Office for Nuclear Regulation

ONR GUIDE			
LC36: ORGANISATIONAL CAPABILITY			
Document Type:	Nuclear Safety Technical Inspection Guide		
Unique Document ID and Revision No:	NS-INSP-GD-036 Issue 1		
Date Issued:	March 2021	**Review Date:**	March 2026
Approved by:	Kulvinder McDonald	Professional Lead – Operational Inspection Specialism	
Record Reference:	CM9 Folder 1.1.3.979. (2019/330874)		
Revision commentary:	Issue 1 - New document issued		

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Published 03/21

1 INTRODUCTION

1.1 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 inspection guide is one of the suite of documents provided by ONR for this purpose.

2 PURPOSE AND SCOPE

2.1 This document provides guidance to inspectors to enable them to carry out inspections of Licence Condition 36 (Organisational Capability) in a consistent and proportionate manner. It is concerned with how a licensee demonstrates that it has and will maintain adequate organisational capability to ensure the safe operation of the licensed site. In order to promote a consistent regulatory approach, this Inspection Guide has incorporated some guidance previously included in:

- NS-TAST-GD-065 - Function and Content of the Nuclear Baseline [Ref. 7.1];
- NS-TAST-GD-049 - Licensee Core Safety and Intelligent Customer Capabilities [Ref. 7.2];
- NS-TAST-GD-048 - Organisational Change [Ref. 7.3].

Nevertheless, inspectors should refer to these documents and those listed at Section 7 for further guidance as necessary. Inspectors should note that, in addition to ONR's guides, licensees are likely to use the Nuclear Industry Safety Directors' Forum Good Practice Guide on Nuclear Baseline and Management of Organisational Change [Ref. 7.4]. Inspectors should, therefore, be aware of the content of this guide also.

2.2 This guide does not indicate when or to what extent LC36 compliance inspections should be carried out; these are matters to be covered in ONR Divisional intervention plans. The guide is intended, however, to inform LC36 compliance inspections by inspectors and the guidance can be used in part or whole as appropriate. Site Inspectors should consult ONR's Leadership and Management for Safety (LMfS) specialist inspectors for support and advice or when considering more expansive or longer running inspections.

3 LICENCE CONDITION 36: ORGANISATIONAL CAPABILITY

3.1 LC36(1): The licensee shall provide and maintain adequate financial and human resources to ensure the safe operation of the licensed site.

3.2 LC36(2): Without prejudice to the requirements of paragraph 1, the licensee shall make and implement adequate arrangements to control any change to its organisational structure or resources which may affect safety.

3.3 LC36(3): The licensee shall submit to ONR for **approval** such part or parts of the aforesaid arrangements as ONR may **specify**.

3.4 LC36(4): The licensee shall ensure that once approved no alteration or amendment is made to the approved arrangements unless ONR has **approved** such alteration or amendment.

3.5 LC36(5): The aforesaid arrangements shall provide for the classification of changes to the organisational structure or resources according to their safety significance. The arrangements shall include a requirement for the provision of adequate documentation to justify the safety of any proposed change and shall where appropriate provide for the submission of such documentation to ONR.

3.6 LC36(6): The licensee shall if so **directed** by ONR halt the change to its organisational structure or resources and the licensee shall not recommence such change without the **consent** of ONR.

4 PURPOSE OF LICENCE CONDITION 36

4.1 The primary purpose of LC36 is to confirm that a licensee has adequate financial and human resources to ensure the safe operation of the licensed site, and that changes to its organisational structure or resources which may affect safety are adequately controlled.

4.2 LC36 applies to the licensee not just to a licensed site.

- Activities undertaken by a licensee in connection with LC36 at locations away from site (e.g. corporate headquarters, technical centre) are subject to the requirements of the arrangements;
- Where there are tenants on a licensee's site, ONR would expect tenants to have a suitable nuclear baseline and to implement appropriate management of change arrangements.

4.3 In complying with LC36 the licensee should be able to demonstrate the following.

- The licensee understands the hazards and risks of its undertakings, is operating in accordance with its safety case and is complying with the licence conditions.
- The licensee is reducing risk so far as is reasonably practicable, and implementing improvements in a timely manner.
- The licensee is maintaining an adequate nuclear baseline resource and implementing its arrangements for managing organisational change set out under LC 36(2).
- The licensee has provided the financial resources necessary to meet those needs.
- The licensee has and is maintaining or has in place arrangements to obtain the necessary financial resources.
- The licensee has relevant records and they are being retained in accordance with LC 6.

4.4 A number of other Licence Conditions have links to LC36.

- LC6 (Documents, Records, Authorities and Certificates). Records have an important role in demonstrating that the licensee's organisational structure, staffing and competencies are, and will remain, suitable and sufficient to manage nuclear safety throughout the full range of the licensee's business.
- LC10 (Training). Staff fulfilling roles that may affect nuclear safety must be suitably trained to fulfil those roles.
- LC11 (Emergency Arrangements) provides requirements for the licensee to have an adequate emergency organisation established to be able to respond effectively to any incident emerging on the site in order to ensure the protection of both site personnel and the public.
- LC12 (Duly Authorised and Other Suitably Qualified and Experienced Persons). Only suitably qualified and experienced persons (SQEP) perform any duties which may affect the safety of operations on the site.
- LC14 (Safety Documentation) provides requirements, via the Safety Case(s), of what SQEP are required to undertake safety-related roles and activities.
- LC17 (Management Systems). The arrangements for the management of organisational change and any other arrangements that the licensee may choose to establish relating to the requirements of LC36 should be an integral part of the licensee's management system.
- LCs 19 to 22 (Construction, Installation and Modification of New Plant (LC19), Commissioning (LC21), and Modification or Experiment on Existing Plant

(LC22)). These conditions require a licensee to make and implement arrangements to control construction, modification, commissioning etc. of plant which include arrangements for appropriate control and oversight of work performed by contractors.

- LC26 (Control and Supervision of Operations). The licensee shall ensure that no operations are carried out which may affect safety except under the control and supervision of SQEP appointed for that purpose by the licensee.

4.5 A robust LC36 process is dependent upon a good safety culture and inspectors should be familiar with the expectations of Technical Inspection Guide (TIG) 70 (Safety Culture Guide for Inspectors) [Ref. 7.5]. It is expected that the different steps in the process are seen by personnel at all levels in the organisation to be important defences that help ensure safety, not as obstacles that need to be overcome.

5 GUIDANCE ON ARRANGEMENTS FOR LC36

5.1 This section outlines the requirements and ONR's expectations that the licensee's arrangements should consider in order to comply with LC 36 clauses (1) to (6). Definitions of key terms (e.g. Adequate Resources, Nuclear Baseline, Core Safety Capability and Intelligent Customer) are provided in Section 8.

Requirements

5.2 A licensee's arrangements should take account of the requirement to respond to ONR's primary powers.

- Approve arrangements specified by ONR (LC36(3)) and not amend these without further approval by ONR (LC36(4)).
- Direct that change to a licensee's organisational structure or resources is halted and not recommenced without the consent of ONR (LC36(6)).

ONR does not routinely use its LC36 primary powers; where additional control is required ONR would seek to use derived powers or a flexible permissioning approach as outlined in ONR's guide, 'The Purpose and Use of Permissioning' [Ref. 7.6].

5.3 Arrangements for the provision and maintenance of adequate financial and human resources to ensure the safe operation of the licensed site (LC36(1)) are often distributed throughout wider business management arrangements (e.g. competence management, programme and project management, resource planning and management of organisational change). Organisational capability arrangements specific to the nuclear safety aspects of the business may not, therefore, exist as a discrete suite of documentation or processes. Such arrangements are, however, helpful in demonstrating the provision of a systematic approach to nuclear baseline management; this may be achieved by use of an overarching document which signposts relevant business management arrangements.

5.4 LC36(2) requires the licensee to 'make and implement adequate arrangements to control any change to its organisational structure or resources which may affect safety'.

5.5 Where arrangements are documented, it is expected that they should be compliant with the requirements of LC17. Inspectors should, therefore:

- be conversant with the expectations outlined in Technical Inspection Guide (TIG) 017 (Management Systems) [Ref. 7.7], especially Principle 3 – Effective Processes;
- recognise the guidance at Reference 7.7, paragraph 31, that, 'The inspector should consider using ONR Human and Organisational Capability specialist Inspectors when carrying out such inspections.'

Expectations for the Adequacy of Financial and Human Resources

5.6 Licensees should understand the knowledge, functional specialisms and resources required to maintain control and oversight of safety at all times. They should be able to demonstrate a 'core safety capability' of staff that will include, but not necessarily be limited to, technical, operational and managerial resources. Licensees may choose, however, to use contractors to carry out some activities and are expected to demonstrate that, within their core safety capability, they have sufficient in-house expertise to provide appropriate Intelligent Customer (IC) capability to maintain control and oversight of safety at all times for all activities conducted by contractors. While frequently conducted at site, the IC function may be established at different levels within the licensee's organisation including as a corporate function.

5.7 While licensees may derive their nuclear baseline in different ways, it is ONR's expectation that they should meet the nuclear baseline principles and methodologies outlined at Reference 7.1 (TAG 065 - Function and Content of the Nuclear Baseline). This reference provides a comprehensive list of considerations that an inspector should take into account in assessing the adequacy of the licensee's nuclear baseline.

5.8 The duty holder should be able to demonstrate clearly that roles which have been identified as being part of a nuclear baseline are annotated as such in the licensee's wider business management systems, for example HR databases and project planning tools. This provides a current and comprehensive reference point or 'baseline' upon which a licensee can assess:

- the current state of its human resources required to maintain nuclear safety;
- the potential impact upon nuclear safety of proposed organisational changes.

5.9 Where a licensee has project and programme-based operations (e.g. new nuclear build or decommissioning) both of which require changing organisational structures, staffing levels and competencies, the duty holder should ensure that the nuclear baseline arrangements are appropriate for the changing nature of the activities. For example, the duty holder may choose to break the work programme down into stages with staffing levels and competencies determined for each stage, utilising hold-points to ensure that adequate human resources are in place before the next stage of work commences. The licensee may produce an MoC strategy paper or a paper of principle to set out the basis and holistic view of a staged change. Where this is formalised into an overarching MoC paper, this paper should be categorised via the licensee's MoC categorisation process and it should be categorised in accordance with LC36(5), i.e. in accordance with its safety significance.

5.10 In order to provide an accurate reference point against which nuclear safety implications of proposed organisational changes may be assessed, the status of the nuclear baseline should be kept up to date. Where it is not practical to update the nuclear baseline concurrently with organisational changes, the duty holder should ensure that arrangements have the provision for periodically consolidating and reviewing the nuclear baseline. The review period should be commensurate with the scale and frequency of any changes, for example where there have been only a small number of minor changes then an annual update may be appropriate; for an organisation undergoing frequent, large scale and/or major changes it may appropriate to do this more frequently in order to provide a valid reference point for future organisational changes.

Expectations of Arrangements for the Management of Change

5.11 LC 36(2) requires the licensee to make and implement adequate arrangements to control any change to its organisational structure or resources which may affect safety. ONR interprets this condition to relate specifically to nuclear safety although licensees may wish to apply similar arrangements to manage changes affecting industrial safety, security, environmental matters or other parts of their business.

5.12 There are many drivers for organisational change. Without formal change management, a licensee may not recognise immediately the implications of a proposed course of action. The licensee's arrangements should, therefore, ensure that the nuclear safety implications of a proposed change are considered fully and risks arising from inadequate assessment and implementation of the change are recognised and suitably controlled in order to guard against the following.

- A failure to consider all relevant factors and potential dependencies between related changes.
- The potential for 'salami slicing' in which a major change is decomposed into a series of lesser changes which are treated independently.
- The cumulative impact of more than one change being implemented simultaneously.

5.13 It is expected that the licensee's arrangements for the management of change should achieve the following.

- Reference the nuclear baseline and include a process for its regular update.
- Include an initial screening assessment to identify the potential safety significance of a change proposal and establish a suitable categorisation for determining the level of analysis, justification and challenge commensurate with its unmitigated potential impact on safety should the change be inadequately conceived or executed.
- Make provision for the -
  - Identification, implementation and monitoring of suitable controls to ensure nuclear safety is not adversely affected during implementation of the change.
  - Periodic review of the effectiveness of the overall arrangements and the changes that have been implemented.

5.14 To introduce flexibility into the permissioning process, licensees may prescribe, with ONR agreement, derived powers for use by ONR. These will usually, but not exclusively, be applied when permissioning the highest category of change proposal. Inspectors should note, however, that inclusion of derived powers is not a prerequisite for the licensee's LC 36 arrangements to be considered as adequate, nor does their use preclude ONR using primary powers to exercise regulatory control over modifications.

5.15 Where ONR considers that the use of primary or derived powers may not be appropriate or proportionate to exercise regulatory control and oversight of a licensee's modification proposal, ONR may consider the use of enhanced implementation monitoring and control, in accordance with the expectations set out at Reference 7.6. Where this is the case, the inspector should check that such arrangements are consistent with the expectations set out at Reference 7.6.

5.16 Principle 1 of Reference 7.3 states that the licensee's management of change arrangements should be robust, incorporated as part of the licensee's management system and applied to all activities that have the potential to impact on nuclear safety. Inspectors should check that the arrangements are also applied:

- where a number of changes are to be undertaken in the same area with consequential effect on roles and responsibilities;
- to changes to the Board or Executive team, where changes in the composition and knowledge of either of these teams can have a potentially significant influence over nuclear safety.

5.17 Additionally, while the replacement of one post holder with another should be addressed through the licensee's arrangements made under LC12, the management of change arrangements may provide a risk assessment tool to ensure that any nuclear safety implications are considered appropriately.

5.18 For new build organisations, the management of change arrangements should be proportionate to the phase of the project and be sufficiently flexible to enable the organisation to establish and demonstrate the appropriate level of control, while supporting the development of the company's resourcing strategy. In considering the arrangements, inspectors should recognise that:

- it is important that the arrangements are developed fully and implemented in sufficient time to allow an adequate period of demonstrated working, usually in the region of 12 months prior to the Nuclear Site Licensing (NSL) decision;
- organisations develop rapidly during the pre-application and early NSL assessment phase of the project; a new build organisation may not be 'right first time' and will continue to evolve, particularly during the early stages of a new build project.

5.19 For low hazard sites, typically those below the REPPIR threshold, it may be proportionate for a simplified management of change process to be applied. It is however still important that an adequate risk assessment is undertaken for organisational changes on these lower hazard sites to ensure the organisational capability is suitable to manage nuclear safety. It is particularly important that a proportionate process allowing flexibility is developed to manage staff reduction prior to entry of a site into care and maintenance.

6 GUIDANCE ON INSPECTION OF ARRANGEMENTS AND THEIR IMPLEMENTATION

6.1 The purpose of the LC36 inspection is to consider the adequacy of the arrangements and effectiveness of their implementation in maintaining an organisation with adequate financial and human resources to ensure the safe operation of the licensed site. The inspection should be conducted in accordance with the guidance provided in ONR-INSP-GD-064 – General Inspection Guide [Ref. 7.8].

Inspection of Arrangements

6.2 While the licensee may not have a discrete suite of organisational capability arrangements specific to the nuclear safety aspects of the business, the inspector should confirm that the relevant organisational capability arrangements are as follows.

- Adequate and appropriate to:
  - provide and maintain adequate financial and human resources to ensure the safe operation of the licensed site;
  - control any change to the organisational structure or resources which may affect nuclear safety.
- Authorised by an appropriate senior manager.
- In date.

6.3 The inspector should check that the arrangements make provision for submissions for approval to ONR of such part or parts of the arrangements that ONR may specify and whether ONR has approved parts of the LC 36 arrangements. If so, the inspector should confirm that the approved arrangements are in place, implemented and subject to configuration control and oversight.

6.4 The inspector should check that the roles and responsibilities of personnel directly involved in managing activities that could affect nuclear safety are specified adequately and that the level of management team involvement defined in the arrangements is both appropriate and implemented.

6.5 More detailed considerations are outlined at Annex A.

Inspection of Implementation of Arrangements

6.6 The conduct of the intervention should focus on personnel with different roles and responsibilities for the management, implementation and impact of the licensee's LC36 arrangements as detailed at Table 1 below:

GROUP	PURPOSE
Board / Executive	Examine the understanding and commitment of the licensee's leadership and senior management to maintaining the organisational capability to meet the nuclear safety needs of the business.
LC 36 Sponsor / Owner	Clarify any issues from the review of the licensee's arrangements and understand the effectiveness of their implementation.
Management	Examine their understanding of the arrangements and their role in: ▪ implementing the arrangements and the impact of that implementation on managing the current baseline and organisational change; and/or ▪ The governance and oversight of LC36.
Workforce	Assess the understanding of the arrangements and the impact of their implementation throughout the organisation.

Table 1 – Role Holder Groups with Distinct LC36 Responsibilities

6.7 In support of ONR's enabling regulation philosophy, inspectors may wish to consult the licensee's internal regulator to understand their view of the arrangements for compliance with LC36 and the effectiveness of their implementation.

6.8 Inspectors are advised to adopt a staged approach, which provides a structured, incremental, and comprehensive approach to checking the understanding and implementation of LC36 arrangements.

- Stage 1 - The organisation's understanding of management arrangements.
- Stage 2 - The adequacy of human and financial resources to ensure the safe operation of the site under planned operational circumstances.
- Stage 3 - Implementation of management of change arrangements.

6.9 The balance of effort on each stage will be dependent upon the number, type and severity of issues and concerns identified and the time and resources available for the inspection.

6.10 Inspectors should consider the following.

- LC36 applies to the licensee, not just a licensed site. Inspectors may wish to examine compliance with arrangements at locations other than the licensed site.
- Licensees often use contractors or agency staff. Inspectors should establish where, how and to what extent contractors are used, noting that new build and decommissioning sites will often use a high proportion of contractors and/or agency staff, some of whom may be embedded on the baseline. The duty holder needs to be able to demonstrate that LC36 arrangements encompass the use of contractors and that IC and effective supervision requirements are being met [Ref. 7.3]. Inspectors should consider whether the scope or depth of the inspection merits the inclusion of a visit to contractors' offices.

6.11 The duty holder should be informed where it is considered that there is a need for visits to locations other than the licensed site.

6.12 Considerations that may assist structuring the inspection are outlined at Annexes B, C and D.

Stage 1 - The organisation's understanding of management arrangements

6.13 The inspector should check the understanding of the LC36 management arrangements at all levels of the organisation by considering the following.

- Understanding of LC36 arrangements and their integration with wider business management arrangements (e.g. HR arrangements).
- Understanding of roles and responsibilities which could impact nuclear safety.
- Understanding of the importance of SQEP in technical and governance roles.
- Effectiveness of LC36 governance.
- Effectiveness of communication on organisational capability matters that could impact nuclear safety.

6.14 The inspector should check that organisational capability role holders are SQEP against any specific responsibilities and competence requirements.

6.15 Specific considerations for assessing the understanding of the LC36 management arrangements are provided at Annex B.

Stage 2 - The adequacy of human and financial resources under planned operational circumstances

6.16 The inspector should check that individuals in post can realistically carry out their baseline roles to the required standard and capacity; it is not sufficient to show that all roles are occupied.

6.17 The inspector should check that the licensee is monitoring the adequacy of human resources routinely by the following means.

- Vulnerability analysis, including mitigation actions and implementation plans.
- Organisational capability health indicators (e.g. Safety Performance Indicators (SPIs), Key Performance Indicators (KPIs)).
- Links between the LC36 process and the licensee's operating experience and organisational learning process(es) in accordance with the expectations of Nuclear Safety Technical Inspection Guide – Incidents on the Site, NS-INSP-GD-007 [Ref. 7.9].

6.18 For any nuclear baseline document that has completed the licensee's due process, the identification of significant Licensee/Regulatory Issues and concerns is indicative of underlying problems with the LC36 arrangements and/or their implementation.

6.19 The financial resources of a licensee are not ordinarily the focus of routine inspection activities. Inspectors should check for indirect evidence that may indicate a reduction in the ability or willingness of the licensee to provide or maintain adequate financial resources to ensure safety.

- Failure to resource plant improvements.
- Staff shortages that are not being filled.
- Posts filled with personnel who are not fully SQEP/extended periods to achieve full SQEP.
- Headcount reduction management of change that is not aligned to reductions in operational programme or improved ways of working.
- Delays in delivering activities such as maintenance.

6.20 Where such indicators are found, the inspector should check whether it is attributable to other factors (for example difficulties in identifying SQEP resource; technical difficulties or disagreements etc.). Annex 4 of TAG 048 (Reference 7.3) provides further detail on financial resources.

- If so, progress the matter in the normal manner.
- If not, elevate the matter in accordance with the guidance at Reference 7.3. (Note: the approach should be the same where the licensee's budget is controlled by another body (for example, the Nuclear Decommissioning Authority (NDA) or a parent organisation).)

6.21 Specific considerations for assessing the adequacy of human and financial resources are provided at Annex C.

Stage 3 - Implementation of management of change arrangements to meet future conditions

6.22 Inspectors should review the register of change proposals and select and check a sample of change proposals. This should include corporate changes which may affect safety on site.

6.23 For each change proposal sampled from the register, the inspector should check:

- the substantiation document for the change;
- the implementation plan for the change;
- the oversight and governance of the proposal.

6.24 The check should also address the following.

- The potential nuclear safety significance of a proposed change is understood, and a suitable categorisation has been applied.
- The level of analysis and justification is appropriate to the categorisation.
- The level of oversight and governance is appropriate to the categorisation and recorded adequately.
- Suitable controls to ensure that nuclear safety is not adversely affected have been identified and implemented (or will be implemented).
- Appropriate mechanisms exist to monitor the change implementation.
- An appropriate implementation plan (e.g. communications plan, hold point control etc) has been defined and implemented (or will be implemented).
- For proposals that have been implemented -
  - implementation actions have been closed out fully;
  - a Post Implementation Review (PIR), proportionate to the categorisation of the change, has been completed in a timely manner.

6.25 If the sample checks give cause for concern, inspectors should consider 'calling in' changes (at any category level) for specialist assessment.

6.26 Check the implementation of the licensee's review and audit processes to identify how the duty holder monitors, reviews and improves the management of change process.

6.27 Specific considerations for assessing the adequacy of implementation of management of change arrangements are provided at Annex D.

6.28 Engage with Leadership and Management for Safety Inspectors within ONR's Human and Organisational Capability (HOC) for advice and support in planning, delivering and reviewing LC36 inspection activities and managing any issues arising.

7 REFERENCES AND FURTHER READING

7.1 Nuclear Safety Technical Assessment Guide - Function and Content of the Nuclear Baseline, NS-TAST-GD-065; Revision 4.

7.2 Nuclear Safety Technical Assessment Guide - Licensee Core Safety and Intelligent Customer Capabilities, NS-TAST-GD-049, Revision 7.

7.3 Nuclear Safety Technical Assessment Guide - Organisational Change, NS-TAST-GD-048, Revision 6.

7.4 Safety Director's Forum - Nuclear Baseline and the Management of Organisational Change - A Good Practice Guide, Issue 3.

7.5 Nuclear Safety Technical Inspection Guide – Safety Culture Guide for Inspectors, NS-INSP-GD-070, Revision 1.

7.6 Nuclear Safety Permissioning Guide - The Purpose and Use of Permissioning, NS-PER-GD-001; Revision 4.

7.7 Nuclear Safety Technical Inspection Guide – Management Systems, NS-INSP-GD-017, Revision 5.

7.8 Nuclear Safety Technical Inspection Guide – General Inspection Guide, ONR-INSP-GD-064, Revision 3.

7.9 Nuclear Safety Technical Inspection Guide – Incidents on the Site, NS-INSP-GD-007, Revision 4.

7.10 Nuclear Safety Technical Assessment Guide - Training and Assuring Personnel Competence, NS-TAST-GD-27, Revision 6.

7.11 Nuclear Safety Technical Assessment Guide - Staffing Levels and Task Organisation, NS-TAST-GD-61, Revision 4.

7.12 Nuclear Safety Technical Assessment Guide – Function and Content of a Safety Management Prospectus, NS-TAST-GD-72, Revision 3.

7.13 Nuclear Safety Technical Assessment Guide - Challenge Culture, Independent Challenge Capability (including an Internal Regulation function) and the provision of Nuclear Safety Advice, NS-TAST-GD-080; Revision 3.

8 DEFINITIONS

8.1 **Adequate Resources.** In the context of organisational capability, adequate resources is defined as sufficient, funded staffing levels to work safely and deliver an adequate work programme; it is not sufficient to identify the minimum staffing levels alone.

8.2 **Nuclear Baseline.** The Nuclear Baseline is the means by which the licensee demonstrates that its organisational structure, staffing and competencies are, and remain, suitable and sufficient to manage nuclear safety throughout the full range of the licensee's business. It also provides the foundation from which organisational changes can be assessed in accordance with the licensee's arrangements made under Licence Condition 36. [TAG 065 – Reference 7.1]

8.3 **Core Safety Capability.** The knowledge, functional specialisms and resources that the licensee should maintain within its own organisation in order to be able to control and oversee safety at all times. This core safety capability should be a sustainable entity and will include technical, operational and managerial elements. The licensee's 'Intelligent Customer' and 'Design Authority' capabilities are sub-sets of the overall core safety capability. [TAG 049 – Reference 7.2]

8.4 **Intelligent Customer.** The IAEA's definition of the Intelligent Customer (IC) function is as follows -

"An organisation (or individual) that has the competence to specify the scope and standard of a required product or service and subsequently assess whether the supplied product or service meets the specified requirements."

ONR considers that the concept of Intelligent Customer relates to the attributes of an organisation rather than the capabilities of individual post holders. The ONR Safety Assessment Principles define IC as follows -

"The capability of an organisation to understand where and when work is needed; specify what needs to be done; understand and set suitable standards; supervise and control the work; and review, evaluate and accept the work carried out on its behalf".

8.5 **Primary Powers.** Primary powers are created through attaching conditions to the site licence as required by section 4 of the Nuclear Installations Act (NIA) 1965. The six primary powers (specification, approval, consent, direction, agreement and notification) are explicit in the wording of the standard 36 LCs and are therefore legally binding on all licensees. [NS-PER-GD-001 – Reference 7.6]

8.6 Derived Powers. The licensee can choose within its arrangements to provide administrative 'powers' to ONR through which ONR derives the ability to permission selected activities on the licensed site. [NS-PER-GD-001 – Reference 7.6].

9 GLOSSARY OF TERMS

ALARP	As Low As Reasonably Practicable	NIA 65	Nuclear Installations Act 1965
IAEA	International Atomic Energy Agency	NSC	Nuclear Safety Committee
IC	Intelligent Customer	NSL	Nuclear Site Licence
KPI	Key Performance Indicator	OCC	Organisational Change Committee
LMfS	Leadership and Management for Safety	PIR	Post-Implementation Review
LC	Licence Condition	REPPIR	Radiation (Emergency Preparedness and Public Information) Regulations 2001
NB	Nuclear Baseline	SPI	Safety Performance Indicator
NDA	Nuclear Decommissioning Authority	SQEP	Suitably Qualified and Experienced Persons

10 ANNEX A – CONDUCTING AN LC36 INSPECTION: GENERAL CONSIDERATIONS

Arrangements

10.1 The review of LC36 arrangements should consider whether the licensee has a systematic approach to nuclear baseline management through effective processes for maintaining an organisation with suitable resources and competences to deliver nuclear safety.

10.2 In reviewing arrangements for new build and decommissioning sites, inspectors should consider the appropriateness of the arrangements to the current status of the projects to which they apply.

10.3 For an LC36(2) inspection, consideration should be given to reviewing the Change Register alongside the management of change arrangements.

10.4 Using the requirements and expectations of LC36 arrangements outlined in Section 5 as a guide, the questions and considerations below provide a structured approach to the review. The identification of any notable or persistent shortcomings should assist in defining the scope of the inspection.

Key Elements

- Are the arrangements readily available, accessible, up-to-date and controlled under an LC17 (Management Systems) compliant management system?
- Do the arrangements state explicit requirements for self-evaluation and independent evaluation?
  - Periodic review and update of the nuclear baseline.
  - Reviews of performance indicators and vulnerability metrics including mitigation actions and associated implementation plans.
  - Independent safety reviews.
  - Reviews of implementation of the arrangements and plans for improvement.
- Are the governance arrangements clear and simple, providing explicit linkage to nuclear safety and direct line of sight from the Board/Executive to front line?
- Do the arrangements include provision for their maintenance through improvements resulting from continuous monitoring and periodic review?
- Is there an integrated approach to learning with regard to organisational capability (pulling together lessons from internal and external events, investigations, evaluations, organisational changes etc.)?
- How is the effectiveness of actions arising from organisational learning evaluated?
- Do the arrangements contain linkages to indicators of a reduction in the ability or willingness to provide or maintain adequate financial resources?
- Does the nuclear baseline contain a substantiation of the 'right size and structure' for the licensee organisation (e.g. are the organisational design principles defined) and not a presumption that the existing structure is adequate?
- Are the policy and practices for the IC function and use of contractors appropriate?
- Does the licensee maintain a live nuclear baseline or do the arrangements include provision for the periodic review and consolidation of the baseline commensurate with the scale and frequency of any changes?
- Do the licensee’s arrangements for controlling changes to its organisational structure or resources include a specific focus on nuclear safety?
- Do the arrangements apply at all levels in the organisation including the Board or Executive team?

- Do the arrangements apply where a number of changes are to be undertaken in the same area or there is a consequential effect on roles and responsibilities?
- Do the arrangements include the following?
  - Derived powers that have been agreed with ONR?
  - A comprehensive risk assessment process to ensure the full consideration of the nuclear safety implications and risks arising from inadequate assessment and implementation of a proposed change are recognised and suitably controlled?
  - Provision for classification of the change according to the level of potential risk to nuclear safety and is the level of analysis, justification and challenge appropriate to the classification?

Support Elements - Arrangements

- How are the links to other relevant LCs, as outlined at para 4.4, recognised?
- How are the arrangements integrated with wider business management arrangements (e.g. is there an overarching document which signposts relevant business management arrangements)?
  - Are they linked to HR processes?
  - Is HR involved in assessing implications of changes for workforce planning and training and taking action as appropriate?
  - Do the arrangements make provision for additional oversight and specific checks during times of high operational or organisation stress?
  - Do event investigations/root cause analyses identify underlying systemic issues related to organisational capability and how such findings collated, considered and acted upon?
- Do the arrangements include provision for enhanced implementation monitoring and control of a proposed organisational change by ONR and are they consistent with the expectations in NS-PER-GD-001 Revision 4?
- Are similar, linked changes managed in a coordinated manner (e.g. under an overarching management of change)?
- Are changes defined, managed and implemented pro-actively?

11 ANNEX B – CONDUCTING AN LC36 INSPECTION: CONSIDERATIONS FOR ASSESSING THE UNDERSTANDING OF LC36 MANAGEMENT ARRANGEMENTS

Inspectors should consider checking the understanding throughout the organisation of the following Key Elements.	**Board / Executive**	**LC36 Owner**	**Management**	**Workforce**
Key Elements				
The importance of having SQEPs in key organisational capability roles, including those associated with management of change.	X	X	X	X
The importance of management of change and other LC36 arrangements as an integral part of business strategy implementation, nuclear safety and resource management.	X	X	X	
The need for the Board/Executive to visibly commit to and resource the nuclear baseline and management of change as key business processes.	X	X		
The need to regularly review that management of change arrangements are up to date and being applied consistently across the entire organisation.	X	X	X	
How the arrangements and governance are integrated into wider nuclear safety management (i.e. recognising the links to relevant LCs).		X	X	X
How continuous monitoring and periodic review are intended to be used to maintain and improve the arrangements.		X	X	
Whether the quality measures for the baseline organisation and early warning indicators of potential problems or pressure points within different areas that are likely to have an adverse effect on the nuclear baseline are understood and appropriate.	X	X	X	
Whether the PIs and metrics, particularly those used at senior levels, are comprehensive, sufficiently relevant to nuclear safety and used in combination with other, qualitative sources of information (e.g. audits/reviews, operating experience).	X	X	X	X
How a robust and effective LC36 process is maintained during periods of high operational and organisational stress.	X	X	X	
How individuals are made aware of their LC36 roles, responsibilities and SQEP requirements and whether those SQEP requirements are met.		X	X	X
How the leadership and senior management promote, establish and uphold robust standards for the nuclear baseline (e.g. ‘walk the talk’ regarding safety over production; response when doubts or concerns are raised).	X	X	X	X
Support Elements				
How the arrangements and governance are integrated into the wider business management arrangements and governance.		X	X	
How the importance of maintaining robust arrangements is communicated.		X	X	X
How the arrangements are communicated.		X	X	X
Whether personnel find the arrangements clear and easy to use.		X	X	X
How does the organisation learn from implementation of the arrangements in order to maintain them up-to-date?		X	X	

Table 2 - Considerations for Assessing the Understanding of LC36 Management Arrangements

12 ANNEX C – CONDUCTING AN LC36 INSPECTION: CONSIDERATIONS FOR ASSESSING THE ADEQUACY OF HUMAN AND FINANCIAL RESOURCES

Inspectors should assess the understanding of the need for adequate resources and adequacy of resources for current operations by checking the following Key Elements.	**Board / Executive**	**LC36 Owner**	**Management**	**Workforce**
Key Elements – Human Resources (Note, there are no Support Elements)				
Whether personnel understand the current nuclear baseline for their area and how it fits into the overall baseline organisation.			X	X
Whether the organisational structure meets the nuclear safety needs of the business (particularly if the needs have changed).	X	X	X	X
That posts and roles are filled, individuals achieve SQEP in a timely manner and records are maintained adequately.	X	X	X	X
That the Intelligent Customer function is appropriate to maintain control and oversight of safety at all times for all activities conducted by contractors.	X	X	X	X
What contingency measures and/or remedial actions are in place and how they are managed.		X	X	X
The understanding of the need for regular monitoring of the state of the organisation to ensure that nuclear safety is not progressively degraded over time as a result of baseline vulnerabilities and/or operational pressures.	X	X		
Whether there are indications that nuclear safety is being progressively degraded over time as a result of baseline vulnerabilities and/or operational pressures.	X	X	X	X
That appropriate succession planning is in place.	X		X	X
Key Elements – Financial Resources (Note, there are no Support Elements) – see also Annex 4 of TAG 048 (Reference 7.3)				
The understanding of the need to provide adequate financial resources.	X	X	X	X
Whether there are indications of inadequate financial resources or a reduction in the provision of adequate financial resources?	X	X	X	X
How senior management respond to concerns over the provision of financial resources being raised.	X		X	X

Table 3 - Considerations for the Assessment of the Adequacy of Human and Financial Resources

13 ANNEX D – CONDUCTING AN LC36 INSPECTION: CONSIDERATIONS FOR ASSESSING THE IMPLEMENTATION OF MANAGEMENT OF CHANGE ARRANGEMENTS

Inspectors should assess the understanding of the need for management of change and adequacy of changes made to meet future conditions by checking the following Key Elements.	**Board / Executive**	**LC36 Owner**	**Management**	**Workforce**
Key Elements				
The Board/Executive understands its role in ensuring that the implications of significant and complex changes are fully assessed prior to implementation.	X			
The Board/Executive understands its role in providing oversight of significant and complex changes and ensuring that the objectives of the changes are met.	X			
Whether there is a willingness to delay the programme if problems arise with organisational capability with no appropriate contingency identified.	X			
The understanding of the importance of regularly monitoring the state of the organisation to ensure that nuclear safety is not progressively degraded over time as a result of a succession of changes.	X	X		
The understanding of the need to use a consistent methodology, which is integral to the management system, to assess the implications of all proposed organisational changes.		X	X	
The understanding and use of appropriate optioneering in identifying the most suitable change proposal.		X	X	
How the potential risks to nuclear safety from inadequate assessment and implementation of a proposed change are assessed?		X	X	
The understanding and application of cumulative risk assessment.		X	X	
How the implications of changes for workforce planning and training are assessed and how the completion of resultant actions is monitored.		X	X	
How implementation plans are designed (e.g. staging of changes where appropriate, use of enabling actions), executed and reviewed during and post-implementation.		X	X	X
How the adequacy of Management of Change is recorded.		X	X	
How contingency arrangements are considered and implemented if problems arise with organisational capability and/or for reasonably foreseeable changes.		X	X	X
Support Elements				
How proportionality of the level of analysis, justification and challenge to the potential risks to nuclear safety is achieved.		X	X	
How the organisational design principles meet the nuclear safety needs of the business.		X	X	X
How the workforce is involved in the development of change proposals.			X	X
How the implications of significant management of change proposals and progress of implementation are communicated.		X	X	X

Table 4 - Considerations for the Assessment of the Adequacy of Implementation of Management of Change Arrangements