Assessment of **Safety-Related Compliance Claims** (SRCC)

An assessment framework for the evaluation of Safety-Related Compliance Claims for use by Independent Safety Assessors

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Change History

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Please send suggestions for improvements, for consideration by the Working Group to:

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Cover Images (clockwise from top left)

- Nuclear power plant
- Euro fighter
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Contents

1.   Purpose of this document

To provide general guidance on evaluating the quality of the claim presented in a documented Safety-Related Compliance Claim (SRCC) made by others. It is intended to be used by Independent Safety Assessors (ISAs), and by customers, purchasers, or Users of safety-related systems who are acting in a safety assessment role, whose judgements about safety are supported by SRCCs.

The guidance is intended to address the process of scrutinizing the claim as presented in the SRCC, rather than scrutiny of the evidence underpinning the claim.

2. Scope

SRCCs may be issued to address the safety aspects of products, services, systems, organisations, and individuals for various purposes.

At this time, this document primarily addresses Product and System-related SRCCs, with some attention to Organisation-Capability SRCCs.

3. Terminology, Abbreviations, Acronyms, and Definitions

Accreditation	The formal process of establishing the competency of a Certification Body (CertB) to undertake assessments in a defined domain. Requires a defined Certification Scheme, Assessor Competency requirements, and CertB assessment. UK national Accreditation is undertaken by the UK Accreditation Service (UKAS).
Accredited Certificate*	A *certificate issued by an Accredited Certification Body.
Accredited Certification Body (ACertB)	A compliance assessment organisation which has national Accredited status within the specific safety domain to issue *Certificates of Compliance to specified criteria. Certification bodies will be Accredited for a specific scope, and will perform compliance assessment according to published criteria. *Certificates will identify the Issuing Certification Body and the Accreditation Authority.
Certificate*	A term reserved exclusively for a SRCC issued by a Certification Body.
Certification Body (CertB)	A compliance assessment organisation which has, or assumes, authority within the specific safety domain to issue *Certificates of Compliance to specified criteria. Certification bodies may be Accredited for a specific scope (ACertB), or may operate unaccredited in areas in which they claim to be competent.
CASS	The CASS Scheme Ltd. Providers of a scheme for the formal Accreditation of Certification Bodies (CertB) assessing to IEC61508 and IEC61511. The Accredited Scheme provides for subsequent certification by Accredited CertBs of the Functional Safety Management (FSM) for Organisations, and Accredited assessment of Standards Compliance (for products and systems).
Entity	The subject of the SRCC.
FSM	Functional Safety Management. The organisational aspects related to procedures, records, competency, audit, and assessment of compliance to standards. *Certificates of FSM compliance require a published scheme, compliance criteria, and organisation assessment by a CertB.
Issuer	The author of the SRCC.
ISA	Independent Safety Assessor, or a person acting in that role to scrutinize an SRCC.
SRCC	Safety-Related Compliance Claim. A documented claim about the safety-related properties of a defined Entity, supported by an assessment.
SRCC criteria	The defined set of requirements against which compliance is claimed in the SRCC.
Target	The item intended to be deployed by the User, for which the SRCC Entity is claimed to be relevant. Note that the Target and Entity may be different.
Target Application Context	A short description of the required functionality and operational context for the Target (e.g. for a valve:- clean service, tight shut-off, de-energise-to-trip) or a reference to User-defined typical application descriptions.
User	The organisation deploying the Target system or product for functional safety purposes.
User Requirements	The User's safety-related requirements for the Target, which may be broader than or different from the compliance criteria of the SRCC.
UKAS	The UK National Accreditation Body for Certification Bodies.

*Note that 'Certificate' has a specific definition.

4.   Introduction

Customers, purchasers, ISAs, and Users of safety-related systems are frequently offered a Safety-Related Compliance Claim (SRCC), generically often referred to as a "Certificate", as evidence of compliance of a product, subsystem, or complete safety system, with respect to some defined safety-related criteria or defined standard. The intended purpose of such SRCCs is to remove the requirement for the ISA (or the person undertaking this ' ISA scrutiny' role) to re-evaluate all of the evidence which was made available to the Issuer, by accepting the Issuer's claim.

In such situations, it becomes necessary to establish the extent to which the information in the SRCC is relevant to the specified requirements of the Target project, and the extent to which the information provided by the Issuer can be trusted.

The ISA is thus faced with an initial decision as to whether to 'trust' (use in any way) the SRCC, or reject it as evidence. When a decision to 'trust' is taken, it may not be practical to attempt to calibrate the 'degree of trust' in such cases, but it is possible to rank the verifiable properties of the SRCC, and the credentials of the Issuer, such that the quality of the evidence provided in the SRCC can be evaluated. Having evaluated the properties, some judgement may then be formed about the SRCC in the context of the Target application, taking into account risk factors etc.

Given that, in principle, an SRCC can be:

- anything from a data sheet, or an informal letter, through to a formally Accredited certificate and assessment report,
- provided by an internal project team or external independent body,
- produced in response to conformance requirements specified by the User, or requirements defined in other standards or informal documents

then the ISA needs to understand the provenance of the SRCC to know how much confidence can be placed in it.

The guidance in this paper addresses the range of quality of evidence made available for the various properties of a SRCC, such that the ISA can apply some level of judgement based on a clear set of criteria.

5.   Properties of SRCCs

Typically, an SRCC in a specified application context will (should) have the following properties or attributes.

	Property	Description
Issuer Credentials	Independence	A level of independence of the Issuer from the designer.
Issuer Credentials	Competence	Be produced by people whose competence has been evaluated.
SRCC Content	Completeness	Be complete in scope and supporting evidence with respect to explicitly identified requirements.
SRCC Content	Verifiable	Traceability of competency and evidence used to support the claims made.
SRCC Content	Valid	Genuine, unaltered, current, not expired, and managed under a formal document and revision control scheme.
project-context-specific property	Relevance	Relevant to the intended User systems, and the specified User Requirements.

This document considers how to evaluate the extent to which each of the properties is addressed by the SRCC.

6. Overview of methodology

This document adopts a check-list approach in assessing the properties of a SRCC, which facilitates the optional use of a calibrated weighting, if appropriate, for the overall quality of the SRCC.

Specific weighting and overall judgement criteria need to be established before commencing the evaluation of the SRCC.

The methodology addresses the SRCC in a single specific application context, and the SRCC must be re-evaluated when the application or deployment context is different.

The methodology addresses:

Establishing judgement criteria	Defining the basic reference criteria you intend to use for each of the SRCC properties (see 7).
Establishing the Entity reference information	Preparing for the SRCC assessment by assembling the relevant information about the Entity e.g. model, application context, functional requirements, User Requirements, etc (see 7).
Evaluating a specific SRCC	The process by which the specific SRCC is evaluated, the evidence collected, and the judgement formed (see 7.6.2).

These main phases are presented in detail in sections 7 (Preparation) and 8 (Evaluation), each considering the following:

Preliminary Judgements	Consider any project-related SRCC acceptance criteria. Identify any concerns about the issuer or integrity of the SRCC and ensure they are addressed through the evaluation process.
Relevance	Establish that the Entity, scope, application context, and compliance criteria specified in the SRCC are sufficiently relevant to the Target requirements, and evaluate the overall relevance.
Credentials of the Issuer	Evaluate the overall credentials of the Issuer, taking into account the extent of Accreditation, independence, and competency evidence provided in the SRCC.
Completeness, Traceability, & Scope	Evaluate the extent to which the SRCC actually addresses compliance with its own stated compliance criteria, and the extent to which all appropriate evidence was considered and is traceable.
Validity, Authenticity, Currency	Evaluate the extent to which the SRCC can be confirmed as genuine, current, and un-modified, and that the Issuer Accreditation licence (or equivalent) is current where appropriate.
Consideration of level of risk	Establish the basis of judgement with respect to the quality of the SRCC as a function of the risk associated with the Target item.
Forming a Judgement	Consider the results of the separate evaluations of SRCC properties, apply the pre-determined judgement criteria in the relevant risk context, document all concerns, judgements, and recommendations for further actions where appropriate.

The methodology is intended to relate to all types of SRCC, from informal to formal, and to all types of compliance criteria from User Specifications to National and International Standards. The highest quality rating will be achieved by SRCCs with a formally accredited compliance assessment, issued by an independent organisation, using published assessment criteria to published standards.

7. Preparation & Establishing Judgement Criteria

It is important to establish the basic criteria which will inform all judgements related to SRCCs on a project. These criteria should be established and documented before considering any specific SRCC, because criteria may evolve over time with experience, and it is necessary to know which set of criteria were used to form a particular judgement consistent judgements must be founded on a common documented set of criteria the opportunity for 'making an exception' is significantly reduced if all of the anticipated circumstances have been fully considered in advance of undertaking an evaluation.

Judgement Criteria are addressed here primarily in the context of the identified SRCC properties.

The activities identified in this section as 'Preparation' are those which are necessary before assessing the SRCC. The results of those preparation activities are documented in the Tables of the corresponding 'Evaluation' section - i.e. the Preparation activities define the criteria to be used in the Evaluation Tables.

The methodology in this document presumes that the ISA undertaking the evaluation of the SRCC is competent to have undertaken an appropriate assessment of the Entity against the User Requirements, and thus be competent to judge whether others have actually done so.

This may not always be the case, and where this is not valid, the ISA will need to record a result of 'not verified' against a particular aspect, and specify the minimum quality criteria necessary for any SRCC which would indicate to the ISA that appropriately qualified people have undertaken the assessment. (see 7.3 and 8.3) e.g. "I am unable to evaluate compliance against xyz standard, and therefore require that only SRCCs from Accredited Issuers be considered."

7.1 Preparation - Preliminary Judgements

Preliminary judgements are usually made on the basis of previous experience of SRCCs from a specific Issuer, or are pre-determined by documented project requirements which preclude certain types of SRCC.

Such judgements usually result in a decision to reject the SRCC, or to accept it with certain qualifications.

7.1.1 Preparation - Project-Specific SRCC Constraints

These are criteria typically imposed by the User as part of the project criteria, and used directly in the evaluation (see 8.1) There are no additional judgement criteria to be prepared or determined by the ISA with respect to these pre-existing User-defined constraints on the acceptability of certain SRCCs.

7.1.2 Preparation - Previous Experience

Previous ISA experience of an Issuer is primarily related to the credibility and reputation of the Issuer. Unresolved concerns can arise from:

- previous experience of scrutiny of an SRCC from the same Issuer where an ISA had to expend significant additional effort to establish adequate confidence a claim,
- previous cases where the ISA failed to establish that confidence because e.g., some attributes of the Issuer credentials or SRCC properties were not addressed.

The pre-requisite when taking prior history into account is that the records related to the previous experience with all Issuers must be documented and available for reference.

Review the table in 8.1.2 and consider whether the judgement criteria are appropriate to the project. Document all changes/additions to guidance on forming a judgement.

7.2 Establishing Criteria- Relevance

It is necessary to establish the extent to which the SRCC is relevant to the actual User (Target Project) requirements. The sub-sections are concerned with establishing the check-list criteria by which those judgements about relevance will be made.

- Relevance to the Target compliance requirements.
- Relevance to the Target Application.
- Relevance to the Target environment.
- Relevance to the Target equipment model/version.

7.2.1 Preparation - Relevance of the SRCC related to the User Requirements

The User Requirements may extend beyond the Compliance Requirements of certain specified standards, but many SRCCs limit themselves to addressing only the requirements of the published standard. There may be User Requirements which are not addressed by published standards.

(Evaluation of an SRCC against its own Compliance Criteria is addressed in section 7.4.2).

A pre-requisite is a copy of all of the specified User Requirements, and a schedule showing which of those requirements is expected to be addressed by the SRCC.

Preparation	Comment
Verify that the User Requirements are sufficiently well documented that a good quality SRCC could be readily evaluated against them.	This is a check to ensure that uncertainties with respect to the User Requirements do not distort the subsequent SRCC evaluation.
Prepare a check-list detailing any acceptable equivalent compliance reference documents, if relevant.	Typically expect to see explicit references in the SRCC to the same documents used by the User to define the User Requirements, including formal standards and User documents. Where alternatives or equivalents exist, the ISA should decide which would be acceptable, and which would not.
Prepare a check-list detailing the information the ISA expects to see in the SRCC which would demonstrate that the User Requirements have been explicitly addressed. (Note 1)	The check-list list needs to be explicitly or implicitly the complete set of information which an ISA would have sought about the Entity, had the ISA personally undertaken the assessment against the given User Requirements. This check-list is applicable throughout the evaluation process.

Notes:

1. For IEC 61508 compliance checklists, see Annex A.
2. Where recognised standards define the SRCC Compliance Criteria, they should be fully defined in the SRCC including year, part, and, where relevant, clause number.
3. SRCC should include a statement of its scope of coverage related to the Compliance Criteria, with reference to any further details and limitations incorporated in the schedule to the SRCC.
4. If no specific Part or Clause restrictions are given it should be assumed, and verified where necessary, that conformity with all Parts and Clauses of the referenced standard is being claimed.

7.2.2   Preparation - Relevance of Application-related information

A SRCC may not address all the required functional aspects of an Entity in its Target Application Context. In particular, detailed scrutiny is necessary when the Entity is to be used in a novel, modified, or unusual way, which may not correspond to the application assumptions associated with the SRCC, and caution may be advised if it is not obvious that the SRCC information provided fully addresses the Target application requirements.

The SRCC application-related information is that which characterises the intended functional usage of the Entity, and assumptions about the application may have influenced the way the properties have been assessed in an SRCC. Aspects may include, but are not limited to, assumed safe states (open/closed), continuous or on-demand operational mode, gas-tight closure, frequency of proof-testing, etc.

An SRCC could also relate to software tools or other safety related entities, and have operational system requirements or constraints.

As preparation, the ISA should establish whether the table provided in section 8.2.2 adequately addresses the project context, and establish the appropriate weight/colour for the recorded results.

To evaluate whether the SRCC context is relevant, the ISA will need to have a detailed understanding of the User Requirements, and have prepared a documented schedule of which of those functional aspects are expected to be addressed by the SRCC. Consider what application-related information will be critical, and what conclusions should be drawn if information is missing or conflicting with requirements.

For each Entity, in each specific application (functional task) define the critical application criteria which will need to be addressed by an SRCC, ideally as a check-list - e.g. for a valve:

■   shut-off application: normally open; closure within x seconds, gas tight for safety; closure on loss of power,
■   vent application: normally closed, open within y seconds for safety, energise to open, closed on loss of power.

Notes:

1. The SRCC must specify which functions of the Entity are covered by the SRCC. If appropriate, all assumptions related to the safe state must be defined, as well as any specific diagnostic measures assumed to be provided by external equipment.
2. Reference should be made to any limitations or restrictions to application of the Entity.
3. Reference to the manufacturer's instructions, especially the safety manual or equivalent, should be included.
4. Sufficient information should be stated or referenced to enable use of the product in any safety-related application intended or claimed on the SRCC.
5. Specific safety-related attributes are defined in some standards. Where compliance is claimed against a specific standard, those attributes must be addressed.

7.2.3 Preparation - Relevance of environment

Environmental factors are those which characterise the intended operational Target environment, and may differ from those assumed or specified for the Entity in the SRCC. Aspects may include operating temperature, humidity, pressure, mobility, access for maintenance, EMC, corrosive or inflammable atmosphere etc.

In preparation, the ISA should establish whether the table provided in section 8.2.3 adequately addresses the project context, and establish the appropriate weight/colour for the recorded results.

To evaluate whether the SRCC environment is relevant, the ISA will need to have a good understanding of all aspects of the intended operational Target environment, preferably compiled as a check-list of critical environmental requirements for each Entity against which to evaluate any SRCC. Logically this can be combined in tabular form with application data from 7.2.2.

Notes:

1. The SRCC should define all relevant environmental and other restrictions on use.
2. The SRCC should define or reference all specific maintenance and proof test requirements, if these are necessary to maintain the safety-related performance of the Entity.

7.2.4 Preparation - Relevance of the SRCC to the equipment model under consideration

The criteria by which to evaluate the extent to which the Entity in the SRCC is the same as that which has been selected to be deployed (the Target).

The SRCC must relate to a defined Entity, which should be specifically characterised by model number, revision level, and date. The Target, for which the SRCC has been offered as evidence, should be identical.

The pre-requisite is that the ISA has established that the table in 8.2.4 is appropriate to the project context, that the appropriate weight/colour for the categories has been defined, and that detailed information about the model number and revision level of the Target is available.

Notes:

1. The full name and address of the Entity supplier, and a unique and unambiguous identifier for the Entity should be given, and a list of the specification documents such as drawings, should be given in a schedule or annex to the SRCC if necessary to identify the specific Entity.

7.3 Preparation - Credentials of the issuer

The following sub-sections address aspects of independence and competency of the Issuer, and the extent to which those have already been verified. Independence and competency are addressed separately.

It is important that the Issuer of an SRCC be unambiguous. For formally issued Certificates, the matter is clear. For more indirect claims, the Issuer may be less obvious e.g. where a claim for acceptability of an Entity is based on a supplier claiming to "be an approved supplier" on the basis of having been subjected to audit by a User organisation, or by an ISA organisation, then the Issuer is the organisation undertaking the audit. The quality and scope of that audit become the subject of the SRCC evaluation.

7.3.1 Preparation - Independence of the issuer

The table in section 8.3.1 provides guidance on assessing the level of independence between the Issuer of the SRCC and the Entity for which the claim is being made. This methodology places high value on independence, and formal records of independent assessment.

The pre-requisites are:

■ that the ISA should establish the provenance of each Entity with respect to the people and/or organizations (including external consultants, advisors etc) involved in the design and development lifecycle, such that judgements about the independence of the Issuer of any SRCC will be unambiguous. e.g., who really made/designed the item; was the Issuer involved in design/consultancy role; was part or all of the design subcontracted, and was that formally managed,
■ the ISA should review the table in 8.3.1 defining the levels of independence of the Issuer as used in this methodology, ensure that they are appropriate to the situation, and establish the appropriate weighting factors to be applied. If other classifications of independence are considered necessary, incorporate them into the table, also with appropriate weighting. Any new classifications should involve criteria related to independence which are not subjective, are readily verifiable, and do not overlap with assessment of other Issuer credentials (i.e. exclude competency, Accreditation status).

The assessment of the independence of the Issuer is an SRCC-specific activity (see 8.3.1).

7.3.2 Preparation - Accredited Status of Issuer Competence

This methodology places high value on Accreditation status, and the associated formal records of competency assessment. It is important to evaluate strictly the Accreditation Status of the issuer, without making further judgments here about competence of the individuals involved. This process does not evaluate individual competency.

Accreditation is a formal concept employing the nominated National Accreditation Service for the sector. (See also ANNEX B - Notes on Accreditation).

For example, the United Kingdom Accreditation Service (UKAS) is the sole national Accreditation body recognised by the UK government to assess, against internationally agreed standards, organisations that provide certification, testing, inspection and calibration services.

Accreditation demonstrates the competence, impartiality and performance capability of these evaluators. The domain-specific expertise rests with the Accredited bodies e.g. CAAi Certification Body (CAAiCB) is certified by the United Kingdom Accreditation Service (UKAS).

Thus, a hierarchy can be established, with Accredited Certification Bodies at the top and self-declaration at the bottom, distinguished by the level of formality and extent and quality of peer-review, without taking into consideration of the specific competency of the individual author of an SRCC (which is outside of the scope of this methodology).

In between are Issuers who are subject to scrutiny by Accredited bodies, and Issuers who use non-Accredited bodies (or consultants) who perform independent assessment of Issuers and of SRCCs (on behalf of the client, or the industry).

Some industry sectors choose to rely on their own independent assessment regimes for the assurance of competent assessments. Consequently, an Independently Assessed Issuer of an SRCC may deserve a quality rating equivalent to that of Accredited status, depending on who performed the independent assessment, but would need to be able to provide the evidence associated with formal Accreditation to secure that level of confidence.

Issuers operating Functional Safety Management (FSM) schemes will be operating a documented competency assurance scheme.

The preparation required is for the ISA to review the table of the defined degrees of Accreditation Status (see section 8.3.2 for the table and descriptions), and to develop a weighting factor (and colour code) for each which is appropriate to the situation. If the sector does not yet have an appropriate Accreditation hierarchy, this methodology will intentionally return a Medium/Low weighting for all Issuers. Recognize that this is a complex area, with many shades of grey, and may involve extended background searching to establish the Accreditation status of Issuers operating outside of the UK/UKAS environment.

In some domains it may be appropriate to consider other specific qualifying factors (e.g. licensing or other certification of individuals) which may be considered to elevate the quality of the Accreditation Status, but those must be non-subjective and readily established criteria, and be incorporated into an extension of the table before undertaking the SRCC assessment (see 7.3.3).

7.3.3 Preparation - Issuer Competence Traceability

This methodology presumes that traceability of competency could be addressed through available records of the Accreditation and independent assessment processes in section 8.3.1and 8.3.2 where necessary, for all but the three lowest levels:

- Non-Accredited Certification Body.
- Non-Accredited FSM-Certified Issuer.
- Self-Declared Issuer.

Even there, all CertBs and FSM-Certified Issuers should be operating some form of documented competency scheme, even though their activities may not be accredited, and records of the competency of the Issuer and the competency assessment processes adopted should be available for inspection on request.

This implies that, in principle, the competency of the Issuer should be taken as being commensurate with the Accreditation Status, unless there is reason to call for some separate validation criteria.

Preparatory work is only then required if a significantly different ranking to that implicit in section 7.3.2 is adopted, and the criteria for establishing traceability of Issuer competence must be separately documented and ranked accordingly.

7.4 Preparation - Completeness Criteria

The requirement is for the SRCC to be complete in scope and have traceable verifiable supporting evidence with respect to the specified SRCC compliance criteria. It is important to recognise that Completeness of the SRCC is evaluated against the compliance criteria as defined in the SRCC, which may differ from the User Requirements for the Target item in the project. Any mis-match against User Requirements is addressed within Relevance (section 7.2, and 8.2). The required preparation is to ensure that the ISA has a defined concept of 'Completeness' against which to evaluate the SRCC.

7.4.1 Preparation - Completeness related to the supporting evidence

An SRCC should have supporting evidence, and the access to that evidence, or need for access, will vary depending on the circumstances. Since the primary purpose of an SRCC is to obviate the need for everyone to re-evaluate the evidence every time, the role of the ISA, in the context of this guidance, will predominantly that of ensuring that the evidence considered by the Issuer was appropriate and sufficient, rather than evaluating the evidence directly.

This section is therefore concerned with the scrutiny of the SRCC, and not with the process of independent assessment of the evidence itself.

Reference must be provided to all evidence submitted to the Issuer (documents, drawings, reports) and to all Issuer produced information (SRCC identifier, documents, compliance assessment reports).

Reference to the Issuer's report in the SRCC should ensure traceability to the evidence of compliance on which the issuing of the SRCC is based.

The pre-requisite is a description (ideally as a check-list) of the information which the ISA considers to be appropriate and sufficient. This set of appropriate information will need to be detailed and comprehensive when evaluating SRCCs issued by non-accredited issuers outside of fully documented compliance schemes, and be consistent with the information the ISA would require if performing the assessment of the Entity (see the Notes to the table in 8.4.1, and section 7.2.1).

Fully documented schemes implemented by Issuers will define the documentation and evidence requirements for the assessment of compliance.

The ISA should also establish the appropriate levels of discrimination, and the associated weighting factors to be used in the evaluation table (see 8.4.1) and document the proposed factors and guidance.

7.4.2 Preparation - Completeness related to the stated SRCC compliance criteria

All SRCCs will claim compliance to a defined set of requirements or standards. Those requirements and standards are the SRCC Compliance Criteria, and may be different from the User (Target) Requirements.

The User Requirements may extend beyond the SRCC Compliance Criteria of certain specified standards, but many SRCCs limit themselves to addressing only the Compliance Criteria of the published standard, or even only a defined sub-set of those criteria.

User Requirements should be separately identified, and any mis-match addressed individually, (see section 7.2.1).

Similarly, User Requirements may only be a defined subset of the Compliance Criteria of a standard, and an SRCC with a limited scope may still be appropriate to the User Requirements. In such cases, it may be appropriate to only consider the extent of SRCC compliance against the User Requirements (section 7.2.1).

An SRCC may have been developed for a limited purpose, or have been intended to address only a limited set of parameters or other properties of an Entity. The SRCC thus may not address all the Compliance Criteria within a published standard.

An SRCC with limited scope or partial coverage may exclude certain hardware, or software, certain operational modes, maintenance information, etc. and a check for Completeness of coverage is required to avoid assumptions about the scope of compliance claimed by the SRCC.

Where multiple SRCCs relate to one Entity, or multiple Entities are combined, applying a weighting may be an iterative process since it requires an overview of all submitted SRCCs.

Pre-requisite preparation is an understanding of the full scope of Compliance Criteria addressed by the standards which could reasonably be expected to be referenced in the SRCC. (The extent to which User Requirements fall within the scope addressed by the referenced standard is covered in section 7.2.1).

The ISA should review the Completeness criteria as presented in the Table in 8.4.2, and pre-determine the appropriate weighting factors to be applied when undertaking SRCC assessments.

7.5 Preparation - Validity Criteria

This section addresses:

- Authenticity of the SRCC document.
- Currency and validity of the SRCC Issuer FSM aspects.
- formal document and revision control.

The ISA should establish whether other domain-specific categories should also be taken into account, and establish the weighting factors in the tables related to Validity to be applied when undertaking SRCC assessments (see sections 8.5.1, 8.5.2, and 8.5.3).

7.6   Preparation - Forming a Judgement

The processes used by individual ISAs in reaching judgements using a formal procedure such as this will mature over time, and with experience. The methodology considered in this paper may be overly simplistic for some situations, and proposes no more than three weighting factors which are broadly 'Good-Caution-Poor' represented as Green/Yellow/Red related to SRCC properties, with ISA judgement on how to address results other than Good/Green in an overall judgement taking the Risk context into account.

7.6.1   Preparation - Forming Judgement on SRCC Properties

One pre-requisite is for the ISA to consider how the overall judgement of SRCC quality will be used, and by whom, and to structure the recording of results and the setting of criteria to suit that purpose.

- In situations where the overall final judgement will either be 'Acceptable' or 'More Work Needed', then the ISA may wish to structure the weighting such that all Yellow/Red results are indicative of 'More Work Needed' and the colour just provide an indication of the extent of the work required. 'Red' would become 'lot more work' and not necessarily 'Reject'.
- In situations where alternative competing Entities are being considered for a Target application, and where the quality of the offered SRCC will play a role in making that choice, then the ISA may wish to establish firm criteria which result in a more rigorous Accept/Reject status, with little or no 'Caution/Yellow'.

All judgement criteria should be established before evaluating an SRCC, and it is recommended that known 'good' and known 'poor' examples of SRCCs be used to validate the criteria, before being faced with 'borderline' situations in practice.

There are five general evaluation categories of SRCC properties (see tables sections 6 and 7.6.2) and the ISA should consider the following when setting the judgement criteria:

a. consider whether each property category has equal overall weighting,
b. consider whether a low quality in one category can be mitigated by high quality in any other category, and whether that is already addressed by conclusions from (a) above,
c. consider how best to combine the results from each category in reaching an overall judgement, and how best to present/ report the findings,
d. establish a weighting factor for every item in the table, for each applicable risk category.

Record the judgement criteria in a table against each of the SRCC properties (e.g. table in 7.6.2) and record the risk-related qualifiers (e.g. the separate risk columns of table in 7.6.2). Consideration of Judgement will normally be conditional on consideration of Risk (see 7.6.2).

When setting the weighting factors, it is important to exclude any contribution in which the competency of the ISA (the methodology user) could be involved. That is to say, the first evaluation of the SRCC must be objective and record as accurately as possible the properties of the SRCC as presented.

Any consideration of mitigating circumstances should be done after the first evaluation is complete, at the time when an overall judgement is to be formed - e.g. where an ISA is competent to apply detailed scrutiny to an SRCC, this could be considered equivalent to some additional level of independent review of the SRCC, and it is possible that an SRCC with medium/low weighting on Credentials may be considered acceptable if the data quality is high.

7.6.2   Preparation - Consideration of Risk

To form an overall judgement, it will also usually be relevant to consider the Target safety context and level of risk involved. This methodology addresses the risk context separate from an assessment of the quality of the SRCC, and establishes the guidance on final judgements in line with the intended purpose of the SRCC evaluation. It should also be noted that an initial consideration of risk may be appropriate, before undertaking any further scrutiny of an SRCC, and not expending resources where the risk is not sufficiently high.

After evaluating all of the SRCC properties, the overall judgement related to acceptability or the need for further evidence will be conditioned by considering the level of risk involved. The approach will result in a defined level of risk, from low to high or quantified, and a required/desired quality factor of the supporting SRCC (also either low-to-high or quantified). The overall acceptability criteria developed and applied by the ISA should be documented (example tables below), and each risk category will normally have its own set of judgement criteria. There would be an expected correlation between increasing risk and increasing required quality of the supporting SRCC.

This activity requires some experience of evaluating SRCCs, and it is recommended that known 'good' and known 'poor' examples be used to validate the matrix in low and high risk applications, before being faced with 'borderline' situations in practice.

Where guidance related to risk is to be provided for each specific property, prepare a table similar to that below, which is an overview of the SRCC Properties aligned with the Judgement Criteria from section 7.6.1(see also 8.6), with separate columns

for each Risk Category which will be considered. Define the appropriate risk categories. Record in the table, or in associated notes, all weighting factors/colours to be applied related to the assessment result, and differences to be applied vs. Risk. Examples are given for some result tables, but they are illustrative only and not intended as general guidance.

Example **(see table, below)**: The ISA considers that final judgement guidance with respect to the Independence of the Issuer (ref section 8.3.1) should be conditional on the level of risk for the Target Application Context, and that different levels of Independence should be required for Low, Medium, and High Risk categories. The ISA prepared the Independence quality weighting criteria in Table 8.3.1 (Independent of Risk) and the ISA has chosen to specify Medium and High weight Independence quality as the 'acceptable' criteria across the Low, Medium, and High Risk Categories as shown below. Since the 'Medium' quality weighting criteria in Table 8.3.1 were defined as Independent Person or Independent Department, the ISA realised that was not sufficient discrimination to define what was considered a necessary requirement for 'Medium Risk' and so added an additional requirement for Independent Department for Medium Risk applications.

If only a single Risk Category is going to be relevant, only one Risk Category column would be prepared.

Examples of acceptable quality properties varying as a function of Risk

	Risk Category →	Low	Medium	High
Ref. Section	Evaluation Category ↓	Required Quality	Required Quality	Required Quality
8.1.1	Project Acceptability Criteria (Yes/No)	Apply full criteria, result Yes/No	same	same
8.1.2	Previous Experience of Issuer	Good - Yes Unresolved - Caution Mistrust - No	same	same
	Review of unresolved concerns	Fully addressed - Yes Not addressed - No	same	same
8.2.1	Target Scope Relevance	(ISA defined)	(ISA defined)	(ISA defined)
8.2.2	Application Relevance	(ISA defined)	(ISA defined)	(ISA defined)
8.2.3	Environment Relevance	(ISA defined)	(ISA defined)	(ISA defined)
8.2.4	Equipment Model Relevance	Accept earlier version SRCC	Exact model only	Exact model only
8.3.1	Independence of Issuer	Minimum/Medium	Medium + Independent Dept	High (Independent Org)
8.3.2	Accreditation status of Issuer	Medium or High	Medium or High	High only
8.4.1	Completeness of supporting evidence	(ISA defined)	(ISA defined)	(ISA defined)
8.4.2	Completeness Scope of SRCC	(ISA defined)	(ISA defined)	(ISA defined)
8.5.1	SRCC Authenticity	(ISA defined)	(ISA defined)	(ISA defined)
8.5.2	SRCC Currency & validity	(ISA defined)	(ISA defined)	(ISA defined)
8.5.3	Issuer FSM Currency & validity	(ISA defined)	(ISA defined)	(ISA defined)

Numerical/quantified weighting tends to permit a high score in one area to out-balance a low score in another, which may not be appropriate.

Qualitative ranking (low to high) permits areas of weakness to be identified, but requires judgement criteria and guidance to be generically established before-hand e.g.

- If 'Green' results are considered to be readily achievable, consider the circumstances in which anything less would be acceptable.
- Define any situations when any 'Red' results could still be acceptable, including consideration of risk categories.
- Define any situations in which 'Yellow' results are acceptable without further investigation.
- Define situations when only 'Green' is acceptable throughout.
- Define the overall judgement criteria when considering the results in all categories, breaking down the guidance into groups as appropriate e.g.
    - for risk category X all results for Relevance and Completeness shall be at least Y (Yellow/Green).

8. Evaluating a Specific SRCC

This section contains checklists and tables which are provided as informative examples only, and which are **all** intended to be modified and calibrated by the ISA as the result of working through the preparation in Section 7.

When evaluating an SRCC, an ISA should be using his/her own calibrated version of these tables, and not the ones provided here.

8.1   Evaluating - Preliminary Judgements

Preliminary judgements are usually made on the basis of previous experience of SRCCs from a specific Issuer, or are pre-determined by documented procedures which preclude certain types of SRCC.

Such judgements usually result in a decision to reject the SRCC, or to accept it with certain qualifications based on an assessment of the quality of the information now being provided.

8.1.1   Evaluating - Project - Specific SRCC Constraints

Establish whether certain types of SRCC are proscribed or mandated by the customer or the applicable procedures, e.g.

a.   where only SRCCs issued by certain agencies may be used,
b.   where the use of explicitly licensed parts or staff is mandated,
c.   where certain levels of Accreditation or Independence of the issuer have been mandated,
d.   where certain attributes of the supplier are mandated (e.g. ISO9001 Certified; Permitted Suppliers List).

Document all preliminary judgements. Record the result in the table section 8.6.

8.1.2   Evaluating - Previous Experience

Previous experience is primarily related to the credibility and reputation of the Issuer. Unresolved Concerns can arise from

- previous experience of scrutiny of an SRCC from the same Issuer where an ISA had to expend significant additional effort to establish adequate confidence a claim,
- previous cases where the ISA failed to establish that confidence because e.g., some attributes of the Issuer credentials or SRCC properties were not addressed.

Experience	Description	Judgement
Good	No negative concerns, no issues unresolved.	Accept
Unresolved Concerns (note 1)	Document the concerns, and examine those areas in depth when considering the quality of the SRCC.	Accept with Caution and subject to confirmation
Review of unresolved concerns (note 2)	Confirmation after completion of the SRCC review that the unresolved historical concerns have been addressed.	Accept/Reject
Cause for mistrust	Documented negative experience. not acceptable.	Reject
Cause for rejection	Project-Specific Criteria. Proscribed SRCC Issuer or Type of SRCC. Classed as not acceptable.	Reject

Notes:

1.   The historical loss of confidence in an Issuer should not preclude initial consideration of the current SRCC, but will attract close scrutiny to ensure previous concerns have been addressed.
2.   Any unresolved concerns about the SRCC issuer should be resolved during the evaluation. A second review after completion of the SRCC evaluation is required when a Caution has been set at 8.1.2 to ensure those have been addressed.

Document all preliminary judgements in this or an equivalent table. Transfer the result to the table section 8.6.

Review the result at the end of the overall SRCC evaluation if Caution/Yellow was initially recorded.

8.2   Evaluating - Relevance

Relevant to the User's Target systems, and the specified User Requirements and application environment

- Relevance to the Target compliance requirements.
- Relevance to the Target Application.
- Relevance to the Target environment.
- Relevance to the Target equipment model/version.

8.2.1 Evaluating - Relevance of the SRCC to the User Requirements

Using the information and check-list prepared in 7.2.1, undertake a review to establish whether the User Requirements are met by the Compliance Criteria defined in the SRCC. User Requirements beyond the SRCC Compliance Criteria should be separately identified and addressed individually.

Document all judgements in this or an equivalent table. Transfer the result to the table (section 8.6).

Scope	Description related to requirement	Weight
Full scope	All expected information about the Entity is referenced in the SRCC.	Green
Partial scope	Only some information about the Entity is referenced in the SRCC. Other (named) related SRCCs address all other required aspects.	Yellow or Green
Incomplete	Only some information about the Entity is referenced in the SRCC. No other related SRCCs address the required missing information.	Red

Notes:

1. 'Not Verified' is not a permitted result here. The ISA must be competent to assess whether the SRCC claim, if valid, would address the User Requirements.
2. If 'Partial' then the initial result would probably be Yellow, and final result Green only if the other SRCCs prove to be acceptable at the 'second pass' review.

8.2.2 Evaluating - Relevance of Application-related information

Using the User Requirements, and checklist prepared in 7.2.2, evaluate whether the SRCC application context is relevant to the Target application.

Document all judgements in this or an equivalent table. Transfer the result to the table (section 8.6).

Relevance	Description related to requirement	Weight
Identical	All required safe and dangerous failure modes addressed.	Green
Similar	Some failure modes not addressed.	Yellow
Dissimilar	Critical failure modes are different, or not addressed. Different operating mode.	Red

8.2.3 Evaluating - Relevance of environment

Using the check-list prepared in 7.2.3, evaluate whether the environment context of the SRCC is relevant to the Target environment.

Document all judgements in this or an equivalent table. Transfer the result to the table (section 8.6).

Relevance	Description related to requirement	Weight
Identical	All required environmental aspects addressed.	Green
Similar	Some environment parameters not addressed.	Yellow
Dissimilar	critical environmental aspects are different, or not addressed.	Red

8.2.4 Evaluating - Relevance of the SRCC to the equipment model under consideration

Using the information prepared in 7.2.4, evaluate whether the Entity addressed in the SRCC is relevant to the Target item.

Document all judgements in this or an equivalent table. Transfer the result to the table (section 8.6).

Relevance	Description related to requirement	Weight
Identical	The Target item is the same as that referenced in the SRCC.	high
Similar	The Target item is similar to that referenced in the SRCC, but differs by model number or revision level which has been addressed by the Issuer.	med to high
Dissimilar	The Target item is different from that referenced in the SRCC, by model number or revision, and the differences have not been addressed by the Issuer of the SRCC.	low

8.3 Evaluating - Credentials of the issuer

The following sub-sections address aspects of independence and competency of the Issuer, and the extent to which those have already been verified.

8.3.1 Evaluating-Independence of the issuer

Using the information prepared in section 7.3.1, evaluate the independence of the Issuer from those responsible for the design/development lifecycle of the Entity (for products, systems).

Document all judgements in this or an equivalent table. Transfer the result to the table (section 8.6).

Independence of Issuer	Description	Weight
Independent Assessor Organisation	Organisation that is separate and distinct, by management and other resources, from the organisations responsible for the activities that take place during the development lifecycle of the Entity.	High
Independent Assessor Department	Department that is separate and distinct from the departments responsible for the activities which take place during the development lifecycle of the Entity.	Medium
Independent Assessor Person	Person who is separate and distinct from the activities which take place during the development lifecycle of the Entity, and does not have direct responsibility for those activities.	Medium
Non-independent Issuer's published Report	A SRCC Issuer whose published reports are not independent, nor subject to any independent assessment.	low
Non-independent Issuer's un-published/ internal Report	A SRCC compiled and made available to the User or ISA by an Issuer whose internal/ unpublished reports are neither independent nor subject to any independent assessment.	low
User's internal Entity register (Note 1)	A preferred Entity register for which no SRCC exists.	low

Notes:

1. The claim for an Entity may be that it is an item in a 'Permitted item' User register (e.g. recommended spare part; 'proven device' list; previous project usage etc.). If the evidence supporting the registration of the Entity in that Register is not known or not available for scrutiny, no judgement about the independence of the assessment of suitability of the Entity can be made.
2. Be alert to any situations in which the Issuer has also been involved with other roles in the development lifecycle of the Entity (e.g. design consultancy), whilst recognizing that this is unlikely to be documented in the SRCC.

8.3.2 Evaluating - Accreditation Status of the Issuer

Using the information prepared in section 7.3.2, evaluate the Accreditation Status of the Issuer.

Document all judgements in this or an equivalent table. Transfer the result to the table (section 8.6).

Issuer Accreditation Status	Description	Weight, typical
Accredited Certification Body (ACertB)	Accredited as competent to undertake certification activities. The accredited scope for the Certification Body must include the Entity being certified.	high
FSM-ACertB Certified Issuer	Issuer holds a Functional Safety Management (FSM) Certificate from an ACertB as competent to issue SRCCs, but is not a Certification Body. Issuers who operate under a Certified FSM scheme are typically consultancies, service providers, or suppliers who have been Certified by an ACertB as complying with the requirements of a defined published overall safety management scheme. If issuing compliance assessment reports is part of the scope of the Issuer's certified activity, then the management of the competency of staff and content of the issued report will be covered by the scheme used by the ACertB, and should be available for scrutiny.	high
Independently assessed Certification Body	A non-Accredited CertB whose competency has been independently assessed, according to published criteria, as appropriate for the scope of the SRCC. Assessment of the CertB competency may be by the User. Relative weighting may be dependent on the ISA confidence in the independent assessor. e.g. a CertB which has been contracted to undertake assessments and issue SRCCs on behalf of an industry body, and subject to specific competency requirements and review by that body.	medium
Independently assessed Issuer	A SRCC issuer whose FSM processes, reports, and staff competency are not subject to CertB assessment. Competency has been independently assessed, according to published criteria, as appropriate for the scope of the SRCC. Assessment of Issuer competency may be by the User. Relative weighting may be dependent on the ISA confidence in the independent assessor. e.g. a supplier claiming compliance with industry-specific requirements (nuclear, FDA) and subject to User or industry association assessment; an Issuer audit by the ISA's own organisation.	medium
Non-Accredited Certification Body	A CertB whose competency and assessment processes have not been Accredited or independently assessed for the scope of the SRCC. E.g., a CertB normally operating in other associated fields, or one operating without an umbrella Accreditation scheme for the scope of the SRCC i.e. is effectively self-declaring its competency.	medium/low
FSM-Certified Issuer	A SRCC issuer whose FSM processes, reports, and staff competency are subject to non-Accredited CertB Functional Safety Management certification.	low
Self-Declared Issuer	A SRCC Issuer whose competency and assessment processes have not been not accredited or independently assessed for the scope of the SRCC. e.g. Consultants providing assessment services based primarily on reputation; Suppliers issuing declarations of compliance for their own entities.	low

Notes:

1. Accredited Certification Bodies will be performing assessments according to a published assessment scheme. The SRCC should identify the scheme, and the Accreditation authority.
2. Formally Accredited Certification Bodies will usually also be applying generic assessment schemes which may address type examination only, type examination + inspection of samples from production, type examination + QA surveillance and re-assessment. You should satisfy yourself that the applied schemes are appropriate for your User Requirements.
3. An FSM-ACertB Certified Issuer will be operating according to independently assessed published procedures and management practices which are intended to demonstrate the competency and integrity of the issued SRCCs, and which are subject to inspection by the ACertB.
4. Certification Bodies are not obliged to seek Accredited Status for all of their activities, and Accreditation Schemes may not be available from UKAS for some activities. Consequently, it is appropriate to seek confirmation that the scope of the SRCC falls within the CertB's current Accreditations. Current Accreditation status for accredited bodies will be available on the Accreditation body web site.
5. For FSM and other capability-related SRCCs, as opposed to product/system compliance assessments, reference must be included to the field(s) of technology, the industry sector, the generic types of products or platforms for which the FSM conformity assessment has been made.
6. Formal Accreditation services are undertaken on a national basis. Where a national Accreditation service is not available (e.g. non-UK CertBs), the CertBs may be operating on a 'self policing' basis, and consequently it is appropriate to seek confirmation of the processes and competency assessment practices by which the CertB claims to be competent to undertake the issuing of the SRCC.

8.3.3 Evaluating - Issuer Competence Traceability

There is no further ranking here with respect to traceability of Issuer competence, assuming that records of traceability are addressed by the formality of the associated degree of Accreditation.

Where there is any cause for concern that this is not addressed, then apply the criteria developed in 7.3.3.

Document all judgements in an appropriate table. Transfer the result to the table (section 8.6).

8.4 Evaluation - Completeness Criteria

The requirement is for the SRCC to be complete in scope and have traceable verifiable supporting evidence with respect to the specified SRCC compliance criteria.

It is important to recognise that Completeness of the SRCC is evaluated against the compliance criteria as defined in the SRCC, which may differ from the User Requirements for the Target in the project.

Any mis-match against User Requirements is addressed within Relevance (section 7.2, and 8.2).

8.4.1 Evaluation - Completeness related to the supporting evidence

Using the information prepared in section 7.4.1, evaluate the extent to which appropriate evidence has been used to support the claim in the SRCC.

Document all judgements in this or an equivalent table. Transfer the result to the table (section 8.6).

Supporting evidence	Description related to requirement	Weight
Fully described	All the expected appropriate information used as evidence to support the SRCC claim is referenced in the SRCC, and traceable to specific documents and revisions...	high
Partial. Some evidence not scrutinised.	Only some expected appropriate information about the Entity is referenced in the SRCC. The SRCC is deficient in either not referencing all of the evidence used, or has incomplete traceability, or the Issuer did not consider the missing evidence. The criticality/weighting factor will be dependent on the criticality of the missing evidence.	Medium to low
Incomplete	Little or no information about traceable evidence used to support the claims made in the SRCC is referenced in the SRCC.	Low to zero

Note: the following would be normally expected

1. The reference number, date, revision, and title of the report(s) in which the conduct of the conformity assessment and the evidence of conformity are recorded.
2. The signature, name, and role of the person authorising the SRCC are included.
3. Issuer Accreditation status and the name of any Accreditation body is given on the SRCC.
4. The compliance criteria, against which conformity is claimed, are specified.
5. The name of any certification system being used that is additional to the assessment of compliance to the defined SRCC compliance criteria.
6. Name & address of the SRCC holder are stated.
7. The Entity to which the conformity statement relates is specified.
8. The assessment results are provided.
9. Limitations as to the use of a product Entity in safety functions are described.
10. Limitations and qualifications to the conformity statement are given.

8.4.2 Evaluating - Complete related to the stated SRCC compliance criteria

Using the information prepared in section 7.4.2, evaluate the extent to which the compliance criteria of the standards referenced in the SRCC have been addressed by the SRCC.

Document all judgements in this or an equivalent table. Transfer the result to the table (section 8.6).

Scope of SRCC	Description related to SRCC-referenced compliance criteria	Weight
Fully defined	All Compliance Criteria of the SRCC- referenced standards are addressed by the SRCC. No misunderstanding about SRCC scope. (Relevance of SRCC scope to User Requirements is addressed under 7.2.1 and 8.2.1).	High
Fully defined Partial scope	Only some compliance criteria are addressed in the SRCC. Other (named) related SRCCs address all required aspects of the Entity.	Medium (Note 1)
Incomplete	Only some information about the Entity is referenced in the SRCC. No other related SRCCs address the required missing information.	Low (Note 1)

Notes:

1. Weighting factors for partial scope SRCCs will be conditional on whether other SRCCs, or other assessment activities, address the missing compliance criteria, and whether the overall combination represents a complete coverage. This methodology does not address the multi-stage iterative nature of this process. It is recommended that a weighting factor which properly reflects an incomplete assessment be applied for each specific SRCC, such that appropriate further action can be taken.
2. For reference, guidance on Product SRCCs with limited scope see CASS27: http://www.61508.org/cass/wp-content/uploads/2013/11/CASS27-Rev-0_RULES_PRODUCT_CERTIFICATION-WITH_LIMITED_CLAIM_OF_CONFORMITY.pdf

8.5 Evaluating - Validity

This section addresses:

- Authenticity of the SRCC document.
- Currency and validity of the SRCC Issuer FSM aspects.
- formal document and revision control.

8.5.1 Evaluating - Authenticity of the SRCC

Purpose - to establish the provenance of the SRCC.

It is important for the User to be assured that the SRCC which has been presented as evidence is either the latest current version, or is the version appropriate to the intended Target item, has not been withdrawn by the Issuer, is complete as intended by the Issuer, and has not been modified in any way.

Evaluate the extent to which the authenticity of the SRCC can be verified.

Enter the judgement in this or a similar table, and transfer the result to the table (section 8.6).

Authenticity	Description	Weight
Verified	A managed register of SRCCs is available from the Issuer, and the SRCC has been directly issued from the Issuer to the User, or to the ISA, or the SRCC can be conveniently verified as identical in all respects to that held by the Issuer. No evidence of missing pages or reports, or modification of signatories or approval dates etc.	Green
Not Verified	No register of SRCCs is available from the Issuer, or the SRCC has not been directly issued from the Issuer to the User (or to the ISA), and no convenient means of verifying the content of the SRCC against the Issuer's master copy.	Red

Notes:

1. The Issuer name and address must be stated on the SRCC.
2. A unique identifier for the SRCC must be stated on the SRCC.
3. The name and signature of the individual who approved the issuing of the SRCC must be on the document, and dated.
4. The authenticity of SRCCs which are not managed by the Issuer under a formal document control process (date, document number, revision number) will be difficult to verify.

8.5.2 Evaluating - Currency and validity of the SRCC Issuer FSM aspects

Purpose - to ensure that the issuer of the SRCC has maintained all of the declared attributes of compliance which underpin the established confidence.

Issuers of SRCCs should be operating Functional Safety Management procedures and Quality Management Systems which address management of their own competency and documentation management. Those procedures should be subject to formal periodic review intended to demonstrate the compliance of the Issuer to their own procedures. They may be the subject of more than one auditing process (e.g. Accredited CertB for FSM and ISO 9001 audit for QMS)

The aspects addressed here are for each and all relevant bodies which form the hierarchy underpinning the integrity of the SRCC, according to their published validity criteria.

- Accreditation of Certification Body.
- FSM Certification of Issuer.
- Independently Assessed Issuer.

Each relevant body should be listed and rated, such that the validity of the Accreditation chain supporting the SRCC can be assessed.

Enter the judgement in this or a similar table, and transfer the result to the table (section 8.6).

SRCC Currency & validity	Description	Weight
Current	Has a date of issue, and date of expiry.	Green
Lapsed		Yellow
No validity information available		Red

8.5.3 Evaluating - Currency and validity of the Entity-related FSM aspects

This is only applicable when an SRCC relates partly or wholly to the competency of the services provided by an Entity (e.g. company), or relates to the processes employed by a company to produce an Entity. The purpose is to ensure that the supplier has maintained all of the declared attributes of compliance which underpin the established confidence.

Entities (e.g. companies) should be operating Functional Safety Management (FSM) procedures which address management of their own competency and documentation management. Those procedures should be subject to formal periodic review intended to demonstrate the on-going compliance of the Entity to their own procedures.

The aspects addressed here are for each and all relevant Entities.

- FSM of an Entity product or system supplier.
- FSM of an Entity service supplier.

For SRCCs related to products and systems, leave this section blank.

For SRCCs related to the provision of services and design/development capability:

Enter the judgement in this or a similar table, and transfer the result to the table (section 8.6).

Issuer FSM Currency & validity	Description	Weight
Current	Has a date of issue, and date of expiry.	Green
Lapsed		Yellow
No validity information available		Red

8.6 Evaluating - Forming a Judgement

Consider the results of the separate evaluations, apply any predetermined judgement criteria, document all concerns, judgements, and recommendations for further actions where appropriate.

It may be helpful to consider the results of each general category to form an overall judgement.

Results from Section 8.1.1 and 8.1.2 are Yes/No initial checks on the acceptability of the SRCC.

Results from section 8.2 relate to relevance, and will, in general, not be subject to any further mitigation or secondary review – the SRCC either is, or is not, relevant.

Results from 8.3 may influence some of the results from 8.4. In particular, a very high quality score for Independence and Accreditation status would usually also lead to an expectation of high quality of Completeness in 8.4 and in some situations, with experience, it may become appropriate to reduce the effort spent on evaluating Completeness at 8.4 for SRCCs with high quality in section 8.3 (i.e. learning to trust the value of independent Accredited issuers).

If any aspect in 8.4. is recorded as 'not verified' because the complexity and/or competency required is beyond that which the ISA can bring to review the SRCC, then a very high quality result in 8.3 may be considered in mitigation.

The preparation at 7.6.2 will have defined a matrix relationship between level of risk, from low to high or quantified, and required/desired quality factors for specific aspects of the supporting SRCC (also either low-to –high or quantified) for achieving acceptance.

The summary table (next page) in this section includes provision for recording overall judgements at various risk categories.

To apply consideration of risk, transfer the quality assessment of the SRCC from each of the sub-sections of section 8.2, 8.3, 8.4, and 8.5 to this table in 8.6, and apply the appropriate risk category guidance from the table at 7.6.2.

Overall recommendations, whether related to accept/reject or related to identifying the extent to which additional information is deemed necessary in order to proceed, need to be tailored for each specific risk category.

Apply formal document management to the records produced from this process.

Summary Table of the assessed quality of the SRCC properties:

Report No	[Enter the unique identifier for this ISA judgement record]	
SRCC ID	[Enter the unique reference to the SRCC being evaluated]	
Application context	[Enter the reference to the Target Application Context] (use multiple columns, or multiple sheets, for the same Entity in different Target Application Contexts when appropriate)	
Ref. Section	**Evaluation Category**	**Result** **Colour coded** **(optional)**
8.1.1	Project Acceptability Criteria (Yes/No)	
8.1.2	Previous Experience of Issuer	
8.2.1	Target Scope Relevance	
8.2.2	Application Relevance	
8.2.3	Environment Relevance	
8.2.4	Equipment Model Relevance	
8.3.1	Independence of Issuer	
8.3.2	Accreditation status of Issuer	
8.4.1	Completeness of supporting evidence	
8.4.2	Completeness Scope of SRCC	
8.5.1	SRCC Authenticity	
8.5.2	SRCC Currency & validity	
8.5.3	Issuer FSM Currency & validity	
Risk category	[Enter the Risk Category which the overall judgement relates to] (use multiple columns if appropriate for multiple risk categories)	Low
Overall judgement	Summary of decision, concern, recommendations	Colour coded (optional)

The results of the overall evaluation of the SRCC will usually lead to one of the following conclusions:

Result of SRCC evaluation	
SRCC accepted	Document the decisions and the judgement criteria.
SRCC not sufficient	Document the decisions and the judgement criteria. Identify inadequacies and concerns. Define all specific additional evidence/information necessary for acceptance.

9. Bibliography & references

- The CASS Scheme Ltd: Rules for issue and use of product certification with a limited claim of conformity
  http://www.61508.org/cass/wp-content/uploads/2013/11/CASS27-Rev-0_RULES_PRODUCT_CERTIFICATION-WITH_LIMITED_CLAIM_OF_CONFORMITY.pdf
- The CASS Scheme Ltd: Checklist Of Content Of CASS Product Certificates
  http://www.61508.org/cass/wp-content/uploads/2013/11/CASS29-Rev-0-Checklist_for_Product_Certificates.pdf
- Sira Test and Certification: Understanding SIL certificates.pdf
  http://www.siracertification.com/UserDocs/Sira%20Articles/Understanding%20SIL%20certificates.pdf
- Background to Accreditation
  http://en.wikipedia.org/wiki/Accreditation

10.   ANNEX A - Notes on Assessing IEC 61508 Compliance

Where IEC 61508 compliance is specified as part of the User Requirement, it is recommended that the compliance assessment scheme published by The CASS Scheme Ltd (http://www.61508.org/cass/)be used as guidance in evaluating an SRCC assessment, supported by the CASS29 document - CHECKLIST OF CONTENT OF CASS PRODUCT CERTIFICATES - which will include, among others:

- Hardware failure rates and hardware fault tolerance.
- The basis of calculation of the failure rates, e.g. Mil 217, IEC TR 62380, etc.
- The hardware fault tolerance of the product.
- The subsystem type, A or B.
- The diagnostic test interval, where appropriate.
- The scope and coverage of diagnostic tests, where appropriate.
- Systematic safety integrity - The highest SIL in which the product may be used based on the measures used to avoid and control failures.

See also IEC 61508-2 Annex D for a description of the expected contents of the Safety Manual for Compliant Items.

11. ANNEX B - Notes on Accreditation

Primary references are:

- http://en.wikipedia.org/wiki/Accreditation

The IAF is the world association of Conformity Assessment Accreditation Bodies:

- http://www.iaf.nu/

The European co-operation for Accreditation or **EA** is the relevant European body:

- http://www.european-accreditation.org/information/national-accreditation-bodies-having-been-successfully-peer-evaluated-by-ea

For the UK:

- http://www.ukas.com/

How do you find out whether the Issuer is Accredited?

1. Ask them, and then check that the Accreditation Body is in the list from EA or IAF.

   a. Check that the scope of the Accreditation explicitly covers the standards addressed in the SRCC.
   b. Ask to see a copy of the scheme criteria by which their competency is judged.

2. UK Accredited Certificates, and most other European Certificates include the name of the Accreditation Body.

3. Search the Issuer's web-site for the name of their national accreditation body. Most are proud of their Accreditation, but some make it difficult to find (or have none).

4. Search the database of accredited certification bodies on the national accreditation body website, filtered by the number of the standard against which you are seeking compliance.

5. Do not presume accreditation. Many Certification Bodies operate as 'self regulating' (closed private bodies) in areas which are not mandated by law. If an SRCC does not bear an accreditation mark, presume that the Issuer is not formally Accredited to undertake that assessment.