



Independent Safety Assessment in the Railway Industry

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what is ISA?

▶ what is Independent Safety Assessment?

▷ CENELEC ENV 50129

- '...to provide additional assurance that the necessary level of safety has been achieved.'

▷ 'The Yellow Book – Chapter 14' Independent Professional Review

- 'Engineering Safety Management activities you carry out must be reviewed by professionals who are not involved in the activities concerned.'

- <http://www.yellowbook-rail.org.uk/site/contents.html>

▷ 'The Yellow Book – Application Note 4 – Independent Safety Assessment' provides further guidance

▷ Network Rail requires that any product intended for use on the infrastructure should be subject to independent assessment to examine the fitness and safety of the product for its intended application

what is the aim of ISA?

- ▶ to give an independent professional opinion that risks have been reduced to an acceptable level
 - ▷ ensure risks have been reduced (ALARP in UK)
 - ▷ provide confidence in claims made about risk

levels of independence

- ▶ based on level of risk
- ▶ 'Yellow Book' guidance derived from IEC 61508

Minimum level of independence	Safety Integrity Level			
	SIL1	SIL2	SIL3	SIL4
Independent person	HR	HR	NR	NR
Independent department	–	HR	HR	NR
Independent organisation	–	–	HR	HR

- ▶ Network Rail product acceptance
 - ▷ 3 levels of independent safety assessment – depth of assessment and independence of assessor is proportionate to complexity and potential risk
 - ▷ only accredited ISA suppliers can carry out level 3 assessments

issues affecting independence

- ▶ consultancy by assessor or company for client
- ▶ advising the project during the assessment
- ▶ ISA becoming part of the solution
 - ▷ when reporting concerns, do not suggest solutions
- ▶ ISA should continually monitor and report independence
- ▶ YB3 Application Note 4 provides more guidance:
 - ▷ ISA must not suggest how project should carry out its development
 - ▷ critical that the project owns any design decisions
 - ▷ does not preclude ISA working closely with project

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ISA competency

- ▶ Network Rail can provide list of ISA accredited suppliers
- ▶ Network Rail ISA Accreditation Scheme
 - ▷ ISA organisation
 - ▶ use/modify category definitions supplied by Network Rail
 - ▶ assess individuals against categories
 - ▶ complete competency matrix including organisational competency
 - ▶ review and submit
 - ▷ Network Rail
 - ▶ reviews/queries matrix
 - ▶ audits ISA organisation including review of evidence to substantiate competency matrix
 - ▶ maintains list of accredited ISA organisations
- ▶ criticisms: rail specific, open to interpretation, may not align with business needs

the ISA team

- ▶ analyse project requirements to determine competency profile
- ▶ appoint lead ISA
- ▶ assign specialists
- ▶ provide competency justification
 - ▷ if ISA supplier cannot meet all competency requirements then can subcontract assessment activities but subject to same process

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our approach to assessment

- ▶ framework to assessment which encourages risk-based thinking and creativity
- ▶ principles which include ensuring an active approach
- ▶ assuring product safety
- ▶ assuring process compliance
- ▶ assuring organisation and personnel competency
- ▶ identify safety and programme risk
- ▶ communicating ISA viewpoints
- ▶ the toolkit

finding the important issues

- ▶ find problems early
- ▶ minimise programme risk
- ▶ think laterally and creatively
- ▶ risk-based thinking
- ▶ don't be bound to documents, standards and checklists
- ▶ use of 'diverse analysis'
- ▶ take a system view – look for what is missing
 - ▷ look from a different angle to the project
 - ▷ see what the project may have missed
- ▶ liaise with other ISAs

risk-based approach

- ▶ independently identify safety risks
 - ▷ eg use structured brainstorming
- ▶ specify assessment activities to mitigate these
- ▶ track risks throughout the assessment
- ▶ report non-safety risks

ISA planning

▶ inputs

- ▶ client remit and programme
- ▶ system characteristics
- ▶ applicable standards
- ▶ assessment principles
- ▶ safety risks
- ▶ toolkit

▶ outputs

- ▶ technical, quality and resource plan
- ▶ risk register

toolkit examples

- ▶ document review
- ▶ audit, observation, witness, interviews etc
- ▶ organisational and personnel competency
 - ▷ culture, organisation, independence, competency etc
- ▶ safety and programme risks
 - ▷ workshops, reviews, risk register etc
- ▶ general methods
 - ▷ checklists, sampling, vertical slice analysis, diverse analysis etc

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communicating

- ▶ ISA plan
- ▶ safety notices
- ▶ review records
- ▶ assessment and reports
 - ▷ structure the assessment/audit claims to provide a defensible argument
- ▶ meetings/on-site presence

working relationships

- ▶ develop a good ISA/project relationship
- ▶ gain respect and trust
 - ▷ ISA should be seen not as a threat, but a benefit to project
- ▶ understand the project
 - ▷ people, product, process, programme
- ▶ on-site presence
 - ▷ early identification of issues
 - ▷ response to queries
 - ▷ understanding of project
 - ▷ resolution of issues
- ▶ continual communication
- ▶ be proactive and responsive

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ISA and Notified Bodies

- ▶ **Notified Body**
 - ▷ statutory role, safety authority is HSE, contracted by contracting entity
 - ▷ more standards based (evaluation of compliance against TSIs etc)
- ▶ **ISA**
 - ▷ safety authority is Network Rail, not necessarily appointed by contracting entity
 - ▷ more risk-based (uses professional judgement)
- ▶ **ISA and NoBo could be the same**
- ▶ **NoBo activities can benefit from**
 - ▷ creative approach – prioritisation based on risks
 - ▷ cooperative approach – identifying problems early

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- ▶ our approach to assessment is carried out within a framework which encourages risk-based thinking and an active approach
- ▶ we have shown that significant benefit can be gained from
 - ▷ creative assessment
 - ▷ cooperative assessment
- ▶ our approach has been shown to work through application to a number of significant projects
- ▶ ISA can deliver significant added value to projects