

LC20: Modification to Design of Plant Under Construction			
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Table of Contents

1. Introduction	2
2. Purpose and Scope	2
3. Licence Condition 20: Modification to Design of Plant Under Construction	3
4. Purpose of Licence Condition 20	4
5. Guidance on Arrangements for LC20	5
6. Guidance on Inspection of Arrangements for LC20	6
7. Guidance on Inspection of Implementation of LC20 Arrangements	11
8. Safeguards Requirements	13
9. Further Reading	13
10. References	14

1. Introduction

- 1.1. Many of the licence conditions attached to the standard nuclear site licence require, or imply, that licensees should make arrangements to comply with regulatory obligations under the conditions. ONR inspects compliance with licence conditions, and also with the arrangements made under them, to judge the suitability of the arrangements made and the adequacy of their implementation. Most of the standard licence conditions are goal setting, and do not prescribe in detail what the licensees' arrangements should contain; this is the responsibility of the duty-holder who remains responsible for safety. To support inspectors undertaking compliance inspection, ONR produces a suite of guides to assist inspectors to make regulatory judgements and decisions in relation to the adequacy of compliance, and the safety of activities on the site. This technical inspection guide (TIG) is one of the suite of documents provided by ONR for this purpose.

2. Purpose and Scope

- 2.1. The purpose of this guidance is to facilitate a consistent approach to LC20 compliance inspection and to provide assistance to inspectors while carrying out their duties in this area. The guidance should not be regarded as mandatory. Although every attempt has been made to deal with all the key features that are likely to arise in inspecting for compliance with this licence condition, additional aspects may need to be examined to ensure a comprehensive and complete inspection.
- 2.2. 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.
- 2.3. The guidance provided is split into four main elements:
- a) Purpose of the Licence Condition.
 - b) Guidance on arrangements for LC20.
 - c) Guidance on inspection of arrangements.
 - d) Guidance on inspection of implementation of arrangements.

3. Licence Condition 20: Modification to Design of Plant Under Construction

20(1) The licensee shall ensure that no modification to the design which may affect safety is made to any plant during the period of construction except in accordance with adequate arrangements made and implemented by the licensee for that purpose.

20(2) The licensee shall submit to ONR for approval such part or parts of the aforesaid arrangements as ONR may specify.

20(3) The licensee shall ensure that once approved no alteration or amendment is made to the approved arrangements unless ONR has approved such alteration or amendment.

20(4) The aforesaid arrangements shall provide for the classification of modifications according to their safety significance. The arrangements shall where appropriate divide modifications into stages. Where ONR so specifies the licensee shall not commence nor thereafter proceed from one stage to the next of the modification without the consent of the ONR. The arrangements shall include a requirement for the provision of adequate documentation to justify the safety of the proposed modification and shall, where appropriate, provide for the submission of this documentation to ONR.

4. Purpose of Licence Condition 20

- 4.1. This Licence Condition is part of the group of conditions (LCs 19 - 22 & 35) designed to provide a system of rigorous and appropriate regulatory control of changes to plant or processes on the licensed site. These changes may be brought about by construction, modification or commissioning of new plant, commissioning, modification or experiment on existing plant including any change of process, and decommissioning. The purpose of this Condition is to control the modification to design of plant under construction. The term modification is defined in Licence Condition 1(1). The application of this particular Condition is limited to modifications to plant under construction and is intended to ensure proper consideration of the safety implications before the modifications are implemented.
- 4.2. The actual process of construction and installation shall be progressed under arrangements made under LC 19.
- 4.3. Changes to an existing facility or process shall be progressed under arrangements made under LC 22.
- 4.4. Specific requirements for decommissioning including strategies and programmes shall be progressed under arrangements made under LC 35.

5. Guidance on Arrangements for LC20

- 5.1. In addition to the general requirements for all Licence Conditions the licensee's arrangements shall satisfy the specific Licence Condition requirements which are:
- a) A clear requirement that the arrangements control modification to the design of plant during the period of construction. 20 (1).
 - b) The requirement to submit for **approval** to the ONR those parts of the arrangements ONR may **specify**. 20 (2).
 - c) The requirement that once **approved** by ONR arrangements can't be altered or amended without the **approval** of ONR. 20 (3).
 - d) A system of classification of modifications according to their safety significance which takes due account of the modification being inadequately conceived or executed. 20 (4).
 - e) The requirement to allow where appropriate the modification to be divided into stages. 20 (4).
 - f) The requirement that where ONR so **specifies** the licensee shall not commence nor proceed from one stage to the next without the **consent** of the ONR. 20 (4).
 - g) The requirement for the provision of adequate safety documentation to justify the safety of the proposed modification and where appropriate provide for the submission of this documentation to ONR. 20 (4).

6. Guidance on Inspection of Arrangements for LC20

- 6.1. The following list includes elements of good practice which have been compiled from information currently available. This list is neither exclusive nor exhaustive and will be subject to review and revision in the light of operational experience. In particular, the inspector is referred to Technical Inspection Guide NS-INSP-GD-022 for Licence Condition 22 [1] on modifications or experiments on existing plant since this contains much relevant additional detailed guidance which has not been included here to avoid unnecessary duplication.
- 6.2. It should be recognised that modifications during construction, in contrast to LC22 modifications, may not be fully developed designs with the full detail and evidence to be provided by the project's normal engineering sequences as the project develops. This is generally considered reasonable as any nuclear risk is not realised until the active commissioning phase. In such situations the purpose of a LC20 modification is to provide confidence that the design modification / justification is sufficiently mature such that it can be included within the extant reference configuration. The modification should acknowledge that the full justification is not available, and a number of future activities should be defined identifying points that require resolution to fully substantiate the modification. There must be adequate arrangements to ensure any such future activities are appropriately tracked and implemented. In such cases the arrangements must ensure that the full justification is available, and all required future activities are implemented before any radiological hazard is introduced.
- 6.3. If licensees have generic model(s) for arrangements, then it is for the site to justify any deviation from the model(s). Site staff should be able to demonstrate how their arrangements meet the regulatory requirements.
[Note: not all licensees use generic models].
- 6.4. Arrangements shall address the licence condition requirements.
- 6.5. Arrangements should include a system for classification by safety significance of modifications to design based on hazard, which takes due recognition of the works being inadequately conceived or executed and should include a review process for each classification commensurate with safety significance, i.e., robust review / assessment for the most significant safety classification and referral to the relevant safety committee or Nuclear Safety Committee as appropriate. Arrangements should be specific about assuming the worst that can happen, i.e., inadequately conceived or executed, without reference to risk. The use of a risk-based classification system frequently results in lower categories being applied; however, the risk assumption used offers the

potential for inadequate conception. Good practice classification systems have categories linked to potential doses to members of the public and workers on the site. In addition, where there is the potential for significant off-site doses or where dose limits for workers on the site could be exceeded, such proposals should be referred to ONR as well as clearing the licensee's own due process (this may be by informing ONR or requesting ONR's agreement for the most significant category of modifications under the licensee's arrangements). Further more detailed guidance on inspection of arrangements for classification of modifications by safety significance can be found in Technical Inspection Guide NS-INSP-GD-022 covering LC22 [1].

- 6.6. Arrangements should include an independent process for the licensee to review the appropriateness of the classifications allocated to modifications to ensure that they are neither under nor over classified. The process should include checking by the licensee's independent safety departments and Nuclear Safety Committee (NSC) as appropriate to the significance of the modification. This is important given that under categorisation can result in safety significant modifications not receiving the required scrutiny and oversight warranted by their safety significance (by the duty holder or regulator in appropriate cases). Conversely over classification has the potential to divert resource / focus from those modifications that genuinely have significant impact on nuclear safety.
- 6.7. In addition, arrangements should ensure that the safety significance of a series of related modifications are considered holistically and where appropriate captured in a single appropriately categorised modification proposal to prevent significant modifications being split down into a series of lower-level modifications.
- 6.8. Arrangements should recognise the need for the licensee to consider the cumulative effect of multiple modifications by taking a holistic view.
- 6.9. The classification system for safety significance should be consistent with that used for LC19, 21, 22 and 35. However, in contrast with LC22, the arrangements for LC20 need to differentiate between what is a design change and what is just part of the normal design development process.
- 6.10. Arrangements should include a requirement for modification proposals to be systematically compiled, reviewed, assessed, revised, extended, validated, verified, approved or cancelled by staff who are SQEP/DAP. Such staff will typically reside within the licensee's Design Authority or equivalent department. The process should include as a minimum multiple agreement, separate assessment and independent authorisations prior to implementation. Where appropriate, independent company safety departments expert staff and the licensee's NSC should also confirm satisfaction with the proposal.

- 6.11. Arrangements should (where appropriate) recognise that where the Responsible Designer / Architect Engineer raising LC20 modifications is external to the licensee's organisation, the licensee needs to be able to demonstrate that the Intelligent Customer role is fulfilled.
- 6.12. Arrangements should identify the requirements for the licensee's construction / installation programme(s) to include adequate time for assessment of safety submissions by ONR and/or other regulators. This time should be independent of that required for their own internal peer review processes, which should be complete before submission to the regulators.
- 6.13. Arrangements should require an implementation Quality Plan or similar scheme for modifications to plant under construction which addresses:
- 1) all hazards during design, construction and installation (nuclear, conventional, environmental).
 - 2) procedures - what needs to be done - how it is done - how it is closed out.
 - 3) issues tracking and close-out.
 - 4) responsibilities and how the licensee controls the work of contractors.
 - 5) the requirement for contractors to comply with licensees' arrangements and systems of work.
- 6.14. For further guidance on the regulation of conventional health safety matters and applicable legislation such as Construction (Design and Management) Regulations 2015 ONR inspectors should refer to the following inspection guides:
- "Dealing with matters of evident concern and potential major concern" [2]
 - "The Regulation of Life Fire Safety on Nuclear Licensed Sites" [3]
 - "Construction (Design and Management) Regulations" [4]
- 6.15. Inspectors should be aware of the requirement for conformity marking of applicable products. This can be by either by "CE" marking or via "UKCA" marking prior to the 1 January 2023 and via "UKCA" marking only from this date. Further guidance is available from "Using the UKCA marking" [5]
- 6.16. The arrangements should require that the case for each modification considers its impact on extant safety cases (including any interfacing safety cases) and that the associated modification safety case is integrated into the affected safety cases in a timely manner.
- 6.17. Safety case submissions should be supported by appropriate engineering / process detail to enable regulators to assess their adequacy.

- 6.18. Arrangements should require that there is a clear linkage to other supporting arrangements e.g., LC12 SQEPs, LC14 Safety Documentation, LC19 Construction or Installation of New Plant, LC24 Operating Instructions and LC28 Examination, Inspection Maintenance and Testing.
- 6.19. A new licensee will need to provide justification of how it is going to implement its LC20 arrangements. The licensee may initially choose to implement interim arrangements in advance of implementing its full LC20 arrangements in which case the licensee will need to propose suitable criteria for judging its readiness for full implementation of the LC20 arrangements at a later stage. The readiness criteria will need to consider:
- 1) definition of the reference design configuration.
 - 2) progress with the management of any modifications proposed for the reference design configuration.
 - 3) that the LC20 procedures and guidance reflect lessons learned from the application of the interim arrangements.
 - 4) the training of SQEP personnel in the use of the arrangements and guidance;
 - 5) application of the licensee's due governance process to the adoption of the arrangements for compliance with LC20, including adequate internal communication of the implementation of the arrangements, completion of independent technical assessment, and appropriate consultation with the Nuclear Safety Committee.

6.1. ONR Permissioning of Modifications

- 6.20. Arrangements should include provisions for the permissioning of modifications by ONR through issue of Primary Powers licence instruments under LC20 and define the persons within the licensee organisation responsible for this.
- 6.21. To introduce flexibility into the permissioning process, licensees may prescribe, with ONR agreement, 'derived' powers for use by ONR usually but not exclusively when permissioning the highest category of modification proposal. The 'derived' powers defined in a licensee's LC20 arrangements may include agreement, notification, acknowledgement and specification but not approval, consent or direction. However, derived powers have no formal legal basis and constitute administrative arrangements agreed between ONR and the licensee. Inspectors should note that inclusion of derived powers are not a prerequisite for the licensee's LC20 arrangements to be considered as adequate, nor does their use preclude the use of primary powers to exercise regulatory control over modifications.

- 6.22. Arrangements should allow ONR to agree or acknowledge and opt in or out of regulatory hold points as appropriate (flexibility for ONR permissioning activities).
- 6.23. ONR may wish to reserve judgment on the adequacy of the arrangements pending their full implementation and practical application to design modifications arising during the construction phase of a project.

7. Guidance on Inspection of Implementation of LC20 Arrangements

- 7.1. Inspectors are required to apply their experience and discretion to determine the extent and depth of a particular inspection and the following list of areas for inspection of the implementation of the arrangements for compliance with LC 20 has been compiled from best information available. This list is neither exclusive nor exhaustive and will be subject to review and revision in light of operational experience.
- 7.2. Sample check licensee's safety classification system for modification to design of plant under construction and challenge as necessary.
- 7.3. Sample check that the licensee has in place adequate training for the LC20 modifications process (including the classification of modifications) with appropriate competencies included in relevant role profiles (or equivalent).
- 7.4. Sample check the licensee's control of implementation of the modification to design of plant under construction including:
- 1) whether work has been approved before commencement.
 - 2) whether appropriate liaison has taken place to meet other regulatory requirements. (ONR may not be the lead regulator in all areas i.e., planning approval, CDM regulations, fire certificate, environmental aspects).
 - 3) whether responsibilities are clearly defined and recognised, including interfaces between licensees and contractors.
 - 4) whether instructions have been written for significant on-site activities.
 - 5) whether control and supervision of staff and contractors is adequate.
 - 6) whether adequate segregation is in place to limit interaction with other operational plant.
- 7.5. Sample check the application of the licensee's system in place for progressing issues arising from modification of design of plant under construction including the management of technical queries, concessions, and omissions.
- 7.6. Sample check that there are appropriate links to the safety case requirements for any modification to design of plant under construction and that those responsible for undertaking and implementing these activities are aware of/have access to the safety case requirements.

- 7.7. Sample check that the licensee has adequate arrangements for identifying the current status and progress of modifications throughout construction and that these are fully completed, i.e., that relevant drawings, operating and maintenance instructions are produced to ensure that prior to entering normal operations the status of all plant and modifications is adequately reflected in the safety case.
- 7.8. Sample check time limits for completion of modification of design of plant under construction and that there are no undue delays. Although delays may largely be a commercial matter for the licensee, clearly there is a need for the inspector to ensure that this does not impact upon ONR's ability to assess any safety documentation in support of the release of any hold point. Additionally, undue delays should not adversely affect the ability of the licensee to deliver project milestones that may have been declared elsewhere, i.e., decommissioning programmes. Progress on some activities may be critical to the success of others, the knock-on effects of delays should be recognised by the licensee.
- 7.9. Sample check that activities associated with the modification of design of plant under construction have been completed, or adequately progressed, to enable the facility or process to progress from one stage to the next. Areas to consider here include:
- 1) training (SQEPs).
 - 2) completion of documentation including drawings, instructions and procedures.
 - 3) maintenance schedule updated and implemented to reflect new status.
 - 4) operating rules and or instructions updated and implemented to reflect new status as appropriate.
 - 5) adequate controls are being exercised over temporary plant / construction aids e.g., hard wire links for C&I, defeat of interlocks, spades in process lines.
 - 6) as built is as designed and specified.
 - 7) all regulatory and other hold point points have been honoured and have received appropriate authorisation.
- 7.10. Where ONR consent is required to proceed beyond a hold point sample check that licensees due process has been completed in addition to the elements listed in 7.9 above.

8. Safeguards Requirements

- 8.1. Regulation 3 of the Nuclear Safeguards (EU Exit) Regulations 2019 (NSR19) makes specific requirements of operators regarding the timeliness of submitting Basic Technical Characteristics (BTC) documents to ONR where plant or facilities are modified during construction. Such BTCs contain safeguards relevant aspects of facility design and their timely submission is the basis for early safeguards engagement with ONR and, if necessary, the IAEA. Where a licensee has proposed a modification to plant under construction, the inspector should contact ONR Safeguards to ensure that the requirements for BTCs in NSR19 have been complied with.

9. Further Reading

- 9.1. Further useful information can be found in:

IAEA Safety Guide NS-G-2.3 Modifications to Nuclear Power Plants.
https://www-pub.iaea.org/MTCD/publications/PDF/Pub1111_scr.pdf

10. References

- [1] ONR, “NS-INSP-GD-022 - LC22 Modification or Experiment on Existing Plant”.
- [2] ONR, “NS-INSP-GD-051 - Dealing with matters of evident concern and potential major concern”.
- [3] ONR, “NS-INSP-GD-073 - The Regulation of Life Fire Safety on Nuclear Licensed Sites”.
- [4] ONR, “NS-INSP-GD-074 - Construction (Design and Management) Regulations”.
- [5] UK Gov, “Using the UKCA Marking,” [Online]. Available:
<https://www.gov.uk/guidance/using-the-ukca-marking>.