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| ONR Technical Assessment Guide  Organisational change |



ONR Technical Assessment Guide (TAG)

Organisational change

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| 7.1 | Minor update to align key definitions across all organisational capability guidance and amplify guidance on significant large-scale and/or complex change, including the use of:   * Strategy Papers. * Overarching MoCs. * Implementation MoCs. |

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# Introduction

1. ONR has established its Safety Assessment Principles (SAPs) (ref. [1]) which apply to the assessment by ONR inspectors of safety cases for nuclear facilities that may be operated by potential licensees, existing licensees, or other duty-holders. The principles presented in the SAPs are supported by a suite of guides to further assist ONR’s inspectors in their technical assessment work in support of making regulatory judgements and decisions; this technical assessment guide (TAG) is one of these guides.

# Purpose and scope

1. The purpose of this TAG is to assist inspectors in making informed judgements and decisions on the adequacy of existing or prospective licensee’s arrangements and their implementation, to ensure that changes to organisational structure or resources which may affect safety are adequately controlled in accordance with the requirement of nuclear site licence condition (LC) 36 ‘Organisational Capability’ as set out in [Appendix 1](#_Appendix_1:_Licence). [Appendix 2](#_Appendix_2:_Guidance) of this TAG also provides guidance on how Inspectors should approach the requirement for licensees to provide and maintain adequate financial and human resources to fulfil their obligations in respect of nuclear safety.
2. This TAG incorporates guidance for inspectors in judging the adequacy with which licensees’ arrangements have been implemented and should be read in conjunction with ref. [2]. Factors that the inspector may wish to consider concerning the way in which a licensee’s arrangements are implemented are set out in [Appendix 3](#_Appendix_3:_Guidance).
3. ONR guidance on assessing arrangements to provide and maintain adequate human resources is presented in ref. [3]. Together, these guides provide comprehensive advice to inspectors on the requirements of LC 36, as such they should be considered in combination when judging the adequacy of a licensee’s arrangements for LC 36.
4. The nuclear industry [Safety Directors’ Forum](https://nuclearinst.com/Safety-Directors-Forum) (SDF) has also published three guides relevant to organisational capability (refs. [4], [5] and [6]).   
   ONR considers the SDF guides to be consistent with the guidance in this TAG.
5. The following definitions are applicable to this assessment guide:

Table 1 - Table of definitions

| Term/acronym | Description |
| --- | --- |
| Contractor | Any organisation or individual person that provides a product or service for a licensee under a commercial contract that is: not in the licensee’s direct employment or formally seconded to the licensee from the licensee’s parent company, are subject to licensee's Intelligent Customer oversight and are employed by companies external to the licensee/licensee's parent company. |
| Core safety capability | This capability is a subset of the Nuclear Baseline (NB) and should reside within the licensee organisation, but does not necessarily require direct employment by the licensee organisation (for example, embedded contractors).  Core safety capability is the knowledge, experience and resources that the licensee should maintain within its own organisation in order to be able to ensure enduring control and oversight of nuclear safety at all times.  The licensee’s ‘Intelligent Customer’ (IC) and ‘Design Authority’ (DA) functions should form part of the core safety capability. |
| Implementation/enactment a management of change (MoC) proposal | Generally referred to as an MoC, an implementation (or enactment) MoC proposal provides the:   * Detailed description of the change, associated risks and categorisation; * Implementation plan and control measures to enact change safely and effectively; * Approach to post implementation evaluation |
| Intelligent Customer (IC) | IC enables the organisation to maintain a clear line of sight to the safety case and underpinning justification for products or services bought on its behalf.  IC is 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; and own the outputs. |
| Nuclear Baseline (NB) | The Nuclear Baseline (NB) is the means by which the licensee demonstrates that its organisational structure, staffing and their 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 LC 36. The nuclear baseline should contain all posts/roles that could have a direct or indirect impact on nuclear safety, both immediate and latent. |
| Nuclear safety | The achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation risks. |
| Organisational capability | The concept of organisational capability relates to the combination of organisational structures (shape and size), functional specialisms, competence (both individual and collective) and resource capacity to conduct defined activities. Organisational capability is defined in the context of multiple factors including the operating lifecycle stage of the facility. |
| Overarching management of change (MoC) proposal | An organisation-level framework to enable the standard, consistent and reliable production of multiple implementation MoCs associated with significant large-scale and/or complex change.  The overarching MoC does not, of itself, implement change but describes at the organisational-level the:   * Change. * Aggregated and interface risk assessment, with associated categorisation. * Change strategy. * Governance arrangements. * Assumptions and enabling activities. * Programme of underpinning implementation MoCs. |
| Post (Job) | A position identified on an organisational structure |
| Role | A specific work activity/responsibility  Note:   * Licensees may choose to break down a post into constituent roles which are assigned to that post profile/job description;   Or,   * Limit roles to additional activities/responsibilities assigned to an individual |
| Strategy papers | Each licensee will have its own defined approach to producing a business strategy. In general, however, it should provide an overview of the vision, major actions and associated success criteria, investments, programmes of change and their alignment and a framework and guidance to enable more detailed interpretation of the strategy.  The business strategy may be defined through a single paper or through a series of documents that, from an organisational capability perspective, provide the frame and guide for strategic organisational planning. These may include a:   * **People (or Organisational Capability) Strategy** – Explanation of the strategy and the rationale for it * **Paper of Principles** – Strategic-level principles that provide persistent direction and guide strategic planning * **Concept of Operations** – The framework and guidance on how the defined organisation is intended to work so that others can interpret the strategy and apply it to the production of more detailed plans and programmes of change. * **Strategic Plans** – High-level direction of the means of implementing the strategy |

# Relationship to licence and other relevant legislation

## The Management of Health and Safety at Work Regulations

* Health and Safety Arrangements - Regulation 5 requires employers to have arrangements as appropriate, having regard to the nature of activities and the size of the undertaking, for the effective planning, organisation, control, monitoring and review of the preventive and protective measures;
* Health and Safety Assistance - Regulation 7 requires an employer to appoint one or more competent persons to assist him in undertaking the measures he needs to comply with the requirements and prohibitions imposed on him, ensuring that the number of persons, the time available to them and the means at their disposal are adequate for the size of the task and associated risk; and
* Capabilities and Training - Regulation 13 requires an employer to ensure his employees are provided with adequate health and safety training.

## Nuclear Site Licence Conditions

1. The following site licence conditions (LCs) are relevant to this TAG:

* **LC 6 – Documents, Records, Authorities and Certificates**.   
  The licensee shall make adequate records to demonstrate compliance with any of the conditions attached to the nuclear site licence.   
  The licensee’s MoC arrangements should include provision for the identification and management of records arising from implementation of the arrangements.
* **LC 10 – Training**. The licensee shall make and implement adequate arrangements for suitable training of all those on site who have responsibility for any operations which may affect safety. Staff fulfilling NB roles, as roles which may affect safety, shall be suitably trained to fulfil those roles.
* **LC12 – Duly Authorised and Other Suitably Qualified and Experienced Persons**. The licensee shall make and implement adequate arrangements to ensure that only suitably qualified and experienced persons perform any duties which may affect the safety of operations on the site. Persons fulfilling management of organisational change roles, as roles which may affect the safety of operations, shall be suitably qualified and experienced to fulfil those roles.
* **LC 17 – Management Systems**. The licensee shall establish and implement adequate quality management arrangements in respect of all matters which may affect safety. MoC arrangements should be an integral part of the licensee’s management system.
* **LC 26 – 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 suitably qualified and experienced persons appointed for that purpose by the licensee. Persons fulfilling MoC roles, as roles which may affect the safety of operations, should be SQEP.
* **LC 36 – Organisational Capability.** The licensee shall provide and maintain adequate financial and human resources to ensure the safe operation of the licensed site, and make and implement arrangements to control any change to its organisational structure or resources which may affect safety.

# Relationship to Safety Assessment Principles, WENRA Reference Levels, and IAEA Safety Standards and Guides

## Safety Assessment Principles

1. The Safety Assessment Principles (SAPs) for Nuclear Facilities (ref. [1])provide a framework to guide regulatory decision making in the nuclear permissioning process. They are supported by TAGs which further aid the decision-making process. The following principles are relevant to this TAG:

* **MS.1 – Leadership**. Identifies the need for oversight of nuclear safety performance and a Management System.
* **MS.2 – Capable Organisation**. Identifies the need for changes to the organisation to be systematically evaluated to ensure that they do not adversely affect nuclear safety management capabilities.
* **MS.3 – Decision Making**. Identifies the need for decision making to be based on processes that ensure the conflict between nuclear safety and other business goals, including commercial and schedule pressures and external influences, are recognised and resolved.
* **MS.4 – Learning**. Identifies the need for lessons to be learned from internal and external sources to continually improve leadership, organisational capability, safety decision making and safety performance
* **EHF.5. – Task Analysis**. Identifies the need to conduct proportionate analysis of all tasks important to safety to justify the effective delivery of the safety functions to which they contribute. The analysis should be applied to all actions identified as impacting safety and the administrative controls needed to remain within operating rules for normal operation or return back to normal operations. The workload of personnel required to undertake these actions and controls should be analysed and demonstrated to be reasonably achievable. The analysis should help define operator roles and responsibilities, staffing levels, personnel competence and training needs and communication networks.   
  The workload of personnel and its impact on the effective completion of tasks important to safety should be reviewed in periodic safety reviews and as part of emergency demonstration exercises.
* **EHF.11. – Staffing Levels**. Specifies that there should be sufficient competent personnel available to operate the facility in all operational states.
* **DC.7. – Decommissioning Organisation**. Identifies that the safety case should demonstrate an appropriate management organisation, and adequate personnel resources, to ensure that decommissioning can be completed safely. The continued suitability of these should be demonstrated through an organisation and staffing baseline. The design of the organisational structure will depend upon the activities to be carried out and will need to be determined on a case-by-case basis.
* **AM.1. Planning and Preparedness**. Specifies that the accident management strategy should identify the number of operators and other site staff needed to address different types of accidents and the skills that they need.

## Technical Assessment Guides

1. The following TAGs are applicable to this TAG:

* **NS-TAST-GD-027 – Training and Assuring Personnel Competence**   
  (ref. [7]) - This TAG addresses the means by which the licensee demonstrates that it has a systematic approach to identification and delivery of personnel competence and its training processes and arrangements for assuring personnel competence.
* **NS-TAST-GD-049 – Licensee Core and Intelligent Customer Capabilities** (ref. [8]) - This TAG addresses the means by which the licensee demonstrates that it has sufficient in-house expertise to maintain control and oversight of nuclear safety at all times, and the use and oversight of contractors whose work has the potential to impact on nuclear safety
* **NS-TAST-GD-050 – Periodic Safety Reviews** (ref. [9]) - This TAG expects a Periodic Safety Review (PSR) to review changes to the licensee’s organisational structure and resources to consider their cumulative impact and to determine if the current position is adequate for continued safe operation of the plant or site
* **NS-TAST-GD-061 – Staffing Levels and Task Organisation** (ref. [10]) - This TAG provides detailed guidance to support the assessment of the approaches and methods used by applicants and licensees to derive, validate and monitor staffing arrangements; and to specify task organisation, in particular, the design of shift work systems and team design.
* **NS-TAST-GD-065 – Function and Content of the Nuclear Baseline**   
  (ref. [3]) - This TAG addresses 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 provides the foundation from which organisational changes can be assessed.
* **NS-TAST-GD-072 – Function and Content of a Safety Management Prospectus** (ref. [11]) -Element 4 of this TAG requires a licensee to have adequate structures and resources to meet the nuclear safety needs of the business.
* **NS-TAST-GD-077 – Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services**   
  (ref. [12]) – specifies that the Licensee should maintain an ‘Intelligent Customer’ capability for all work carried out on its behalf by suppliers that may impact upon nuclear safety
* **NS-TAST-GD-079 – Licensee Design Authority Capability** (ref. [13]) - sets out the broad principles which underpin ONR’s expectations of a licensee’s arrangements to provide and maintain an adequate Design Authority (DA) capability.
* **NS-TAST-GD-080 – Nuclear Safety Advice and Independent Challenge** (ref. [14]) – provides guidance to support the assessment of the adequacy of organisational capability for nuclear safety advice and independent challenge.

## Licensing of Nuclear Installations

1. ONRs ‘Licensing Nuclear Installations’ (ref. [15]) sets out ONRs expectations of a licensee’s Nuclear Baseline (NB) as a demonstration that the licensee has suitable and sufficient organisational structures, staffing and competences in place to effectively and reliably carry out those activities which could impact on nuclear safety.
2. It also sets out ONR’s expectation that the organisational and management structures set out in the NB will not be static and that they should evolve as the licensee’s organisation develops.

## WENRA Reactor Safety Reference Levels

1. The objective of The Western European Nuclear Regulators Association (WENRA) is to develop a common approach to nuclear safety in Europe by comparing national approaches to the application of International Atomic Energy Authority (IAEA) safety standards. The Reactor Harmonisation Working Group Report – WENRA Safety Reference Levels for Existing Reactors 2020 (ref. [16]), represents good practices in the WENRA member states.
2. This TAG is consistent with the WENRA Safety Reference Levels for Existing Reactors (ref. [16]). The Issues of relevance to this TAG are:

* Para B1.1 addresses a justified organisation:

“The organisational structure for safe and reliable operation of the plant, and for ensuring an appropriate response in emergencies, shall be justified and documented.”

* Para B1.2 requires management of change:

“The adequacy of the organisational structure, for its purposes according to B1.1, shall be assessed when organisational changes are made which might be significant for safety.”

* Para B3.1 states that a resource assessment for the organisational structure is needed:

“The required number of staff for safe operation, and their competence, shall be analysed in a systematic and documented way.”

* Para B3.5 addresses core safety capability and employee/contractor resource balance:

“The licensee shall always have in house, sufficient competent staff to understand the licensing basis of the plant (e.g., Safety Analysis Report or Safety Case and other documents based thereon), as well as to understand the actual design and operation of the plant in all plant states.”

* Para B3.6 addresses the intelligent customer role:

“The licensee shall maintain, in house, sufficient and competent staff and resources to specify, set standards, manage and evaluate safety work carried out by contractors.”

* Para C3.1 requires an integrated management system:

“The main aim of the integrated management system shall be to achieve and enhance nuclear safety. Other demands on the licensee and the licensee’s management system shall be considered in unison with nuclear safety, in order to help preclude their possible negative impact on nuclear safety.”

## IAEA Safety Standards

1. The IAEA Safety Standards (Requirements and Guides) are the benchmark for the SAPs in 2014 and are recognised by ONR as relevant good practice. They should, therefore, be consulted, where relevant, by the inspector, although it should be appreciated that they are design standards rather than regulatory standards.

* Fundamental Safety Principle Number 1 states:

“The prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks.”

1. This principle cites the responsibility of the licensee for safety throughout the lifecycle of a facility or activity. It affirms the licensee’s responsibility for establishing and maintaining the right skills and competences.
2. IAEA documents of relevance include:

* Specific Safety Guide SSG-72 – The Operating Organisation for Nuclear Power Plants (ref. [17])
* Specific Safety Requirements SSR-2/2 – Safety of Nuclear Power Plants: Commissioning and Operation (ref. [18])
* General Safety Requirements GSR Part 2 - Leadership and Management for Safety (ref. [19])

1. SSG-72 (ref. [17]) and SSR-2/2 (ref. [18]) include key elements of the management system and the structure of the operating organisation that are embodied in the NB or Safety Management Prospectus (SMP):

* Requirement 3 of the SSR 2/2 – Structure and functions of the operating organization states:

“The structure of the operating organization and the functions, roles and responsibilities of its personnel shall be established and documented.”

* SSR 2/2, Para 3.8 considers responsibilities, authority and lines of communication for the safe operation of the plant:

“Functional responsibilities, lines of authority, and lines of internal and external communication for the safe operation of a plant in all operational states and in accident conditions shall be clearly specified in writing.”

* SSR 2/2, Para 3.9 considers the organisational structure and organisational change:

“The structure of the operating organization shall be specified so that all roles that are critical for safe operation are specified and described. Proposed organizational changes to the structure and associated arrangements, which might be of importance to safety, shall be analysed in advance by the operating organization.”

1. GSR Part 2 defines the requirements for establishing, assessing, sustaining and continuously improving leadership and management for safety in organisations. Requirement 9 focuses on provision of resources and requirement 12 focuses on fostering a culture for safety.
2. GSR Part 2 requires that:

“Provision is made in the management system to identify any changes (including organisational changes) that could have significant implications for safety and to ensure that they are appropriately analysed.”

“Planned reviews of the management system take account of changes in the organisation.”

1. The following reports produced by IAEA are also directly relevant:

* International Nuclear Safety Advisory Group INSAG 18 – Managing Change in the Nuclear Industry: The Effects on Safety (ref. [20])
* General Safety Guide GS-G-3.1 – Application of the Management System for Facilities and Activities (ref. [21])
* General Safety Guide GS-G-3.5 - The Management System for Nuclear Installations (ref. [22])

1. **IAEA Safety Report INSAG 18** (ref. [23]) -Through consideration of both organisational safety and effects on the individual, the report discusses how and why change can challenge the maintenance of high levels of safety and what can be done to control that challenge and reap all the benefits of change.
2. **IAEA Safety Guides GS-G-3.1 and GS-G-3.5** (refs.[24]and[22]) -   
   These documents provide generic guidance to aid in establishing, implementing, assessing and continually improving a management system.

# Advice to Inspectors

## Purpose and scope of organisational change

1. A licensee’s organisational capability is fundamental to its ability to maintain nuclear safety. LC 36 is stated in full at [Appendix 1](#_Appendix_1:_Licence).
2. 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. Of note, some of the principles may also be considered good practice for the control of changes to the management system arrangements made under LC 17.
3. [Appendix 2](#_Appendix_2:_Guidance)provides guidance to inspectors on the approach that should be taken to assessing the financial resources aspects of this requirement.
4. Ref. [3]sets out ONR’s expectations that a licensee should have a NB to provide a demonstration that it has suitable and sufficient organisational structures, staffing and competences in place to effectively and reliably carry out those activities which could impact on nuclear safety.
5. Ref. [3], supplemented by other guidance such as ref. [7], is, therefore, instrumental in setting out ONR’s expectations of the way in which a licensee shows that it has, and maintains, adequate human resources. The NB also provides a clear description of the currently intended staffing levels as a reference point or ‘baseline’ against which the licensee can assess the potential impact on nuclear safety of proposed organisational changes, noting that it will also be affected by changes in business objectives such as lifetime extensions.
6. The purpose of management of change (MoC) is to provide a structured, coherent and comprehensive approach to maintaining nuclear safety throughout changes to the nuclear safety organisation.
7. The licensee’s MoC arrangements should ensure that the nuclear safety implications of a proposed change are fully considered and that risks arising from inadequate assessment and implementation of the change are recognised and suitably controlled. These arrangements should be part of a licensee’s management system.
8. There are many drivers for organisational change, and, without formal change management, a licensee may not immediately recognise the implications of a proposed course of action. Examples of drivers for organisational change and their potential implications are given in   
   [Appendix 4](#_Appendix_4:_Examples).
9. It is important that the full implications of a proposed change or a series of changes are assessed prior to implementation of the change(s). This is to guard against a failure to consider all relevant factors and potential dependencies between related changes, and the potential for 'salami slicing'in which a major change is decomposed into a series of lesser changes which are treated independently. This applies to changes at all levels in the organisation including the very top of the organisation (i.e., 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.
10. Changes should be classified according to nuclear safety significance.   
    Broad guidance for inspectors on the classification of organisational changes is given in [Appendix 5](#_Appendix_5:_Guidance). The level of assessment required should be proportionate to the potential nuclear safety significance of the change.
11. It should be noted that replacing one post holder with another post holder on a like-for-like basis need not constitute a trigger for the application of MoC arrangements as this should ordinarily be addressed through the licensee’s arrangements made under LC 12. However, where several changes are to be undertaken in the same area or there is a consequential effect on roles and responsibilities, the arrangements should be applied.
12. In addition to this TAG and ref. [3], inspectors should be familiar with the nuclear industry GPG (refs. [4], [5] and [6]). This guidance was produced, and is maintained, by an industry working group that includes ONR.   
    Where licensees can demonstrate that their arrangements are consistent with the guidance in the GPG, inspectors should regard this as meeting the expectations of this TAG and sufficient for compliance with the LC.
13. For new build organisations, it is important that MoC arrangements are fully developed 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. It is recognised that new build organisations develop rapidly during the pre-application and early NSL assessment phase of the project. However, implementation of these arrangements should enable an organisation to establish and demonstrate the appropriate level of control, while supporting the development of the company’s resourcing strategy. This should enable ONR to gain confidence in the company’s approach to building a nuclear competent organisation.
14. ONR recognises that, unlike mature licensee organisations, 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. The organisation should ensure that its MoC arrangements are proportionate to the phase of the project and sufficiently flexible to enable rather than constrain organisational development.
15. ONR acknowledges that for low hazard sites, typically those below the REPPIR threshold, it may be proportionate for a simplified MoC 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.
16. Significant, large-scale and complex change in licensee organisations may arise from changes to business strategy in response to either external or internal factors. Such changes generally originate from Board or Executive level direction articulated through strategy papers that provide the framework and direction for more detailed design and planning.

## ONR permissioning of organisational change

1. To introduce flexibility into the permissioning process, licensees may prescribe, with ONR agreement, ‘derived’ powers for use by ONR usually but not exclusively when permissioning the highest category of change proposal. The ‘derived’ powers defined in a licensee’s LC 36 arrangements may include agreement, notification, acknowledgement and specification but not approval, consent or direction. However, derived powers have no formal legal basis and constitute administrative arrangements agreed between ONR and the licensee. Inspectors should note that inclusion of derived powers are not a prerequisite for the licensee’s LC 36 arrangements to be considered as adequate, nor does their use preclude the use of primary powers to exercise regulatory control over modifications. This guidance provides advice to inspectors on ONR’s expectations for adequate licensee arrangements required under LC 36 (2).
2. The licensee’s arrangements may also include provision for enhanced implementation monitoring and control of a proposed organisational change by ONR, where ONR considers that the use of primary or derived power Licence Instruments may not be appropriate or proportionate to exercise regulatory control and oversight of a licensee’s modification proposal. Where this is the case, the inspector should check that such arrangements are consistent with the expectations set out in ref. [25].
3. This guidance provides advice to inspectors on ONR’s expectations for adequate licensee arrangements required under LC 36 (2).

## Principles of organisational change

1. There are some broad principles which underpin ONR’s expectations of a licensee’s MoC arrangements. These are set out below and then each principle is discussed in more detail in the following sections.
2. The 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;
3. The Board of the licensee/Executive should own and support the MoC arrangements and ensure that they are embedded throughout the organisation;
4. The arrangements should reference the nuclear baseline and include a process for updating it on a regular basis;
5. The arrangements should 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;
6. The licensee should assess and justify the safety of a proposed change, commensurate with its unmitigated potential impact on safety should the change be inadequately conceived or executed, identify and implement suitable controls to ensure nuclear safety is not adversely affected and monitor the implementation of the change.
7. The licensee should periodically review the effectiveness of the overall arrangements and the changes that have been implemented.

### Principle one

1. A licensee’s MoC arrangements should be robust, incorporated as part of the management system and applied to all activities that have the potential to impact on nuclear safety.
2. ONR considers organisational capability to be a function of the people in the context of the processes and tools used. It is expected, therefore, that licensees will take an holistic view across these three areas. It is good practice for MoC processes to be aligned with other company change processes such as those for engineering change established under LC 22.
3. The licensee should have formal, systematic arrangements in place to assess, monitor and review organisational changes to ensure that they are managed in a co-ordinated, consistent and effective manner.   
   These arrangements should be owned and supported by the licensee Board/Executive.
4. These arrangements, which may be approved by ONR under primary powers, should be part of the licensee’s management system, and ideally be integrated with the organisation’s HR processes rather than being separate and additional. This also means that the resource implications of change can be considered as part of the overall management of the organisation and its capabilities. They should set out the roles and responsibilities for managing changes with clearly assigned responsibilities for originating, peer review, approval, monitoring, close-out of individual changes and post change reviews.
5. The scope of the licensee’s arrangements should include all organisational changes that could potentially affect nuclear safety, not just roles and posts included in the NB. The licensee needs to be able to demonstrate through a proportionate application of its arrangements that it can influence or mitigate the impact of such changes so that nuclear safety is not compromised.   
   This may, for example, include the impact on the licensee of proposed actions or decisions made by parent companies or parent body organisations where these could impact on the licensee’s capability or its management of nuclear safety. The licensee should also consider the potential effects on culture and morale arising from the change.
6. The scope of the arrangements should also include important enabling and support functions such as human resources, finance and procurement where these have the potential either directly, or through consequential change, to impact on the licensee’s management of nuclear safety.
7. The arrangements should allow for the:

* Use of the MoC process as a flexible risk assessment tool where appropriate. Examples of when this might be necessary include when assumptions used in defining the NB are challenged (such as long-term absences and long-standing vacancies, which are outside the definition of the utilisation factor (ref. [3])). The default assumption should be that all posts and changes have the potential to affect safety management unless it can be demonstrated otherwise.
* Development of temporary changes with clearly defined duration, review period(s) if appropriate, and exit strategy. The exit strategy may include options to revert to the original organisation or formalising the change. Examples of when this might be necessary include long-term absences or post vacancies and backfilling for short-duration secondments.

1. Proposed changes should be assessed using a consistent methodology.   
   The methodology should be applied to all proposed changes to make and record an early judgement of the potential impact on nuclear safety.   
   ONR’s expectations of a methodology are set out in Principles four and five.
2. Staff involved in ensuring or assuring the quality of MoC proposals should be suitably qualified and experienced persons (SQEP) to do so and SQEP requirements for staff fulfilling key roles within the arrangements should be clearly defined. The importance of SQEP input to a MoC assessment cannot be over emphasised as staff experienced in the MoC process can apply that experience and judgement to avoid the potential pitfalls that less experienced staff may not be aware of.
3. Staff implementing LC 36 arrangements should be given specific training in MoC theory and principles as well as the licensee’s arrangements.   
   They should not be deemed to be competent based on seniority.
4. The arrangements should ensure that individual change proposals are clearly identified and that details of the change (that is change category and other important attributes) are recorded in a change register.   
   Documentation used to assess, decide upon, monitor, review and close-out the change should be retained for current and future reference in accordance with the licensee’s arrangements under LC 6. ‘Documents, Records, Authorities and Certificates’.
5. The arrangements should consider and, where possible, allow for the reversibility of changes or the application of contingency plans should subsequent performance monitoring indicate that the change has been inappropriately conceived or inadequately implemented. The extent of the reversibility may be related to the significance of the change and the availability of effective countermeasures. For larger, more significant changes, consideration should also be given to the options for how the objectives of the change can be achieved, including a justification of the chosen option. The development of a communications plan should also be considered.
6. All change proposals should be subject to a proportionate level of scrutiny and challenge, analogous to expectations for modifications to existing plant made under LC 22 ‘Modification or Experimentation on Existing Plant’.   
   The level of scrutiny is likely to increase with potential significance.   
   Where the safety significance of a proposed change is judged to be high, the arrangements should provide for seeking advice from the Nuclear Safety Committee (NSC) (or identified equivalent status body where appropriate), and senior management oversight of the effectiveness of the process and implementation of individual changes.
7. The licensee’s arrangements should require approval to be formally granted by a SQEP prior to implementation of a change subject to satisfactory confirmation that any enabling actions have been completed, and for the change to be formally signed off on completion.
8. The effectiveness of implementation of the arrangements should be routinely monitored and reviewed as part of the licensee’s normal assurance processes.
9. The inspector should consider whether:

* The licensee has formal, documented MoC arrangements which are an integral part of its management system;
* The arrangements apply to all aspects of the licensee’s activities, including changes at Board or Executive team level, that have the potential to affect nuclear safety, and have they been promulgated to all parts of the licensee’s organisation;
* The documented arrangements are clear, available to end users and up to date;
* The arrangements use a methodology which is easy to understand and follow;
* The methodology is being consistently interpreted and applied across the licensee organisation;
* Roles and responsibilities for implementing the MoC arrangements are clearly defined, integrated with the management system and understood by staff with MoC process roles;
* SQEP requirements for staff fulfilling key roles within the arrangements are clearly defined;
* Staff fulfilling key MoC arrangements are demonstrably SQEP for those roles and they have a suitable level of authority within the licensee’s organisation;
* All change proposals are logged in a change register and records are available to substantiate the key decisions made in support of significant changes in accordance with the licensee’s arrangements for LC 6;
* The arrangements are subject to the processes of independent review and audit operated by the licensee.

### Principle two

1. The Board of the licensee/Executive should own and support the MoC arrangements and ensure that they are embedded throughout the organisation.
2. A licensee’s MoC arrangements should be peer reviewed and implemented consistently and effectively, and a visible commitment to these arrangements should be made by the licensee Board/Executive. The Board/Executive should be able to show that it actively uses the MOC arrangements and supports the MoC process by regularly reinforcing to the workforce the importance of having and following a robust change process.
3. The Board/Executive should ensure that SQEP resources are put in place to develop the MoC arrangements, to implement them and to maintain oversight of the way in which the arrangements are used. This should include provision for suitable levels of challenge and independent peer review of change proposals as part of the licensee’s corporate governance arrangements, and for seeking advice from the NSC or identified equivalent status body where appropriate.
4. The MoC arrangements should apply throughout the company, up to and including the Executive team and Board, noting that strategic and complex changes to the structure or staff composition of a business may often originate at this level.
5. Significant, large-scale, complex change in mature licensee organisations will frequently arise from changes to business strategy in response to either external or internal factors. Such changes are generally initiated at Board level with the intent and high-level approach defined through the licensee’s approach to producing a business strategy. In general, the business strategy should provide an overview of major actions, investments, programmes of change and their alignment, and a framework and guidance to enable more detailed interpretation of the strategy through the licensee’s MoC arrangements
6. The business strategy may be defined through a single paper or through a series of documents that, from an organisational capability perspective, provide the frame and guide for strategic organisational planning. These may include a:

* **People (or Organisational Capability) Strategy** – Explanation of the strategy and the rationale for it
* **Paper of Principles** – Strategic-level principles that provide persistent direction and guide strategic planning
* **Concept of Operations** – The framework and guidance on how the defined organisation is intended to work so that others can interpret the strategy and apply it to the production of more detailed plans and programmes of change.
* **Strategic Plans:** High-level direction of the means of implementing the strategy

1. To ensure that the interfaces between, and the aggregated impact of, components of large-scale, complex change are managed effectively to maintain nuclear safety, the licensee’ arrangements should include provision for the development of overarching proposals and subordinate implementation changes.
2. An overarching MoC defines the organisation-level framework to enable the standard, consistent and reliable production of multiple implementation MoCs associated with large-scale, complex change. The overarching MoC does not, of itself, implement change but describes at the organisational-level the:

* Change.
* Aggregated and interface risk assessment, with associated categorisation.
* Change strategy (such as phasing and sequencing; governance and oversight).
* Change implementation governance arrangements.
* Assumptions and enabling activities to reduce uncertainty and ambiguity in the production of implementation MoCs.
* Programme of underpinning implementation or enactment MoCs.

1. An implementation or enactment MoC proposal is generally referred to as an MoC; it provides the:

* Detailed description of the change, associated risks and categorisation;
* Implementation plan and control measures to enact change safely;
* Approach to post implementation evaluation.

1. Progress with, and the effectiveness of, the implementation of significant, large-scale, complex changes should be regularly monitored by the Board/Executive. The Board/Executive should establish an oversight process for this purpose as appropriate.
2. It is expected that the licensee Board/Executive will proactively discuss significant, large-scale, complex changes with ONR at an early stage.   
   This will allow the licensee to share its intentions with ONR and for ONR to provide advice and guidance as appropriate. It will also help ONR to understand the licensee’s business drivers and to schedule and prioritise its own resources as appropriate.
3. The Board/Executive should satisfy itself that MoC arrangements are embedded throughout the organisation and that suitable provision is made to periodically review the effectiveness of the arrangements, and to monitor the cumulative effects of changes on the overall health of the licensee organisation. It should ensure that the reasons for, and progress with, significant, complex changes are communicated to the workforce.
4. The inspector should consider whether:

* The Board and Executive are able to demonstrate their commitment to effective management of organisational change;
* The Board and Executive has regularly satisfied itself that the MoC arrangements are adequate and that they are being implemented effectively;
* There is a governance process that ensures appropriate oversight of, and challenge to, all proposed changes;
* The Board/Executive is involved in assessing the implications of changes which may have a greater potential impact on nuclear safety as part of the licensee’s governance arrangements;
* The Board/Executive is aware of the need to discuss more significant, large-scale, complex changes with ONR at an early stage;
* The licensee’s governance arrangements provide for an oversight process to monitor implementation and provide strategic guidance and support for more significant changes;
* The Board/Executive regularly seeks assurance that implementation of more significant, large-scale and complex changes is proceeding satisfactorily;
* The licensee’s communication arrangements adequately convey the reasons for, and progress with, implementation of significant changes to the workforce.

### Principle three

1. A licensee’s MoC arrangements should reference the nuclear baseline and include a process for updating it on a regular basis.
2. A licensee should have an NB which provides a demonstration that it has suitable and sufficient organisation structures, staffing and competences in place to effectively and reliably carry out those activities which could impact on nuclear safety.
3. The NB should act as a reference point or ‘baseline’ against which the licensee can assess the potential impact on nuclear safety of proposed organisational changes. Individual change assessments should reference the baseline where the proposed change is likely to have an impact on it.
4. The NB should be dynamic and updated as changes are made to the organisational structure and resources, and periodically reviewed to consolidate changes.
5. The NB should be used as an integral part of the licensee’s resourcing processes.
6. The inspector should consider whether:

* The NB is up to date and reflective of the licensee’s current organisation;
* MoC assessments include a reference to the NB and identify whether or not the proposed changes affect baseline roles;
* The NB is regularly reviewed to ensure that it is up to date and incorporates changes affecting baseline roles;
* The MoC arrangements take account of the cumulative effects of low category changes on the NB;
* The MoC arrangements take account of baseline vulnerabilities when completing the risk assessment of the change;
* The MoC arrangements are integrated with human resource processes;
* There is evidence that the resource implications of proposed changes are shared with human resources as part of the change assessment process;
* Resource actions arising from individual MoC assessments have been closed and, if not, that unresolved actions are being managed.

### Principle four

1. It is important that a proposed change is assessed prior to implementation to ensure that the implications of the change are fully understood.   
   The assessment can be considered as an organisational risk assessment which identifies the potential risks associated with the proposed change, including risks arising both from the outcome of a proposed change and the process of transition.
2. The licensee’s MoC arrangements should include provision for an initial screening assessment to identify the potential nuclear safety significance of a proposed change in the event that the change is inadequately conceived or executed. The output of this assessment should be used to identify where:

* Due to the scale, complexity, duration and/or end state uncertainty of the proposed change, it is preferable to divide the overall change into smaller, more manageable elements. In this instance, the screening assessment should recommend the production of an overarching framework within which the subordinate changes will be defined, implemented and evaluated;

Or,

* The change can be implemented through a discrete change proposal.   
  In this instance, the output of the assessment will inform the classification of the change (as required by LC 36 (5)), which in turn is related to the level of analysis, justification and scrutiny that the licensee gives to the change proposal.

1. The screening assessment should be formally recorded in a MoC register (refer to Principle one) once internal licensee approval to further develop the proposal has been gained.
2. Change classification or categorisation methodology should consider the risks associated with the change being inadequately conceived or executed and should not take planned mitigation into account. ONR expects the change classification or category of all changes to be independently challenged prior to implementation proportionally.
3. ONR normally expects the number of change proposals which fall into the top category to be relatively few. These ordinarily include proposals which constitute wholesale organisational change, or which potentially challenge the basis upon which the licence was granted. Licensees usually have three further categories of change proposal for less significant changes.   
   Broad guidance on classification of organisational changes is given in   
   [Appendix 5](#_Appendix_5:_Guidance)for illustrative purposes, and there is guidance in the SDF’s GPG (ref. [4]).
4. Where the licensee judges that the overall change is to be enacted through multiple implementation changes within an overarching framework, the licensee is to ensure that the initial screening assessment considers not only the potential nuclear safety significance of each change in isolation but also the aggregated impact of the changes.
5. ONR expects that Organisational Capability Strategy papers, Papers of Principles and Concepts of Operations will not be categorised. Further, ONR expects that no change will be enacted through an overarching MoC.   
   Rather, change will be enacted through detailed, subordinate implementation MoC proposals, each of which will be subject to the licensee’s MoC arrangements including a screening assessment and categorisation.   
   While some licensees find it useful to categorise the overarching MoC proposal as well as each implementation change proposal, ONR’s expectation is that the aggregated risk is assessed and reflected in the categorisation of the discrete change proposals. In categorising changes made under the framework of an overarching MoC, where the overarching proposal is:

* Not categorised, the licensee should demonstrate how aggregated risk has been considered within the categorisation of the individual implementation proposals;
* Is categorised, the licensee should justify within the underpinning implementation change proposals any reduction in the categorisation of the proposal from that of the overarching proposal.

1. The licensee’s arrangements should make appropriate provision for engaging ONR and, in the case of significant, large-scale or complex changes, early engagement. This will allow ONR to provide advice and guidance to the licensee as appropriate and should simplify ONR permissioning of such changes since it will have prior knowledge of the rationale for the change and gained confidence in the licensee’s approach to assessing the implications of the change. This early engagement is particularly important in a number of cases, for example where a licensee is planning to reduce staff numbers through a redundancy programme where a statutory consultation period may apply. ONR will expect engagement to have commenced before the statutory consultation period is invoked. Further examples include where significant change is planned to the management of the organisation.
2. ONR expects:

* The licensee’s arrangements to affirm that Category 1 changes shall not proceed without the formal **agreement** of ONR and for such changes to be submitted in writing to ONR in accordance with LC 36 (5). In such circumstances it is prudent for the licensee to ensure that sufficient time is built into the change programme to provide for ONR assessment of the proposed change. The licensee should facilitate this through early engagement with ONR so that the level of regulatory interest can be established and resources can be put in place to assess the change.
* The licensee’s arrangements for Category 2 change proposals should require the change to be submitted in writing to ONR a suitable period before the proposed implementation date. This is at least 20 working days. If, during this period, ONR informs the licensee in writing that ONR wishes to review the proposal before it proceeds, the licensee’s arrangements should confirm that the change will not proceed until ONR **agreement** is obtained. It is, again, clearly in the licensee’s interests to give ONR early notice of Category 2 changes where possible so that any potential issues can be discussed and resolved without undue impact on the licensee’s programme or a need to invoke the derived power in the licensee’s arrangements. Where ONR does not intend to exercise the derived power and permission the change, ONR should formally communicate this to the licensee in writing so that it may proceed with the proposed change earlier if it chooses. The basis for ONR’s decision not to exercise the derived power should be documented.
* Category 3 and 4 changes should be entered into the licensee’s MoC register which should be available for periodic sampling by the inspector. If ONR informs the licensee in writing that ONR wishes to review the proposal before it proceeds, the licensee’s arrangements should confirm that the change will not proceed until ONR **agreement** is obtained.

1. Where an **agreement**, in accordance with the licensee’s own arrangements, is needed from ONR to allow a proposed change to proceed, the inspector should arrange for the change to be formally assessed, and a Project Assessment Report (PAR) produced, in accordance with ONR’s permissioning procedure. Once ONR is satisfied that the change may proceed, a Licence Instrument will be issued to the licensee to permission the change.
2. Application of the classification methodology and implementation of MoC arrangements should not allow changes, which if assessed in totality could constitute a Category 1 or 2 change, to be reduced to a number of smaller, lower significance changes (i.e., the arrangements should not allow ‘salami slicing’). Some changes may be borderline between two classifications or categories. In these situations, ONR expects the licensee to take a conservative position and consider the change at the higher level. Some changes may attract key stakeholder interest. In these situations, ONR expects the change to be categorised in accordance with the licensee’s arrangements. Occasionally a higher level of scrutiny can be applied; this will be viewed positively but is not expected to be normally adopted.
3. Over time, and with experience, a licensee may develop an appreciation of the likely category for individual changes and will form a view based on an initial, informal assessment. This initial assessment should not be used in place of a comprehensive assessment for significant changes, nor should the change originator pre-judge the categorisation of a change without an appropriate assessment of the implications of the change.
4. The inspector should consider whether:

* An initial screening assessment has been prepared to identify the potential impact of the change proposal on nuclear safety significance and categorise the proposal;
* The risk assessment uses a clear, consistent and well-informed approach which identifies potential risks arising both from the final outcome of the change and the process of transition;
* The classification methodology is easy to understand and is being applied objectively and consistently, throughout the licensee’s organisation;
* There is a checking process to confirm that changes have been correctly categorised and challenged by a SQEP;
* Safeguards are in place to avoid under-categorisation of changes or ‘salami slicing’;
* The licensee’s arrangements:
  + Identify, and meet ONR’s expectations for, the need to communicate Category 1 and 2 change proposals to ONR
  + Include a derived power which will allow ONR to provide formal agreement to change proposals;
  + Encourage authors of change proposals to make provision for timely engagement with ONR.

### Principle five

1. The licensee should assess and justify the safety of a proposed change, commensurate with its potential impact on safety, identify and implement suitable controls to ensure nuclear safety is not adversely affected and monitor the implementation of the change.
2. Changes which are identified via the initial screening assessment as falling into categories 1, 2 and 3 (as illustrated in [Appendix 5](#_Appendix_5:_Guidance)), should be subject to a more detailed assessment which is documented as part of the justification for the change. The justification should ordinarily include:

* A statement of the reason for and objectives of the change. This is typically identified in the ‘initial screening assessment’;
* A risk assessment;
* An implementation plan.

1. Changes assessed as having a significant potential impact on nuclear safety (that is Category 1 and Category 2) should be subject to a more detailed risk assessmentwhich is documented as part of the justification for the change. The risk assessment should be proportionate to the nuclear safety significance and complexity of the change being proposed. The assessment should identify the ‘enablers’, or arrangements that need to be put in place to facilitate the change proposal and ensure that risks are controlled.   
   These should include actions required to mitigate the risks arising from both the outcome of the change and during transition as appropriate. The licensee may identify a need to undertake a formal workload assessment for changes that have the potential to impact on the workload of an individual(s).
2. In many cases achieving an adequate assessment is unlikely without active consultation with the staff affected by the proposed change at an appropriate stage. Although this can be sensitive, many post holders will have a unique knowledge of how they carry out their work and what its demands are.
3. The risk assessment for a significant, large-scale, complex change proposal may indicate that it is preferable to divide the overall change into smaller, more manageable elements. This may have advantages in that elements can be assigned to different leads that have better-defined responsibilities and knowledge for taking a change forward. However, there are risks in this approach because potential dependencies between these elements may be missed. For example, an individual responsible for one element may make assumptions about the continued provision of resources or arrangements that might be affected by changes to other elements.
4. In such instances, the licensee should produce an overarchingMoC proposal to define the scope of the overall proposal and set a single, coherent framework for managing the different elements which are encompassed within it. The risk assessment for the overarching MoC should take a broader cross-cutting perspective, including consideration of the:

* Risks arising at the interfaces between the various elements.
* Aggregated risk arising from multiple implementation/enactment MoCs.

1. Further guidance on overarching documents, including overarching MoC proposals, may be found in the SDF’s UK Nuclear Industry Guide to Overarching MoC and Principles Papers (ref. [6])
2. ONR expects the licensee to put in place suitable processes for endorsing change proposals. Usually, Category 3 and Category 4 changes may be endorsed by the originator or local process owner following an independent review of the classification or category. Category 1 and Category 2 changes plus overarching MoC proposals, however, should be endorsed by an individual who has a full understanding of the implications of the proposed change. Such individuals are more likely to be at a more senior level in the licensee organisation.
3. As noted in Principle 3, justification documents for Category 1 and Category 2 changes may need advice by a Nuclear Safety Committee or an equivalent body in accordance with the licensee’s arrangements.
4. The mitigating actions and enablers identified in the risk assessment should, following endorsement, be addressed in an implementation plan.   
   The implementation plan should show how the mitigating actions and enablers will be delivered and managed. It should include a clear definition of responsibilities for taking forward the change and maintaining a suitable level of managerial oversight. For example, the inspector should be able to find evidence that documentation has been endorsed to confirm both the completion of enabling actions and that the change may proceed.
5. The output of a risk assessment may indicate that it is preferable to introduce the change on a phased or staged basis as a means of best managing the risks associated with the change. This should be reflected in the implementation plan, and the licensee should consider introducing stage gates, or hold points, as necessary to manage the process. ONR interaction may be considered appropriate by the licensee or ONR for some of these stages, depending on the nuclear safety significance.
6. The implementation plan should also include indicatorsthat can be used to monitor progress in implementing the change and provide confidence that no adverse effects are being realised. These indicators may be qualitative or quantitative as appropriate. They should primarily be ‘leading’ indicators that consider the potential consequences of the change being inadequately conceived or executed such as training completed; overtime worked; maintenance backlogs etc., rather than ‘lagging’ indicators which typically monitor reduction in accident rates.
7. Significant changes (that is those identified as Category 1 or Category 2 in [Appendix 5](#_Appendix_5:_Guidance)),should have Board/Executive oversight, using indicators and any other appropriate measures, to confirm that changes are being correctly managed. If a change is not proceeding satisfactorily the Board/Executive should identify and sponsor remedial action. This monitoring should be proportionate to the significance of the change and continue for the life of the change. It should also include a post-completion review to confirm both that the change has been implemented as intended and that the objectives of the change have been satisfactorily achieved.
8. Where possible, the implementation plan should reflect potential contingency actions that may be required if the change is not proceeding as planned. Where potential consequences are high it may be appropriate for the licensee to maintain for a suitable period the capability to reverse the change.
9. Justification documents should be formally signed off when the change is complete and should be retained as a record in accordance with the licensee’s LC 6 arrangements. It can be helpful to ‘close out’ the change at an appropriate date, after the outcome has been monitored and sufficient confidence has been gained that the change need not be reversed or altered significantly.
10. ONR recognises that there may be instances where the implementation of a proposed change is delayed. In such circumstances, it is incumbent on the licensee to ensure that all aspects of the proposal remain valid before enacting the change. ONR expects that the licensee’s MoC governance forum will conduct a routine review of the change register. It should, therefore, be aware of situations where there is a lag between approval and implementation of a change proposals and should have local arrangements for re-review and, if necessary, re-approval of an MoC when there is delayed implementation. These local arrangements should consider factors such as significance of the change to be implemented and volume and significance of interfacing changes implemented and proposed since the change was initially approved.
11. Under LC 36 (6), ONR may **direct** a licensee to halt a change to its organisation structure or resources if it is concerned the change may have been inadequately conceived or executed. In practice, it is envisaged that this power will be used rarely. In such circumstances, ONR and the licensee should discuss the proposed change and seek to resolve any issues such that an agreed way forward is established. If ONR is content that the proposed change, amended, if necessary, may proceed then it will provide a formal **consent** to permit it to progress.
12. The inspector should consider whether:

* Assessments of proposed changes are proportionate to the significance and category of the change;
* Assessments have been carried out by competent persons and adequately consider the range of potential consequences should the change be inadequately conceived or executed;
* The licensee has acknowledged the need to develop an ‘overarching ‘ MoC assessment as a means of defining and coordinating larger, more complex changes;
* The licensee’s arrangements provide for a staged approach to implementing larger, complex changes and make provision for ONR intervention as appropriate;
* Justification documents have been formally endorsed to confirm that proposed changes may proceed and signed off upon completion of necessary enabling actions by a SQEP;
* Changes have been adequately documented to enable the objective of the change, and the change categorisation to be clearly understood;
* Enabling and mitigating actions for Category 1 and Category 2 changes are relevant and satisfactorily address the identified risks;
* The licensee’s senior management and the Nuclear Safety Committee have been involved in considering the implications of a Category 1 change, or an overarching MoC proposal that encompasses a Category 1 change, prior to implementation;
* Arrangements are in place in the licensee organisation to monitor Category 1 and Category 2 changes and, in the event that a change is not proceeding satisfactorily, to initiate remedial action;
* Suitable qualitative or quantitative indicators have been developed for significant changes and if they are linked to enabling and remedial actions;
* The indicators are being used to monitor the effectiveness of implementation of significant changes;
* There is a process to check the quality and consistency of justification documents;
* Justification documents are filed within a site-wide system and available for scrutiny;
* There is a post-change review process to enable learning points from successful and unsuccessful changes to be taken into account for future changes and, if appropriate, incorporated into the licensee’s MoC arrangements.

### Principle six

1. The licensee should periodically review the effectiveness of the:

* Arrangements, to confirm that they are working satisfactorily and to identify process improvements.
* Application of the MoC process, especially to more significant, larger and more complex changes.

1. Regular reviews should also be conducted of the totality of changes implemented and the cumulative impact on the organisation to confirm that neither nuclear safety nor organisational capability are being degraded by a succession of changes.
2. Reviews may take the form of formal audit by a licensee’s assurance function or management reviews as part of a structured approach to business improvement. The learning gained should be reflected, where appropriate, in briefings, modifications to training and changed arrangements.
3. It is important that the senior management are engaged in the review process to demonstrate leadership and commitment to the MoC arrangements.
4. The inspector should consider whether:

* The arrangements provide for the Board/Executive to monitor the effectiveness of implementation of more significant, larger-scale and/or more complex changes;
* There is a formal review process to confirm that the MoC arrangements are operating satisfactorily;
* Senior management are engaged in the review process and how their leadership and commitment is demonstrated to the workforce;
* The review process involves persons other than those with a MoC process role to ensure that the views of originators and implementers are captured;
* The outcome of reviews is shared with the workforce;
* There is a mechanism for sharing learning and building that learning back into the arrangements as part of continuous improvement;
* The cumulative effects of multiple changes on both nuclear safety and organisational capability have been considered by senior management and if there is any evidence of action being taken to avoid the potential degradation of the licensee organisation.

# Appendix 1: Licence Condition 36 - Organisational Capability

Licence Condition 36 requires that:

1. The licensee shall provide and maintain adequate financial and human resources to ensure the safe operation of the licensed site.
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. The licensee shall submit to ONR for **approval** such part or parts of the aforesaid arrangements as the Executive may **specify**.
4. The licensee shall ensure that once approved no alteration or amendment is made to the approved arrangements unless the ONR has **approved** such alteration or amendment.
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 the ONR.
6. The licensee shall if so **directed** by the ONR halt the change to its organisational structure or resources and the licensee shall not recommence such change without the **consent**of the ONR.

# Appendix 2: Guidance to inspectors on the approach to be undertaken for assuring compliance with the ‘adequacy of financial resources’ aspect of LC 36(1)

## Purpose and scope

The purpose of this Appendix is to support a proportionate and consistent regulatory approach to ONR inspection and assessment against the financial resource’s aspect of LC 36 (1) ‘Organisational Capability’.

Regarding the requirement to *maintain*adequatefinancial resources, ONR’s view is that the licensee should be able to clearly demonstrate that it:

* Understands the hazards and risks of its undertakings and is operating in accordance with its safety case and complying with the licence conditions;
* Is reducing risk so far as is reasonably practicable, and implementing improvements in a timely manner where these are identified as ALARP;
* Is maintaining an adequate NB resource and implementing its arrangements for managing organisational change set out under LC 36(2);
* Has assessed what financial resources are necessary to continue to meet those needs;
* Has, and is maintaining, or has in place arrangements to obtain, the necessary financial resources; and
* Has relevant records and they are being retained in accordance with LC 6.

## Guidance on inspection of arrangements

### Regulatory approach

The financial resources of a licensee are not ordinarily the focus of routine inspection activities. Rather, inspectors should be alert to 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. Evidence may include failure to resource plant improvements; staff shortages that are not being filled; delays in delivering activities such as maintenance etc. Should indications be found that investment in safety-related plant or people may not be adequate to provide and maintain safety, the inspector should seek to establish whether it is attributable to other factors   
(for example difficulties in identifying SQEP resource; technical difficulties or disagreements etc.) and, if so, to progress the matter in the normal manner.

If the safety issue cannot be resolved to the satisfaction of the inspector, and financial resource issues are identified as a possible factor, this matter should be elevated to the relevant Superintending Inspector and Head of Profession for consideration. It is anticipated that discussions will take place with the licensee to determine the cause of the issue and attempt to resolve it. This may entail an ONR review of safety cases; annual financial accounts, plans for construction and key financial decision points; investment plans; lifetime plans, the NB and other documents. If the issue cannot be resolved, and failure to comply with LC 36(1) is suspected, consideration may be given to engaging external expert financial advice to inform the process of establishing ONR’s enforcement options. The need to take this course of action is expected to be rare.

Where the licensee's budget is controlled by another body (for example, the Nuclear Decommissioning Authority (NDA) or a parent organisation), financial (and other resourcing) arrangements are likely to be set out in contractual arrangements such as a Shareholders Agreement between the licensee and the controlling body.   
ONR may seek to examine these documents. ONR anticipates that the controlling body will co-operate with the licensee in ensuring the adequacy of the resources needed for safety, and to meet its obligations under HSWA Section 3(1).   
The licensee, however, retains an absolute responsibility for nuclear safety.

## Government assurances regarding a licensee’s financial standing

ONR will approach the relevant government department at the time of processing a licence application, or responding to a request for relicensing, to seek its assurances regarding the applicant’s financial status. ONR may, on rare occasions when it deems it relevant, also seek such assurances from government to inform ONR’s approach. Government assurances will be used by ONR to provide confidence that, at the point of licensing, an organisation’s financial arrangements are adequate to enable it to fulfil its obligations as a nuclear site licence holder. After the granting of a licence, the approach set out above will be followed.

# Appendix 3: Guidance for inspectors on the factors that may be considered when inspecting the licensee’s implementation of its MoC arrangements

The following ‘short-form’ guidance is provided to assist inspectors to judge the adequacy of licensees’ arrangements to comply with LC 36 clauses (2) to (5).

This Appendix complements the more detailed guidance in the main body of this TAG and provided at ref. [2]; reference to that material should be made where appropriate.

## MoC arrangements

Interview a sample of Board, Executive and Lead Team members to examine their knowledge of:

* The importance of MoC arrangements as an integral part of business strategy implementation, nuclear safety and resource management;
* The need for the Board/Executive to visibly commit to management of organisational change as a key business process;
* The need for the implications of all proposed organisational changes to be formally assessed using a consistent methodology which is an integral part of the licensee’s management system;
* The Board/Executive’s role in ensuring that the implications of significant and complex changes are fully assessed prior to implementation;
* The Board/Executive’s role in providing oversight of significant and complex changes and ensuring that the objectives of the changes are met;
* 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;
* The need to regularly review that the licensee’s MoC arrangements are up to date and are being consistently applied across the entirety of the licensee organisation;
* The importance of having SQEPs in key MoC roles.

Check that the baseline contains a substantiation of the ‘right size and structure’ for the licensee organisation. Check that there is not a presumption that the existing structure is adequate.

Check that the arrangements are linked to human resource processes and that Human Resources is involved in assessing implications of changes for workforce planning and training and acting appropriately.

Interview some of the managers proposing changes and key role holders such as reviewers to examine their knowledge of:

* Roles and responsibilities;
* Staging of changes where appropriate;
* The value of enabling actions which have been properly identified and managed i.e. verifiably closed out;
* Use of performance indicators and contingency measures or remedial actions, and that they have been properly identified and managed;
* The importance of reviews at appropriate times during implementation.
* Records requirements.

Confirm that the arrangements are being adhered to by discussion with staff at various levels throughout the licensee’s organisation.

Check the change register and observe if:

* There are similar, linked changes which should have been managed in a coordinated manner i.e. under an umbrella or overarching management of change, and given a higher change category;
* There is evidence of ‘salami slicing’ of a larger change into a series of smaller changes.

Check the licensee's implementation of its review and audit processes and examine:

* Periodic review and update of the NB;
* Reviews of performance indicators during and after implementation;
* Categorisation reviews;
* Independent safety reviews;
* Reviews of implementation of the arrangements and plans for improvement.
* Reviews of cumulative effects of change on the organisation.

Check the licensee’s communication arrangements to confirm whether the workforce understands the implications of significant changes and is kept informed of implementation progress.

* Check that arrangements exist to periodically update the NB and that the baseline is up to date and reflective of the licensee organisation.

## Implementation of change proposals

Select a sample of change proposals for checking. The sample should include top category changes if there have been any, and lower category changes throughout the range of significance. The sample should ideally include any corporate changes which may affect safety on site. Consider ‘calling in’ changes (at any or all category levels) for specialist assessment.

For each change proposal in the sample:

* Check the register of change proposals to confirm that change proposals for significant changes were reviewed and authorised through the appropriate route and available in time to provide 20 working days’ notice for ONR assessment prior to implementation if required.
* Make a judgement about the accuracy of the classification of the change.
* Check that the substantiation document for significant changes includes where appropriate:
  + A clear description of the objectives of the change;
  + A reference to the NB;
  + A risk assessment which has been used to inform the classification of the change;
  + A detailed implementation plan with timescales, including staging of the change where appropriate;
  + Enabling actions as precursors to implementation of the change;
  + Performance indicators to monitor the effectiveness of implementation;
  + Contingency plans and remedial actions;
  + Shadow working to confirm planned arrangements where appropriate.
* Check that authorisation to proceed with the proposed change was granted by a SQEP.
* Check that all enabling actions for significant changes were satisfactorily closed out before the appropriate parts of the change were implemented. Verify a sample of the actions if appropriate.
* Check that the performance indicators were used to monitor implementation progress and that contingency plans or remedial actions were invoked at an appropriate time.
* Check that the change proposal was signed off as complete by a SQEP.
* Check that the objectives of the change were met.
* Check that any staff implications have been satisfactorily addressed, for example:
  + Vacancy filling and recruitment;
  + Training and development.
* Check that the baseline has been updated to reflect the impact on baseline roles where appropriate.

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# Appendix 4: Examples of drivers for organisational change

This appendix provides some examples of drivers for organisational change and the potential implications for nuclear safety if a change is inadequately conceived or executed.

* **Cost reduction.** Thismay result in inadequate resources being available to fulfil baseline organisational roles.
* **Sales, acquisitions, mergers or creation of subsidiary companies.** This may lead to a loss of nuclear related expertise at Board and Executive level, resulting in a lack of understanding of what is required to maintain the defence in depth which is essential to the achievement of very high levels of safety. Corporate mergers may result in a lack of harmonisation of standards and procedures, and a lack of clarity of managerial responsibilities and accountabilities.
* **Downsizing, re-engineering and outsourcing.** This may result in understaffing and lack of competent staff or 'intelligent customer'capability to make an informed judgement. It may lead to instances where there is insufficient competent staff available to assess the safety significance of activities with the potential to impact on nuclear safety, or the loss of ‘corporate memory’ in a particular field.
* **Reduction of the numbers of layers of management.** This may result in inadequate supervision or oversight of staff work, or an unacceptable increase in individual workload or management spans of control.
* **Organisational development.** This is particularly appropriate in the case of new build organisations where the organisation structure may change several times as the project progress both within a particular project phase and as the project progresses from one phase to the next.
* **Organisational restructuring and change initiatives.** This may result in competent staff being diverted to restructuring/change projects.
* **Downgrading the Head of Safety post** so that he or she is no longer a member of the licensee’s Executive or Board, resulting in a loss of independent, authoritative advice for nuclear safety at Board level.
* **Relocation of offices.** Thismay result in the loss of key staff and expertise in critical areas.
* **Changes in policies for recruitment and training of staff.** This may result from national skills shortages, demographics etc leading to vacancies not being filled, recruitment of poor quality staff, and degradation of the competence of individuals and the organisation as a whole.
* **Change in Board /Executive.** Although not necessarily an organisational change this change could still result in significant safety risks.   
  Organisational change control can be used as a flexible risk assessment tool in these cases, which is seen as good practice, allowing the organisation to manage potential risks.

# Appendix 5: Guidance on the classification of organisational changes

The approach to classifying changes may vary according to licensee. The following example classifications are provided for illustrative purposes to guide the inspector:

* Category 1 changes, which if inadequately conceived or executed, could result in a **major reduction** in the standards of nuclear safety with the potential for on-site and off-site impact such as:
  + Wide ranging company or site changes that have the potential to affect the validity of, or basis on which, the nuclear site licence was granted.
  + Changes resulting in the granting of a new site licence.
  + Sale, acquisition or merger of a licensee organisation or a nuclear licensed site.
  + Changes involving more than one business unit, division or site.
  + Large-scale downsizing or outsourcing of a nuclear safety significant function.
* Category 2 changes, which if inadequately conceived or executed, could result in a **significant reduction** in the standards of nuclear safety with the potential to affect a large proportion of or the whole of a site such as:
  + Changes that affect people within a whole facility.
  + Changes that affect a whole department or large groups of staff.
  + Changes that affect several layers of management.
  + Significant reduction in the size of a team that has an EH&S role.
  + Changes with significant potential to adversely impact on a site’s emergency response.
  + Changes resulting in a significant transfer of key EH&S accountabilities and responsibilities such as those associated with DAP duties.
  + Changes in staff shift patterns
* Category 3 changes, which if inadequately conceived or executed, could result in a **minor reduction** in the standards of nuclear safety with the potential to affect a single plant, department or business unit such as:
  + Changes that affect staff within one process area or a significant part of a plant.
  + Changes that affect a small group of staff, such as part of a department.
  + Small reduction in the size of a team.
  + Changes in management accountabilities/responsibilities that have a small impact on EH&S.
  + Transfer of responsibilities between departments/units.
* Category 4 changes with **negligible** *or* **no effect** on nuclear safety such as:
  + Changes to organisational responsibilities that do not lead to a significant increase in the workload of any line manager or group of staff.
  + A reduction in the size of a team that has little or no EH&S role.
  + Staff being moved or leaving following completion of a project or package of work.

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# Glossary and Abbreviations

IAEA International Atomic Energy Agency

SAP Safety Assessment Principle(s)

TAG Technical Assessment Guide(s)

WENRA Western European Nuclear Regulators’ Association