

Guidance on the Procurement of Independent Safety Assessors



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- Euro fighter
- Oil and natural gas offshore platform
- London Underground

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Introduction

Independent safety assessment is the formation of a judgement, separate and independent from any system design, development or operational personnel, that the safety requirements for the system are appropriate and adequate for the planned application and that the system satisfies those safety requirements. It is increasingly being used to obtain assurance of safety. (See ISA Working Group document '[What Is Independent Safety Assessment \(ISA\)?](#)')

Procurement of independent safety assessment includes ensuring that both the independent safety assessor(s) (ISA)¹ and the work for which they are contracted are fit for purpose. This carries a safety responsibility, in that safety may be compromised if either the independent safety assessor does not provide, or the contract does not permit, an adequate assessment of safety.

This guidance for the procurement of independent safety assessment addresses the perceived need for guidance that:

- Addresses the particular responsibilities that apply to independent safety assessment.
- Applies consistently to all industry sectors, procuring organisations and types of procurement (including internal ISAs).
- Is consistent with the reasonable expectations of independent safety assessors who work in accordance with the ISA Working Group [Code of Practice for Independent Safety Assessors](#).

The guidance provides a benchmark for procurement processes and procedures, it is not intended to replace, augment or define them.

The guidance may be used and referenced by:

- **Purchaser technical staff:** to ensure that adequate information is provided for procurement of an independent safety assessment.
- **Purchaser procurement staff:** to guide procurement of the services of an independent safety assessor.
- **Independent safety assessors and their employers:** to identify what can reasonably be expected during procurement of their services.

This Guidance on the Procurement of Independent Safety Assessment has been produced by the [ISA Working Group](#). The aims of the ISA Working Group are:

- To promote the ISA role of a safety professional as a means of providing independent safety assurance to the supplier, purchaser and user.
- To promote the ISA role of a safety professional in standards.
- To support safety professional development by defining minimum standards, identifying training that meets minimum standards and supporting resources.
- To provide support for professional ISAs by developing guidance and providing information that affects their role.

Purpose

To provide a benchmark for good practice in the procurement of independent safety assessment.

- This guidance should be used to benchmark procurement processes and procedures, it is not intended to replace, augment or define such processes and procedures.
- This guidance is provided in the form of requirements that are followed by additional amplification, interpretation or guidance which is boxed.
- Procurement processes and procedures that satisfy all of the requirements may be regarded as complying with good practice for the procurement of independent safety assessment services. Non-compliance with boxed bullet points is acceptable if there is reasonable justification (e.g. due to organisation-specific or sector-specific factors).

Footnote

- ¹. In general usage and depending on context, the abbreviation ISA may mean Independent Safety Assessor, Independent Safety Auditor, Independent Safety Advisor, Independent Safety Assessment or Independent Safety Assurance. In this guidance note, ISA will mean Independent Safety Assessor unless it is part of the title of a referenced document or group, in which case the meaning is as used in the title.

Applicability

The procurement of any safety assessment in which the assessor is required to be independent.

- This guidance is applicable to procurement processes and procedures for all industry sectors, procuring organisations and types of procurement (e.g. competitive tender; single tender; framework agreement).
- It applies to both internal procurement (i.e. ISA from within the organisation) and external procurement (i.e. ISA from another organisation).
- It addresses procurement from the time at which the need for independent safety assessment is identified to the time at which a binding agreement to provide independent safety assessment services is entered into (e.g. contract signature for external procurement or acceptance of an internal work order for internal procurement).

Terminology and interpretation

This guidance is based on an underlying generic procurement model in which a procurer, on behalf of an end-user (client), obtains independent safety assessment services from a supplier by means of a contract which includes the engagement of an ISA (which might be an ISA team), the assessment being carried out on outputs from a target project.

Depending on the specific situation, different parts of the underlying generic procurement model may be represented by the same or different organisations. For example:

- Procurer and client are parts of the same organisation (typical situation).
- For internal procurement, the supplier, procurer and client are parts of the same organisation.
- Where an ISA acts on behalf of a customer that is purchasing a system from an external supplier, the end user and the target project are in different organisations.

Terms used in the generic procurement model are defined as follows:

Procurement	Any activity which is intended to result in independent safety services being provided, whether or not it is actually called 'procurement'.
Procurer	The organisational entity that enters into a binding agreement for the acquisition of independent safety assessment services. A procurer will typically be the user of the services. However in exceptional cases a procurer might acquire the services on behalf of a 3 rd party.
Supplier	The organisational entity that enters into a binding agreement with a procurer to provide independent safety assessment services. A supplier might be a company or other organisation, an individual or a discrete part of a company or other organisation.
Client	The organisational entity which is the end user of the independent safety assessment. The client might be the producer, purchaser or funder of the system that is the subject of the assessment. The client will typically also be the procurer of the independent safety assessment services. However, in exceptional cases a client might use a separate organisation to acquire the services on their behalf.
Target project	The activities which produce the item(s) for which independent safety assessment is needed (typically a system or part of a system). These activities need not be called a project by the client.
ISA contract	The binding agreement for the supply of independent safety assessment to be carried out by an ISA (or ISA team) which a supplier and procurer enter into. If an internal ISA is used, 'ISA contract' refers to the internal work order (or other internal agreement) under which the ISA services are provided.
ISA Plan	A plan produced by an ISA for carrying out an independent safety assessment. The plan might be part of a document with wider scope and need not be called 'ISA Plan'.

Users of this guidance should ensure that they understand how the generic procurement model, and in particular the terms defined above, applies to their specific situation.

Guidance

The procurement process and activities shall:

1. Establish the scope of the independent safety assessment.

- The system or subsystem to be assessed should be clearly identified.
- The application and operational context for which safety is to be assessed should be clearly identified.
- Any exclusions, exceptions and limitations in respect of the independent safety assessment should be clearly identified.

2. Provide sufficient information for a prospective ISA to determine the ISA activities, resources and timescales needed for the independent safety assessment.

- The procurer should endeavour to provide sufficient information as soon as possible after an invitation to tender.
- Applicable safety standards should be declared, in particular any standards that put requirements on independent safety assessment.
- The scope of the independent safety assessment should be included in the information provided.
- Project documentation to be included in, or excluded from, the independent safety assessment should be identified.
- All deliverables required from the ISA should be specified.
- If the target project makes use of graded levels for safety related activities, attributes or evidence (e.g. Safety Integrity Level (SIL); Development Assurance Level (DAL); Assurance Evidence Level (AEL)), the levels applicable to the system functions to be assessed should be declared as they may have a significant impact on the time and cost of an independent safety assessment.
- The procurement process should include an opportunity for a prospective ISA to identify and obtain from the procurer any information they need that was not initially provided.
- The opportunity for a meeting between prospective supplier, procurer and (if different) client during the procurement process should be considered if the project is large, complex or novel.
- Any and all constraints and limitations on the client that may affect the work to be carried out by the ISA should be made clear during procurement (e.g. client not able to provide full access to information from a component or subsystem supplier due to commercial or international trade restrictions).

3. Address the level of security to be adopted by the supplier.

- The level of security may have a significant impact on the time and cost of an independent safety assessment.
- All aspects of security should be addressed, including national, commercial, electronic and communications.
- Post-ISA contract security should be addressed (e.g. for storage of documents and electronic data by the supplier).
- Any special security measures required of the supplier, including personnel vetting, should be specified during procurement.

4. Require the ISA to adhere to appropriate professional conduct.

- Adherence to the ISA Working Group document '[Code of Practice for Independent Safety Assessors \(ISAs\)](#)' is recommended.

5. Ensure that an ISA will be engaged to carry out independent safety assessment only if they are demonstrably competent to undertake the assessment activities, to make judgements regarding safety for the relevant system and to communicate effectively the results of their work.

- Any features of the system to be assessed that may require special or unusual ISA competences (e.g. because of a particular technology or application) should be declared to potential suppliers.
- Persons who are to determine whether an ISA is competent should themselves be competent to make that judgement.
- The ISA Working Group document '[Competency Framework for Independent Safety Assessors \(ISAs\)](#)' may be used by the procuring organisation as a basis for assessing ISA competence.
- Evidence that a supplier manages ISA competence in accordance with the ISA Working Group document '[Competency Framework for Independent Safety Assessors \(ISAs\)](#)' should be regarded as contributing to demonstration of ISA competence.
- If an ISA team is required, or is offered by a supplier, assessment of ISA competence should include team working and organisational competences.

6. Facilitate and respect the independence of an ISA.

- Organisational and other arrangements should be identified so as to facilitate ISA independence.
- An ISA shall not be required by contract or by organisational or other arrangements to do anything that, in their judgement, might compromise their independence.
- An ISA should not be subject to explicit or implicit penalties that might compromise their independence of judgement (e.g. payment only if the client accepts the conclusions of an ISA report is not acceptable as it puts pressure on the ISA to conclude what the client wants to see rather than an honest, independent judgement).

7. Facilitate and encourage good communication and an open working relationship between the ISA, the client, the target project team and other relevant persons.

- The main lines and means of communication between ISA, client and target project team should be identified.
- The ISA should be granted access to outputs from target project verification, validation and quality assurance activities (if any) unless there is good reason not to do so.
- For an extended project, there should be defined arrangements for the ISA to update the client in respect of the ISA assessment and for the ISA to be updated on relevant aspects of the target project. These may include formal progress reports, ISA attendance at project safety meetings, regular progress meetings and including the ISA in distribution lists for client project safety documents.
- If ISAs from more than one organisation are to be involved, an open working relationship among the ISAs should be encouraged and facilitated by measures such as contracts and non-disclosure agreements. These should address the limits of responsibilities, joint working arrangements, communications and ISA access to documents and data produced by another ISA organisation.

8. Ensure that the ISA can, without detriment or penalty, raise safety concerns relevant to the independent safety assessment with persons in the client organisation who are able to address them.

- Key client posts with safety responsibilities (e.g. project safety manager; project manager; company safety director) should be identified in procurement documentation.
- The ISA should not be subject to explicit or implicit penalties for escalating a safety concern to a higher level of client management if it is not possible to resolve it with the target project team.

9. Ensure that the ISA can have timely access to all information necessary for them to fulfil their ISA responsibilities.

- Means for ensuring timely access to target project documents should be identified during procurement (e.g. by including the ISA in the distribution list).
- If access to certain documents is constrained to specific locations, the means by which the ISA can have timely access to such documents should be identified during procurement.
- If rights of ISA access to 3rd party information is necessary, this should be addressed during procurement.

10. Provide for continuity and consistency of safety assessment throughout the project.

- A commitment should be obtained from the supplier organisation that they will use their best endeavours to provide the same ISA throughout the independent safety assessment contract.
- Provision should be made for the supplier organisation to provide an alternative ISA of adequate competence if the original ISA is no longer available for reasons beyond their control (e.g. ISA is ill or leaves the organisation).
- If the project is of long duration (e.g. more than a few years), procurement should recognise that it is not reasonable to expect to have the original ISA throughout the project (e.g. because of ISA career development needs). The supplier should therefore be required to address succession planning.
- If it is necessary to use ISAs from different organisations during a project, there should be arrangements for ensuring continuity and consistency of safety assessment.

11. Require that the ISA works in accordance with an agreed ISA plan produced by the ISA that minimises disruption or delay to the target project.

- The ISA plan may be either a specific document or included in a document with wider scope and need not be called 'ISA plan'.
- Sufficient information should be provided to the supplier during procurement for them to be able to produce an ISA plan that is sufficient both for resourcing and cost estimates by the supplier and assessment by the procurer and client.
- Production of a definitive ISA plan should involve interaction with the client (e.g. to avoid including assumptions that might or might not be valid but could be resolved by the client). If such interaction is not possible during the procurement process, or is not considered necessary, an ISA plan produced during procurement should be regarded as a draft and subject to immediate update on commencement of the ISA work.
- Provision should be included in the ISA contract for the ISA plan to be changed during the duration of the contract in the light of ISA findings and changes to the target project.
- Procurement should recognise that an ISA must give priority to safety, thus some disruption or delay to the target project or programme may be unavoidable (e.g. if the target project has a decision point for which input from the ISA assessment is needed but the target project's schedule does not allow sufficient time for an adequate ISA assessment before the decision point).
- The ISA plan should include all required deliverables and ISA outputs.

12. Address the data retention policy applicable to records held by the supplier at the end of the ISA contract.

- The supplier is likely to have to take into account the resources and costs associated with data retention in determining a price for the independent safety assessment contract.
- Both hard copy and electronic records should be addressed.
- Records acquired from all sources should be addressed, including records generated by the supplier, records provided by the client, records provided from the target project and records obtained from 3rd parties.
- The data retention policy should be consistent with ownership of intellectual property rights and any agreements regarding information owned by 3rd parties.
- The level of security to be applied to retained records should be addressed.
- The possibility that records may need to be transferred to an ISA from another organisation should be addressed (e.g. if different ISAs are to be used for different phases of a project).

13. Ensure that the above points 1 to 12 are addressed in the end contract with the supplier of an ISA if the independent safety assessment is contracted through a third party.

- If an ISA is engaged via an agency or similar, the end contract with the supplier of the ISA is to be interpreted as the legally binding terms under which the ISA is engaged to carry out the independent safety assessment.
- The procurer should ensure that they have the right to check that points 1 to 12 are addressed in the contract with the supplier of the ISA.
- The procurer should ensure that the ISA is made aware of their responsibilities under points 1 to 12.
- The procurer should ensure that they have the right to decline the services of an ISA who does not satisfy the above points 4 (professional conduct) and 5 (competence).