Introduction, background and Help for Completion of Part 3 of CASS32 'CASS Functional Safety Management Declaration lodged with CASS-appointed body'

Document History

Revision	Date	
0	2 Feb 2011	1st issue

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Reference and related documents

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

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)

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 & Terminology

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

Part 3	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)
TCSL	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.

Introduction

For an overview and for guidance to the CASS Functional Safety Management Declaration process, please refer to CASS33, Help and guidance for Completion of Part 1 of the 'CASS Functional Safety Management Declaration Lodged with CASS-appointed body'

This document provides guidance on completing Part 3 of CASS32, The CASS Functional Safety Management Declaration Lodged with a CASS-appointed Body. Part 3 is concerned with providing the evidence for operational implementation, compliance tracking, reporting, and managing Functional Safety by reference to the owner's existing operational and project records.

The guidance given for the FSM TOEs in this document (see section: " Completing the table in Part 3 ") is generally also relevant to the Declaration Part 2 Table 4, although the evidence requirements there are related to the evidence for compliance with the requirements of the standard. For specific guidance on completing Part 2, please refer to CASS 34.

Paragraphs within boxes are example extracts from the CASS32 Declaration form, for information only. The entries must be made in the Declaration, not in this HELP document.

Completing Part 3's opening section

Part 3 begins with the date upon which the declaration of Functional Safety Management has been completed by the safety manager and acknowledged by the Board or Managing Director, i.e. the owner of the Declaration.

The opening lines of this part 3 of the declaration are:

PART 3: FUNCTIONAL SAFETY MANAGEMENT SELF-ASSESSMENT REPORT

Date:

Safety Manager or equivalent (write name here):

Signed: Date:

Board chair or Managing Director (write name here):

Signed: Date:

The Date is the date for which the information in part 3 was completed. The Declaration is not intended to stop you from improving your Functional Safety Management systems and so there is a date at which the statements made were true. This is the relevant "Date" in this "Part 3" section.

The relevant personnel to sign for this part depends upon the structure of the business undertaking the safety instrumented systems work and the more common situations are as follows:

The "owner" is an individual:

If an "owner" is an individual then that individual is both the safety manager and the board chair for their own-self-employment. For completeness, and for the avoidance of doubt, the "owner" should write their name on both the line for the "Safety Manager or equivalent" and on the "Board chair" line and sign and date both. The date next to the signature should be the date it was signed.

The "owner" is a partnership:

If a partnership is completing the document then the partnership will need to identify the partner that has overall responsibility for ensuring that the partnership as a whole undertakes its safety work properly. That role is equivalent to that of a "Safety Manager" and so that partner should write their name against the role of "Safety Manager or equivalent" and sign for that role and date their signature. The partnership will have meetings of the senior partners which is usually equivalent to a board meeting of a company. It is a good idea that it be agreed at such a meeting which of the partners is to sign on behalf of the whole partnership. The nominated person should then write their name against "Board chair or Managing Director" and sign for that role and date their signature.

Note that for the partner taking the equivalent role to the Safety Manager, the name allocated should be in agreement with the statement made against the responsibilities for safety assigned and defined on the organisation chart, or equivalent, that has been referred to in response to item 3 of the CASS32 Part 3 table and in answer to IEC61508 2nd edition Part 1 Clause 6.2.3.

The "owner" is a business or company:

If the form is being completed by a business or company then such a business will have responsibilities for safety assigned and defined on the organisation chart, or equivalent, that has been referred to in response to item 3 of the CASS32 Part 3 table and in answer to IEC61508 2nd edition Part 1 Clause 6.2.3. The statement made in response to the responsibility for safety under the standard should be that of the Safety Manger or equivalent and should be the name written against "Safety Manager or equivalent" at the beginning of part 3 of the CASS32 declaration form. That person should then sign for that role and date their signature.

A business or company will also have a board and/or a Managing Director. The name written here is signing on behalf of the business or company as a whole. The person accepting that responsibility, whether they are a board member or a Managing Director, should write their name against "Board chair or Managing Director". That person should then sign for that role and date their signature.

Understanding the table structure in Part 3

The table in Part 3 of the CASS32 Functional Safety Management declaration lists all of the information required in order to claim compliance with the IEC61508 2nd edition. This also meets the needs of IEC61511 1st edition.

The structure of the table is shown below:

Item	Target of Evaluation (TOE)	Requirement (for all SILs)	Systems and procedures in place	Documentary evidence	IEC 61508 2nd edition clause references	Notes
		Purpose				

The purpose and intended content for each column is described below:

The "Item" column:

Item
This column gives an item number that is used for reference throughout this set of Help documents and the Declaration itself.

Do not change the "Item numbers" shown in the item number column of the table. The numbers are the same as those given in Part 2 Table 4.

The "Target of Evaluation (TOE)" column:

Target of Evaluation (TOE)
This column shows the title of each part of the Functional Safety Management system that should be described. The title is written in terms of which attribute of the FSM should be evaluated.

IEC61508 Part 1 clause 6 contains all the basic, fundamental components of a Functional Safety Management (FSM) system that should be present. In order to demonstrate that a Functional Safety Management system complies with the standard it is necessary to evaluate the management system that exists. The titles show the various attributes of the FSM as 'targets of evaluation' ("TOE") that are to be assessed in order to demonstrate that the FSM system in place complies with the standard, and that the FSM is followed and applied appropriately. The list of TOEs is the same as given in Part 2 Table 4 of the Declaration.

Do not change the content of this column.

The "Requirement (for all SILs)" column:

Requirement (for all SILs)
Purpose
This column shows the purpose of the requirement of the standard and, hence, also the purpose that needs to be fulfilled by the systems and procedures for Functional Safety Management.

The statements made in the neighbouring columns on this row will fulfil the purpose described in this column. A "SIL" is a safety integrity level. Some aspects of the standard refer to aspects such as checking of assessments according to the SIL rating (1 to 4) but Functional Safety Management applies to all SIL ratings.

Do not change the content of this column.

The "Systems and procedures in place" column:

Systems and procedures in place
This column provides the space in which you describe and list the systems and procedures employed by you to achieve the purpose shown in the same row and in the preceding column.

All systems and procedures must be documented, but the form in which they are documented is not mandated (paper, electronic etc). What is essential is evidence for the existence of the systems and procedures, and evidence showing them in operation. The evidence requirement is dealt with in the next column of the table. The list of all your relevant systems and procedures will be the same as those given in CASS32 Part 2 Table 4.

Include the specific document reference and revision identifiers for the systems and procedures.

The "Documentary Evidence" column:

Documentary evidence
This column provides the space in which you identify the documentary evidence for deployment of and appropriate compliance to the owner's systems and procedures from operational records etc. The systems and procedures are those that have been documented and described on the same row and in the preceding column.

The evidence for the deployment of documented systems and procedures, and evidence demonstrating current compliance to those systems and procedures should include documented relevant internal or external assessments of current or recently completed projects, day-to-day operations, and relevant periodic audit reports.

This will typically include, where available,

- Project assessment reports with specific references to project documented records where evidence of each of those procedures being followed has been verified (e.g. a routine project compliance summary report by a project/ departmental manager)
- periodic FSM audit records references (e.g sample annual audit reports by company QA manager or safety department manager)
- The names of the individuals, roles, and the level of independence associated with any assessment / audit reports, and the verification of those individuals acting in conformance with the compliance plan for the TOE. (Note that the justification of the appropriateness of those individuals conducting those activities will have been addressed in the compliance plan for that TOE in Part 2 Table 4)

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The information provided here may be detailed, or may be provided as a cross-reference to a separate report, provided that report and its location is identified and listed as part of the Declaration.
For general guidance on conducting appropriate assessments, see The CASS Guide to Functional Safety Management Assessment (www.CASS.uk.net)

The "IEC61508 2nd edition clause references" column:

IEC61508 2nd edition clause references
This column gives the reference from the standard for the relevant clause and paragraph.

The format of the reference shown in this column begins with the IEC61508 2nd edition Part number and is followed by the clause number, and so on. Example: the reference nomenclature 1:6.1.8 denotes IEC61508 2nd edition, Part 1, clause 6, paragraph 1, item 8.

Do not change the content of this column.

The "Notes" column:

Notes
This column gives space for additional explanatory notes of your choosing

There is no requirement provide additional notes and so this column can be left blank. The space is provided for the owner to insert notes that assist the reader of the declaration in understanding anything written in, or omitted from, that row.

Completing the table in Part 3

In Part 2 of the Declaration, you have identified the specific methods and procedures by which you intend to comply with requirements of the standard, and have identified for each of those a 'conformance plan', in which you have argued/ demonstrated that the procedure is appropriate and will be compliant if followed as intended. You will also have identified the evidence you intend to collect to demonstrate operational compliance with your processes on a day-to-day basis.

In Part 3 of the Declaration, you will be identifying the existing evidence supporting your claim that those procedures are in place, and are being followed appropriately. Part 3 Table is organised in the same general structure as Part 2 Table 4, against the same set of TOEs.

In Part 3 of the Declaration it is necessary to write something in the "Systems and procedures in place" column and in the "Documentary evidence" column for every item in the table. For some owners involved in IEC61508 not every item will be applicable and so it may be appropriate to write "Not applicable because ..." in a row within the column. However, it is essential that a statement that a row is "Not applicable because ..." must be reflected in the scope shown in part 2 of the Declaration as well as being explained here in Part 3. For example, if the owner's part in the safety instrumented system does not include operation and maintenance then it is not applicable to have a procedure for operation and maintenance performance analysis and so, in this example, the owner might write "Not applicable because operation will be undertaken by X" (where "X" is the name of the third party).

It is not sufficient to write "Not applicable" or to 'Strikethrough' a TOE in Part 3 without explanation. The majority of basic Functional Safety Management applies to all owners.

The list of TOEs in the table in Part 3 of the Declaration comprises:

1. Functional Safety Management
2. Functional Safety Policy
3. Organisation and Responsibilities
4. Identification of relevant lifecycle phases
5. Documentation structure and content policy

6. Techniques and Measures of conformance plan
7. Corrective action procedure
8. Competence assessment process
9. Procedure for handling of hazardous incidents and near-misses
10. Procedure for Operating & Maintenance performance analysis
11. Functional safety audit process
12. Modification process for Safety related systems
13. Procedures for maintaining information on hazards with respect to Safety-Related Systems or to the Safety Instrumented Function.
14. Configuration Management procedures
15. Procedures for provision of training and information for the emergency services
16. Functional safety Management - Formal Reviews
17. Supplier assessment process
18. Functional safety assessment

Each of these relates to a specific set of clauses in IEC61508, as given in the Declaration Part 3 Table column " IEC 61508 2nd edition clause references". A detailed consideration of the required information for each of the above is given in the following sub-sections.

1. Functional Safety Management

This requires that an owner has explicitly considered all of the steps required to demonstrate compliance to IEC61508, and that the means by which that compliance will be achieved have been documented and deemed to be appropriate to the owner's intended scope of work. Unless specific effort has been undertaken (and documented) to incorporate all aspects of Functional Safety Management into the Owner's Quality Manual, reference to compliance to an internationally recognised Quality Standard will not be sufficient.

Accordingly, the requirement of this opening section is 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. Clause 6.1.1 of IEC61508 part 1 requires that we specify the responsibilities in the management of functional safety. In clause 6.2.1 of IEC61508 part 1 the standard talks about a typical organisation appointing one or more persons to take overall responsibility for a list of functions and duties. To get to this point we need to document what those functions and activities are, so in this opening section we identify the technical activities and the management requirements that accompany those activities.

The evidence required here will be that which demonstrates that the Functional Safety Management system defined by the owner in Part 2 of the Declaration has been applied appropriately in practice on projects and day-to-day operations, by reference to the operational or project records of planning, verification and validation, compliance tracking and reporting which are managed for all of the activities undertaken.

2. Functional Safety Policy

For a team to work together they need to have common policies for safety so that conflicting and inconsistent approaches to safety are avoided. In this section of the declaration the owner identifies the policy statements and strategies that are being applied to the use of the safety instrumented system(s). Many owners will have a documented safety policy related to internal methods of safe working for their staff. This requirement for a Functional Safety Policy is different, and is aimed at high-level corporate ownership of all lifecycle processes related to the development and deployment of safety-related systems. Such policies may relate to adherence to certain standards, codes of practice, industry guidance, competency criteria etc and should set out to direct and govern the owner's overall operational ethos or 'corporate culture' with respect to functional safety.

The evidence required here is that which demonstrates the existence of the policy, the evidence of broad understanding and dissemination of that policy within the organisation covered by the Declaration, and the evidence of adherence to that policy in day-to-day management of the business.

3. Organisation and Responsibilities

Clause 6.1.1 of IEC61508 part 1 requires that we specify the responsibilities in the management of functional safety. In clause 6.2.1 of IEC61508 part 1 the standard talks about a typical organisation appointing one or more persons to take overall responsibility for a list of functions and duties.

It is possible to refer here to a project plan with a list of duties and nominated members of the team against each duty either by name or by job title. Many businesses use organogram charts to show management structures and duties so the owner could use such approaches, or similar, to define the people responsible for each function and activity and the management structure behind it. Such organisation charts can also indicate the lines of communication between the members of the management team (clause 6.2.2 of IEC61508 part 1).

Where 'multi-discipline project teams' exist alongside engineering skill-based departmental management structures, organisation charts and allocations of functional safety responsibility must be clearly defined within the IEC61508 lifecycle roles at the 'operational team' level. Ensure that all processes are 'owned', and that all handovers and transfers of ownership are positively managed.

The evidence required will be that necessary to verify from project or operational records and compliance reports that all roles and responsibilities were allocated, and that individuals involved in a specific activity over the project duration were always operating within their defined roles, relating a project plan of named 'ownership' to records of appropriate actions by named individuals.

4. Identification of relevant lifecycle phases

The activities shown in the answer to item 1 in this table all fit within the lifecycle of a safety instrumented system and here the lifecycle phases that are relevant to the owner's activities are listed. There can often be an iteration taking place between documenting the response to question 1, the list of activities and responsibilities the identification of the safety lifecycle phases. Each time a lifecycle phase is identified then the extent of activities required become clearer and the responsibilities that come with those activities is also clarified.

The lifecycle phases are those given in IEC61508 Part 1 Figures 2, 3, and 4 . This provides the context within which the Declaration should be considered relevant, and the scope of activities for which the owner is claiming to have appropriate evidence of compliance. No assumptions should be made related to the owner's activities in lifecycle phases other than those identified in this section.

Identifying lifecycle phases pre-defines certain activities and documents which would normally be expected see IEC61508 Part 1, Table 1, and those would be expected to form the basis of the documentation plan.

The evidence required here will be that which demonstrates that all activities undertaken on projects or day-to-day operations were addressed by documented lifecycle procedures, and that all planned project and operational lifecycle activities were undertaken, typically by reference to checklists,

project tracking reports and summaries, compliance reports or other operational tracking records designed to collect and demonstrate compliance for this activity.

5. Documentation structure and content policy

In all good engineering a documented system should be properly constructed, tested and maintained. In Part 2 of the Declaration the owner describes the documents that are to be produced and the function of each one. As a consequence of understanding the documents that are necessary it also becomes possible to document which documents are to be communicated to others and to whom (see clause 6.2.4 of IEC61508 part 1).

The evidence required here will be that which demonstrates that the documentation policy has been followed in practice in day-to-day operations and on projects, by reference to the management and project records and compliance reports which are used to track and manage that activity.

6. Techniques and Measures of conformance plan

Whether software or hardware is involved in the safety instrumented system, specific techniques and measures may be needed to show compliance with the standard. The owner of the declaration has identified in Part 2 the conformance plan for each of the activities, which demonstrates how the requirements of the standard are to be met by the planned activities. That conformance plan should also include the plan for capturing the evidence that the activities have been appropriately carried out.

The evidence required here is that which demonstrates that the planned techniques and measures were applied appropriately on projects or in the day-to-day activities, by reference to the records and compliance reports in the owner's process which are intended to track and monitor compliance for this activity.

7. Corrective action procedure

In any safety system management scheme it is essential that non-conformances and deviations from the expected behaviour are identified. The consequence is that a plan for corrective action must be identified, agreed, implemented, checked and verified. The way the entire process of corrective action is to be handled has been identified in Part 2, along with the types of records which will be made available.

The evidence required here is that which demonstrates that the defined corrective action procedure has been followed on projects and day-to-day activities, with reference to the specific management and project tracking records and compliance reports which monitor this activity.

8. Competence assessment process

Each activity will require competent people to be involved. The level of competency required needs to be assessed to match the activity and the competency of the people assigned the responsibility for the safety system needs to be assessed. In some cases personnel involved in a safety system will need some level of supervision to competently complete an activity. The matching of competencies required to the people undertaking each task or activity needs to be managed. The owner identifies their competency management system in Part 2 of the Declaration, defines which records will be available as evidence of implementation, and how those records will be used to meet the competency requirements of the standard.

The evidence required here is that which demonstrates that the defined competency assessment process is followed, by reference to the company records and compliance reports which track that process. It is also required to demonstrate that the individuals fulfilling the defined roles on projects and day-to-day activities have the appropriate competency, by reference to the management and project records of the named individuals undertaking the planned roles and responsibilities, and the competencies specified as necessary to fulfil those roles.

Note that Regulators are requiring that safety management is properly covered. Whether or not the owner's business activities are in the UK, the UK's safety authority, the HSE has published an excellent and clear guide to competency management systems which any owner will find helpful. See the HSE guidance - “Managing Competence for Safety Related Systems” July 2007. The document, both parts 1 and 2, are available as a free download from the HSE's website at www.hse.gov.uk

At the time of writing this help page the HSE guidance can be found at http://www.hse.gov.uk/consult/condocs/competence.htm

but if it has been moved elsewhere on the HSE's website then a search on the title of the competency management system guidance will reveal its location.

The HSE guidance will show what is expected of a competency management system that checks and monitors the competencies of everyone involved in safety instrumented systems and at every stage of their lifecycle.

9. Procedure for handling of hazardous incidents and near-misses

Any hazardous incident that occurs or near-miss event cannot be ignored. Lessons need to be learned on every occasion and to make that possible an event should be properly studied and documented. The lessons learned from the event can then be communicated to everyone involved in the safety instrumented system and any corrective action that is necessary can be planned, authorised, managed and implemented. Even if the system fully responded correctly and no corrective action is needed the near-miss or incident is itself either a demand on the safety instrumented system, or a major test of the effectiveness of the associated procedure which should be documented and can be later compared to the system designer's statement about the frequency or handling of such events.

The owner of the declaration will document the procedures and systems to be used when responding to, and recording, hazardous incidents and near misses in Part 2.

The evidence required here is that which demonstrates that the procedure is followed in practice on projects and in operation, by reference to the owners operational records and compliance reports designed to track and address these activities.

10. Procedure for Operating & Maintenance performance analysis

It is important to understand that this item doesn't just ask that the owner describes how the safety system is operated and maintained. Within the procedures used for operation and maintenance there needs to be reviews of the work undertaken and analysis of any faults that are detected. Some faults will be equipment faults but some errors will arise from human bad-practice. The review and analysis systems, that allow the operations and maintenance to be managed to ensure that the required safety integrity is achieved and maintained, have been identified and justified in Part 2.

The evidence required here is that which demonstrates that the defined procedures are employed in practice, by reference to the owners operational records and compliance reports designed to track and monitor this activity.

11. Functional safety audit process

Regular functional safety audits are required under the IEC61508 standard. The standard also indicates the degree of independence of those undertaking audits as being related to the safety integrity level (SIL) of the safety instrumented function. Where a system has multiple safety instrumented functions then the SIL used is the highest of each of the safety instrumented functions unless the owner of the declaration shows that the systems are operating independently of each other. The owner's audit process and resulting records has been defined and justified in Part 2.

The evidence required here is that which demonstrates that the owner's defined audit process is employed in practice, by reference to the owners records and compliance reports designed to track and monitor this activity on projects or during operation, including reference to the appropriate records of the individuals, their competencies, and the levels of independence involved.

12. Modification process for Safety related systems

Safety depends on the safety instrumented function operating fully and correctly on demand. Any alteration to the safety function needs to be addressed by fully defined procedures which are appropriate for the SIL of the safety function. The owner of the declaration will have identified and justified in Part 2 the systems and procedures to be used to ensure that all proposed changes are fully assessed prior to implementation and, when implemented, that the entire process is fully managed and that the safety loop is fully tested.

The evidence required here is that which demonstrates that the defined procedures are employed in practice, by reference to the owners operational and project records and compliance reports designed to track, audit, and monitor this activity.

13. Procedures for maintaining information on hazards with respect to Safety-Related Systems or to the Safety Instrumented Function.

The suitability and efficacy of the safety instrumented functions can be affected not only by events in the user's own specific application but also by events in other similar applications. There is value in exchanging information and learning from such findings. The owner will have described and justified their systems and procedures for exchanging information, assessing the information and learning from it, in Part 2.

The evidence required here is that which demonstrates that the defined procedures are employed in practice, by reference to the owners operational and project records and compliance reports designed to track, audit, and monitor this activity.

14. Configuration Management procedures

During development, modification, and maintenance of the safety instrumented function it is important that unauthorised components or software do not accidentally enter the system. Management of the construction and configuration will be documented and justified by the owner in Part 2. The system documented will also show at what point the system is first applied and how it is initiated. The procedure will then show how each component of the safety instrumented function can be identified uniquely and how no component of software can enter service that has not been authorised for use with the safety instrumented function.

The evidence required here is that which demonstrates that the defined procedures are employed in practice, by reference to the owners operational and project records and compliance reports designed to track, audit, and monitor this activity.

15. Procedures for provision of training and information for the emergency services

For some safety instrumented functions the emergency services may be involved, e.g. after the plant has been made safe in order to restore the plant to a stage in which maintenance and operation can safely restart.

Whenever the involvement of the emergency services is a possibility the owner will have identified the systems and procedures in place for training and working with the emergency services in Part 2. The owner will also have indicated the frequency of re-training events and meetings for information exchange.

The evidence required here is that which demonstrates that the defined procedures are employed in practice, by reference to the owners operational records and compliance reports designed to track and monitor this activity.

16. Functional safety Management - Formal Reviews

This is a general requirement for formal management review and decision making procedures relating to the overall management and monitoring of Function Safety within the owner's scope. The procedure and processes for formal reviews, and the resulting records, will have been defined in Part 2.

The evidence required here is that which demonstrates that the defined procedures are employed in practice, by reference to the owners records and compliance reports designed to track and monitor this activity, typically involving minutes of Procedure Review meetings, project compliance review meetings, attendance lists, action tracking documents, records of reviewed documents, etc.

17. Supplier assessment process

The owner will have identified and justified in Part 2 how suppliers used as part of the provision of safety instrumented functions will be assessed for their quality assurance, and how the owner's auditing should ensure that what is delivered meets specification and functions correctly before the system is put into service and whilst in use.

For sub-contracted services the owner's process should have specified in Part 2 how the competency requirements for the services will be managed.

The evidence required here is that which demonstrates that the defined procedures are being employed in practice, by reference to the owner's records and compliance reports designed to track and monitor this activity. Typically by reference to supplier assessment records, supplier certification records, goods inwards assessments, product acceptance records, project management summary records for compliance to requirements for purchased items and purchased services etc.

18. Functional safety assessment

When a safety instrumented function has been assessed as being needed, evaluated, specified, design, built, installed, commissioned and tested then the standard requires that the final system is investigated through an overall review. The purpose of the investigation is to arrive at a judgement on the adequacy of the functional safety achieved to demonstrate that the requirements of the standard have been met.
The owner will have identified and justified in Part 2 the management systems that are in place for this Functional safety Assessment, including how the competency of those making the assessment is assessed and the requirements for their independence from those undertaking the original work, from the project, and from the companies involved (see IEC61508 Part 1 second edition Tables 4 and 5).

The requirement for Functional safety Assessment can be found in IEC61508 Part 1 2nd edition clause 8.

The evidence required here is that which demonstrates that the Functional Safety assessments have taken place as planned, according to the defined procedures, by reference to the owners records and compliance reports designed to track and monitor this activity. Typically by reference to records of functional safety assessment reports on a per-project, per installation, or per planned activity basis as appropriate to the owner's scope of work. The evidence would typically include reference to the appropriate records of the individuals, competencies, and levels of independence involved.