

NUCLEAR SAFETY DIRECTORATE - BUSINESS MANAGEMENT SYSTEM

SITE INSPECTION AND ENFORCEMENT
GUIDANCE: LC 17 QUALITY ASSURANCE

T/INS/017

ISSUE 001

Approved By: *P Gardner*

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1. Purpose & Scope

1.1 The purpose of this guidance is to facilitate a consistent approach to LC 17 compliance inspection and to provide assistance to inspectors while carrying out their duties in this area.

1.2 The guidance does not indicate when or to what extent these compliance inspections should be made as these matters are covered in individual inspectors inspection programmes.

1.3 The guidance provided is split into four main elements:

- 1) Purpose of the Licence Condition
- 2) Guidance on arrangements for LC 17.
- 3) Guidance on inspection of arrangements.
- 4) Guidance on inspection of implementation of arrangements.

2. Licence Condition

2.1 LICENCE CONDITION 17 - QUALITY ASSURANCE

17(1) Without prejudice to any other requirements of the conditions attached to this licence the licensee shall make and implement adequate quality assurance arrangements in respect of all matters which may affect safety.

17(2) The licensee shall submit to the Executive for approval such part or parts of the aforesaid arrangements as the Executive may specify.

17(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.

17(4) The licensee shall furnish to the Executive such copies of records or documents made in connection with the aforesaid arrangements as the Executive may specify.

3. Purpose of Licence Condition

3.1 The purpose of this condition is to require the licensee to set out the managerial and procedural arrangements that will be used to initiate, control and monitor those actions which may affect safety. This will include all procedures and arrangements made by the licensee to comply with all conditions.

4. Guidance on arrangements for LC 17.

4.1 The following list of elements provide NSD's views on what the Licensee's arrangements should include to meet both the requirements of the LC and well recognised standards. The list is not exhaustive and will be subject to review and revision. If licensees have generic model(s) for arrangements then it is for the site, or plant, to justify any deviation from the model(s). **[note: not all licensees use generic models].**

4.2 Arrangements should be provided to comply with LC 17. LC 17 is one of the LCs which requires arrangements to be made and implemented.

4.3 Arrangements should address the licence condition requirements. (i.e. They should facilitate regulation via the LC).

4.4 The arrangements should enable the licensee to respond to any Specification from the Executive. Such arrangements should identify the person responsible for responding to the Specification and they should identify the system whereby constraints, caveats or conditions imposed by the Executive are implemented.

4.5 The arrangements should ensure that arrangements approved under this licence condition by the Executive can only be changed or amended with the Approval of the Executive. The person(s) responsible for ensuring compliance with this requirement should be identified in the arrangements

4.6 The Quality Assurance system should:-

- 1) cover all stages of the lifecycle of a facility.
- 2) be defined in a single document, or a suite of clearly linked documents. The system, or arrangements, are typically organised in a three-tier system.
- 3) describe the management structure with corresponding organisational responsibilities, and identify specific senior management responsible for design, implementation, monitoring, update etc. Of the quality system.
- 4) include Quality Control and inspection activities.
- 5) provide a framework which clearly identifies the arrangements made under all Licence Conditions.
- 6) identify the required level of performance.
- 7) specify the method of preparation and control of documentation such that the requirements of each safety related task are fully specified.
- 8) describe processes for the inspection, review and audit of activities, material and arrangements.
- 9) detail the manner in which non-conformances are identified and corrective and preventative actions taken.
- 10) specify the methods employed to procure items and services to the appropriate level of quality.
- 11) reflect best national and international practice based on appropriate standards, codes and guides.

5. Guidance on inspection of arrangements

5.1 Part 5 of this guidance is to assist inspectors in judging the adequacy of the licensees arrangements. It is not exhaustive and will be subject to review and revision in light of experience. It does however, list aspects of LC 17 that can be

examined during routine inspections.

5.2 Review of Quality Assurance arrangements is normally carried out under NSD's assessment function. Site inspectors will be more involved in the monitoring of the effectiveness of the implementation of top tier and lower tier arrangements, particularly as these relate to all other Licence Conditions.

5.3 Check that QA arrangements are comprehensive and cover all safety related activities performed on the licensed site. It must be noted that licensees may choose to have a single management system which covers safety, quality and environmental aspects. Some licensees may wish to have separate systems. Licensees may operate "paperless" systems utilising Information Technology. Irrespective of this, there should be a clear link from top tier documents through to working level documentation.

5.4 Check that QA arrangements are comprehensive and include reference to the arrangements made for all licence conditions.

5.5 Check that the QA arrangements provide a clear link between top tier policies and lower tier implementation documentation (e.g. Work Instructions).

5.6 Check that the QA arrangements have been authorised at an appropriate level (usually senior management) and that responsibilities have been delegated accordingly. These arrangements should be mandatory on all staff.

5.7 Check that the QA function within the licensee's organisation is sufficiently independent of other business functions that may result in a conflict of interests.

5.8 Check that the licensees implement Quality Control arrangements for procurement and project applications. This normally takes the form of a Quality Plan and inspection schedule.

5.9 Ensure that QA arrangements are based on best national and international practice based on IAEA 50-C-Q Code and associated Guides and ISO 9001:2000. BS 5882 has been withdrawn and any reference to it in the Quality Management System should be removed. ISO 9001 series is the code normally used for such activities as procurement whilst nuclear operations throughout the life-cycle, including fuel, are covered by IAEA 50-C-Q. It should be checked that the appropriate code is being used for the specific process/ operation being looked at.

5.10 Check the extent of the involvement of the corporate centre for quality

(where applicable) in the development of policies and its role in independent audit and review.

5.11 Check that the QA arrangements include procedures for internal audit of the safety related activities and that there is a formal Management Review carried out periodically.

5.12 Check that the QA arrangements enable the timely and effective identification of non-compliances against procedures and specifications and that there are methods in place to rectify these and prevent recurrence.

5.13 Check that the QA arrangements provide for the preparation and use of documents for all systems and processes and which of those documents are defined as records.

5.14 Check that the QA arrangements ensure that acceptable standards of work are defined and in the case of plant items acceptance and/or reject criteria are clearly specified.

6. Guidance on inspection of implementation of arrangements

6.1 Part 6 of this guidance is to assist inspectors in judging the adequacy of the Licensee's implementation of their arrangements i.e. is the licensee doing what their arrangements say they should be. The following list is not exhaustive and will be subject to review and revision. It provide lists of aspects of LC 17 that can be examined during routine inspections.

6.2 Check that the organisational structure and levels of authority are as detailed as in the documentation.

6.3 Check the level of competency of QA and QC resource on site.

6.4 Check the level of QA an QC support from the centre

6.5 Check the adherence to the internal audit schedule and in particular the timeliness and appropriateness of close-out of corrective actions.

6.6 Check the licence compliance matrix document to ensure that there is a comprehensive and logical system for referencing down to lower tier documents.

6.7 Where applicable, check that the site documentation structure is consistent with the corporate model.

6.8 For site sponsored projects check that Quality Plans exist and that these identify the procedures, instructions and levels of inspection, including second and third party. i.e. Those undertakings by licensees on their suppliers and those undertakings by independent services on their suppliers respectively.

6.9 Check the level of use and control of contractors and ensure that these have QA systems compatible with those of the licensee. Check particularly any interfaces where a multi-contractor project is undertaken.

6.10 Check that the documentation centre is working effectively in that users have appropriate issues of documents, drawings and specifications.

6.11 Check the level of independent auditing and the effect of any corrective actions.

6.12 Check that management periodically review the QA system and update and upgrade as appropriate, particularly to reflect external changes and pressures.

6.13 Check that records are being compiled in line with the site record schedules.

7. Other Sources of Information

7.1 For sites that have achieved third party certification to a particular QA standard (e.g. ISO 9001:2000) the site inspector could discuss with the third party accreditation body aspects of the licensee's performance.

7.2 HSG65 : Successful Health & Safety Management provides a useful model which has been used by some licensees to structure some elements of their Quality Management System. Reference to this HSE document may be useful. (See also Managing for Safety at Nuclear Installations - an HMNII publication.)