

A regis	stered copy of this completed self-assessment report ("The Declaration") is held at:
C	ASS-appointed body:
Ad	ddress:
Name of	of Owner making the declaration:
C	ASS-appointed body reference number:
Da	ate accepted for filing un-audited:

NOTE: The owner of this Functional Safety Management Self-Assessment Declaration may be a business or a person or other legal entity.

#### DISCLAIMER

While every care has been taken in developing and compiling the technical schedules and guidance to support the CASS scheme, The CASS Scheme Ltd, the contributors, and their parent organisations accept no liability for any loss, damage or injury caused, arising directly or indirectly in connection with reliance on its contents except to the extent that such liability may not lawfully be excluded under English Law.





This Functional Safety Management Declaration is a declaration solely by the owner named above. The owner is solely responsible for the content and the declarations made therein. Neither the CASS-appointed body nor The CASS Scheme Limited makes any warranty whatsoever concerning the Declaration nor accepts any liability for its contents. The Declaration is un-audited.



### Document History

Revision	Date	
0	31 Jan 2011	First issue
1	7 Feb 2011	Identifies IEC61508 Edition 1/ Edition 2 tables and references
2	7 Feb 2011	Editorial corrections Part 2 Table 1

### **Table of Contents**

Introduction	3
Reference and related documents	4
Abbreviations and terminology	4
Understanding what is in this Declaration	6
PART 1: BASIC DETAILS OF THE OWNER OR BUSINESS	
PART 2: SCHEDULE OF ACTIVITIES OF THE OWNER OR BUSINESS COVERED BY THIS SELF-ASSESSMENT DECLARATION	
PART 2 TABLE 1 - Overall ACTIVITIES COVERED BY THE IEC61508 GROUP OF STANDARDS	10
PART 2 TABLE 2 - ELECTRICAL / ELECTRONIC / PROGRAMMABLE ELECTRONIC SYSTEMS	12
PART 2 TABLE 3 - SOFTWARE FOR SAFETY INSTRUMENTED SYSTEMS	
PART 2 TABLE 4 - FUNCTIONAL SAFETY MANAGEMENT	17
PART 3: FUNCTIONAL SAFETY MANAGEMENT SELF-ASSESSMENT REPORT	19
Annex to Part 3 - Owner Documents submitted as part of the Self Assessment Declaration.	29





### Introduction

Functional Safety Management is essential for all safety-related systems and for all stages of the overall safety lifecycle (IEC61508 2<sup>nd</sup> edition Part 1 Figure 2).

A **Declaration** held by a CASS-appointed body is made available to the relevant national safety authority upon request by that safety authority. A **Declaration** will be held for a period of 10 years from the date accepted for filing of the un-audited **Declaration**.

For a **Declaration** held by a CASS-appointed body to be accepted, all sections of the **Declaration** must be completed<sup>2</sup>.

On each occasion that a customer of the Owner named above requests a copy of the Functional Safety Management Declaration then the CASS-appointed body will contact the Owner named on page 2 to confirm that the customer making the request is a customer of the Owner and then a copy will be made available on payment of an administration fee to the CASS-appointed body by the customer.

Copies of the Functional Safety Management Declaration requested by a relevant national safety body will be made available free of charge, let or hindrance.

<sup>1</sup> In the United Kingdom a relevant national safety authority would be the Health & Safety Executive.

<sup>2</sup> Within the **Declaration** -table The "Systems and procedures in place" column and the "Documentary evidence" column must both be completed for all cases but the "Notes" column need only be completed where relevant.



### Reference and related documents

The following documents are available from www.cass.uk.net

CASS28	CASS Templates For Software Requirements In Relation To IEC 61508 Part 3 Safety Function Assessment (based on IEC61508
	Edition 1)
CASS32	The CASS Functional Safety Management Declaration Lodged with a CASS-appointed Body
CASS33	Help and guidance on CAS32 in general, and on completing Part 1 of CASS32 in particular
CASS34	Help and guidance on completing Part 2 of CASS32
CASS35	Help and guidance on completing Part 3 of CASS32
FSCA Technical Schedules	Section 3 of The CASS Guide. The detailed cross- references to CASS Targets of Evaluation (TOEs) and IEC61508 Edition 1
	clauses applicable to Functional Safety Capability Assessment (FSCA)
The CASS Guide	A Published CASS Document defining the processes related to formal accredited assessment for compliance to IEC61508 Edition 1

Other Documents, not available from www.cass.uk.net

CASS36	Dossier Receipt from a CASS-appointed body, issued to an Owner who has lodged a Declaration

### **Abbreviations and terminology**

<b>0</b> 7			
Conformity Assessment of Safety-related Systems; an abbreviation for The CASS Scheme Ltd.			
CASS32, including any specified attachments.			
Electrical, Electronic, or Programmable Electronic. A descriptive term with reference to the technology of a safety-related system, as used in			
IEC61508			
An Electrical, Electronic, or Programmable Electronic safety-related system			
Functional Safety Capability Assessment. A CASS term used for the assessment of a Functional Safety Management system.			
Functional Safety Management			
the person, business, partnership or other legal entity who is completing the CASS32 form describing and documenting their Functional Safety			
Management system			
When used alone, this is a reference to the specific Part 1 of the Declaration (CASS32) document			
When used alone, this is a reference to the specific Part 2 of the Declaration (CASS32) document			
When used alone, this is a reference to the specific Part 3 of the Declaration (CASS32) document			



PES	A Programmable Electronic safety-related System, usually with the emphasis on being 'programmable' or software-based.
SIL	Safety Integrity Level. An IEC61508 term (q.v.) related to the increasing requirements in terms of performance properties and assessment rigour
	of a safety system with the increasing levels of risk reduction involved, from 1 (low) to 4 (highest)
ΓCSL	The CASS Scheme Ltd.
TOE	Target Of Evaluation. A specific property of a Functional Safety Management system for which the requirements are specified in one or more
	clauses in IEC61508, and for which a demonstration of compliance is required.



### Understanding what is in this Declaration

**PART 1:** 

Details of the owner

Details of the owner. This includes details of all of the locations at which the activities that are covered by the Declaration take place.

#### PART 2:

Scope of work and activities under IEC61508 group of standards carried out by the owner (i.e. Scope of work covered by the Functional Safety Management System)

Part 2 is the scope to which the Functional Safety Management system applies.

In order to understand what is claimed in PART 3, a list of all activities in which an owner may participate or be involved is given in PART 2. The owner will also identify in Part 2 all activities addressed by the standard, but in which they have no involvement.

For each relevant activity the owner will identify the procedure or process used for all activities in which they are involved, and provide a reference to the owner's justification of how those processes have been assessed to be compliant with the requirements of the standard.

#### **PART 3:**

### **Functional Safety Management System in detail**

PART 3 contains the detail of the Functional Safety Management ("FSM") system operated by the owner.

The details of the owner's FSM, referenced against the IEC61508 standard, and supported by the owner's records of evidence of operational day-to-day compliance, is contained in PART 3 of this Declaration.





Safety lifecycle activities undertaken at this location

number using IEC 61508 2<sup>nd</sup> edition Part 1 Figure 2

"Overall Safety Lifecycle"

identified by lifecycle

## CASS Functional Safety Management Declaration Lodged with CASS-appointed Body.

PART 1:	BASIC DETAILS OF THE OWNER	OR BUSINESS		
Date:				
Owner Name:				
Owner addres	s:			
Phone	e number:			
	ner is a company: any registration number:			
Comp	any Registered Address:			
Owner addres	ses at which functional safety activities are underta	ken:		
	Location 1	Location 2	Location 3	
Address				
Telephone:				





For guidance on completing Part 1, please see CASS33



### PART 2: SCHEDULE OF ACTIVITIES OF THE OWNER OR BUSINESS COVERED BY THIS SELF-ASSESSMENT DECLARATION

In the following schedule of activities identify each of the lines that describe an activity <u>not</u> undertaken by your Owner or business as Not Applicable (N/A), or by 'strike-through'. Do not delete rows from the tables.

The remaining activities represent the "Targets of Evaluation" (TOEs) which are relevant for the owner, and for which the information is needed to show conformity with the IEC61508 group of standards.

The "Document" column for relevant activities is to be completed to show the owner's procedure or process or similar for the activity and the "Location" identifies at which of the locations noted in Part 1 the master document resides.

The "Evidence" column identifies the owner's document containing the conformance plan i.e. the evidence (argument) that the procedure in the "Document" column appropriately addresses the requirements of the standard for that TOE.

The reference number in the 'Ref.' column in the tables below is the same reference number as is used in CASS FAQ and Help documents that assist in understanding each activity.

See CASS34 for detailed Help in completing Part 2.

Note that the transition from IEC61508 Edition 1 to Edition 2 is currently in progress. The TOEs in general will be consistent between Edition 1 and Edition 2 except where there are new requirements, but specific clause references will change. Edition 1 TOEs should be regarded as informative guidance when seeking compliance to Edition 2. See the latest version of the Help files for details.

#### For this CASS32 Revision 1:

Table	IEC61508 Edition	Status
Part 2 Table 1	Edition 2	
Part 2 Table 2	Edition 1	Edition 2 under development
Part 2 Table 3	Edition 1	Edition 2 under development
Part 2 Table 4	Edition 2	



### PART 2 TABLE 1 - Overall ACTIVITIES COVERED BY THE IEC61508 GROUP OF STANDARDS

Ref.	Overall TOEs	Document	Evidence	Location	Comments
2.1.1	Overall Safety Life-cycle				
2.1.2	Concept				
2.1.3	Fully Installed E/E/PES				
2.1.4	Fully Commissioned E/E/PES				
2.1.5	Overall Installation &				
	Commissioning Records				
2.1.6	Overall Scope Definition				
	Documents				
2.1.7	Overall Safety Plan				
	Hazard & risk Analysis Report				
2.1.9	, ,				
	Specification				
2.1.10	Safety Requirements				
	Allocation Report				
	Overall Safety Validation Plan				
2.1.12	Overall Operation and				
	Maintenance Plan				
2.1.13	Overall Installation &				
	Commissioning Plan				
2.1.14	E/E/PE System Safety				Also complete Part 2
	Requirements Specification				Table 2 E/E/PES Map
2.1.15	E/E/PE safety-related				
	systems: realisation phase				
	deliverables				



Ref.	Overall TOEs	Document	Evidence	Location	Comments
2.1.16	OTHER Risk Reduction MEASURES: SPECIFICATION and realisation phase deliverables				
	Overall Safety Validation Records				
	Overall Operation, Maintenance & Repair Records				
	Overall Modification & Retrofit Records				
	Decommissioning/disposal Plans & records				
2.1.21	Verification Documentation				



### PART 2 TABLE 2 - ELECTRICAL / ELECTRONIC / PROGRAMMABLE ELECTRONIC SYSTEMS

### MAPPING MATIX FOR **E/E/PES** TARGETS OF EVALUATION

Ref.	CASS E/E/PES TOE	Document	Evidence	Location	Comments
	Process Objects				
2.2.1					IF PES THEN ALSO COMPLETE Part 2 Table 3
	E/E/PES Safety Lifecycle				Software Map
	E/E/PES Objects				
2.2.2	Fully Functioning E/E/PES				
2.2.3	Fully Validated E/E/PES				
	<b>Documentation Objects</b>				
2.2.4	E/E/PES Safety Plan				
2.2.5	E/E/PES Safety Requirements Specification				
2.2.6	E/E/PES Safety Validation Plan				
2.2.7	E/E/PES Design Documentation				
2.2.8	E/E/PES Integration and Test Specification				
2.2.9	E/E/PES Integration and Test Report				
2.2.10	E/E/PES Integration and Test Log				
	E/E/PES Operation and Maintenance Procedures				
2.2.12	E/E/PES Safety Validation Report				
2.2.13	E/E/PES Safety Validation Log				
	E/E/PES Modification Procedures				
2.2.15	E/E/PES Modification Report				



Ref.	CASS E/E/PES TOE	Document	Evidence	Location	Comments
2.2.16	E/E/PES Modification Log				
	9				
	Verification Plans				
2217	E/E/PES Safety Requirements -				
	Verification Plan				
2.2.18	E/E/PES Validation Planning -				
	Verification Plan				
2.2.19	E/E/PES Design and development -				
	Verification Plan				
2.2.20	E/E/PES Integration - Verification				
	Plan				
2.2.21	E/E/PES Operation and				
	Maintenance Procedures-				
	Verification Plan				
2.2.22	E/E/PES Safety Validation -				
	Verification Plan				
2.2.23	E/E/PES Modification - Verification				
	Plan				
	Verification Reports				
2.2.24	E/E/PES Safety Requirements -				
	Verification Report				
2.2.25	E/E/PES Validation Planning -				
	Verification Report				
2.2.26	E/E/PES Design and development -				
	Verification Report				
2.2.27	E/E/PES Integration - Verification				
	Report				
2.2.28	E/E/PES Operation and				
	Maintenance Procedures-				
	Verification Report				
2.2.29	E/E/PES Safety Validation -				
	Verification Report				



Ref.	CASS E/E/PES TOE	Document	Evidence	Location	Comments
2.2.30	E/E/PES Modification - Verification				
	Report				



### PART 2 TABLE 3 - SOFTWARE FOR SAFETY INSTRUMENTED SYSTEMS

### MAPPING MATRIX FOR SOFTWARE TARGETS OF EVALUATION

Ref.	Target of Evaluation (TOE)	Document	Evidence	Location	Comments
	Software Quality Management				
2.3.1	Functional Safety planning				
2.3.2					
	Software safety lifecycle requirements				
2.3.3	Specification of the requirements for				
	software safety function and integrity				
2.3.4	Software safety requirements presentation				
	and reviews by software developer				
2.3.5	Software safety requirements traceability				
2.3.6	Software safety requirements of safety				
	functions and diagnostics				
2.3.7	Validation Planning				
2.3.8	Validation considerations				
2.3.9	Validation Strategy				
2.3.10	Validation plan review				
2.3.1	Design Method				
2.3.12	2 Testability of design				
2.3.13	Modification of design				
2.3.14	Safety considerations				
2.3.15	Self monitoring and diagnostics				
2.3.16	Reuse of design and code components				
2.3.17	Software architecture design				
2.3.18	Programming tools				
	Detailed design and development				
2.3.20	Code Implementation				
2.3.2	Software module testing				



Ref. Target of Evaluation (TOE)	Document	Evidence	Location	Comments
2.3.22 Software integration testing				
2.3.23 Specification of integration tests				
2.3.24 Impact analysis on change				
2.3.25 Documentation of results				
2.3.26 Execution of software safety validation				
2.3.27 Recording of results of the software		·		
safety validation				
2.3.28 Modification procedures				
2.3.29 Authorisation of software modification				
2.3.30 Impact analysis				
2.3.31 Modification of the software				
2.3.32 Verification planning				
2.3.33 Verification of the software (general)				
2.3.34 Software safety requirements verification				
2.3.35 Software architecture verification				
2.3.36 Software				
2.3.37 Software module design verification				
2.3.38 Code and data verification				



### PART 2 TABLE 4 - FUNCTIONAL SAFETY MANAGEMENT

### MAPPING MATRIX FOR FUNCTIONAL SAFETY CAPABILITY ASSESSMENT

Ref.	CASS Functional Safety Capability	Document	Evidence	Location	Comments
	TOE				
2.4.1	Functional Safety Management System				
2.4.2	Functional Safety Policy				
2.4.3	Organisation and Responsibilities				
2.4.4	Identification of relevant life-cycle phases				
2.4.5	Documentation structure and content policy				
2.4.6	Techniques and Measures conformance plan				
2.4.7	Corrective action procedure				
2.4.8	Competence assessment process				
2.4.9	Procedure for handling hazardous incidents & near misses				
2.4.10	Procedure for O&M performance analysis				
2.4.11	Functional safety audit process				
2.4.12	Modification process for safety related systems				
2.4.13	Procedures for maintaining information on hazards with respect to Safety-related systems or Safety Instrumented Functions with respect to Safety-Related Systems				
2.4.14	Configuration management procedures				
2.4.15	Procedures for provision of training and information for the emergency services				



Ref.	CASS Functional Safety Capability	Document	Evidence	Location	Comments
	Functional Safety Management System - Formal Reviews				
2.4.17	Supplier Assessment Process				
2.4.18 I	Functional Safety Assessment				



Data:

## CASS Functional Safety Management Declaration Lodged with CASS-appointed Body.

### PART 3: FUNCTIONAL SAFETY MANAGEMENT SELF-ASSESSMENT REPORT

bato.		
Safety Manager or equivalent (write name here):		
Signed:	Date:	
Board chair or Managing Director (write name here):		
Signed:	Date:	

For guidance on completing Part 3, please see CASS35

The Systems and Procedures in Place are the same as those defined in Part 2 Table 4.

The documentary evidence is that which demonstrates that this TOE has been applied in practice on projects, or on a routine day-to-day basis, by reference to the owner's operational management or project records of compliance for the activities undertaken.

In the following table the nomenclature 1:6.1.8 denotes IEC61508 2<sup>nd</sup> edition Part 1, clause 6, paragraph 1, item 8.

Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	Documentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
1	Functional Safety Management	Purpose To specify all management and technical activities that are necessary to ensure that the E/E/PE safety-related systems achieve and maintain the required functional safety (1/6.1.1) The activities specified as a result of 1/6.2.1 shall be implemented and progress monitored			Part 1 clause 6 Particularly – 1:6.2.1 to 1:6.2.12 inclusive including evidence for all the relevant sub-clauses and 1:6.2.16	



Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	Documentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
2	Functional Safety Policy	Purpose The policy and strategy for achieving functional safety, together with the means for evaluating its achievement, and the means by which this is communicated within the organisation to ensure a culture of safe working  There should be a top level policy statement that reflects the safety goals and objectives of the organisation.			Part 1 clause 6 Particularly – 1:6.2.2 and Figures 2, 3 and 4, Table 1, and 1:6.2.1 first bullet	



Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	Documentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
3	Organisation and Responsibilities	Purpose Identification of the persons, departments and organisations who perform or review safety lifecycle activities and allocation of responsibilities for those activities.  To ensure that all those named, nominated, specified or identified as responsible for management of functional safety activities are informed of the responsibilities assigned to them.  The allocation of responsibilities must be documented, and shall cover all of the scope of the person's functional safety activities.			Part 1 clause 6 Particularly – 1:6.2.3 and Figure 2, 3 and 4, Table1.	



Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	Documentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
4	Identification of relevant lifecycle phases	Purpose The overall E/E/PES or software safety lifecycle phases to be applied The documented plan shall show that there is an understanding of where all persons involved in functional safety fit within the overall safety lifecycle.			Part 1 Clause 6 Particularly – 1:6.2.1 first bullet and Figures 2, 3 and 4, Table 1.	
5	Documentation structure and content policy	Purpose There is a clear definition of the way in which information is to be structured and the extent of information to be documented.			Part 1 clause 6 Particularly – 1:6.2.4 and 1:5.0	



Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	Documentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
6	Techniques and Measures conformance plan	Purpose The selected measures and techniques used to meet the requirements of a specified clause or sub-clause of IEC 61508.  This is evidence of a policy in place which predefines a general approach by which compliance with the requirements of the relevant clauses is intended to be realised.			Part 1 clause 6 Particularly – 1:6.2.12 a)  Compliance techniques and measures will also refer to IEC 61508 Parts 2, 3 and 6.	
7	Corrective action procedure	Purpose The procedures for ensuring prompt follow-up and satisfactory resolution of recommendations arising from: - Hazard and risk, - functional safety assessment, - verification activities, - validation activities, - configuration management.			Part 1 clause 6 and: 1:7.16, 1:7.18, and Part 2 and Part 3 and Part 1 Figures 2, 3 and 4 and Part 1 Table 1 as framework.	



Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	Documentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
8	Competence assessment process	Purpose Procedures are defined for ensuring that those involved with any stage of functional safety in the lifecycle are competent to carry out their activities.  In particular, the following should be specified: - The training of staff in diagnosing and repairing faults and in system testing, - The training of operations staff, - The retraining of staff at periodic intervals.  In the UK the HSE "Managing competence for safety-related systems" is available as a free downloadable document and gives clear guidance and objectives for competency management.  The annex at the end of the FSCA Technical Schedules: "Competency Assessment Process Guidance Note" provides further detail and discussion on this topic.			Part 1 clause 6 Particularly – 1:6.2.1 and1: 6.2.13 and1: 6.2.14 and1: 6.2.15  Figures 2, 3 and 4 and Part 1 Table 1 as framework.	



Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place Documentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
9	Procedure for handling of hazardous incidents and near-misses	Purpose To define procedures which ensure that hazardous incidents (or incidents with potential to create hazards) are analyzed, and that recommendations are made to minimize the probability of a repeat occurrence.		Part 1 clause 6 Particularly – 1:6.2.5 f) and 1:6.2.6	
10	Procedure for Operating & Maintenance performance analysis  This TOE is only relevant to organisations performing either operations or maintenance activities or both.	Purpose To define procedures for analysing operations and maintenance performance. In particular: - recognising systematic faults which could jeopardise functional safety, including procedures used during routine maintenance which detect recurring faults, assessing whether the demand rates and failure rates during operation and maintenance are in accordance with assumptions made during the design of the system.		Part 1 Clause 6.2.12.c  Figures 2, 3 and 4 and Part 1 Table 1 as framework.  Part 1 Figure 7 provides and "Example operations and maintenance activities model".  Part 1 Figure 8 provides an "Example operation and maintenance management model".	



Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	Documentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
11	Functional safety audit process	Purpose The requirements for periodic functional safety audits are clear and in use in accordance with this sub-clause, including: - the frequency of the functional safety audits, - consideration as to the level of independence required for those responsible for the audits - the documentation and follow-up activities.			Part 1 clause 6 Particularly – 1:6.2.7 and 1:8.2.18	
12	Modification process for Safety related systems	Purpose To define the procedures for initiating modifications to the safety-related system or safety instrumented function; - and - To define the required approval procedure and authority for modifications.			Part 1 clause 6 Particularly – 1:6.2.8 a) and 1:6.2.8 b) and Figures 2, 3 and 4, Table 1 as framework and 1:7.16.2.2	



Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	cumentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
13	Procedures for maintaining information on hazards with respect to Safety-Related Systems or to the Safety Instrumented Function.	Purpose To define procedures for maintaining accurate information on potential hazards and accurate information on the safety-related systems.			Part 1 clause 6 Particularly – 1:6.2.9	
14	Configuration management procedures	Purpose To define the procedures for configuration management of the E/E/PE safety-related systems during the overall E/E/PES and software safety lifecycle phases.  In particular the following should be specified: - the stage at which formal configuration control is to be implemented, - the procedures to be used for uniquely identifying all constituent parts of an item (hardware and software), - the procedures for preventing unauthorised items from entering service.			Part 1 clause 6 Particularly – 1:6.2.10 and Figures 2, 3 and 4, Table 1 as framework and 3:6.2.3 : Software configuration management.	



Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	Documentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
15	Procedures for provision of training and information for the emergency services	Purpose To provide training and information for the emergency services.			Part 1 clause 6 Particularly – 1:6.2.11	
16	Functional Safety Management System - Formal Reviews	Purpose To ensure that requirements for functional safety management are formally reviewed by the organisations concerned, and that recommendations or actions arising from that review are acted upon.			Part 1 clause 6 overall, Particularly 1:6.2.1 and 1:6.2.16	
17	Supplier assessment process	Purpose To ensure that suppliers providing services or products (or both) to an organisation having overall responsibility for one or more phases of the safety lifecycle deliver those services and/or products as specified by that organisation and - have an appropriate quality management system.			Part 1 clause 6 Particularly – 1:6.2.17 Note also TOE 8 and 1:6.2.13 to ensure supplier roles are fully addressed.	



Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	Documentary evidence	IEC 61508 2 <sup>nd</sup> edition clause references	Notes
18	Functional Safety Assessment	Purpose To ensure that an organisation's approach to dealing with the Functional Safety Assessment requirements of IEC61508 has been adequately reviewed.			Part 1 clause 6  and: 1:8.1, 1:8.2, 1:8.2.18 and Part 3 Clause 8 and Part 3 Table A10	
					Note that references to IEC61508 part 3 are not applicable for systems not involving software	

### Annex to Part 3 - Owner Documents submitted as part of the Self Assessment Declaration

List of additional Owner documents included as part of this Declaration (Enter 'None' if applicable)