



# **Quality, a regulators perspective.**

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Please note the views expressed are the author's and not necessarily the  
ONR's

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## **ONR mission**

“Securing the protection of people and society from the hazards of the nuclear industry”

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# How can quality contribute to safety?

- Adequate safety cases and designs
- Structures, systems and components which meet the safety functional requirements described in the safety case and design
- Plant is operated or decommissioned within the operational limits and conditions derived from the safety case
- Planned preventative maintenance is carried out to the required standard according to safety significance
- Maintenance is carried out in accordance with the plant maintenance schedule and written
- Legal and regulatory requirements are fulfilled
- Continual improvement

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# Regulatory framework

- Health and Safety at Work etc. Act 1974
- Management of Health and Safety at Work Regulations 1999
- Regulation 5 Health and Safety Arrangements  
*(1) Every employer shall make and give effect to such arrangements as are appropriate, having regard to the nature of his activities and the size of his undertaking, for the effective planning, organisation, control, monitoring and review of the preventive and protective measures.*

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# Nuclear regulation

- Nuclear Installations Act 1965
- Site Licence Conditions
- LC 17 Management Systems
  - (1) Without prejudice to any other requirements of the conditions attached to this licence, the licensee shall establish and implement management systems which give due priority to safety. (Transposing EU council directive 2009/71/EURATOM into UK law)
  - (2) The licensee shall, within its management systems, make and implement adequate quality management arrangements in respect of all matters which may affect safety.

ONR may specify that arrangements must be approved

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# **‘All matters which may affect safety’**

- Applicable to all lifecycle phases (e.g. Design, Safety Case, Procurement, Construction, Manufacture, Commissioning, Operation and Decommissioning)
- Core processes (e.g. safety case, design, construction, operations, maintenance, decommissioning)
- Support processes (e.g., HR, training, competency assessment, procurement,)
- Management processes (e.g. management of change, management review, monitoring)

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# Judging adequacy

- UK health and safety legislation is goal setting and non prescriptive. (e.g. “So far as is reasonably practical” or “adequate quality management arrangements”)
- Inspectors judge adequacy by comparing the duty holders arrangements with ‘relevant good practice’ as described in:
  - Approved Codes of Practice
  - International or British Standards
  - IAEA Standards
  - Industry Standards e.g. NICOPS
- ONR publishes its guidance to inspectors in the form of the Safety Assessment Principles, Technical Assessment Guides and Technical Inspection Guides.

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# T/INS/017 LC 17 management systems – ONR guidance

- LC 17 quality management arrangements should be based on current national or international quality management system standards and that the arrangements should adequately address “all matters which may affect safety”
- ONR encourages the use of GS-R-3 as its purpose is the protection of people and the environment. It also requires an integrated management system which considers safety within one system.
- Other QMS standards may be used but may be more difficult to demonstrate how they are applied to “all matters which may affect safety”. (e.g. ISO 9001)
- A new version of the TIG will be issued shortly and is consistent with GS-R-3.

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# Intervention strategy for management systems

- LC 17 Compliance Inspections by a specialist inspector.
- Routine LC compliance inspections by the site inspector
- Outage Inspections
- Supply Chain Inspections
- Leadership and Management for Safety Interventions

# Leadership & management for safety

## Leadership for safety

Leadership (Board / Exec level down)  
Learning from major events  
Conservative Decisions  
Active Challenge  
Safety Culture

## Quality

Management system  
Documents/records  
Construction/manufacture  
Procurement/supply chain  
Product Quality  
Outage Work

Improve nuclear safety

## Management for Safety

Organisational Capability  
Management of Change  
Intelligent Customer  
Internal Challenge  
Design Authority  
LFE (Continual Improvement)

## LC Compliance

Licensed site  
RA Material  
Nuclear Matter  
Training & SQEP  
Safety cases  
Operations/maintenance  
Decommissioning etc

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# Leadership & management for safety principles

- **MS.1 Leadership** - Directors, managers and leaders at all levels should focus the organisation on achieving and sustaining high standards of safety and on delivering the characteristics of a high reliability organisation.
- **MS.2 Capable organisation** The organisation should have the capability to secure and maintain the safety of its undertakings.
- **MS.3 Decision making** Decisions at all levels that affect safety should be rational, objective, transparent and prudent.
- **MS.4 Learning from experience** Lessons should be learned from internal and external sources to continually improve leadership, organisational capability, safety decision making and safety performance.

# Leadership and management for safety guidance

- Management Systems – T/INS/017
- Training and Assuring Personnel Competence - T/AST/027
- Licensee management of records T/AST/033
- Management for safety T/AST/033
- Management of Organisational Change T/AST/048
- Licensee use of contractors and intelligent customer capability T/AST/049
- Staffing levels and task organisation T/AST/061
- Function and Content of the Nuclear Baseline T/AST/065
- Procurement of nuclear safety related items or services T/AST/077
- Licensee Design Authority Capability T/AST/079

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# Links to ONR guidance

Safety Assessment Principles

<http://www.hse.gov.uk/nuclear/saps/saps2006.pdf>

Technical Assessment Guides

[http://www.hse.gov.uk/nuclear/operational/tech\\_asst\\_guides/index.htm](http://www.hse.gov.uk/nuclear/operational/tech_asst_guides/index.htm)

Technical Inspection Guides

[http://www.hse.gov.uk/nuclear/operational/tech\\_insp\\_guides/index.htm](http://www.hse.gov.uk/nuclear/operational/tech_insp_guides/index.htm)

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Questions?

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