THE USE OF INDEPENDENT SAFETY AUDITORS IN DE&S

GUIDANCE, BEST PRACTICE AND FAOs

S&EP Publication SEP/ASE/ISA/3/1/1 Issue 1
Dated December 2011

Section 1: Introduction

1.1 Background

- 1.1.1 The DE&S Safety Improvement Working Group (SIWG), established in response to the loss of Nimrod XV-230 over Afghanistan in September 2006, conducted an in-depth, wide-ranging review of DE&S safety management activities. One area that came in for particular scrutiny was the use of Independent Safety Auditors (ISAs) in DE&S Acquisition projects. The SIWG final report included the following paragraph and an associated action:
 - 55. The roles, level of independence and scope of involvement of Independent Safety Auditors (ISAs) across DE&S are inconsistent. Generally, ISAs are engaged by PTs and the findings of their activities are not analysed for lessons applicable across the organisation.
 - **Action A3:** Examine the role of ISAs supporting DE&S and consider issues associated with their roles, funding, appointment, reporting and monitoring their effectiveness.
- 1.1.2 Subsequent action was undertaken to review the ISA role in MoD policy, standards and process documents, and survey practice across DE&S Acquisition Projects. The resulting report¹ generated several recommendations. These included the desirability of making available to users some example ISA requirements (e.g. SORs, TORs, contract clauses), based on information taken from Project documents which were considered to represent current good practice. The material is presented in Sections 2 and 3 of this document: in each case, an example document has been drafted, supported by commentary to provide further information. A comprehensive set of Frequently Asked Questions (FAQ) and useful links can be found in Section 4.
- 1.1.3 This information is published in support of document "Guidance for PTs on Contracting ISAs2",

¹ **Report On SIWG Action A3 – ISAs** Safety Assurance Services Ltd Report SAS/2106/04 R01 Draft C of March 2009

² Guidance for Integrated Project Teams. for Use in Contracting for Independent Safety Auditor (ISA) Services Guidance document developed for the MoD Safety Management Offices Group and developed with assistance from Adelard, STG/181/1/9/1 Version 1.0 dated 1 June, 2004. (available on the AOF).

Section 2: Statement of Work for Independent Safety Auditor Support

2.1 Introduction

- 2.1.1 The following text has been generated by S&EP to provide an example to DE&S Project Teams and others who are intending to contract for Independent Safety Auditor support. Such organisations must consider carefully the relevance of this example material to their specific circumstances and requirements. If they are uncertain about how to produce a document to meet their requirements, then they should seek support from safety specialists in their Operating Centre or from the relevant Safety Management Office.
- **2.1.2** Throughout this example document the term "Independent Safety Auditor" is used in full. It is recommended that the abbreviation "ISA" should not be used because of possible confusion with the different role of "Independent Safety Adviser".
- 2.1.3 Throughout this example document the term "Independent Safety Auditor" is used. In some cases the Independent Safety Auditor's role is required to cover Environmental issues as well as Safety. This is permissible and will require the Independent Safety and Environmental Auditor to have additional competences.
- 2.1.4 Some example text is shown highlighted in yellow in the Table below. This must be replaced with correct text that is relevant to the document author's own requirement. Other text is shown where the author is required to choose between options.

Exa	ample Content of Statement of Work for Independent Safety Auditor Support	Comments and Guidance
		 MoD to consider whether this document should be called "Statement of Work", "Statement of Requirement" or something else.
		 A clear Statement of Work for Independent Safety Auditor support may allow firm price contracting, provided that this defines the amount and type of work clearly (e.g. number of on-site audits, number, type and scale of documents to be reviewed, number and duration of meetings to be attended).
		 See also the guidance document on the AOF ("Guidance for Integrated Project Teams for Use in Contracting for Independent Safety Auditor (ISA) Services") which can be found at:
		http://www.aof.mod.uk/aofcontent/tactical/safety/downloads/isaguide.pdf
General		-
1.	This Statement of Work (SOW) is for the provision of Independent Safety Auditor support on the BCD Project to XYZ	 This document is NOT appropriate for the Safety Adviser role. The abbreviation ISA should not be used for the Adviser role.
	Project Team (XYZ) for the period 01 January 2011 to 31 December 2012.	 If the role is also required to cover Environmental issues, then this should be made explicit in the name of the role used throughout this document.
2.	The Independent Safety Auditor will provide assurance by gathering evidence, through a combination of auditing for conformance to planned arrangements, reviewing of project documentation and performing analyses/assessments independent from, and in addition to, those of the DE&S Project Team, the Prime Contractor (GHI), their sub-contractors and suppliers and the military users.	

Ex	ample Content of Statement of Work for Independent Safety Auditor Support	Comments and Guidance
3.	 The scope of the Independent Safety Auditor's work is required to examine the safety management arrangements and records of the following parties involved with the BCD Project [delete or extend as appropriate]: The Prime Contractor (GHI); The Prime's sub-contractors; The Prime's suppliers; The DE&S XYZ Project Team; The Design Authority (if not the Contractor or Project Team); Military Users for this Project; Project Teams for specific capabilities that interface with XYZ. 	 The Independent Safety Auditor can be required audit the Safety Management System and safety records of each of the parties involved in the project, since these form part of the overall safety argument. The balance of attention paid by the Independent Safety Auditor to each authority will change as the project lifecycle proceeds. The Independent Safety Auditor may require access to other companies or organisations. This could cause difficulties with information confidentiality or security and so must be carefully considered when defining the contract. The Independent Safety Auditor only has authority of access to other companies if this is specified in their contract.
4.	The role is as defined in Def Stan 00-56 Issue 4, which states that the Independent Safety Auditor is "an individual or team, from an independent organisation, that undertakes audits and other assessment activities to provide assurance that safety activities comply with planned arrangements, are implemented effectively and are suitable to achieve objectives; and whether related outputs are correct, valid and fit for purpose."	o In the MoD nuclear domain, the Independent Safety Auditor is defined and used in a way that relates only to Audit of processes and excludes Independent Assessment. The latter is conducted through the INSA and IPR processes which mirror practice in the civil nuclear sector. INSA is "Independent Nuclear Safety Assessment" and IPR is "Independent Peer Review".
5.	The Independent Safety Auditor support should be a named individual / team of named individuals [delete as appropriate] with appropriate competences as defined below.	 Even when an Independent Safety Auditor team is employed, the team leader and preferably all the team members should be individually identified It is preferable to employ an Independent Safety Auditor team for most projects. The team enables effective peer review of the assessment's outputs and can provide specialist expertise in areas such as human factors and software integrity assessment. It also has the practical advantage that it is easier to cover for normal staff absence and attend concurrent meetings. An individual is unlikely to have the broad range of competence necessary to act as Independent Safety Auditor for a complex project. It is not necessary for each individual to have the full required competence, only the Independent Safety Auditor team as a whole

Example Content of Statement of Work for Independent Safety Auditor Support		Comments and Guidance
Role	and Responsibility	-
6.	The Terms of Reference (TORs) for the Independent Safety Auditor are defined in the attached document.	 The Independent Safety Auditor should always operate with explicit documented and approved Terms of Reference, so that all parties understand the role, responsibilities and limitations on what they can be asked to do. This is a key finding of the Haddon-Cave review report. It is preferable that the TORs should be prepared by the Independent Safety Auditor's customer prior to placing the contract. See separate example TORs document.
7.	The Independent Safety Auditor is responsible for operating to the agreed TOR and for ensuring that staff with the necessary competences are used at all times. An authorised Independent Safety Auditor has the right and duty to raise significant concerns directly with the project team or contractor, even when outside their agreed scope of work or TOR and should raise unresolved concerns with appropriate Authorities and the relevant Safety Management Office.	

Example Content of Statement of Work for Independent Safety Auditor Support	Comments and Guidance
 8. The Independent Safety Auditor has no executive authority and provides independent information to the decision makers. In order to maintain their independence, the Independent Safety Auditor cannot give specific advice or contribute directly to the safety argument. However, it is legitimate, and helpful in reducing project risk from safety matters, for the Independent Safety Auditor to give general advice that leads to timely production of a satisfactory safety case. General advice is that which would be given to any broadly similar project, and corresponds to the assessment guides produced by the statutory regulators (e.g. the HSE's Approved Codes of Practice and the series of Assessment Guides from the Nuclear Installations Inspectorate). General advice may cover: a framework of appropriate standards and good practice; the selection of suitable analysis techniques; the structure of safety arguments; specific technology and the consequences of technology choices. 	safety processes can provide the necessary additional evidence. Such advice can compromise the Independent Safety Auditor as they then have an interest in the success of the advice. Therefore it is best to provide independent safety consultants for advice rather than the appointed Independent Safety Auditor
Competence Requirements	 Organisations tendering to be appointed as Independent Safety Auditor must demonstrate that they satisfy the project-specific requirements for competence and that they have the necessary depth of resource.

E	xample Content of Statement of Work for Independent Safety Auditor Support	Comments and Guidance
9.	The Independent Safety Auditor should be competent in safety audit skills in the ***** domain(s), including knowledge of relevant safety policy and legislation. The candidate shall demonstrate this against the competence criteria laid out below:	 Individual Independent Safety Auditors should have suitable competences which will vary from case to case, but can be considered under the headings of: Technical competence (general safety); Technical competence (application domain safety); Technical competence (audit); Behavioural competence. Authors of SOWs should take care to ensure that the list of competence requirements is relevant to their specific situation. The information in this document should be considered only to be a starting point.

Exai		tement of Work for Independent Safety Auditor Support	Comments and Guidance
a.	competence cov to underpin the a Firstly, this can	repetence (General Safety): Technical ers the knowledge and experience needed activities of the Independent Safety Auditor. be considered independent of the specific in and technology used:	
	i.	Knowledge and experience of the legal and safety regulatory framework;	
	ii.	Understanding of the principles and concepts of safety; management, e.g. ALARP, hazards, risk and safety requirements.	
	iii.	Knowledge and experience of techniques and methods to determine and analyse safety issues of importance and to make a judgement on the safety of a system. Examples of such knowledge include safety analysis techniques such as HAZOPS and Fault Tree Analysis, and the ability to estimate the necessary resources;	
	iv.	Knowledge and experience of specific standards, guidelines or codes of practice relevant for the project, e.g. Def Stan 00-56 and the applicable safety management JSPs.	
	v.	General skills (e.g. documenting and presenting findings and recommendations).	

Exa	Example Content of Statement of Work for Independent Safety Auditor Support		Comments and Guidance
b.	Technical compe understanding of	petence (Application Domain Safety): tence in the application domain, where an f the specific technologies used and the ise extends the ability to successfully audit system:	 In the ship sector, demonstration of technical competence requires that all key members of the Independent Safety Auditor's team should possess or be working toward an SSMO training certificate.
	i.	Safety engineering knowledge and experience appropriate to the application area and technology, including safety practices appropriate to the organisation and application area;	
	ii.	Engineering knowledge and experience appropriate to the application area (e.g. air traffic control) and technology (e.g. digital network communication);	
	iii.	Experience of other systems engineering disciplines including human factors integration, integrated logistic support and availability, reliability and maintainability would also be advantageous.	

Exan	-	ement of Work for Independent Safety Auditor Support	Comments and Guidance
C.	considers the spe Audit (that is,	cific activities performed as part of a Safety document review, process audits and yses). This includes the ability to:	
	i.	Determine the scope and objectives of the Safety Audit.	
	ii.	Develop and maintain a plan for the activities that comprise a Safety Audit.	
	iii.	Collect and analyse objective evidence to support a judgement about the safety of the system. This may include interviewing personnel at all levels, examining and reviewing documents and observing activities.	
	iv.	Verify the accuracy of information gathered in interviews by observation, measurements and records analyses.	
	V.	Identify, record and investigate clues suggesting possible problems.	
	vi.	Carry out formal process audits against relevant standards, plans, etc.	
	vii.	Make a judgement on the safety of a system.	
	viii.	Document findings including producing formal Safety Audit Reports.	
	ix.	Verify that any actions necessary to address the results of the Safety Audit activities are appropriately completed.	
	х.	Reviews of technical documents.	

Exa	ample Content of Statement of Work for Independent Safety Auditor Support	Comments and Guidance
d.	Behavioural Competence: The qualities and attributes of behaviour and character needed to perform the role of an Independent Safety Auditor effectively including maintaining independence:	
	 Interpersonal skills; 	
	ii. Competence in communicating at all levels of the organisation;	
	iii. Interviewing skills;	
	iv. Reporting and presentation skills;	
	v. Integrity and trustworthiness.	
Inde	pendence Requirements	 Organisations tendering to be appointed as Independent Safety Auditor must demonstrate that they satisfy the project-specific requirements for independence.
10.	The Independent Safety Auditor must be sufficiently independent that there is nothing that might affect or call into question their ability to carry out impartial assessment or audit activities or to make impartial judgements regarding safety.	
		The need for independence does not mean that every project in a project team and every subcontractor has to have a separate Independent Safety Auditor. A single or small number of Independent Safety Auditor s will give a more consistent approach and will acquire domain-specific knowledge more quickly. Of course the Independent Safety Auditor(s) should be independent with respect to all the organisations that they audit.

Example Content of Statement of Work for Independent Safety Auditor Support		Comments and Guidance
 The Independent Safety Auditor for the BCD Project is required to be separated from the prime contractor, design authority and DE&S project team to the extent defined below [choose which one applies and delete the others]: Independent organisation; Independent company; Independent department; Independent person. This requirement applies to all members of the Independent 		 The applicable standards for certain sectors may require particular controls to be established for the management of independence and impartiality. The level of independence should be declared and justified in the Independent Safety Audit Plan.
	Safety Audit team, including any sub-contracted activities.	
Scop	pe of Work	_
12.	The scope of work for the Independent Safety Auditor is to consist of the following [delete or extend as appropriate]:	
	 a. Production and re-issue as appropriate of an Independent Safety Audit Plan; 	
	 Attendance at and contribution to BCD Project Safety Committee meetings; 	
	 c. Planning of, conduct of and reporting on Audits of the BCD Project Safety Management System as operated by The Prime Contractor (GHI); The Prime's sub-contractors; The Prime's suppliers; The DE&S XYZ Project Team; The Design Authority (if not the Contractor or Project Team); Military Users for this Project; Project Teams for specific capabilities that interface with XYZ. 	

Example (Content of Statement of Work for Independent Safety Auditor Support	Comments and Guidance
d.	Reviews of safety documentation including Safety Management Plan, Safety Requirements (incl. in URD and SRD and derived requirements), Software Development Plan, Safety Case Report, Hazard Log, Test/Trial Plan, Test/Trial reports;	o Review report for correctness, completeness, consistency, achievability, conformance to standards and legislation.
e.	Assessment of the Safety elements of tender responses;	 The MoD ISA Guidelines document states that tender assessment can be within the Scope of Work for an Independent Safety Auditor. Care must be taken that it does not compromise independence.
f.	Independent review of safety evidence used in the safety case, such as:	 Covering system hardware, software, human factors and COTS/GFE as well as developmental items.
	 Conduct of safety analyses/assessments independent of the primary assessments conducted by the supplier and/or DE&S project team; 	 Diverse analysis, witnessing, interviewing, traceability checks, vertical slices and inspection at the discretion of the Independent Safety Auditor.
	 Attendance at Tests and/or Trials; 	
	Examination of evidence audit trails;	
	 Review of historical and/or anecdotal evidence used for COTS/GFE items, 	
g.	Review the competence of key people involved in the safety programme;	
h.	Independent review of ALARP arguments used in the safety case:	Check arguments for compliance with relevant standards and HSE guidance.
	Where 'Good Practice' arguments are made, consider whether the 'Good Practice' is relevant and up to date.	
	 Where 'First Principles' arguments are made, consider whether a robust process has been followed, justifiable data has been used and sensitivity to data has been considered. 	

Example Content of Statement of Work for Independent Safety Auditor Support		Comments and Guidance
such as: Desi Docu	mplementation of safety control measures, gn safety features; umented operating procedures; umented maintenance procedures; ning course content;	o To confirm that controls in the Hazard Log are implemented as recorded, so that ALARP claims are valid.
Identification,	at Project Safety meetings (e.g. Hazard Risk Acceptance) to provide independent the process adopted;	 The Independent Safety Auditor should act as an observer of the process (including the competence of the participants) to check whether meetings are conducted in accordance with standards and good practice and must not be involved in the decisions that are reached.
issues raised	and upkeep of a 'Issues Log' to track all by the Independent Safety Auditor and udit trail of how they are being / have been	 Def Stan 00-56 Pt 2 contains the following: 14.6 An audit will usually detect areas where there are deficiencies. It is important that identified deficiencies are rectified. The ensuing corrective actions should be documented and traceable to the deficiency. It may be necessary to work with other agencies, through the Duty Holder, where remedial action is outside the control of the Contractor. 14.7 Where actions taken to resolve deficiencies are completed satisfactorily this should be reported as early as practical, and recorded in the safety audit report. Where they were not completed satisfactorily, the reasons why and any implications should be reported as early as practical.
•	pendent Safety Auditor endorsement (i.e. key safety decisions and assumptions;	O According to the sector, the Independent Safety Auditor may be asked to sign documents produced by the contractor to indicate that they have been reviewed or endorsed by the Independent Safety Auditor. The relevant safety management JSP will provide details. The contract with the Independent Safety Auditor should make it clear if this is required.
m. Production of Statements;	Independent Safety Audit Reports and/or	
n. Delivery of ge	eneric advice to the DE&S project team;	
o. Response to	ad hoc requests for support.	

Example Content of Statement of Work for Independent Safety Auditor Support		Comments and Guidance
Deliv	rerables	-
13.	All deliverables should be produced in MS Office 2003 format.	
14.	All formal communication regarding safety that is made by the Independent Safety Auditor shall be clear, timely, objective and documented and shall distinguish fact and evidence from opinion and judgement.	
15.	All deliverables should be reported concurrently to both the Prime Contractor and the DE&S Project Manager.	
16.	The major deliverables will consist of the following [delete or extend as appropriate]:	
	a. Independent Safety Audit Plan;	
	b. Independent Safety Audit Reports;	These should be produced prior to major programme milestones, such as the start of trials and acceptance into service. Normally they will follow a new version of the safety case. They should typically contain: an assessment of the safety argument; a short summary of the Independent Safety Auditor's activities since the previous report; references to the documents produced; references to the documents examined; a discussion of any particular safety issues; and conclusions and recommendations on the safety of the activities covered by the safety case. Reference to the requirements of domain-specific JSPs should be made. In some sectors (e.g. the ship sector), the Independent Safety Audit Report is included within the Safety Case Report.
	 c. Formal records of each Safety Management System Audit conducted. This is expected to include: Audit Plan; Record of Audit meeting(s); Audit Report; Record of each non-conformance or observation raised. 	

Exam	Example Content of Statement of Work for Independent Safety Auditor Support			Comments and Guidance
	d.	Reports on each of the Safety documents submitted for review by the Independent Safety Auditor (e.g. Safety Management Plan, Safety Requirements, Safety Case Report, Hazard Log, Test/Trial Plan, Test/Trial reports).	0	According to the sector, the Independent Safety Auditor may be asked to sign documents produced by the contractor to indicate that they have been reviewed or endorsed by the Independent Safety Auditor. The relevant safety management JSP will provide details. The contract with the Independent Safety Auditor should make it clear if this is required.
	e.	Progress Reports.	0	Reports summarising progress against the Independent Safety Audit Plan as contracted. These will be produced according to the demands of the project but may, typically, be on a quarterly basis.
	f.	Record of advice given.	0	Advice should always be generic. Advice may be given verbally, but substantive advice should be documented in written papers.

Section 3: ISA Terms of Reference

3.1 Introduction

- 3.1.1 The following text has been generated by S&EP to provide an example to DE&S Project Teams and others who are intending to appoint an Independent Safety Auditor. Such organisations must consider carefully the relevance of this example material to their specific circumstances and requirements. If they are uncertain about how to produce a document to meet their requirements, then they should seek support from safety specialists in their Operating Centre or from the relevant Safety Management Office.
- 3.1.2 Throughout this example document the term "Independent Safety Auditor" is used in full. It is recommended that the abbreviation "ISA" should not be used because of possible confusion with the different role of "Independent Safety Adviser".
- 3.1.3 Throughout this example document the term "Independent Safety Auditor" is used. In some cases the Independent Safety Auditor's role is required to cover Environmental issues as well as Safety. This is permissible and will require the Independent Safety and Environmental Auditor to have additional competences.
- 3.1.4 Some example text is shown highlighted in yellow in the Table below. This must be replaced with correct text that is relevant to the document author's own requirement. Other text is shown highlighted in turquoise where the author is required to choose between options.

Example Content of Terms of Reference for Independent Safety Auditor		Comments and Guidance	
		 The Independent Safety Auditor should always operate with explicit documented and approved Terms of Reference, so that all parties understand the role, responsibilities and limitations on what they can be asked to do. This is a key finding of the Haddon-Cave review report. It is preferable that the TORs should be prepared by the Independent Safety Auditor's customer prior to placing the contract. 	
Gen	eral	-	
2.	This Terms of Reference (TORs) is for the role of Independent Safety Auditor support on the BCD Project to XYZ Project Team (XYZ) for the period 01 January 2011 to 31 December 2012. The Independent Safety Auditor will operate in accordance with the IET/BCS Code of Practice for Independent Safety Assessors: http://www.theiet.org/factfiles/isa/isa-code-page.cfm which covers the following: Independence; Competence; Competence; Advice; Integrity; Priority of Safety; Escalation; Management and Planning.	 This document is NOT appropriate for the Safety Adviser role. The abbreviation ISA should not be used for the Adviser role. If the role is also required to cover Environmental issues, then this should be made explicit in the name of the role used throughout this document. This Code of Practice applies to Auditors as well as Assessors and is relevant to defence and non-defence sectors. Information from the Code of Practice is not repeated in this TORs document. 	
3.	The Independent Safety Auditor will operate in accordance with an appropriate quality assurance system.		

Example Content of Terms of Reference for Independent Safety Auditor		Comments and Guidance
4.	The Independent Safety Auditor will provide assurance by gathering evidence, through a combination of auditing for conformance to planned arrangements, reviewing of project documentation and performing analyses/assessments independent from, and in addition to, those of the DE&S Project Team, the Prime Contractor (GHI), their sub-contractors and suppliers and the military users.	
5.	The scope of the Independent Safety Auditor's work is required to examine the safety management arrangements and records of the following parties involved with the BCD Project [delete or extend as appropriate]: • The Prime Contractor (GHI); • The Prime's sub-contractors; • The Prime's suppliers; • The DE&S XYZ Project Team; • The Design Authority (if not the Contractor or Project Team); • Military Users for this Project; • Project Teams for specific capabilities that interface with XYZ.	 The Independent Safety Auditor can be required audit the Safety Management System and safety records of each of the parties involved in the project since these form part of the overall safety argument. The balance of attention paid by the Independent Safety Auditor to each authority will change as the project lifecycle proceeds. The Independent Safety Auditor may require access to other companies or organisations. This could cause difficulties with information confidentiality or security and so must be carefully considered when defining the contract. The Independent Safety Auditor only has authority of access to other companies if this is specified in their contract.
6.	The role is as defined in Def Stan 00-56 Issue 4, which states that the Independent Safety Auditor is "an individual or team, from an independent organisation, that undertakes audits and other assessment activities to provide assurance that safety activities comply with planned arrangements, are implemented effectively and are suitable to achieve objectives; and whether related outputs are correct, valid and fit for purpose."	o In the MoD nuclear domain, the Independent Safety Auditor is defined and used in a way that relates only to Audit of processes and excludes Independent Assessment. The latter is conducted through the INSA and IPR processes which mirror practice in the civil nuclear sector. INSA is "Independent Nuclear Safety Assessment" and IPR is "Independent Peer Review".
7.	The Independent Safety Auditor has no executive authority and provides independent information to the decision makers.	
Task	s	 The text in this section should be identical to that under 'Scope of Work' in the SOW document.

Exa	Example Content of Terms of Reference for Independent Safety Auditor		Comments and Guidance
8.		ndependent Safety Auditor shall undertake the following [delete or extend as appropriate]::	
	a.	Production and re-issue as appropriate of an Independent Safety Audit Plan;	
	b.	Attendance at and contribution to BCD Project Safety Committee meetings;	
	C.	Planning of, conduct of and reporting on Audits of the BCD Project Safety Management System as operated by The Prime Contractor (GHI); The Prime's sub-contractors; The Prime's suppliers; The DE&S XYZ Project Team; The Design Authority (if not the Contractor or Project Team); Military Users for this Project; Project Teams for specific capabilities that interface with XYZ.	
	d.	Reviews of safety documentation including Safety Management Plan, Safety Requirements (incl. in URD and SRD and derived requirements), Software Development Plan, Safety Case Report, Hazard Log, Test/Trial Plan, Test/Trial reports;	o Review report for correctness, completeness, consistency, achievability, conformance to standards and legislation.
	e.	Assessment of the Safety elements of tender responses;	 The MoD ISA Guidelines document states that tender assessment can be within the Scope of Work for an Independent Safety Auditor. Care must be taken that it does not compromise independence.

Example C	Content of Terms of Reference for Independent Safety Auditor	Comments and Guidance
f.	Independent review of safety evidence used in the safety case, such as: Conduct of safety analyses/assessments independent of the primary assessments conducted by the supplier and/or DE&S project team; Attendance at Tests and/or Trials; Examination of evidence audit trails; Review of historical and/or anecdotal evidence used for COTS/GFE items,	 Covering system hardware, software, human factors and COTS/GFE as well as developmental items. Diverse analysis, witnessing, interviewing, traceability checks, vertical slices and inspection at the discretion of the Independent Safety Auditor.
g.	Review the competence of key people involved in the safety programme;	
h.	 Independent review of ALARP arguments used in the safety case: Where 'Good Practice' arguments are made, consider whether the 'Good Practice' is relevant and up to date. Where 'First Principles' arguments are made, consider whether a robust process has been followed, justifiable data has been used and sensitivity to data has been considered. 	o Check arguments for compliance with relevant standards and HSE guidance.
i.	Review the implementation of safety control measures, such as: Design safety features; Documented operating procedures; Documented maintenance procedures; Training course content;	 To confirm that controls in the Hazard Log are implemented as recorded, so that ALARP claims are valid.
j.	Attendance at Project Safety meetings (e.g. Hazard Identification, Risk Acceptance) to provide independent assurance in the process adopted;	 The Independent Safety Auditor should act as an observer of the process (including the competence of the participants) to check whether meetings are conducted in accordance with standards and good practice and must not be involved in the decisions that are reached.

Example Content of Terms of Reference for Independent Safety Auditor		Comments and Guidance
k.	Development and upkeep of a 'Issues Log' to track all	o Def Stan 00-56 Pt 2 contains the following:
	issues raised by the Independent Safety Auditor and provide an audit trail of how they are being / have been managed;	14.6 An audit will usually detect areas where there are deficiencies. It is important that identified deficiencies are rectified. The ensuing corrective actions should be documented and traceable to the deficiency. It may be necessary to work with other agencies, through the Duty Holder, where remedial action is outside the control of the Contractor.
		14.7 Where actions taken to resolve deficiencies are completed satisfactorily this should be reported as early as practical, and recorded in the safety audit report. Where they were not completed satisfactorily, the reasons why and any implications should be reported as early as practical.
I.	Formal Independent Safety Auditor endorsement (i.e. signature) of key safety decisions and assumptions;	 According to the sector, the Independent Safety Auditor may be asked to sign documents produced by the contractor to indicate that they have been reviewed or endorsed by the Independent Safety Auditor. The relevant safety management JSP will provide details. The contract with the Independent Safety Auditor should make it clear if this is required.
m.	Production of Independent Safety Audit Reports and/or Statements;	
n.	Delivery of generic advice to the DE&S project team;	
0.	Response to ad hoc requests for support.	
Advice		 The Independent Safety Auditor may only provide advice if it is clear that it cannot compromise their independence.

Exa	mple Content of Terms of Reference for Independent Safety Auditor	Comments and Guidance
9.	The Independent Safety Auditor cannot give specific advice or contribute directly to the safety argument. However, the Independent Safety Auditor will be required to provide advice to the XZY Project Safety Committee / Panel and the XYZ Project Manager on the following general matters: • a framework of appropriate standards and good practice; • the selection of suitable analysis techniques; • the structure of safety arguments; • the making of tolerability claims; • specific technology and the consequences of technology choices.	o In order to maintain their independence, it is legitimate, and helpful in reducing project risk from safety matters, for the Independent Safety Auditor to give general advice that leads to timely production of a satisfactory safety case. General advice is that which would be given to any broadly similar project, and corresponds to the assessment guides produced by the statutory regulators (e.g. the HSE's Approved Codes of Practice and the series of Assessment Guides from the Nuclear Installations Inspectorate). General advice may cover:
Repo	orting and Communication	-
10.	All deliverables will be reported concurrently to both the Prime Contractor and the DE&S Project Manager.	
11.	The Independent Safety Auditor will track the issues raised to a satisfactory resolution. Such issues would include non-conformances, deficiencies and areas for improvement.	o Def Stan 00-56 Pt 2 contains the following:
		14.6 An audit will usually detect areas where there are deficiencies. It is important that identified deficiencies are rectified. The ensuing corrective actions should be documented and traceable to the deficiency. It may be necessary to work with other agencies, through the Duty Holder, where remedial action is outside the control of the Contractor.
		14.7 Where actions taken to resolve deficiencies are completed satisfactorily this should be reported as early as practical, and recorded in the safety audit report. Where they were not completed satisfactorily, the reasons why and any implications should be reported as early as practical.
Esca	lation of Concerns	-

Exa	mple Content of Terms of Reference for Independent Safety Auditor	Comments and Guidance
12.	The Independent Safety Auditor has the right and duty to raise significant concerns directly with the project team or contractor, even when outside their agreed scope of work or TOR and should raise unresolved concerns with appropriate Authorities and the relevant Safety Management Office.	 It is possible that the Independent Safety Auditor and the contractor will become deadlocked over some aspect of the safety argument, and the project team will wish to seek another opinion. The relevant SMO may be able to provide informal assistance and advice on the way forward (although the project team remains responsible for deciding the way ahead). Also, if the Independent Safety Auditor has significant concerns that they do not believe are being adequately addressed, the relevant SMO may be approached for assistance. When the Independent Safety Auditor considers that safety is not being given sufficient priority or is not addressed adequately, the Independent Safety Auditor should make best endeavours to ensure that the information is communicated to all appropriate parties, giving their reasons. If the Independent Safety Auditor identifies a safety issue that is outside their remit, they should ensure that appropriate persons are notified.
13.	If at any time the Independent Safety Auditor believes that the authorised resources and effort are not sufficient to carry out their work satisfactorily, they should raise this as soon as possible with the appropriate person or organisation.	
Independence and Professional Integrity		 The Independent Safety Auditor needs to be sufficiently independent that there is nothing that might affect or call into question their ability to carry out impartial assessment or audit activities or to make impartial judgements regarding safety.
14.	Should the Independent Safety Auditor be aware of any potential Conflict of Interest in respect of their current or previous work for the MOD or the Contractor that might affect or call into question their independence, then they should raise the matter in writing to the XZY Project Safety Committee / Panel and the XYZ Project Manager.	 A decision on whether to proceed must be taken in accordance with the Conflicts of Interest Commercial Policy Statement: http://www.aof.mod.uk/aofcontent/tactical/toolkit/downloadsindexed/coi/coi_cps.pdf
15.	The Independent Safety Auditor is responsible for operating to the agreed TOR and for ensuring that staff with the necessary competences are used at all times.	

Section 4: Frequently Asked Questions on Independent Safety Auditors

Q1: What does "ISA" stand for ?

In the MoD acquisition community "ISA" stands for Independent Safety Auditor. In some non-defence sectors ISA stands for Independent Safety Assessor. These roles are essentially the same (see Q2 below). The ISA must be independent of the system design, acquisition and operation functions, so that an unbiased view can be formed in checking or reviewing the safety work and arrangements of the main parties.

A supplier, company or project can call in external safety advisors. However, this is not considered to be within the ISA role as defined in current international and UK standards. Independent Safety Auditors are sometimes asked to give advice to a supplier, company or project, but this may compromise the independence of the ISA role and function (see Q6: below). The term "ISA" should **not** be used for the purely advisory role.

Q2: What is the Independent Safety Auditor's role?

Def Stan 00-56 says that the Independent Safety Auditor is "an individual or team, from an independent organisation, that undertakes audits and other assessment activities to provide assurance that safety activities comply with planned arrangements, are implemented effectively and are suitable to achieve objectives; and whether related outputs are correct, valid and fit for purpose."

The Independent Safety Auditor provides assurance by gathering evidence, usually through a combination of **auditing** for conformance to planned arrangements, **reviewing** of project documentation and **performing analyses/assessments** independent from, and in addition to, those of the main parties.

In the MoD nuclear domain, the Independent Safety Auditor is defined and used in a way that relates only to **Audit** of processes and excludes **Independent Assessment**. The latter is conducted through the INSA and IPR processes which mirror practice in the civil nuclear sector. INSA is "Independent Nuclear Safety Assessment" and IPR is "Independent Peer Review".

In some cases the Independent Safety Auditor's role covers Environmental issues as well as Safety. This is permissible and will require the Independent Safety Auditor to have additional competences (see Q8: below).

It is good practice for the Independent Safety Auditor's role to be defined in appointment-specific Terms of Reference (TOR), often contained in the Independent Safety Audit Plan. These should be understood by all parties. Project teams should themselves define the detail of the TOR, based on the requirements of the domain JSPs that apply to their project and also the particular needs of their project. These will inform the level of independence required and limits on advice that may be expected from the Independent Safety Auditor (see Q6: below).

See also: "Guidance for Integrated Project Teams for use in Contracting for Independent Safety Auditor (ISA) Services"

http://www.aof.mod.uk/aofcontent/tactical/safety/downlo
ads/isaguide.pdf

See also: UK ISA Working Group's "What is Independent Safety Assessment?"

http://www.theiet.org/factfiles/isa/isa-intro-page.cfm

Q3: Is the Independent Safety Auditor an individual or a team?

It is preferable to employ an Independent Safety Auditor team for most projects. The team enables effective peer review of the assessment's outputs and can provide specialist expertise in areas such as human factors and software integrity assessment. It also has the practical advantage that it is easier to cover for normal staff absence and attend concurrent meetings.

An individual is unlikely to have the broad range of competence necessary to act as Independent Safety Auditor for a complex project. It is not necessary for each individual to have the full required competence, only the Independent Safety Auditor team as a whole.

Even when an Independent Safety Auditor team is employed, the team leader and preferably all the team members should be individually identified.

Q4: What authority and responsibility does the Independent Safety Auditor have ?

An Independent Safety Auditor provides an independent second opinion to support a decision maker, but does not make the decision for them.

The Independent Safety Auditor has no executive authority and the ISA's customer (e.g. MoD project team, supplier, operating authority) accepts full responsibility for safety. The customer may overrule an Independent Safety Auditor's recommendations but in such cases a robust justification for the decision should be recorded.

The Independent Safety Auditor is responsible for operating to the agreed TOR and for ensuring that staff with the necessary competences are used at all times. An authorised Independent Safety Auditor has the right and duty to raise significant concerns directly with the project team or contractor, even

when outside their agreed scope of work or TOR and should raise unresolved concerns with appropriate Authorities and the relevant Safety Management Office.

The Independent Safety Auditor only has authority of access to other companies if this is specified in their contract (see Q10: below).

See also: UK ISA Working Group's "Code of Practice for Independent Safety Assessors (ISAs)"

http://www.theiet.org/factfiles/isa/isa-code-page.cfm

Q5: Does my Project Need an Independent Safety Auditor?

The Policy requirements on the need for projects to appoint an Independent Safety Auditor are set slightly differently for each domain and are defined in the domain safety JSP as follows:

- For maritime projects JSP 430 Ship Safety Management, requires that an ISA is commissioned to undertake an independent review to confirm that the safety regime has been implemented in accordance with the policy and that outputs of the regime, including the safety case, are comprehensive. The ISA is expected to endorse the safety case report. However, the requirement for an ISA may be waived for projects that are of sufficiently low complexity or risk.
- In the Land domain, JSP 454 Land Systems Safety and Environmental Protection, uses very similar wording to JSP 430, but the bias is changed. JSP 454 does not mandate that projects should always use an ISA, but does recommend it for projects with significant risk or complexity.
- Under JSP 553, the Military Airworthiness Regulations, project team leaders are required to ensure that Designers' safety cases are independently assessed. The requirement is broken down into two elements:
 - o Independent Safety Audit (process audit against the safety plan) and
 - Independent Technical Evaluation (technical analysis of the safety case evidence).

The requirement is obligatory for systems in higher risk classes and desirable in other cases where novel, complex, or high-risk systems are involved. JSP 553 also recognises that Independent Safety Audit should support the in-service safety case, requiring the Release To Service Authority to ensure that the level of required independent safety audit and evaluation of the safety case is identified and applied, and an Independent Safety Auditor appointed where appropriate.

The functional safety JSPs allow varying amounts of discretion in whether an ISA is required for a given project, and what they are tasked to do. The factors affecting this decision include the potential risk involved (i.e. the risk before mitigation), the degree of complexity and novelty of the undertaking.

It is sensible to conduct a preliminary hazard identification exercise as early as possible in a project, to identify the general type and level of risks that might be expected. This can often be done at a functional or capability level, before any of the actual system design is known. This analysis can then inform judgements about the level of assurance that will be required for the project. Where the system is particularly complex, or involves novel technologies or solutions, there will be greater uncertainty and more assurance is likely to be required. If however it is decided **not** to appoint an Independent Safety Auditor (and the relevant JSP permits it), then that decision should be recorded and justified.

Q6: Can an Independent Safety Auditor offer advice?

In order to maintain their independence, the Independent Safety Auditor cannot give specific advice or contribute directly to the safety argument. However, it is legitimate, and helpful in reducing project risk from safety matters, for the Independent Safety Auditor to give general advice that leads to timely production of a satisfactory safety case. General advice is that which would be given to any broadly similar project, and corresponds to the assessment guides produced by the statutory regulators (e.g. the HSE's Approved Codes of Practice and the series of Assessment Guides from the Nuclear Installations Inspectorate). General advice may cover:

- a framework of appropriate standards and good practice;
- the selection of suitable analysis techniques;
- the structure of safety arguments;
- the making of tolerability claims;
- specific technology and the consequences of technology choices.

Suppliers and Project Teams often need in-depth independent safety advice, particularly if the Independent Safety Auditor identifies an evidence shortfall in what safety processes can provide the necessary additional evidence. Such advice can compromise the Independent Safety Auditor as they then have an interest in the success of the advice. Therefore it is best to provide independent safety consultants for advice rather than the appointed Independent Safety Auditor.

Q7: What does "Independent" mean?

The Independent Safety Auditor needs to be sufficiently independent that there is nothing that might affect or call into question their ability to carry out impartial assessment or audit activities or to make impartial judgements regarding safety.

It is highly desirable for the Independent Safety Auditor to be from an organisation totally separate from the contractor. Where it is not possible to achieve total separation, the project team should justify the acceptability of the arrangements that they authorise. Arrangements that may give sufficient independence include the use of companies in the same group as the contractor, but otherwise independent, or organisations or departments in the contractor's firm that are independent to board level.

The need for independence does not mean that every project in a project team and every subcontractor has to have a separate Independent Safety Auditor. A single or small number of Independent Safety Auditor s will give a more consistent approach and will acquire domain-specific knowledge more quickly. Of course the Independent Safety Auditor(s) should be independent with respect to all the organisations that they audit.

Q8: What competences are required for an Independent Safety Auditor?

Individual Independent Safety Auditor s should have suitable competences which will vary from case to case, but can be considered under the following headings (see also information referenced from Q13: below):

• Technical competence:

- Safety and technical skills such as performing HAZOPS;
- Understanding the principles and concepts of safety and safety management;
- Assessment and auditing skills (e.g. process audits, document reviews);
- o General skills (e.g. documenting and presenting findings and recommendations).

Behavioural competence:

 the qualities and attributes of behaviour and character needed to perform the role of an ISA effectively including maintaining independence.

Knowledge:

- Safety or engineering knowledge of the domain, system, application area or technology;
- Legal and safety regulatory framework, standards, quidelines or codes of practice;
- Experience of other systems engineering disciplines, e.g. software, human factors.

See also: UK ISA Working Group's "Competency Framework for Independent Safety Assessors (ISAs)"

Q9: Does the Independent Safety Auditor cover the Supplier, the MoD or both?

Safety Audit involves examining safety management activities across the whole safety regime (including user, acquisition authority and supplier). The audit should consider whether these activities comply with planned arrangements, are implemented effectively and are suitable to achieve objectives; and whether related outputs are correct, valid and fit for purpose. The Independent Safety Auditor should be able audit all parties within the overall safety regime.

Generally, at an early stage of a project's lifecycle the MoD (or specialist contractors acting on its behalf) take the lead role in safety, as they examine the safety implications of the capability requirement, explore options and define the technical safety requirements for the URD and SRD. During the Demonstration and Manufacture stages of the lifecycle, a supplier will usually have the lead role on safety, whilst the user authority has a critical safety responsibility for in-service safety management.

The Independent Safety Auditor should audit the Safety Management System and safety records of each of these parties, since these form part of the overall safety argument. The balance of attention paid by the Independent Safety Auditor to each authority will change as the project lifecycle proceeds.

Q10: How should an Independent Safety Auditor be contracted on my Project?

In the majority of cases, the project team contracts the Independent Safety Auditor on the project. However, the project team may direct the contractor to contract the Independent Safety Auditor instead (e.g. if the contractor is an integration house performing a co-ordination role previously done by MoD). In that case the contractor should employ an Independent Safety Auditor who is acceptable to the project team in terms of competence and scope of work.

It is MOD Policy to use the Framework Agreement on Technical Support (FATS) to engage an external organisation to act as Independent Safety Auditor. FATS lists organisations that have been assessed as having the necessary competences to act as Independent Safety Auditor on MoD Projects.

Organisations tendering to be appointed as Independent Safety Auditor must demonstrate that they satisfy the project-specific requirements for independence and competence and that they have the necessary depth of resource.

Information on MoD's approach to Conflicts of Interest is available on the AOF to help in understanding potential or actual COIs with an Independent Safety

Auditor in respect of their current or previous work for MOD or the Contractor.

A clear Statement of Work for Independent Safety Auditor support may allow firm price contracting, provided that this defines the amount and type of work clearly (e.g. number of on-site audits, number, type and scale of documents to be reviewed, number and duration of meetings to be attended).

The Independent Safety Auditor may require access to other companies or organisations. This could cause difficulties with information confidentiality or security and so must be carefully considered when defining the contract.

See also: "Guidance for Integrated Project Teams for use in Contracting for Independent Safety Auditor (ISA) Services"

http://www.aof.mod.uk/aofcontent/tactical/safety/downlo
ads/isaguide.pdf

See also: MOD Commercial Policy Statement "Safety in Contracts"

 $\frac{http://www.aof.mod.uk/aofcontent/tactical/toolkit/downloadsindexed/safeincon/safei}{ncon_cps.pdf}$

See also: MOD Commercial Toolkit on "Conflicts of Interest"

http://www.aof.mod.uk/aofcontent/tactical/toolkit/content/topics/coi.htm

Q11: How much resource will the Independent Safety Auditor require?

The cost of employing an Independent Safety Auditor should be commensurate with the risk associated with the project. A lack of resources is a poor justification for placing limits on the scope of Independent Safety Auditor work or level of involvement of the Independent Safety Auditor. Experience shows that the costs of correcting a deficiency attributed to inadequate Safety Audit significantly outweigh any savings made.

Q12: What should be done if there is a disagreement that becomes deadlocked?

It is possible that the Independent Safety Auditor and the contractor will become deadlocked over some aspect of the safety argument, and the project team will wish to seek another opinion. The relevant SMO may be able to provide informal assistance and advice on the way forward (although the project team remains responsible for deciding the way ahead). Also, if the Independent Safety Auditor has significant concerns that they do not believe are being adequately addressed, the relevant SMO may be approached for assistance.

Q13: Where can I find more information on Independent Safety Auditors and Assessors?

MoD DE&S Acquisition Operating Framework

• Guidance for Integrated Project Teams for use in Contracting for Independent Safety Auditor (ISA) Services

http://www.aof.mod.uk/aofcontent/tactical/safety/downlo
ads/isaguide.pdf

• MOD Commercial Policy Statement "Safety in Contracts"

 $\frac{\text{http://www.aof.mod.uk/aofcontent/tactical/toolkit/downloadsindexed/safeincon/safei}}{\text{ncon_cps.pdf}}$

UK ISA Working Group:

http://www.theiet.org/publicaffairs/panels/isa/aims.cfm

and their publications:

What is Independent Safety Assessment ?
 http://www.theiet.org/factfiles/isa/isa-intro-page.cfm

• Code of Practice for Independent Safety Assessors (ISAs)

http://www.theiet.org/factfiles/isa/isa-code-page.cfm

• Competency Framework for Independent Safety Assessors (ISAs)

http://www.theiet.org/factfiles/isa/comp-frame-page.cfm

- Guidance on use of accident and incident data by ISAs

 http://www.theiet.org/factfiles/isa/isa-accident-page.cfm
- Documents useful to Independent Safety Assurance (ISA)

http://www.theiet.org/factfiles/isa/isa-doc-page.cfm