LC 17- Management Systems			
Doc. Type	ONR Technical Inspection Guide (TIG)		
Unique Doc. ID:	NS-TAST-GD-017	**Issue No.:**	8
Record Reference:	2020/120036		
Date Issued:	July 2022	**Next Major Review Date:**	July 2027
Prepared by:		Quality Inspector	
Approved by:		Operational Inspection Professional Lead	
Professional Lead:		Deputy HOC Professional Lead - Quality	
Revision Commentary:	Routine review of document. No substantive changes. Update of associated relevant ONR Guidance and inclusion of explicit guidance to highlight when part inspections of management systems are undertaken. Minor reformatting to align with document template.		

Table of Contents

1. Introduction

1. Many of the licence conditions attached to the standard nuclear site licence require, or imply, that licensees should make arrangements to comply with regulatory obligations under the conditions. ONR inspects compliance with licence conditions, and also with the arrangements made under them, to judge the suitability of the arrangements made and the adequacy of their implementation. Most of the standard licence conditions are goal setting, and do not prescribe in detail what the licensees' arrangements should contain; this is the responsibility of the duty-holder who remains responsible for safety. To support inspectors undertaking compliance inspection, ONR produces a suite of guides to assist inspectors to make regulatory judgements and decisions in relation to the adequacy of compliance, and the safety of activities on the site. This technical inspection guide (TIG) is one of the suite of documents provided by ONR for this purpose.

2. Purpose and Scope

2. The purpose of this guidance is to facilitate a consistent and effective approach to Licence Condition (LC) 17 compliance inspection. It describes ONR's expectations for 'adequate' quality management arrangements and should be used by Inspectors when carrying out their duties in this area.

3. The guidance consists of three main elements which will help Inspectors plan their site inspection programmes and LC 17 compliance inspections. Section 4 provides a brief overview to help Inspectors fully understand the scope of the arrangements needed to fulfil the requirements of LC 17. Section 5 provides more detailed guidance that Inspectors should use to judge the adequacy of the licensee's LC 17 arrangements and their implementation. Section 6 seeks to provide practical guidance on approaches that an Inspector may take to organising inspections of the topics addressed within the LC 17 arrangements.

4. The guidance contained in this document is consistent with IAEA Safety Standard No GSR Part 2, "Leadership and Management for safety".

3. Licence Condition (LC) 17: MANAGEMENT SYSTEMS

5. 17(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.

6. 17(2) The licensee shall, within its management systems, make and implement adequate quality management arrangements in respect of all matters which may affect safety.

7. 17(3) The licensee shall submit to the ONR for approval such part or parts of the aforesaid management systems or part or parts of the aforesaid quality management arrangements as the ONR may specify.

8. 17(4) The licensee shall ensure that once approved no alteration or amendment is made to the approved management systems or approved quality management arrangements unless the ONR has approved the alteration or amendment.

9. 17(5) The licensee shall furnish to the ONR such copies of records or documents made in connection with the aforesaid quality management arrangements as the ONR may specify.

4. Purpose of Licence Condition

10. The purpose of this licence condition is to ensure that all the licensee's management systems give due priority to safety so that any actions or decisions taken do not have an adverse effect on safety. It also requires the licensee to apply quality management principles to all activities that may affect safety. This includes those associated with the procurement, design, construction, manufacture, commissioning, operation and decommissioning of the installations on the site including the preparation and review of safety documentation.

11. This document assists in implementing Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom, by highlighting ONR's regulatory expectations underpinning the relevant licence conditions and or legislation. The following Directive Article is addressed in this document:

8b(2) In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that the competent regulatory authority and the licence holder take measures to promote and enhance an effective nuclear safety culture. Those measures include in particular:

(a) management systems which give due priority to nuclear safety and promote, at all levels of staff and management, the ability to question the effective delivery of relevant safety principles and practices, and to

report in a timely manner on safety issues, in accordance with Article 6(d);(See Section 5.6 Principles 1,2,3,4, LC7 and NS-INSP-GD-007.

5.   Guidance on Arrangements for LC17

13. This TIG recognises IAEA Safety Standard No. GSR Part 2, 2016, "Leadership and Management for Safety" as relevant good practice for the purposes of compliance with LC 17. GSR Part 2 emphasises that leadership for safety, management for safety, an integrated management system and a systemic approach are essential to the specification and application of adequate safety measures and the fostering of a strong safety culture. ONR SAP MS.1 also recognises that good leadership is key to achieving high levels of safety and establishing and sustaining a positive safety culture. The prevalent attitudes within a duty-holder's organisation and the framework of the arrangements established by the duty-holder underpin safety culture.

14. ONR considers GSR Part 2 to be relevant good practice. A Licensee should be able to show that it either uses this standard or that its arrangements meet the expectations of the standard.

15. This TIG provides guidance for Inspectors assessing the management systems arrangements. Guidance for inspectors assessing leadership and culture aspects is provided in the following TIG and TAGs:

- NS-INSP-GD-070 Safety Culture Guide for Inspectors

- NS-TAST-GD-050 (Annex 1), Periodic Safety Reviews

- NS-TAST-GD-072, Function and Content of a Safety Management Prospectus

- NS-TAST-GD-080, Challenge Culture, Independent Challenge Capability (including an Internal Regulation function), and the Provision of Nuclear Safety Advice

- NS-TAST-GD-107 Safety Leadership

- TD-HOC-GD-002 Leadership and Management for Safety Reviews

16. Management systems can be large and complex and ONR Inspectors generally assess the adequacy of LC17 on an ongoing basis, as part of their interventions and engagement on other topics in addition to periodically programmed dedicated inspection of LC17 arrangements. Inspectors should consider the outcomes of such inspections alongside inspections and assessments of leadership and culture to form a complete judgement against relevant good practice such as IAEA GSR Part 2. When forming judgements on the adequacy of part of a management system, inspectors should make this clear in any

intervention records so as not to imply that the whole of the management system has been inspected.

17. In the course of their programmed inspections of licence condition arrangements, Inspectors assess the effectiveness of processes which map well to licence conditions, e.g.: maintenance, plant modifications, radioactive waste handling, OPEX, etc. However, other processes important to safety may not map directly to licence conditions, for instance:

- Design control.

- Governance.

- Supply chain management

- Work control.

- Project management.

- Risk management.

- Conduct of operations.

- Internal regulation.

- Configuration management.

18. Inspectors should consider incorporating risk proportionate and targeted inspections of such processes into their intervention programmes (for instance, as themed inspections as per ONR-INSP-GD-059).

19. Where applicable, Inspectors should be aware of the level of involvement of the licensee's corporate centre in developing the LC 17 arrangements and its role in the independent assessment and review processes. If the corporate centre provides any generic model procedures, Inspectors should be satisfied with these models and should ensure that the licensee's procedures are consistent with them or that any deviations from them are justified.

6. Guidance on Inspection of Arrangements and their Implementation

Principle 1 – Ownership and leadership.

20. Senior Management (see Section 8.1) demonstrably own, value and use their Management System to achieve their business aims whilst giving due priority to safety:

- Through a shared leadership belief that an effective safety culture must be underpinned by an effective and efficient management system.

- By advocating adherence to the management system.

- Developing and deploying effective governance, internal challenge and independent assessment arrangements.

Guidance for Inspectors

21. Safety shall be paramount within the management system, overriding all other demands. Senior Management should demonstrate their ownership of the management system, by, for instance:

- Being aware of the requirements of IAEA GSR Part 2 and how their management system supports a positive safety culture.

- Producing their management system policy and describe the steps they have taken to implement it.

- Understanding the structure of their management system; describing how the various processes with their internal and external interfaces support safe delivery of their business objectives.

- Appointing suitable Process Owners.

- Demanding and promoting adherence to the management system requirements.

- Setting and monitoring performance targets related to the business objectives.

- Ensuring that their expectations, vision, values, behaviours and conduct, including procedural compliance, are shared and promulgated by the front-line supervisors. The arrangements for achieving this

should be documented (Licensees generally do this through the deployment of a conduct of operations / work manual / handbooks or such like).

- Understanding the crucial role that supervisors play in achieving safety. Senior Management will ensure that supervisors' leadership skills are adequate for their tasks (See LCs 10, 12 and 26).

- Routinely engaging with front line supervisors and workers through management walk-rounds, briefings, meeting with safety representatives, etc.

- Developing and deploying effective governance, internal challenge and independent assessment arrangements (see NS-TAST-GD-080).

- Being receptive to all sources of feedback relating to the effectiveness and efficiency of the management system, and using this to drive the ongoing development and improvement of the management system to ensure that it remains effective and efficient.

- Appointing an individual (a management systems or quality manager for instance), who:

  - reports directly to Senior Management,

  - is supported by Senior Management,

  - is given suitable resources to ensure the ongoing development and improvement of the management system.

- Carrying out a periodic review of the management system that addresses safety as a priority.

Principle 2 – Integrated, focused, and optimised.

22. Senior Management understands their changing business requirements and challenges, and proactively develop their management system accordingly.

- The scope of the management system covers all the Licensee's activities, from board to shop floor. It will also covers interfaces with external organisations where this is important to safety, for instance:- their supply chain; their customers; regulators; etc.

- The extent and detail of management system controls is applied in a proportional manner depending upon risk and complexity of activities.

- The management system integrates all elements of management including safety, health, environment, security, safeguards, quality,

societal and economic elements such that safety is never compromised.

- The Senior Management pursue vigorously all opportunities to improve the effectiveness and efficiency of the management system by:

    - Setting and achieving objectives for continual improvement.

    - Responding and learning from positive and negative events and situations both internally and externally.

    - Adequate resources are available for management system development.

    - Responding and learning from positive and negative events and situations both internally and externally.

    - Establishing effective performance monitoring and feedback mechanisms.

    - Encouraging everyone to contribute improvement suggestions.

    - Critically reviewing performance.

    - Establishing a learning and questioning attitude at all levels of the organisation;

    - Championing improvements

Guidance for Inspectors

23. Duty-holders should use an integrated management system. This approach is a requirement of GSR Part 2 and is encouraged by ONR as it ensures safety is considered in all the licensee's activities and is not confined to the quality/safety management system. It also promotes a more consistent approach to treatment of other areas such as environment, security, safeguards, transport, and other business activities, and reduces the likelihood of incompatible arrangements.

24. Senior Management should demonstrate that they understand the nature of their business; the nuclear safety risks associated with their business activities and ensure that adequate management system controls are implemented to mitigate these risks.

25. The risk profile will change on a facility throughout its life cycle. The drivers of changing risks include: - changing customer demands; changing technology and techniques; changes to plant operation and configuration; aging plant and obsolescence; OPEX, organisational change; improvement programmes; changes to legislation; financial constrains; etc. Senior Management should

demonstrate how they consider the impact of such changes on their management system requirements and update the arrangements accordingly.

26. The management system arrangements should ensure that adequate controls are applied to processes and activities to achieve consistent, safe outcomes. This requires a graded approach, whereby the extent of controls applied to activities are proportional to the risks associated with achieving safe outcomes.

27. A system of 'grading' is usually applied to safety related activities (e.g.: plant modifications, spares procurement, work control, etc.) to ensure that the right level of control is applied (e.g.: enhanced supervision, inspection, internal governance, audits, consultation with Regulators, etc.).

28. Achieving consistently correct grading of activities is often challenging and usually requires competent judgement. Therefore it is generally not sufficient to just define the grading system and grading criteria, but also to provide training on risks and the efficacy of the various measures that can be applied to mitigate them.

29. Senior Management should be demonstrably striving for improvement in safety performance and their commitment to all improvement activities should be clear. Expect Senior Management to articulate clearly the key components of their various improvement initiatives, their personal involvement in these and awareness of the status of improvements.

Principle 3 – Effective processes.

30. The management system comprises a hierarchy of processes which deliver and support the achievement of business objectives.

- The needs of processes that directly achieve the business aims (e.g.: operations, decommissioning, manufacturing, project management, etc.) determine the scope and extent of support processes (e.g.: safety cases and design, supply chain management, technical and engineering support, assurance, etc.).

- Process ownership is assigned to suitable senior personnel who have the necessary support, resources and authority to consult, develop, deploy, monitor and improve the processes across all relevant functions.

- Personnel use and value the process arrangements, providing feedback for improvement.

Guidance for Inspectors

31. The Inspector needs to understand how such processes holistically support compliance with most licence conditions. In carrying out inspections against LC17 Inspectors should inspect some of these processes on a targeted and

proportionate basis. The Inspector should consider using ONR Quality and Human and Organisational Capability specialist Inspectors when carrying out such inspections.

32. It is expected that the licensees' Senior Management be able to describe: - the hierarchy of processes, their importance to nuclear safety; how they interact to deliver their business objects and comment on their effectiveness and what improvements are being made, or envisaged, to improve their effectiveness.

33. It is important that senior management on sites are given awareness training in their roles and responsibilities and in management system processes with regards to nuclear safety. This is especially important where there is a high turnover of senior management coming into the organisation; NDA sites for instance.

34. The way in which Senior Management appoint Process Owners should be clear.

35. Process Owners should receive sufficient Senior Management commitment and resource to carry out their roles.

36. The Inspector needs to confirm that Process Owners are carrying out their roles effectively. For instance, that Process Owners:

- Plan and monitor the effective implementation of process arrangements.

- Ensure their process meets changing business needs and safety risks.

- Consider their process arrangements in terms of the needs of other process and interdependencies (e.g.: overall site requirements, inputs from and outputs to other processes cross dependencies, etc.) and liaise with other Process Owners as necessary.

- Involve users in developing arrangements (e.g.: writing of instructions and procedures, developing computer systems, physical and environmental arrangements, development of training material and provision of training, etc.).

- Know how effective their process is. They can provide underpinning details and data for assertions of process performance, including: feedback from user groups and other Process Owners, KPI figures, audit and inspection reports, benchmarking data, etc.

- Review their process accordingly to bring about process improvement.

37. For organisations with multiple sites, Process Ownership may reside within a corporate function or an individual site. Inspectors should confirm that the individual responsible for deploying the process on their site is identified and liaises with the corporate owner in developing and improving the process.

38. The Inspector should confirm that personnel carrying out activities associated with a process understand their role in ensuring safe outcomes and know how to report shortcomings and suggest improvements

Principle 4 – Visible, accessible and used.

39. The management system is structured such that all personnel:

- Understand the purpose of the management system.

- Know what it looks like, know what their role is and know what parts of the management system apply to them.

- Understand why it is important to comply with instructions and procedures, to report mistakes and make improvement suggestions.

- Can easily access the information relevant to their job.

- The level of detail is pitched at their level of task competency.

Guidance for Inspectors

40. Everyone on site should understand: - the need for a management system; their role and what is expected of them, what information they need to do their job safely and correctly, and how / where to get it.

41. The management system must ensure that the right information is available to the right person, in the right place, in the right format / medium at the right time. This usually involves a combination of: access by personnel to computer based process controls (e.g.: work control, permit systems, plant modification databases, etc.), computer based document systems for reference and training; the issue of work packs for individual jobs; controlled paper instruction files for use in restricted areas; etc.

42. Users should be involved in the development of processes and their supporting arrangements (procedures, instructions etc.).

43. Policies should be developed and deployed for the use of instructional material, e.g..: instruction in hand and checks signed off as the job progresses, instructional material taken to the job, or available to the users for reference and training.

7.   Further Reading

- ONR-INSP-GD-059, ONR Compliance Inspection Guide.

- NS-TAST-GD-072, Function and Content of a Safety Management Prospectus.

- NS-TAST-GD-077, Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services

- NS-TAST-GD-080, Challenge Culture, Independent Challenge Capability (including an Internal Regulation function), and the provision of Nuclear Safety Advice

- IAEA Safety Standard GSR Part 2 – Leadership and Management for Safety

- BS EN ISO 9001: 2015, QUALITY MANAGEMENT SYSTEMS – Requirements

- The Chartered Quality Institute's publication, 'Nuclear Quality Knowledge'. https://www.quality.org/article/cqi-nuclear-special-interest-group-nucsig