Publish the information to the other organisations through the End User.	List of functional safety team.
	EPC contractor's Plant/process subcontractor(s)	**C/I**	Identify the relevant people, confirming that they have the required competencies – these are likely to be plant and process engineers, rather than functional safety engineers. Publish the information to the other organisations through the EPC Contractor.	List of functional safety team.
	EPC contractor's functional safety consultant	**C/I**	Identify the relevant people, confirming that they have the required competencies. Publish the information to the other organisations through the EPC Contractor.	List of functional safety team.
	EPC contractor's safety system subcontractor	**C/I**	Identify the relevant people, confirming that they have the required competencies. Publish the information to the other organisations through the EPC Contractor.	List of functional safety team.

5.6 Table 4 – Agree and Define Functional Safety Working Methods

TABLE 4	AGREE AND DEFINE FUNCTIONAL SAFETY WORKING METHODS			
Share and review each organisation's requirements, obligations and expectations for the functional safety work. Discuss, agree and define the approach, plan, methods, tools and deliverables. Agree the means by which integrity (hardware reliability, hardware fault tolerance and SIL) will be assessed, determined, confirmed and documented				
See IEC 61508-1:2010 Clauses 6.2.4-6.2.12.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
End User's and EPC contractor's expectations. Project specification and/or contract documentation. EPC contractor's own Procedures. Sub-contractors' own procedures.	EPC Contractor	**R**	Convene meeting(s) to discuss and agree functional safety working methods. Prepare and issue documentation to define functional safety working methods for the project. Obtain End User's confirmation.	Definition of agreed approach, methods, tools and deliverables. Definition of agreed means by which integrity will be assessed, determined, confirmed and documented.
	End User	**C/A**	Review documentation, attend meeting(s) and provide confirmation of acceptance once document is satisfactory. Integrate definitions produced by EPC Contractor into own working documents as required.	Confirmation of acceptance. Working documents in line with definitions.
	End User's Engineer	**C**	Provision of advice and recommendations.	Working documents in line with definitions.
	EPC contractor's Plant/process subcontractor(s)	**C/I**	Review documentation, attend meeting(s) and integrate definitions produced by EPC Contractor into own working documents as required.	Working documents in line with definitions.
	EPC contractor's functional safety consultant	**C/I**	Review documentation, attend meeting(s) and integrate definitions produced by EPC Contractor into own working documents as required.	Working documents in line with definitions.
	EPC contractor's safety system subcontractor	**I**	Review documentation, attend meeting(s) and integrate definitions produced by EPC Contractor into own working documents as required.	Working documents in line with definitions.

5.7 Table 5 – Agree and Define Safety Related Software Management

TABLE 5	AGREE AND DEFINE SAFETY RELATED SOFTWARE MANAGEMENT			
Agree how safety related software will be managed and how its SIL compliance will be achieved, documented and certified.				
See IEC 61508-1:2010 Clause 6.2.10 and IEC 61508-3:2010 Clause 6.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
End User's and EPC contractor's expectations. Project specification and/or contract documentation. EPC contractor's own Procedures. End User's own Procedures. Sub-contractor's own Procedures.	EPC Contractor	**R**	Convene meeting(s) to discuss and agree safety related software management for the project. Prepare and issue documentation to define safety related software management for the project. Obtain End User's confirmation.	Definition of agreed approach, methods, tools and deliverables. Definition of how SIL compliance will be achieved, documented and certified.
	End User	**C/A**	Review documentation, attend meeting(s) and provide confirmation of acceptance once document is satisfactory. Integrate definitions produced by EPC Contractor into own working documents as required.	Confirmation of acceptance. Working documents in line with definitions.
	End User's Engineer	**C**	Provision of advice and recommendations.	Working documents in line with definitions.
	EPC contractor's Plant/process subcontractor(s)	**C/I**	Review documentation, attend meeting(s) and integrate definitions produced by EPC Contractor into own working documents as required.	Working documents in line with definitions.
	EPC contractor's functional safety consultant	**C/I**	Review documentation, attend meeting(s) and integrate definitions produced by EPC Contractor into own working documents as required.	Working documents in line with definitions.

	EPC contractor's safety system subcontractor	**C/I**	Review documentation, attend meeting(s) and integrate definitions produced by EPC Contractor into own working documents as required.	Working documents in line with definitions.

5.8 Table 6 – Agree and Define Tolerable Risk Issues

TABLE 6	AGREE AND DEFINE TOLERABLE RISK ISSUES			
End User to define or confirm the tolerable risk criteria to be applied to the project.				
See IEC 61508-1:2010 Clause 7.4.2.10 and IEC 61508-5:2010 Annex A2.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
All party's tolerable risk documentation. Project specification and/or contract documentation. Industry and/or regulatory guidance.	EPC contractor	**R**	Convene meeting(s) (as required) to discuss and meet the tolerable risk criteria requirements of the end user. Prepare and issue documentation to define tolerable risk criteria to be applied to the project. Obtain End User's confirmation.	Definition of tolerable risk criteria.
	End User	**C/A**	Review documentation, attend meeting(s) and provide confirmation of acceptance once document is satisfactory. Integrate definitions produced by EPC Contractor into own working documents as required.	Confirmation of acceptance. Working documents in line with definitions.
	End User's Engineer	**C**	Provision of advice and recommendations.	Working documents in line with definitions.
	EPC contractor's Plant/process subcontractor(s)	**C/I**	Review documentation, attend meeting(s) and integrate definitions produced by EPC Contractor into own working documents as required.	Working documents in line with definitions.
	EPC contractor's functional safety consultant	**C/I**	Review documentation, attend meeting(s) and integrate definitions produced by EPC Contractor into own working documents as required.	Working documents in line with definitions.
	EPC contractor's safety system subcontractor	**C/I**	Review documentation, attend meeting(s) and integrate definitions produced by EPC Contractor into own working documents as required.	Working documents in line with definitions.

5.9 Table 7 – Prepare for Hazard Identification

TABLE 7	PREPARE FOR HAZARD IDENTIFICATION			
Provide documented information to cover the nature, arrangement and functionality of all of the plant and process within the functional safety scope. This is likely to include P&IDs; Control Philosophy; Requirements Specification; Operating instructions and other outline design documentation.				
See IEC 61508-1:2010 Clauses 7.3.2.2-7.3.2.6.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Project specification and/or contract documentation. Plant and process design. Plant and process documentation. Project documentation management process.	EPC Contractor	**R**	Obtain, develop and provide controlled documentation to describe the plant and process within the functional safety scope.	Plant and process documentation.
	End User	**C**	Review plant and process documentation to facilitate role in Hazard Identification activity.	
	End User's Engineer	**I**	Review plant and process documentation to facilitate role in Hazard Identification activity.	
	EPC contractor's Plant/process subcontractor(s)	**C**	Obtain, develop and provide controlled documentation to describe the plant and process within the subcontractor's scope.	Plant and process documentation.
	EPC contractor's functional safety consultant	**I**	Review plant and process documentation to facilitate role in Hazard Identification activity.	
	EPC contractor's safety system subcontractor		No direct contributory role or responsibility.	

5.10 Table 8 – Hazard Identification

TABLE 8	HAZARD IDENTIFICATION			
Instigate, carry out and record an activity to identify potentially hazardous events within the defined scope that require functional safety assessment. This could be through HAZOP or HAZID-type processes.				
See IEC 61508-1:2010 Clause 7.4				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Plant and process documentation. Hazard Identification procedure (part of functional safety working methods).	EPC Contractor	**R**	Lead, carry out and record a hazard identification process (possibly HAZOP or enriched HAZOP). If HAZOP, engage, subject to End User approval, the (independent) chair for the HAZOP. Obtain and address other party's comments on the documentation.	List of potentially hazardous events to be subject to functional safety assessment. List, with justifications, of issues considered but not to be subject to functional safety assessment.
	End User	**C**	Instigate (through inclusion in contractual requirements), attend and contribute to hazard identification process. Review and comment on EPC Contractor's documentation.	Comments on EPC Contractor documentation.
	End User's Engineer	**C**	Attend and contribute to hazard identification process. Review and comment on EPC Contractor's documentation.	Comments on EPC Contractor documentation.
	EPC contractor's Plant/process subcontractor(s)	**C**	Attend and contribute to hazard identification process. Review and comment on EPC Contractor's documentation.	Comments on EPC Contractor documentation.
	EPC contractor's functional safety consultant	**C**	Attend and contribute to hazard identification process. Review and comment on EPC Contractor's documentation.	Comments on EPC Contractor documentation.
	EPC contractor's safety system subcontractor	**I**	No direct contributory role or responsibility.	

NOTE: Some organisations conduct some or all of the Hazard Identification and the preparation for and the conducting of the initial functional quantification together in a single workshop type session using Risk Graph or LOPA. Some organisations conduct these as separate exercise doing the initial functional safety quantification as a desktop exercise using LOPA or FTA. If necessary, the contents of this table should be modified to suit the approach to be used.

5.11 Table 9 – Prepare for Initial Functional Safety Quantification

TABLE 9	PREPARE FOR INITIAL FUNCTIONAL SAFETY QUANTIFICATION

For each potentially hazardous event to be subject to functional safety assessment obtain, develop and document the information required to carry out the initial functional safety quantification. This information will include;

- Relevant plant and process information.[4]
- The hazard and the mechanism by which it occurs.
- The initiating causes.
- All defences that can reduce the likelihood of occurrence.
- All mitigations that can reduce the consequences of occurrence.
- The likely human exposure should the event occur.
- The possible safety function(s).

See IEC 61508-1:2010 Clause 7.4

INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Hazard Identification documentation. Plant and process design documentation. Plant, process and engineering expertise. Operating information. Occupancy information. **NOTE:** Some organisations conduct some, or all, of the Hazard Identification, and the preparation for, and the conducting of, the initial functional quantification together in a single workshop type	EPC contractor's functional safety consultant	**R**	For each potentially hazardous events to be subject to functional safety assessment obtain, develop and document the information required to carry out the overall safety requirements allocation and the initial functional safety assessment. Obtain and address other party's comments on the documentation.	Documentation containing the required information.
	EPC contractor	**C/A**	Carry out the EPC contractor's functional safety consultant role if no separate consultant appointed. Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor 's functional safety consultant's documentation.
	End User	**C**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.

[4] This activity, and especially preparing for the overall safety requirements allocation, has to involve plant and process expertise as well as functional safety expertise.

session using Risk Graph or LOPA. Some organisations conduct these as separate exercises doing the initial functional safety quantification as a desktop exercise using LOPA or FTA. If necessary, the contents of this table should be modified to suit the approach to be used.	End User's Engineer	**C**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	EPC contractor's Plant/process subcontractor(s)	**C**	Provide plant and process information and contribute as required and as requested. Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	EPC contractor's safety system subcontractor		No direct contributory role or responsibility.	

5.12 Table 10 – Initial Functional Safety Quantification

TABLE 10	INITIAL FUNCTIONAL SAFETY QUANTIFICATION			
For each potentially hazardous event to be subject to functional safety assessment carry out the overall safety requirements allocation and perform a quantitative or semi-quantitative assessment of the as-current or as-currently-designed plant and process to determine any requirement for an E/E/PE safety function[5]. Document all initial functional safety quantifications.				
See IEC 61508-1:2010 Clause 7.4-7.6 and IEC 61508-5:2010 Annex B.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Documentation from "Prepare for initial functional safety quantification" activity. Plant, process and engineering expertise. Initial functional safety quantification procedure (part of functional safety working methods). Reliability data from Vendors and/or reliability data bases.	EPC contractor's functional safety consultant	**R**	Carry out and document the overall safety requirements allocation. Carry out and document the initial functional safety quantifications. Obtain and address other party's comments on the quantifications and the documentation.	Documented initial functional safety quantifications.
	EPC contractor	**C/A**	Carry out the EPC contractor's functional safety consultant role if no separate consultant appointed. Attend and participate if done in a workshop. Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	End User	**C**	Attend and participate if done in a workshop. Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	End User's Engineer	**C**	Attend and participate if done in a workshop. Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.

[5] This activity and especially the overall safety requirements allocation has to involve plant and process expertise as well as functional safety expertise.

	EPC contractor's Plant/process subcontractor(s)		Attend and participate if done in a workshop. Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	EPC contractor's safety system subcontractor		No direct contributory role or responsibility.	

NOTE: Some organisations conduct some, or all, of the Hazard Identification, and the preparation for, and the conducting of, the initial functional quantification together in a single workshop type session using Risk Graph or LOPA. Some organisations conduct these as separate exercise doing the initial functional safety quantification as a desktop exercise using LOPA or FTA. If necessary, the contents of this table should be modified to suit the approach to be used.

5.13 Table 11 – Safety Requirements Specification

TABLE 11	SAFETY REQUIREMENTS SPECIFICATION			
For each required safety function determine the safety function, hardware reliability, hardware fault tolerance and safety integrity level (SIL). Document this in the Safety Requirements Specification along with all additionally required information to; • Allow the factory-built part of the safety related systems to be specified, designed, implemented, installed and set-to-work. • Allow the required field equipment (instruments, actuators etc) to be specified. • Allow the O&M implications to be reviewed.				
See IEC 61508-1:2010 Clause 7.10 and IEC 61508-2:2010 Clause 7.2.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Documentation from all earlier activities.	EPC contractor's functional safety consultant	**R**	Carry out the required determinations. Prepare the Safety Requirements Specification. Obtain and address other party's comments on the determinations and the Safety Requirements Specification.	Safety Requirements Specification
	EPC contractor	**C/A**	Carry out the EPC contractor's functional safety consultant role if no separate consultant appointed. Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	End User	**C**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	End User's Engineer	**C**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	EPC contractor's Plant/process subcontractor(s)	**C**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.

	EPC contractor's safety system subcontractor	**C/I**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.

5.14 Table 12 – Human Factors Issues

TABLE 12	HUMAN FACTORS ISSUES			
Assess the human tasks (can be related to demands or risk reduction) included in the functional safety assessments and determine any implications for the design of equipment and systems.[6]				
See IEC 61508-1:2010 Clauses 7.4.2.3 and 7.4.2.10 and IEC 61508-2:2010 Clause 7.4.5.2 i)				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Documentation from all earlier activities.	EPC contractor's functional safety consultant	**R**	Review the human factors functional safety issues and define any human factors design requirements. Obtain and address other party's comments on the documentation.	Human factors design requirements.
	EPC contractor	**C/A**	Carry out the EPC contractor's functional safety consultant role if no separate consultant appointed. Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	End User	**C**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	End User's Engineer	**C**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	EPC contractor's safety system subcontractor	**C/I**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.
	EPC contractor's Plant/process subcontractor(s)	**C/I**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on EPC Contractor's functional safety consultant's documentation.

[6] Human factors apply to more than plant operator ergonomics. They apply to any human activity related to functional safety and safety related equipment and systems, including activities in control rooms and in the field and activities related to operation, testing and maintenance.

5.15 Table 12 – Design Factory-Built Scope

TABLE 13	DESIGN FACTORY-BUILT SCOPE			
Prepare and document a design of the factory-built part of the equipment and systems to implement each safety function. Carry out and document suitable assessment and integrity calculations to demonstrate compliance with the safety requirements specification.				
See IEC 61508-2:2010 Clause 7.4				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Safety Requirements Specification. Human factors design requirements. OEM/supplier information and documentation.	EPC contractor's safety system subcontractor	**R**	Carry out and document the designs. Carry out and document the assessments and calculations. Obtain and address other party's comments on the documentation.	Design documentation. Integrity assessment and calculations. Spurious trip rate assessment and calculations.
	EPC contractor	**C/A**	Carry out the EPC contractor's safety system subcontractor role if no separate contractor appointed. Review and comment on the EPC contractor's safety system subcontractor's documentation.	Comments on the EPC contractor's safety system subcontractor's documentation.
	EPC contractor's functional safety consultant	**C/A**	Review and comment on the EPC contractor's safety system subcontractor's documentation.	Comments on the EPC contractor's safety system subcontractor's documentation.
	End User	**C**	Review and comment on the EPC contractor's safety system subcontractor's documentation.	Comments on the EPC contractor's safety system subcontractor's documentation.
	End User's Engineer	**C**	Review and comment on the EPC contractor's safety system subcontractor's documentation.	Comments on the EPC contractor's safety system subcontractor's documentation.
	EPC contractor's Plant/process subcontractor(s)		No direct contributory role or responsibility.	

5.16 Table 14 – Design / Select Field Equipment Scope

TABLE 14	DESIGN/SELECT FIELD EQUIPMENT SCOPE			
Prepare and document a design of the field equipment and systems to implement each safety function. Carry out and document suitable assessment and integrity calculations to demonstrate compliance with the safety requirements specification.				
See IEC 61508-2:2010 Clause 7.4				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Safety Requirements Specification. Human factors design requirements. Plant and process design. OEM/supplier information and documentation.	EPC Contractor	**R**	Carry out and document the designs. Carry out and document the assessments and calculations. Obtain and address other party's comments on the documentation.	Design documentation. Integrity assessment and calculations. Spurious trip rate assessment and calculations.
	EPC contractor's functional safety consultant	**C**	Provision of advice and recommendations. Review and comment on the EPC contractor's documentation.	Comments on the EPC contractor's documentation.
	EPC contractor's Plant/process subcontractor(s)	**C/I**	Provision of advice and recommendations. Review and comment on the EPC contractor's documentation.	Comments on the EPC contractor's documentation.
	End User	**C**	Review and comment on the EPC contractor's documentation.	Comments on the EPC contractor's documentation.
	End User's Engineer	**C**	Review and comment on the EPC contractor's documentation.	Comments on the EPC contractor's documentation.
	EPC contractor's safety system subcontractor		If appropriate, review and comment on the EPC contractor's documentation.	Comments on the EPC contractor's documentation.

5.17 Table 15 – Second Functional Safety Quantification

TABLE 15	SECOND FUNCTIONAL SAFETY QUANTIFICATION			
Consolidate the E/E/PE system design, assessment and integrity information into the second functional safety quantification. Confirm that the provision of the E/E/PE system results in the residual risk complying with the tolerable risk criteria.				
See IEC 61508-2:2010 Clause 7.4.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Documentation from all earlier activities. Second functional safety quantification procedure (part of functional safety working methods). Reliability data from Vendors and/or reliability data bases.	EPC contractor's functional safety consultant	**R**	Receive information from EPC contractor's safety system subcontractor and consolidate into the functional safety assessment. Compare protected residual risk with tolerable risk criteria. Obtain and address other party's comments on the documentation.	Second functional safety quantification documentation.
	EPC contractor	**C**	Carry out the EPC contractor's functional safety consultant role if no separate consultant appointed. Review and comment on the EPC contractor's functional safety consultant's documentation. Resolve any excessive residual risks identified through provision of additional risk reduction or through a concession from the End User.	Comments on the EPC contractor's safety system subcontractor's documentation. Resolution of any excessive residual risks identified.
	End User	**C/A**	Review and comment on the EPC contractor's functional safety consultant's documentation. Consider means of resolving any excessive residual risk with the EPC contractor.	Comments on the EPC contractor's safety system subcontractor's documentation.
	End User's Engineer	**C**	Review and comment on the EPC contractor's functional safety consultant's documentation. Provision of advice and recommendations.	Comments on the EPC contractor's safety system subcontractor's documentation.

	EPC contractor's Plant/process subcontractor(s)	**C**	Review and comment on the EPC contractor's functional safety consultant's documentation. Provision of advice and recommendations.	Comments on the EPC contractor's safety system subcontractor's documentation.
	EPC contractor's safety system subcontractor	**C**	Review and comment on the EPC contractor's functional safety consultant's documentation.	Comments on the EPC contractor's safety system subcontractor's documentation.

5.18 Table 16 – Fabricate Factory-Built Safety Related Systems

TABLE 16	FABRICATE FACTORY-BUILT SAFETY RELATED SYSTEMS			
Fabricate the safety related system(s) to the documented design.				
See IEC 61508-2:2010 Clauses 7.4.9.1-7.4.9.3 and IEC 61508-3:2010 Clause 7.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Design documentation (factory-built scope). Working documents in line with Functional safety working methods and safety related software management definitions.	EPC contractor's safety system subcontractor	**R**	Build equipment, software and systems to the documented design and in line with the working methods and safety related software management definitions. Carry out visual inspections, calibration and cold and hot testing. Provide as-built, installation and set-up documentation. Obtain and address other party's comments on the documentation.	Built system. As-built documentation. Integrity certification and compliance statements. Installation and set-up documentation. Calibration records. Test records.
	EPC contractor	**C/A**	Carry out the EPC contractor's safety system subcontractor role if no separate contractor appointed. Review and comment on the EPC contractor's safety system subcontractor's documentation.	Comments on the EPC contractor's safety system subcontractor's documentation.
	EPC contractor's functional safety consultant	**C**	Review and comment on the EPC contractor's safety system subcontractor's documentation.	Comments on the EPC contractor's safety system subcontractor's documentation.
	End User	**C**	Review and comment on the EPC contractor's safety system subcontractor's documentation.	Comments on the EPC contractor's safety system subcontractor's documentation.
	End User's Engineer	**C**	Review and comment on the EPC contractor's safety system subcontractor's documentation.	Comments on the EPC contractor's safety system subcontractor's documentation.
	EPC contractor's Plant/process subcontractor(s)		No direct contributory role or responsibility.	

5.19 Table 17 – Prepare for FAT (E/E/PE System Verification)

TABLE 17	PREPARE FOR FAT (E/E/PE SYSTEM VERIFICATION)			
Prepare the FAT test strategy, methods and documentation. Define the method for dealing with faults and non-conformances.				
See IEC 61508-2:2010 Clauses 7.9.2.1-7.9.24				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Design documents (factory-built scope). Project specification and/or contract documentation. Functional safety FAT procedure (part of working methods definition).	EPC contractor	**R/A**	Define the FAT test strategy and requirements. Agree the method for dealing with faults and non-conformances. Obtain and address other party's comments on the documentation. Review and comment on the FAT test documentation.	FAT strategy and requirements documentation. Comments on the FAT test documentation.
	EPC contractor's functional safety consultant	**C**	Provision of advice and recommendations. Review and comment on the FAT strategy, requirements and test documentation.	Comments on the FAT strategy, requirements and test documentation.
	EPC contractor's safety system subcontractor	**C**	Review and comment on the FAT strategy and requirements documentation. Provide FAT test methods and test documentation. Produce the FAT test documentation and schedules. Define how results are to be recorded, assessed and interpreted. Agree the method for dealing with faults and non-conformances. Obtain and address other party's comments on the documentation.	Comments on the FAT strategy, and requirements documentation. FAT test documentation
	End User	**C**	Review and comment on the FAT strategy, requirements and test documentation.	Comments on the FAT strategy, requirements and test documentation.

	End User's Engineer	**C**	Provision of advice and recommendations. Review and comment on the FAT strategy, requirements and test documentation.	Comments on the FAT strategy, requirements and test documentation.
	EPC contractor's Plant/process subcontractor(s)		No direct contributory role or responsibility.	

5.20 Table 18 – Conduct and Report FAT (E/E/PE System Verification)

TABLE 18	CONDUCT AND REPORT FAT (E/E/PE SYSTEM VERIFICATION)			
Carry out the FAT as per the documented FAT strategy, requirements and test documentation. Record and interpret results. Deal with faults and non-conformances. Provide a FAT report.				
See IEC 61508-2:2010 Clauses 7.9.2.5, 7.9.2.6 and 7.9.2.8.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Design documents (factory-built scope). Project specification and/or contract documentation. FAT test documentation.	EPC contractor's safety system subcontractor	**R**	Carry out the FAT as per the documented FAT strategy, requirements and test documentation. Record and interpret results. Deal with faults and non-conformances. Provide a FAT report. Obtain and address other party's comments on the documentation.	FAT records. FAT Report.
	EPC contractor	**C/A**	Attend FAT. Review and comment on FAT Report.	Comments on FAT Report.
	EPC contractor's functional safety consultant	**C**	Provision of advice and recommendations. Review and comment on FAT Report.	Comments on FAT Report.
	End User	**C**	Attend FAT. Review and comment on FAT Report.	Comments on FAT Report.
	End User's Engineer	**C**	Review and comment on FAT Report.	Comments on FAT Report.
	EPC contractor's Plant/process subcontractor(s)		No direct contributory role or responsibility.	

5.21 Table 19 – Install Factory-Built and Field Equipment Scopes On Site

TABLE 19	INSTALL FACTORY-BUILT AND FIELD EQUIPMENT SCOPES ON SITE			
Install and integrate factory-built and field equipment scopes on site. Carry out visual inspection and loop/cold testing to confirm built-to-design and to identify faults.				
See IEC 61508-2:2010 Clause 7.5				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Documentation from earlier activities. OEM/supplier documentation.	EPC contractor	R	Install and integrate factory-built and field equipment scopes on site. To be done in line with the integrity management documentation and the safety related software management documentation. Carry out visual inspection and cold testing. Use demonstrably competent staff or subcontractors. Set up and calibrate systems.	Installed equipment and systems. As-built documentation. Inspection records. Loop/Cold testing records.
	EPC contractor's safety system subcontractor	C	Provision of installation and set-up documentation. Carry out any provision or works instructed by the EPC contractor. Provision of support and advice.	
	EPC contractor's functional safety consultant	C	Provision of advice and recommendations.	
	End User	C/A	Witness/audit some of the installation, inspection and cold testing activities and records.	Audit records and/or reports.
	End User's Engineer	C	Provision of advice and recommendations.	
	EPC contractor's Plant/process subcontractor(s)	C	Carry out any provision or works instructed by the EPC contractor.	Completion reports and as-built documentation.

5.22 Table 20 Prepare for E/E/PE System Validation

TABLE 20	PREPARE FOR E/E/PE SYSTEM VALIDATION			
Often part of "commissioning". Plan the test programme and test methods for functional testing and hot testing. Prepare test documentation. Prepare risk assessments as required. Might be combined with Overall Safety Validation.				
See IEC 61508-2:2010 Clause 7.3.				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Documentation from earlier activities. Project and/or contract documentation.	EPC contractor	**R**	Plan the test programme and test methods for functional testing and hot testing. Prepare test documentation. Prepare risk assessments as required. Prepare change control process. Obtain and address other party's comments on the documentation.	Test programme. Test method statements. Test documentation. Risk assessments. Change control process.
	EPC contractor's functional safety consultant	**C**	Provision of advice and recommendations. Review EPC contractor's documentation.	Comments on EPC contractor documents.
	End User	**C/A**	Review EPC contractor's documentation.	Comments on EPC contractor documents.
	End User's Engineer	**C**	Provision of advice and recommendations. Review EPC contractor's documentation.	Comments on EPC contractor documents.
	EPC contractor's Plant/process subcontractor(s)	**C**	Provision of advice and recommendations. Review EPC contractor's documentation.	Comments on EPC contractor documents.
	EPC contractor's safety system subcontractor	**C**	Provision of advice and recommendations. Review EPC contractor's documentation.	Comments on EPC contractor documents.

5.23 Table 21 – E/E/PE System Validation

TABLE 21	E/E/PE SYSTEM VALIDATION			
Often part of "commissioning". Carry out functional testing of equipment and systems, including SAT as required. Carry out hot testing (i.e., with process fluids and plant running) to demonstrate compliance with design. Might be combined with Overall Safety Validation.				
See IEC 61508-2:2010 Clause 7.7				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
As-built documentation. Test programme. Test method statements. Test documentation. Risk assessments. Change control process.	EPC contractor	**R**	Carry out functional testing of equipment and systems, including SAT as required. Carry out hot testing. Update as-built documentation as necessary.	Functional testing records. SAT records. Hot testing records. Change control records. Updated as-built documentation.
	EPC contractor's functional safety consultant	**C**	Provision of advice and recommendations.	
	End User	**C/A**	Witness/audit some/all of the functional testing and hot testing activities and records.	Audit records and/or reports.
	End User's Engineer	**C**	Provision of advice and recommendations.	
	EPC contractor's Plant/process subcontractor(s)	**C**	Provision of advice and recommendations.	
	EPC contractor's safety system subcontractor	**C**	Provision of advice and recommendations.	

5.24 Table 22 – Prepare for Overall Safety Validation

TABLE 22	PREPARE FOR OVERALL SAFETY VALIDATION			
Often part of "commissioning". Plan the test programme and test methods for validation. Prepare test documentation. Prepare risk assessments as required.				
See IEC 61508-1:2010 Clause 7.8				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Safety Requirements Specification. Functional safety quantification documentation. Updated as-built documentation. Project and/or contract documentation.	EPC contractor	**R**	Plan the test programme and test methods for functional testing of the SIFs. Prepare test documentation. Prepare risk assessments as required. Obtain and address other party's comments on the documentation.	Test programme. Test method statements. Test documentation. Risk assessments.
	EPC contractor's functional safety consultant	**C**	Provision of advice and recommendations. Review EPC contractor's documentation.	Comments on EPC contractor documents.
	End User	**C/A**	Review EPC contractor's documentation.	Comments on EPC contractor documents.
	End User's Engineer	**C**	Provision of advice and recommendations. Review EPC contractor's documentation.	Comments on EPC contractor documents.
	EPC contractor's Plant/process subcontractor(s)	**C**	Provision of advice and recommendations. Review EPC contractor's documentation.	Comments on EPC contractor documents.
	EPC contractor's safety system subcontractor	**C**	Provision of advice and recommendations. Review EPC contractor's documentation.	Comments on EPC contractor documents.

5.25 Table 23 – Overall Safety Validation

TABLE 23	OVERALL SAFETY VALIDATION			
Often part of "commissioning". Carry out functional testing of the measures and systems (including the E/E/PE systems) protecting the plant and process to demonstrate compliance with the safety requirements.				
See IEC 61508-1:2010 Clause 7.14				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
Test programme. Test method statements. Test documentation. Risk assessments.	EPC contractor	**R**	Carry out and document functional testing of the SIFs.	Functional testing records. Overall Safety Validation report.
	EPC contractor's functional safety consultant	**C**	Provision of advice and recommendations.	
	End User	**C/A**	Witness/audit all of the functional testing activities and records.	Audit records and/or reports.
	End User's Engineer	**C**	Provision of advice and recommendations.	
	EPC contractor's Plant/process subcontractor(s)	**C**	Provision of advice and recommendations.	
	EPC contractor's safety system subcontractor	**C**	Provision of advice and recommendations.	

5.26 Table 24 – Functional Safety Assessment Review

TABLE 24	FUNCTIONAL SAFETY ASSESSMENT REVIEW			
Carry out a review of all of the functional safety activities and deliverables to ensure that they have been carried out comprehensively and with appropriate quality and rigour. For higher SIL systems this review might need to be carried out independently. Review to be written up as a report.				
See IEC 61508-1:2010 Clause 8				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
All functional safety documentation.	EPC contractor's functional safety consultant	**R**	Carry out or arrange for a review of all of the functional safety activities and deliverables.	Functional Safety Assessment report.
	EPC contractor	**C**	Carry out the EPC contractor's functional safety consultant role if no separate consultant appointed. Review the report and address any shortfalls or non-conformances identified.	Resolution of any shortfalls or non-compliances identified.
	End User	**C/A**	Review the report and address any shortfalls or non-conformances identified.	Resolution of any shortfalls or non-compliances identified.
	End User's Engineer	**C**	Review the report. Provision of advice and recommendations.	
	EPC contractor's Plant/process subcontractor(s)			
	EPC contractor's safety system subcontractor			

5.27 Table 25 - Handover

TABLE 25	HANDOVER			
End User to be provided with; • Evidence of the functional safety achieved. • Evidence that the functional safety was properly determined and addressed throughout all activities. • Information to ensure that the functional safety can be maintained through operations and maintenance. • Information to support future modification and/or de-commissioning of the functional safety systems.				
See IEC 61508-2:2010 Clause 7.6				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
All functional safety documentation.	EPC contractor	**R**	Provide evidence of completion of all functional safety activities. Provide all required certificates and other statements of compliance. Provide O&M documentation, ensuring that this provides the End User with adequate information to maintain safety functionality and integrity.	Evidence of completion. Certificates and compliance statements. O&M documentation.
	EPC contractor's functional safety consultant	**C**	Provision of advice and recommendations.	
	End User	**A**	Receive, review and confirm adequacy of documentation provided. Incorporate requirements to maintain safety functionality and integrity into O&M Procedures.	O&M Procedures relating to functional safety.
	End User's Engineer	**C**	Provision of advice and recommendations.	
	EPC contractor's Plant/process subcontractor(s)			
	EPC contractor's safety system subcontractor			

5.28 Table 26 – Operations & Maintenance (O&M) Obligations

TABLE 26	OPERATIONS & MAINTENANCE (O&M) OBLIGATIONS			
The End User has to carry out (or have carried out) the servicing, maintenance and testing specified in the O&M documentation in order that the functionality and integrity of the E/E/PE systems is preserved. Any modifications to the E/E/PE systems have to be properly assessed.				
See IEC 61508-2:2010 Clause 7.6				
INPUTS	BY WHOM	ROLE	DETAILS	OUTPUTS AND DELIVERABLES
O&M documentation. O&M Procedures relating to functional safety.	End User	**R/A**	Preserve and have available all functional safety documentation created for the project. Carry out (or have carried out) the servicing, maintenance and testing specified in the O&M documentation in order that the functionality and integrity of the E/E/PE systems is preserved. Have any modifications to the E/E/PE systems properly assessed. Update the functional safety documentation as required.	Managed documentation. Servicing, maintenance and testing management procedures, method documents and records. Change control procedures. Modification documentation. Updated functional safety documentation.
	End User's Engineer	**C**	Provision of advice and recommendations.	
	EPC contractor		Preserve documentation and records to be able to respond to enquiries from the End User or regulatory body.	Archived documentation.
	EPC contractor's functional safety consultant		Preserve documentation and records to be able to respond to enquiries from the End User or regulatory body.	Archived documentation.
	EPC contractor's safety system subcontractor		Preserve documentation and records to be able to respond to enquiries from the End User or regulatory body.	Archived documentation.
	EPC contractor's Plant/process subcontractor(s)		Preserve documentation and records to be able to respond to enquiries from the End User or regulatory body.	Archived documentation.

6. Existing and Emerging Standards

- IEC 61508-1:2010, *Functional safety of electrical / electronic / programmable electronic safety-related systems – Part 1: General requirements*
- IEC 61508-2:2010, *Functional safety of electrical / electronic / programmable electronic safety-related systems – Part 2: Requirements for electrical / electronic / programmable electronic safety-related systems*
- IEC 61508-3:2010, *Functional safety of electrical / electronic / programmable electronic safety-related systems – Part 3: Software requirements*
- IEC 61511:2017, *Functional safety – Safety instrumented systems for the process industry sector – Part 1: Framework, definitions, system, hardware and application programming requirements*
- IEC 62061:2021, *Safety of machinery – Functional safety of safety-related control systems*

7. 61508 Association Recommended Practices

This document sets out to describe current best practices in roles and responsibilities for functional safety systems, but does not seek to prescribe specific measures, since these will depend on the application, and any existing constraints of the installation.

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