

ONR GUIDE

Organisational Capability

Document Type:	Nuclear Safety Technical Assessment Guide		
Unique Document ID and Revision No:	NS-TAST-GD-048 Revision 4		
Date Issued:	March 2013	Review Date:	March 2018
Approved by:	Andy Hall	Programme Director	
Record Reference:	Trim Folder 1.9.3.772 (2013/79364)		
Revision commentary:	Revision		

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1. INTRODUCTION

- 1.1. ONR has established its Safety Assessment Principles (SAPs) MS.1 to MS.4 which apply to the assessment by ONR specialist inspectors of the organisational capability of potential and existing licensees. The principles presented in these 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 is one of those guides.

2. PURPOSE AND SCOPE

- 2.1. The purpose of this Technical Assessment Guide (TAG) is to help Inspectors assess whether licensees have put in place, and are implementing, arrangements to demonstrate the adequacy of their financial and human resources, and to manage organisational changes in accordance with the requirement of nuclear site licence condition (LC) 36 'Organisational Capability' as set out in Appendix 1.
- 2.2. It incorporates the guidance for Inspectors in judging the adequacy with which licensees' arrangements have been implemented, originally presented in T/INS/036 'LC36 Control of Organisational Change', thus consolidating related guidance within this single reference document. Factors that the Inspector may wish to consider concerning the way in which a licensee's arrangements are implemented are set out in Appendix 4.
- 2.3. Appendix 5 of this TAG also provides guidance on how Inspectors should approach the revised clause in LC 36(1), added in 2011, which requires licensees to provide and maintain adequate financial and human resources to fulfil their obligations in respect of nuclear safety. The revised LC 36(1) was introduced, together with amendments to LC 17 'Management Systems', to ensure that Nuclear Safety Directive 2009/71/Euratom (NSD) is fully implemented in Great Britain.
- 2.4. ONR guidance on assessing arrangements to provide and maintain adequate human resources is presented in T/AST/065 'Function and Content of the Nuclear Baseline'. The nuclear industry Safety Director's Forum (safetydf.org.uk) has also published a Nuclear Industry Code of Practice (NICoP) 'Nuclear Baseline and the Management of Organisational Change – A Nuclear Industry Code of Practice', with the cooperation of ONR. This guidance should be considered as relevant good practice and inspectors should encourage licensees to be familiar with it and use it where appropriate. Where licensees are able to demonstrate that their arrangements are consistent with the guidance in the NICoP, Inspectors should regard this as meeting the expectations of this TAG and sufficient for compliance with LC 36(2) and LC 36(5).
- 2.5. Appendix 4 of the TAG includes guidance for Inspectors on the factors that may be considered when inspecting the licensee's implementation of these arrangements, previously contained in T/INS/036, which has been withdrawn and replaced by this TAG. The guidance in Appendix 4 complements that in the main body of this TAG and reference to the main body should be made where appropriate.

3. RELATIONSHIP TO NUCLEAR SITE LICENCE AND OTHER RELEVANT LEGISLATION

The following UK legal and other requirements are applicable to this TAG:

- 3.1. The Management of Health and Safety at Work Regulations

- These regulations describe employers' responsibilities, addressing the requirements for control and co-operation with outside undertakings, together with appropriate arrangements for effective planning, organisation, control and monitoring and review. In particular, Regulation 13 requires employers to take into account employees' capabilities as regards health and safety when entrusting tasks to employees.

3.2. Nuclear Site Licence Conditions

The following site licence conditions are of particular relevance 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 management of change arrangements should include provision for the identification and management of records arising from implementation of the arrangements.
- **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, must be suitably qualified and experienced to fulfil those roles.
- **LC 17 – Management Systems.** The licensee shall establish and implement management systems which give due priority to safety. Management of change 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 management of change 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 the organisation or structure which may affect safety.

4. RELATIONSHIP TO SAPS WENRA REFERENCE LEVELS AND IAEA SAFETY STANDARDS

Safety Assessment Principles

4.1. The Safety Assessment Principles for Nuclear Facilities (2006 Edition, Revision 1) provide a framework to guide regulatory decision making in the nuclear permissioning process. They are supported by Technical Assessment Guides (TAGs) which further aid the decision-making process. The following principles are of particular relevance to this TAG:

- **MS.1 – Leadership.** Identifies the need for oversight of nuclear safety performance and a Quality 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 from experience. 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,

Technical Assessment Guides (TAGs)

4.2. The following Technical Assessment Guides are applicable to this TAG:

- **T/AST/027 – Training and Assuring Personnel Competence**

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.

- **T/AST/050 – Periodic Safety Reviews**

Section 4.3 of this TAG expects a 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

- **T/AST/065 – Function and Content of the Nuclear Baseline**

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.

- **T/AST/061 – Staffing Levels and Task Organisation**

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.

- **T/AST/072 – Function and Content of a Safety Management Prospectus**

Element 4 of this TAG requires a licensee how it will have adequate structures and resources to meet the nuclear safety needs of the business.

WENRA Reactor Safety Reference Levels

4.3. 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 IAEA safety standards. There is no direct reference to organisational change in the Reactor Harmonisation Working Group Reference Levels, 2008, but the reference levels in the following harmonisation issues represent good practices in the WENRA member states are relevant and should be taken into account by the Inspector:

- Issue B: Operating Organisation - Organisational Structure. Identifies the need for the adequacy of the organisational structure to be assessed when organisational

changes are made, and for changes to be justified in advance, carefully planned, and evaluated after implementation.

- Issue C: Management System - Objectives. Identifies the need for the management system to achieve and enhance nuclear safety by ensuring that other demands on the Licensee are not considered separately from nuclear safety requirements.

IAEA Safety Standards

- 4.4. The IAEA Safety Standards (Requirements and Guides) were the benchmark for revision of the SAPs in 2006 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. The IAEA Safety Standards do not address the issue of the organisational change explicitly but the Safety Requirements publication GS-R-3 'The Management System for Facilities and Activities' (IAEA 2006) is relevant. It defines the requirements for establishing, implementing, assessing and continually improving a management system. It includes the requirement to evaluate and classify organisational changes according to their importance to safety.
- 4.5. The following report produced by the International Nuclear Safety Advisory Group (INSAG) for the IAEA is also directly relevant:
- **INSAG 18 – Managing Change in the Nuclear Industry:** The Effects on Safety. This 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.
 - **IAEA Safety Standard GS-G-3.1 – Application of the Management System for Facilities and Activities**
This safety guide provides generic guidance to aid in establishing, implementing and assessing and continually improving a management system. Section 4 provides guidance relating to the provision of resources.

5. ADVICE TO INSPECTORS

Background

- 5.1. LC 36(1), which was introduced by a variation to all extant nuclear site licences in July 2011, requires the licensee to provide and maintain adequate financial and human resources.
- 5.2. Appendix 5 provides guidance to Inspectors on the approach that should be taken to assessing the financial resources aspects of this requirement. However, when this variation was introduced, ONR advised that it considered that licensees would already comply with the requirement to provide and maintain *adequate human resources*, by virtue of their Nuclear Baseline.
- 5.3. T/AST/065 'Function and Content of a Nuclear Baseline' sets out ONR's expectations that a licensee should have a nuclear baseline 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.
- 5.4. T/AST/065, supplemented by other guidance such as T/AST/027 'Training and Assuring Personnel Competence', 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 nuclear baseline 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.

- 5.5. 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. Appendix 1 states the licence condition in full. 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.
- 5.6. The licensee's management of change 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.
- 5.7. 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 2.
- 5.8. 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.
- 5.9. Changes should be classified according to nuclear safety significance. Broad guidance for Inspectors on the classification of organisational changes is given in Appendix 3. The level of assessment required should be proportionate to the potential nuclear safety significance of the change.
- 5.10. 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 management of change arrangements as this should ordinarily be addressed through the licensee's arrangements made under LC 12. However, where a number of changes have taken place in the same area or there is a consequential effect on roles and responsibilities, the arrangements should be applied.
- 5.11. In addition to this TAG and T/AST/065, Inspectors should be familiar with the nuclear industry code of practice or NICO_P on 'Nuclear Baseline and the Management of Organisational Change'. This guidance was produced, and is maintained, by an industry working group that includes ONR and Defence Nuclear Safety Regulator (DNSR) representation. Where licensees are able to demonstrate that their arrangements are consistent with the guidance in the NICO_P, inspectors should regard this as meeting the expectations of this TAG and sufficient for compliance with the Licence Condition. The NICO_P is available on the website of the Safety Director's Forum (www.safetydf.org.uk).

Management of Change Principles

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- 5.12. There are some broad principles which underpin ONR's expectations of a licensee's management of change arrangements. These are set out below and then each principle is discussed in more detail in the following sections.
1. 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;
 2. The Board of the licensee should own and support the management of change arrangements and ensure that they are embedded throughout the organisation;
 3. The arrangements should reference the nuclear baseline and include a process for updating it on a regular basis;
 4. 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 and justification;
 5. The licensee should assess and justify the safety of a proposed change commensurate with its potential impact on safety, and monitor its implementation;
 6. The licensee should periodically review the effectiveness of the overall arrangements and the changes that have been implemented.

Principle 1

A licensee's management of change 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.

- 5.13. 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.
- 5.14. These arrangements, which may be approved by the ONR, 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. They should set out the roles and responsibilities for managing changes with clearly assigned responsibilities for originating, peer review, approval, monitoring and close-out of individual changes.
- 5.15. 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 nuclear baseline. This may, for example, include the impact on the licensee of proposed actions or decisions made by 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.
- 5.16. 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. 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.
- 5.17. The arrangements should allow for contingent use of the management of change process where appropriate. Examples of when this might be necessary include long-term absences

and long-standing vacancies. The default assumption should be that all posts and changes have the potential to affect safety management unless it can be demonstrated otherwise.

- 5.18. Proposed changes should be assessed using a consistent methodology. The methodology should be applied to all proposed changes in order 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 4 and 5.
- 5.19. Staff involved in ensuring or assuring the quality of management of change proposals should be suitably qualified and experienced (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 management of change assessment cannot be over emphasised as staff experienced in the management of change process can apply that experience and judgement to avoid the potential pitfalls that less experienced staff may not be aware of.
- 5.20. Managers 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 on the basis of seniority.
- 5.21. The arrangements should ensure that individual change proposals are clearly identified and that details of the change i.e. 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'.
- 5.22. 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.
- 5.23. 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 NSC (or identified equivalent status body where appropriate), and senior management oversight of the effectiveness of the process and implementation of individual changes.
- 5.24. The licensee's arrangements should require approval to be formally granted by a SQEP person 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.
- 5.25. The effectiveness of implementation of the arrangements should be routinely monitored and reviewed as part of the licensee's normal assurance processes.

- 5.26. The Inspector should consider whether or not :
 - The licensee has formal, documented management of change arrangements which are an integral part of its management system;

- It is clear that the arrangements apply to all aspects of the licensee's activities 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 management of change arrangements are clearly defined, integrated with the management system and understood by staff with management of change process roles;
- SQEP requirements for staff fulfilling key roles within the arrangements are clearly defined;
- Staff fulfilling key management of change 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 2

The Board of the licensee should own and support the management of change arrangements and ensure that they are embedded throughout the organisation.

- 5.27. A licensee's management of change arrangements should be peer reviewed and implemented consistently and effectively, and a visible commitment to these arrangements should be made by the licensee Board. The Board should be able to show that it actively uses the MOC arrangements and supports the management of change process by regularly reinforcing to the workforce the importance of having and following a robust change process.
- 5.28. The Board should ensure that SQEP resources are put in place to develop the management of change 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 Nuclear Safety Committee or identified equivalent status body where appropriate.
- 5.29. The management of change arrangements should apply throughout the company, up to and including the Board itself, noting that strategic and complex changes to the structure or staff composition of a business may often originate at Board level.
- 5.30. Progress with, and the effectiveness of, the implementation of significant, complex changes should be regularly monitored by the Board. The Board should establish an oversight process for this purpose as appropriate. An oversight process will be of particular importance where a proposed change is wide-ranging and complex.
- 5.31. It is expected that the licensee Board will proactively discuss significant, 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.

- 5.32. The Board should satisfy itself that management of change 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.
- 5.33. The Inspector should consider whether or not:
- The Board and Executive are able to demonstrate their commitment to effective management of organisational change;
 - The Board has regularly satisfied itself that the management of change 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 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 is aware of the need to discuss more significant, 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 regularly seeks assurance that implementation of more significant 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 3

A licensee's management of change arrangements should reference the nuclear baseline and include a process for updating it on a regular basis.

- 5.34. A licensee should have a nuclear baseline 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.
- 5.35. The nuclear baseline 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.
- 5.36. The baseline should be updated as changes are made to the organisational structure and resources, and periodically reviewed to consolidate changes.
- 5.37. Ideally, the nuclear baseline should be owned by the licensee's human resource function as an integral part of the licensee's resourcing processes.
- 5.38. The Inspector should consider whether or not:

- The baseline is up to date and reflective of the licensee's current organisation;
- Management of change assessments include a reference to the nuclear baseline and identify whether or not the proposed changes affect baseline roles;
- The nuclear baseline is regularly reviewed to ensure that it is up to date and incorporates changes affecting baseline roles;
- The management of change arrangements take account of the cumulative effects of low category changes on the nuclear baseline;
- The management of change 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 management of change assessments have been closed and, if not, that unresolved actions are being managed.

Principle 4

A licensee's management of change 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 and justification.

- 5.39. 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 proposed change and the process of transition.
- 5.40. The licensee's management of change 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 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. The screening assessment should be formally recorded in a management of change register once internal licensee approval to further develop the proposal has been gained.
- 5.41. 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.
- 5.42. 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 addressing change proposals of progressively less significance. Broad guidance on classification of organisational changes is given in Appendix 3 for illustrative purposes, and there is guidance in the NiCoP.
- 5.43. The licensee's arrangements should make appropriate provision for engaging ONR. ONR expects:

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- 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 usually at least 28-30 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 management of change 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.
- 5.44. Where an *agreement*, in accordance with the licensee's own arrangements, is needed from ONR to permission a proposed change to proceed, the Inspector should arrange for the proposed 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.
- 5.45. Application of the classification methodology and implementation of management of change 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'.
- 5.46. 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.
- 5.47. The Inspector should consider whether or not:
- 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 screening 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, if so, that the checker SQEP to fulfil this role;
- 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 and include a *derived power* which will allow ONR to provide formal *agreement* to change proposals as set out in the bullet points in paragraph 5.43;
- The licensee's arrangements encourage authors of change proposals to make provision for timely engagement with ONR.

Principle 5

The licensee should assess and justify the safety of a proposed change, commensurate with its potential impact on safety, and monitor its implementation.

- 5.48. Changes which are identified via the initial screening assessment as falling into categories 1, 2 and 3, as illustrated in Appendix 3, 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.
- 5.49. Changes assessed as having a significant potential impact on nuclear safety i.e. Categories 1, 2 should be subject to a more detailed risk assessment which is documented as part of the justification for the change. The risk assessment should be proportionate to the nuclear safety significance 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 final 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).
- 5.50. 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.
- 5.51. The risk assessment for a large, 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.

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- 5.52. In such instances, the licensee should produce an umbrella or 'overarching' management of change 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 management of change should reference the risks related to specific elements, but should also take a broader cross-cutting perspective.
- 5.53. ONR expects the licensee to put in place suitable processes for endorsing change proposals. Usually, Category 3 and 4 changes may be endorsed by the originator or local process owner. However, Category 1 and 2 changes 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.
- 5.54. As noted in Principle 3, justification documents for Category 1 and 2 arrangements may need to be reviewed and endorsed by a Nuclear Safety Committee or an equivalent body in accordance with the licensee's arrangements.
- 5.55. The factors identified in the risk assessment should, following endorsement, be addressed in an implementation plan. The implementation plan should show how the 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 that enabling actions have been completed and to confirm that the change may proceed.
- 5.56. 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.
- 5.57. 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.
- 5.58. The implementation plan should also include indicators that 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 look at factors such as reduction in accident rates.
- 5.59. Significant changes i.e. those identified as Category 1 or 2 in Appendix 3, should be monitored by the Board, using indicators and any other appropriate measures, to confirm that changes are proceeding satisfactorily, that there is no detriment to nuclear safety and that any offsite implications are being correctly managed. In the event that a change is not proceeding satisfactorily the Board 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 that the objectives of the change have been satisfactorily achieved.

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- 5.60. Where possible, the implementation plan should reflect potential contingency actions that may be required in the event that 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.
- 5.61. Under LC36 (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.
- 5.62. The Inspector should consider whether or not:
- Assessments of proposed changes are proportionate to the significance and category of the change;
 - Assessments have been carried out by competent persons and if they 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’ management of change 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 person;
 - 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 2 changes are relevant and if they satisfactorily address the identified risks;
 - The licensee’s senior management and the Nuclear Safety Committee have been involved in considering the implications a Category 1 change the prior to implementation;
 - Arrangements are in place in the licensee organisation to monitor Category 1 and 2 changes and, in the event that a change is not proceeding satisfactorily, to initiate remedial action;
 - Suitable qualitative or quantitative indicators been developed for significant changes and if they 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 management of change arrangements.

Principle 6

The licensee should periodically review the effectiveness of the overall arrangements and the changes that have been implemented.

- 5.63. The licensee should be encouraged to capture the learning gained from applying its management of change process, especially to larger and more complex changes. This should be reflected, where appropriate, in changed arrangements e.g. training. The arrangements themselves should be subject to periodic review to confirm that they are working satisfactorily and to identify process improvements. 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.
- 5.64. It is important that the senior management are engaged in the review process to demonstrate leadership and commitment to the management of change arrangements. The effectiveness of the arrangements, and the totality of changes and their impact on the organisation, should be regularly reviewed by them to ensure that the arrangements are working satisfactorily and that the organisation is not being degraded as a result of a succession of changes.
- 5.65. The Inspector should consider whether or not:
- The arrangements provide for the Board to monitor the effectiveness of implementation of more significant changes;
 - There a formal review process to confirm that the management of change arrangements are operating satisfactorily;
 - Senior management are engaged in the review process and how is their leadership and commitment demonstrated to the workforce;
 - The review process involves persons other than those with a management of change 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 the organisation have been considered by senior management and if there any evidence of action being taken to avoid the potential degradation of the licensee organisation.

6. APPENDICES

APPENDIX 1: LICENCE CONDITION 36 'ORGANISATIONAL CAPABILITY'

6.1. Licence Condition 36 requires that:

- The licensee shall provide and maintain adequate financial and human resources to ensure the safe operation of the licensed site.

- 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.
- The licensee shall submit to the Executive for *approval* such part or parts of the aforesaid arrangements as the Executive may *specify*.
- The licensee shall ensure that once approved no alteration or amendment is made to the approved arrangements unless the Executive has *approved* such alteration or amendment.
- 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 Executive.
- The licensee shall if so *directed* by the Executive halt the change to its organisational structure or resources and the licensee shall not recommence such change without the *consent* of the Executive.

APPENDIX 2: EXAMPLES OF DRIVERS FOR ORGANISATIONAL CHANGE

- 6.2. This Annex 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.** This may 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 are insufficient competent staffs 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.
 - **Organisational restructuring and change initiatives.** This may result in competent staff being diverted to restructuring/change projects.
 - **Downgrading the Head of Safety** 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 at Board level.
 - **Relocation of offices.** This may result in the loss of key staff and expertise in critical areas.
 - **Changes in policies for recruitment and training of staff.** This may result in vacancies not being filled, recruitment of poor quality staff, and degradation of the competence of individuals and the organisation as a whole.

APPENDIX 3 : BROAD GUIDANCE ON CLASSIFICATION OF ORGANISATIONAL CHANGES

- 6.3. 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.
 - 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.
 - Changes that mainly affect a single management layer.
 - 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.

APPENDIX 4: GUIDANCE FOR INSPECTORS ON THE FACTORS THAT MAY BE CONSIDERED WHEN INSPECTING THE LICENSEE'S IMPLEMENTATION OF ITS MANAGEMENT OF CHANGE ARRANGEMENTS

6.4. 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). In order to promote a consistent regulatory approach, this Appendix incorporates guidance previously included within the inspection guidance T/INS/036. This Appendix complements the more detailed guidance in the main body of this TAG and reference to that material should be made where appropriate.

Management of change arrangements

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

- The importance of management of change arrangements as an integral part of business strategy implementation, nuclear safety and resource management;
- The need for the Board 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;
- Their role in ensuring that the implications of significant and complex changes are fully assessed prior to implementation;
- Their 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 management of change arrangements are up to date and are being consistently applied across the entirety of the licensee organisation;
- The importance of having SQEP staff in key management of change roles.

6.6. 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.

6.7. 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 taking action as appropriate.

6.8. 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.
- 6.9. Confirm that the arrangements are being adhered to by discussion with staff at various levels throughout the licensee's organisation.
- 6.10. 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.
- 6.11. Check the licensee's implementation of its review and audit processes and examine:
- Periodic review and update of the nuclear baseline;
 - 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.
- 6.12. Check the licensee's communication arrangements to confirm whether or not the workforce understands the implications of significant changes and is kept informed of implementation progress.
- Check that arrangements exist to periodically update the nuclear baseline and that the baseline is up to date and reflective of the licensee organisation.

Implementation of change proposals

- 6.13. 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.
- 6.14. 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 28 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 nuclear baseline;
 - 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 person SQEP to fulfil that role.
- 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 person SQEP to fulfil that role.
- 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.

APPENDIX 5: 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**

- 6.15. The purpose of this Annex is to support a proportionate and consistent regulatory approach to ONR inspection and assessment against the financial resources aspect of LC 36 (1) 'Organisational Capability'.

Background

- 6.16. Article 6(5) of the Nuclear Safety Directive 2009/71/Euratom requires member states to ensure that licensees are required to provide and maintain adequate financial and human resources to fulfil their obligations in respect of nuclear safety. In order to ensure that this requirement was fully transposed in Great Britain, LC 36 was changed in July 2011 to introduce a revised LC 36(1) which requires licensees to provide and maintain adequate financial and human resources to ensure the safe operation of the licensed site.
- 6.17. ONR consulted with all nuclear site licence holders on this amendment (and a proposed modification to LC 17) and conducted an impact assessment. ONR also published a supporting note¹ advising that ONR considered licensees would already comply with the requirement to provide and maintain adequate *human resources*, by virtue of their Nuclear Baseline. The note also stated that: "On a day-to-day basis, compliance with legal duties to ensure an appropriate level of nuclear safety is likely to be sufficient evidence of compliance with the licence condition regarding the licensee's *existing* financial resources". With regard to the requirement to *maintain* adequate financial 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 Nuclear Baseline 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 arrangementsRegulatory Approach

- 6.18. 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.

- 6.19. 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 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 nuclear baseline 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.
- 6.20. Where the licensee's budget is controlled by another body (for example, the NDA or a parent organisation), financial (and other resourcing) arrangements are likely to be set out in contractual arrangements 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 meet its obligations under HSWA Section 3(1). The licensee, however, retains an absolute responsibility for nuclear safety.

Accessing external expert advice

- 6.21. Should a forensic accountancy service be needed it will be provided under a Government Buying Solutions Framework (RM662/L12 - Management Consultancy and Accounting Services - Accounting Advice and Services) which covers Forensic Accounting Services.

DECC assurances regarding a licensee's financial standing

- 6.22. ONR will approach the Department for Energy and Climate Change (DECC) at the time of processing a licence application, or responding to a request for relicensing, to seek DECC's assurances regarding the applicant's financial status. ONR may, on rare occasions when it deems it relevant, also seek such assurances from DECC to inform ONR's approach set out in paragraphs 6.18 to 6.20 above. DECC 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. Subsequent to the granting of a licence, the approach set out in paragraphs 6.18 to 6.20 above will be followed.