

NUCLEAR SAFETY DIRECTORATE - BUSINESS MANAGEMENT SYSTEM		
TECHNICAL ASSESSMENT GUIDE LICENCE CONDITION 36 ARRANGEMENTS		T/AST/048
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1. Purpose and Scope

1.1 This document provides guidance to inspectors on judging the adequacy of licensee's arrangements to control any change to its organisational structure or resources which may affect safety - made to satisfy the requirements of licence condition 36 (LC36) (**Appendix 1**). Its purpose is to advise and inform NSD inspectors in the exercise of their professional regulatory judgement. Comments on this guide, and suggestions for future revisions, should be recorded on a Process Improvement Feedback Form (PIFF1) in accordance with DBP 003.

1.2 Particularly important to NII's regulation is the transparency of the processes. In order that a licensee can demonstrate its consideration of safety in relation to proposals for change, its arrangements should apply to all changes to organisation, structure and resources. Judgement as to whether the change will affect safety should be part

of the Licensee's process for managing change.

1.3 NII has a regulatory interest in all changes to a licensee's organisational structure and resources which may:

- 1) affect safety, whether detrimentally or beneficially ;
- 2) affect the licensee's ability to comply with the NI Act and licence conditions;
- 3) alter the basis on which the nuclear site licence was granted; or
- 4) which otherwise affect the organisation and the way in which it works.

1.4 Licence condition 36(1) requires a licensee to "make and implement adequate arrangements to control any change to its organisational structure and resources which may affect safety" on the site. For the purposes of devising adequate arrangements to meet the requirements of LC 36 however NII will concentrate on organisational structures, staffing levels and ways of working that ensure safe operation and licence compliance, including the retention and use by a licensee of an adequate range and depth of technical competence.

1.5 It is important that Inspectors note that licensee's arrangements made under LC36 should not be restricted to a procedure for dealing with individual changes. Arrangements should comprise a complete quality management system for managing change. Thus it should have all the attributes of a quality management system including: policy, organising, planning, monitoring, auditing and review.

1.6 In the context of LC36, "change ... which may affect safety" means changes which could affect the licensee's ability to ensure the safety of its workers and the public and includes changes which could affect its ability to comply with legal safety duties of licensees. It is not restricted solely to the duties imposed by licence conditions but covers all safety legislation and also includes changes at the corporate centre which may affect licensed sites.

2. SAPs addressed

2.1 Principles 316 and 328 relate to the identification of the duties of personnel, the delegation of responsibilities and the specification of

minimum staffing levels.

3. Relationship to licence and other relevant legislation

3.1 Licence condition 36 came fully into force on 1 April 2000, **Appendix 1** gives the text.

4. Advice to assessors

4.1 Licensee's provision for NII's regulatory control

1) Policy

A Licensee's arrangements should facilitate NII's regulatory control.

2) Guidance

A Licensee's arrangements should facilitate NII's regulatory control by:

i) having a hierarchical structure, one part of which arrangements is suitable for submission for approval under LC36(2);

ii) having a change register(s) which lists all changes and their classification in which entries are made in good time to provide for NII's regulatory intervention (normally allowing at least 28 days prior to implementing change);

iii) facilitating requests from NII for details of a change, for its assessment;

iv) requiring the provision to NII of details of all highest significance category changes for NII's agreement, after the proposal has been approved within the licensee's process;

v) If the licensee's arrangements allow for extensive changes to be divided into stages for implementation, the arrangements should also allow for NII to determine which stages, if any, require its prior agreement.

4.2 Licensee's policy for management of change arrangements under LC36

1) Policy

A licensee will have and apply a clear policy for dealing with the safety aspects of controlling, implementing, monitoring and reviewing any change to its organisational structure and resources.

The licensee's management of change process will, as part of its quality assurance system, be subject to the normal process of independent audits and reviews operated by the licensee.

4.3 Licensee's baseline organisational structure

The starting point for the control of changes to organisational structures or resources related to safety will be the output of a systematic process by which the licensee determines the requisite size and structure of its organisation. This "baseline" statement will provide a yardstick against which future organisational change can be judged. The baseline should not be based on an unsubstantiated assertion that the existing resource or structure is adequate.

1) Policy

A licensee will have documentation to describe and justify its organisation, e.g. based on existing QA high level documentation or a management prospectus prepared for licensing.

2) Guidance

A licensee will have a process systematically to establish and maintain its baseline. A range of different techniques are available to licensees to develop a baseline and the depth of the process can vary. Licensees should adopt appropriate regimes of analysis for different parts of their baseline depending on the importance to safety. Licensees should also show how they intend to improve the rigor of the baseline analysis with experience.

The acceptance of an initial baseline provided by a licensee will not indicate that NII is content either with the methodology used or with the adequacy of the levels or configuration of resource used.

The process by which the baseline is determined by the licensee will include:

i) a focus on how, through its organisational structure and staff resources, the licensee assures the safety of the installation on the licensed site taking account, where relevant, of support from elsewhere;

ii) taking account of the legal requirement for the licensee to be the user of the site in day-to-day control of activities through its own direct employees and hence the need to retain sufficient in-house technical resource to enable the licensee to make safety-related decisions;

iii) no presumption that the pre-existing organisational structure is “adequate”;

iv) a substantiation by the licensee of the right size and structure of its organisation to meet its current and future business needs (which will include satisfying the requirements of the NI Act, compliance with nuclear site licence conditions and other health and safety legislation);

v) an investigation, in appropriate circumstances through the use, for example, of task analysis, post profiling, training profiles, etc., to ensure that the licensee has a sufficient number of people with the right skills in the right place at the right time to meet its current and future business objectives (identifying the work loading of each job not solely the safety aspects);

vi) safety-related tasks being included in the total range of roles and responsibilities for posts to show that safety related needs are not compromised by business needs;

vii) the identification of the appropriate skills to meet business needs that address the range of competences which need to be maintained and identify the licensee’s long

term recruitment, training and succession planning requirements;

viii) the use of contractors and other similar resources in support of the licensee's business;

ix) consideration of the requirements on the licensee to retain adequate technical, managerial and supervisory skills and to act as an intelligent customer for obtaining work and safety proposals from such contractors;

x) bench-marking with a range of external organisations to identify best practice in workforce planning processes and systems, involving external consultants or internal specialists as appropriate.

The substantiation of organisational requirements will need to be maintained as a living document updated as changes (increase or decrease) are made to the organisational structure and/or resources. It is anticipated that a major review of the zero-base statement will be needed from time to time, e.g. for a new licence, a periodic safety review, a major change in the phase of operation (such as entering the decommissioning phase) or when it is judged that the accumulation of changes warrants a review.

4.4 Licensee's definition of the scope of its arrangements

1) Policy

A licensee's arrangements will include a definition of the types of organisational or resource change to which its arrangements are to be applied.

2) Guidance

The scope of a licensee's arrangements should include changes which are intended to improve safety not just those with the potential to reduce it. The scope should involve:

i) The consideration of all changes in order to make, and record, an early judgement of

safety impact (rather than omitting changes “with no safety” impact” without formal consideration).

ii) organisational and staffing changes at both the site and the corporate centre, including changes within other organisations upon whose support the licensee relies for compliance with licence conditions and other safety legislation;

iii) staffing changes, whether planned or not, including those which may result in a loss of corporate knowledge or memory;

iv) changes in the level of other resources which, although not apparently directly related to the safety of the plant on the site, may affect the ability of those with safety related responsibilities to continue to undertake their tasks;

v) changes in the pattern of deployment of existing staff resources;

The following are changes to resources. Inspectors should concentrate in the first instance on the above changes to organisational structure and staffing unless there is significant cause for concern relating to changes in the deployment of resources:

i) changes to the level of safety related research activity and funding;

ii) changes in financial support for the development of safety related analytical tools or involvement in safety related collaborative work; and

iii) changes in the availability, and control by the licensee’s Board, of financial resources for safety related work and decommissioning.

4.5 Licensee’s classification of changes

Classification is necessary: firstly, to facilitate the application of the management process by which the effects of proposed changes are considered and sanctioned at an appropriate level for implementation; and secondly, to provide for regulatory intervention by NII, particularly in the case of changes which have the greatest potential impact on safety

1) Policy

The licensee's arrangements will provide for the classification, by the licensee, of a change according to its safety significance.

2) Guidance

To assist the regulatory interface, the top category should be defined in licensees' arrangements in a way which limits the changes to those small number which constitute wholesale organisational change or which potentially challenge the basis upon which the licence was granted (see **Appendix 2** for examples). A licensee's system of classification will:

i) provide for classification of organisational structure or resource changes in accordance with the potential impact of the change on the safety of the nuclear installation and the licensee's ability to continue to comply with licensing requirements, whether that change is occurring on the site, corporately or in an interfacing organisation;

ii) ensure that the impact of a change takes cognisance of both long term and short term effects and consider the implications of a change being inadequately conceived or implemented;

iii) provide for a classification system related to hazard arising from inadequate conception or implementation which could, for example, be on a 4 point scale such as 'major', 'substantial', 'minor', and 'trivial';

iv) ensure that, in the application of the classification system and in the implementation of the change process, a

major change cannot be reduced to a number of smaller, lower category changes, i. e. the arrangements do not allow 'salami slicing';

v) similarly ensure that the overall effects of a number of low category changes are not compounded to produce a change of greater significance;

vi) provide a classification process which ensures that, for borderline cases and instances of doubt, the higher category is applied;

vii) provide a process whereby the classification of each change, the application of the classification process and the decision on safety significance is documented and reviewed independently of the line management chain responsible for the change, with the degree of independence of the review proportionate to the safety significance.

4.6 Licensee's planning for and making changes

1) Policy

A licensee will have, and adequately execute, a process to identify, evaluate, plan, review, and sanction for implementation, all organisational structure or resource changes within scope.

2) Guidance

The process for the implementation of changes to organisational structure or resources will:

i) ensure a consistent approach to the assessment of the safety implications of a proposed change and, where it is confirmed that a change can be made, to provide a written substantiation which is capable of audit and review;

ii) be applied to every change irrespective of its classification in terms of the potential impact on safety, allowing for a safety significance analysis to determine the degree of decision-making detail that needs to be documented;

iii) set out the roles and responsibilities for carrying out the process, with clearly assigned duties for originating proposals, for peer review and management approval, and for seeking advice from the NSC or identified equivalent status body (where appropriate);

iv) if licensees' arrangements allow for extensive changes to be divided into stages for implementation, they should allow for NII to determine which stages, if any, require its prior agreement;

v) give rise to a detailed implementation plan with timescales, prerequisites and contingency plans and, where appropriate, allow for shadow working to confirm planned arrangements;

vi) ensure that all enablers and prerequisites are met before a change can be sanctioned for implementation, e.g. reduction in workload, training and etc.;

vii) direct attention to, and deal with, the knock-on effect of the proposed change on other procedures, instructions and management processes within the licensee's organisation;

viii) address the implications of the proposed change for staff capabilities and working practices, e.g. increased travel, higher workloads and communications;

ix) review further the implications of a change which results in a single person in a

particular technical expertise;

x) require an independent review process at each stage of the implementation plan to monitor through the use of appropriate indicators, for example, the meeting of prerequisites and the operation of countermeasures and contingency plans;

xi) 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 carried out; the extent of reversibility being related to the criticality of the change and the availability of effective countermeasures;

xii) accommodate employee consultation;

xiii) identify the responsibilities and procedure for demonstrating compliance with LC36 requirements;

xiv) provide for the identification and maintenance of adequate records at each stage of decision-making;

xv) having a change register(s) which lists all changes and their classification in which entries are made in good time to provide for NII's regulatory intervention (normally allowing at least 28 days prior to implementing change).

The licensee will need to devise and implement training requirements for those with a role in the application of the management of change process.

4.7 Licensee's transparency

1) Policy

A licensee's management of change system will be part of its Quality

Assurance arrangements.

2) Guidance

The transparency that results will be important, amongst other things, in enabling NSD's regulatory response. It is also a necessary component of licensees' analysis (e.g. annually) of the changes taken as a whole. The transparency of a licensee's management of change process will be provided by its Quality Assurance arrangements and the records therein and be a feature of:

- i) the change register for all changes whatever the classification;
- ii) licensee's arrangements for producing, maintaining, reviewing and updating the baseline;
- iii) a licensee's classification system and an input to its regular review;
- iv) the implementation process;
- v) the review and audit process.

4.8 Licensee's review

1) Policy

A licensee's management of change system will include review and audit processes through its Quality Assurance arrangements.

2) Guidance

In addition to the internal review of the change process a licensee will adopt a performance monitoring procedure which will:

- i) provide for the establishment of realistic and relevant performance measures and indicators to:
 - a) provide feedback on the underlying assumptions leading to the decision to implement a

change; and

b) assess the impact of a number of changes in a business area;

ii) establish not only that the procedures are being followed but that the arrangements are adequate to meet its policy aims;

iii) allow for periodic review of zero-base and, in appropriate cases, comparison against former structures and resource levels and bench-marking with external organisations.

Appendix 1. Text of Licence Condition 36

LICENCE CONDITION 36: CONTROL OF ORGANISATIONAL CHANGE

(1) The licensee shall make and implement adequate arrangements to control any change to its organisational structure or resources which may affect safety.

(2) The licensee shall submit to the Executive for approval such part or parts of the aforesaid arrangements as the Executive may specify.

(3) 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.

(4) 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.

(5) 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 recent changes or proposals which might be classified in a licensee's top category

A2.1 It is felt that the provision of examples will aid in guidance. NII's view is that the following examples, from recent proposals or changes made by licensees, should be classified as "major" (or in the top category):

- 1) outsourcing all technical support to a divested engineering agency;
- 2) wholesale restructuring a company e.g. demerger prior to privatisation;
- 3) taking on contractors in managerial roles so as to challenge who is the "user" of the site;
- 4) Vision 2000 in BE;
- 5) downgrading the head of safety in a company so that he/she is no longer a director;
- 6) the acquisition of another company by a licensee and the placement of that company to operate and control activities on one of its sites.