

Methodology

| | |
|-------------------------------------|---|
| 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. |
| 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 Entity |
| Relevance | Establish that the subject, 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. |
| Final Judgement | Consider the results of the separate evaluations, apply the pre-determined judgement criteria, document all concerns, judgements, and recommendations for further actions where appropriate. |

Forming a judgement

| Ref. Section | Evaluation Category | Weight |
|--------------|---|--------|
| 8 | Project Acceptability Criteria (Yes/No) | |
| 8.1 | Previous Experience of Issuer | |
| 9.1 | Target Scope Relevance | |
| 9.2 | Application Relevance | |
| 9.3 | Environment Relevance | |
| 9.4 | Equipment Model Relevance | |
| 10.1 | Independence of Issuer | |
| 10.2 | Accreditation status of Issuer | |
| 11.1 | completeness of supporting evidence | |
| 11.2 | completeness Scope of SRCC | |
| 12.1 | SRCC Authenticity | |
| 12.2 | SRCC Currency & validity | |
| 12.3 | Issuer FSM Currency & validity | |

8 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.

8.1 Previous Experience

8.2 Consideration of Risk

- Having established that a SRCC is to be considered as supporting evidence, with a quality factor (yet to be assessed), it will also usually be relevant to consider the target safety context and level of risk involved, but to address that separate from an assessment of the quality of the SRCC.

8.1 Previous Experience

| Experience | Description | Weight |
|---------------------|---|--------|
| Good | No negative concerns, no issues unresolved. | 1 |
| Unresolved Concerns | Document the concerns, and examine those areas in depth when considering the quality of the SRCC. | 1 |
| Cause for mistrust | Documented negative experience, or proscribed SRCC Issuer or Type of SRCC. Has an overall weighting factor of zero – not acceptable | 0 |

8.2 Consideration of Risk

| Target Entity Risk category | SRCC quality required* | specific acceptability criteria |
|------------------------------------|-------------------------------|--|
| Low | medium | high relevance and traceability |
| Medium | high | Independently assessed Issuers only |
| High | high | Accredited Certificates only |

9 Relevant

- 9.1 Relevance of the SRCC related to the User requirements
- 9.2 Relevance of the Application-related information
- 9.3 Relevance of the environment
- 9.4 Relevance of the SRCC to the equipment model under consideration

9.1 Relevance of the SRCC related to the User requirements

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 subject SRCC.

| Scope | Description related to requirement | Weight |
|---------------|---|--------|
| full scope | All expected information about the entity is referenced in the SRCC | high |
| Partial scope | Only some information about the entity is referenced in the SRCC. Other (named) related SRCCs address all other required aspects | high |
| Incomplete | Only some information about the entity is referenced in the SRCC. No other related SRCCs address the required missing information | low |

9.2 Relevance of the Application-related information

The pre-requisite is to have a detailed understanding of the user target application requirements, and a schedule of which of those are expected to be addressed by the subject SRCC

| Relevance | Description related to requirement | Weight |
|------------|---|--------|
| Identical | All required safe and dangerous failure modes addressed. | |
| similar | some failure modes not addressed | |
| dissimilar | critical failure modes are different, or not addressed. Different operating mode. | |

Notes

1. Where recognised standards define the SRCC Compliance Criteria, they should be fully defined in the SRCC including year, part, and, where relevant, clause number.
2. 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
3. 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.
4. 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.
5. Reference should be made to all limitations or restrictions to application of the entity.
6. Reference to the manufacturer's instructions, especially the safety manual or equivalent, should be included.
7. Sufficient information should be stated or referenced to enable use of the product in any safety-related application intended or claimed on the SRCC
8. Specific safety-related attributes are defined in some standards. Where compliance is claimed against a specific standard, those attributes must be addressed
9. For claimed IEC 61508 compliance – It is recommended that the compliance assessment scheme published by The CASS Scheme Ltd 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.

9.3 Relevance of Environment

| Relevance | Description related to requirement | Weight |
|------------|---|--------|
| Identical | All required environmental aspects addressed. | |
| similar | some environment parameters not addressed | |
| dissimilar | critical environmental aspects are different, or not addressed. | |

The SRCC should define all relevant environmental and other restrictions on use.

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

9.4 Relevance of equipment..

| Relevance | Description related to requirement | Weight |
|------------|--|-------------|
| Identical | The user target item is the same as that referenced in the SRCC | high |
| similar | The user 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 user 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 |

10 Credentials of the Issuer

- 10.1 Independence of the issuer
- 10.2 Competence of the Issuer and Accreditation Status
- 10.3 Issuer Competence Traceability

10.1 Independence of the issuer

| 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 that is subject of the SRCC | 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 that is subject of the SRCC. | |
| Independent Assessor Person | Person who is separate and distinct from the activities which take place during the development lifecycle of the Entity that is the subject of the SRCC, and does not have direct responsibility for those activities. | |
| Non-independent Issuer's published Report | A SRCC Issuer whose published reports are not independent, nor subject to any independent assessment. | |
| 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 not independent nor subject to any independent assessment. | |
| User's internal Entity register * | A preferred entity register for which no SRCC exists. | low |

10.2 Competence of the Issuer and Accreditation Status

| Issuer | Description | Weight, typical |
|---|---|-----------------|
| Accredited Certification Body (ACB) | <i>Accredited</i> as competent to undertake certification activities. The <i>accredited</i> scope for the Certification Body must include the entity being certified. | high |
| FSM-ACB Certified Issuer | Issuer holds a Functional Safety Management (FSM) Certificate from an ACB 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 ACB 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 ACB, and should be available for scrutiny. | high |
| Independently assessed Certification Body | A non-Accredited CB whose competency has been independently assessed, according to <u>published criteria</u> , as appropriate for the scope of the SRCC. Assessment of the CB competency may be by the User. Relative weighting may be dependent on the ISA confidence in the independent assessor. | med |
| Independently assessed Issuer | A SRCC <i>issuer</i> whose FSM processes, reports, and staff competency are not subject to CB assessment. Competency has been independently assessed, according to <u>published criteria</u> , 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 | med |
| Non-Accredited Certification Body | A CB whose competency and assessment processes have not been <i>Accredited</i> or independently assessed for the scope of the SRCC | med/low |
| FSM-Certified Issuer | A SRCC issuer whose FSM processes, reports, and staff competency are subject to non- <i>Accredited</i> CB Functional Safety Management certification. | low |
| Self-Declared Issuer | A SRCC Issuer whose competency and assessment processes have not been not <i>accredited</i> or independently assessed for the scope of the SRCC. | low |

10.3 Issuer Competence Traceability

..... 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.

11 Complete

- 11.1 Completeness related to the supporting evidence
- 11.2 Complete related to the stated SRCC compliance criteria

11.1

| 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, 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 |

11.2 Complete to stated SRCC compliance criteria

- All SRCCs 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.

| Scope of SRCC | Description related to requirement | Weight |
|---------------|---|--------|
| fully defined | All <i>Compliance Criteria</i> of the referenced standard are addressed by the SRCC, or the specific aspects not addressed are clearly defined. | |
| Partial scope | Only some information about the entity is referenced in the SRCC. Other (named) related SRCCs address all required aspects | |
| Incomplete | Only some information about the entity is referenced in the SRCC. No other related SRCCs address the required missing information | |

12 Validity

- 12.1 Authenticity of the SRCC
 - Purpose - to establish the provenance of the SRCC.
- 12.2 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.
- 12.3 Currency and validity of the Entity-related FSM aspects
 - Purpose – For an SRCC which relates partly or wholly to the competency of the services provided by an *entity*, or processes employed to produce an *entity*, to ensure that the *entity* has maintained all of the declared attributes of compliance which underpin the established confidence