



ONR GUIDE			
LC22: MODIFICATION OR EXPERIMENT ON EXISTING PLANT			
Document Type:	Nuclear Safety Technical Inspection Guide		
Unique Document ID and Revision No:	NS-INSP-GD-022 Revision 6		
Date Issued:	January 2021	Review Date:	January 2022
Approved by:	Kulvinder McDonald	Operational Inspection Professional Lead	
Record Reference:	CM9 Folder 1.1.3.979. (2020/166515)		
Revision commentary:	Update containing the interactions between this licence condition and requirements for Basic Technical Characteristics documents in the Nuclear Safeguards (EU Exit) Regulations 2019.		

TABLE OF CONTENTS

1. INTRODUCTION	2
2. PURPOSE AND SCOPE	2
3. LICENCE CONDITION 22 MODIFICATION OR EXPERIMENT ON EXISTING PLANT	2
4. PURPOSE OF LICENCE CONDITION 22	3
5. GUIDANCE ON ARRANGEMENTS FOR LICENCE CONDITION 22	4
6. GUIDANCE ON INSPECTION OF IMPLEMENTATION OF LC 22 ARRANGEMENTS.....	8
8. FURTHER READING	12
APPENDIX 1 – GUIDANCE TO INSPECTORS ON MODIFICATION CLASSIFICATION	13

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. In these cases ONR undertakes nuclear safety inspections in order to judge the adequacy of the arrangements made and 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 in making regulatory judgements and decisions in relation to the adequacy of compliance, and the safety of activities on the site. This inspection guide is one of a suite of documents provided by ONR for this purpose.

2. PURPOSE AND SCOPE

- 2.1 The purpose of this guidance is to promote a consistent approach to Licence Condition 22 (LC22) compliance inspection and to provide guidance to inspectors in carrying out their duties in this area. It is intended to assist inspectors in making informed judgements and decisions on the adequacy of the licensee's arrangements and their implementation, to ensure that hazards and risks associated with activities involving modifications or experiments on existing plant or process are adequately controlled.
- 2.2 It is essential that licensees make and implement adequate arrangements to control modifications and experiments to ensure that any benefits of updating plant, processes, operations etc. are not jeopardised by the modification activity or the modification itself being inadequately conceived or executed. The guidance provided is split into three main elements:
- Purpose of the Licence Condition
 - Guidance on arrangements for LC 22
 - Guidance on inspection of implementation of arrangements.

3. LICENCE CONDITION 22 MODIFICATION OR EXPERIMENT ON EXISTING PLANT

22(1). The licensee shall make and implement adequate arrangements to control any modification or experiment carried out on any part of the existing plant or processes which may affect safety.

22(2). The licensee shall submit to ONR for approval such part or parts of the aforesaid arrangements as ONR may specify.

22(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.

22(4). The aforesaid arrangements shall provide for the classification of modifications or experiments according to their safety significance. The arrangements shall where appropriate divide the modification or experiment into stages. Where ONR so specifies the licensee shall not commence nor thereafter proceed from one stage to the next of the modification or experiment without the consent of ONR. The arrangements shall include a requirement for the provision of adequate documentation to justify the safety of the proposed modification or experiment and shall where appropriate provide for the submission of the documentation to ONR.

22(5). The licensee shall, if so directed by ONR, halt the modification or experiment and the licensee shall not recommence such modification or experiment without the consent of the ONR.

4. PURPOSE OF LICENCE CONDITION 22

4.1 The purpose of this licence condition is to ensure that arrangements adequately provide for the classification and control of all modifications and experiments, as defined in LC 1(1), on existing plant or processes that have the potential to affect safety directly or indirectly. The arrangements should cover all stages of the modification or experiment, from its initial proposal through to ensuring, prior to commissioning, that adequate preparations are made for its execution and the update of all relevant documents, including plant drawings and safety documentation (LC 6, 14, 15 and 16), operating rules (LC 23), operating instructions (LC 24) and the maintenance schedule (LC 28). The modification or experiment may require personnel to undergo elements of additional training in accordance with LC 10 before the commencement of commissioning and operations, and to demonstrate that staff satisfy the requirement to be SQEP and/or DAP where this is appropriate (LCs 12 & 26). It may also impact on and require updates to decommissioning arrangements (LC 35).

4.2 The terms 'modification' and 'experiment' are defined in LC 1(1) as follows:

- Modification - means any alteration to buildings, plants, operations, processes or safety cases and includes any replacement, refurbishment or repairs to existing buildings, plants or processes and alterations to the design of plants during the period of construction.
- Experiment – means any test or non-routine activity other than an activity carried out pursuant to LC 21 and 28.

4.3 Further, LC 1(1) also defines operations as maintenance, examination, testing and operation of the plant and the treatment, processing, keeping, storing, accumulating or carriage of radioactive material or radioactive waste. Since the definition of a 'modification' includes 'alteration to operations', a modification similarly encompasses changes to such activities defined as 'operations'.

4.4 Based on these definitions, modifications (and experiment) can therefore be wide ranging and may cover aspects such as:

- Proposed modifications to installed and commissioned plant and processes (including procedural changes).
- Proposed experiments and non-routine tests, planned defeat of interlocks and operator workarounds, which change the state of the plant or process which may affect nuclear safety. This includes temporary modifications required to enable such experiments or tests.
- Modifications to any buildings, facilities or parts of the licensed site that may affect nuclear safety.
- Changes / updates to site infrastructures and services.
- Changes to safety cases.
- Changes to criticality clearance certificates.
- Changes to computer-based systems and software relating to safety.

4.5 The actual process of construction and installation shall be progressed under arrangements made under LC 19.

- 4.6 Any modification to the design of new plant under construction shall be progressed under arrangements made under LC 20. "Modification" in this context relates to any change made to an approved design.
- 4.7 Specific requirements for decommissioning including strategies and programmes shall be progressed under arrangements made under LC 35.
- 4.8 For the remainder of the guide, the term 'modification' shall be taken to be 'modification or experiment'.

5. GUIDANCE ON ARRANGEMENTS FOR LICENCE CONDITION 22

General

- 5.1 This section sets out ONR expectations to be considered by inspectors in judging the adequacy of the licensee's arrangements.
- 5.2 The licensee's arrangements must accomplish the purpose for which they are made and must cover the statutory requirements of the condition. They should also encompass relevant industry good practice in order to be confident that risks from undertaking modifications are ALARP. Additional guidance to inspectors in respect of examining the implementation of arrangements is provided in Section 6.
- 5.3 The arrangements should be documented within the licensee's system for managing safety and clearly stated in the site licensee's compliance arrangements. The arrangements should be readily available and accessible, up-to-date, be owned and authorised by an appropriate senior manager and controlled under the licensee's management system established to comply with the requirements of LC 17.
- 5.4 The arrangements should use clear and consistent terminology and define important terms used. In the case of the term "modification", this should be consistent with the LC1 definition and also include modifications made on a temporary basis. Inspectors should check that the arrangements provide a detailed scope defining what constitutes a proposed modification within the requirements of its modification process under LC 22.
- 5.5 In addition to the general requirements for all Licence Conditions the licensee's arrangements shall satisfy the specific Licence Condition requirements which are:
- 1) A clear requirement that the arrangements control modification or experiment on existing plant or processes. 22(1)
 - 2) The requirement to submit for **approval** to ONR those parts of the arrangements that ONR **specifies**. 22(2)
 - 3) The requirement that once **approved** by ONR arrangements cannot be altered without subsequent ONR **approval**. 22(3)
 - 4) A system of classification of modifications or experiments according to their safety significance. 22(4)
 - 5) The requirement to allow where appropriate the modification to be divided into stages. 22(4)
 - 6) The requirement that where ONR **specifies** the licensee shall not commence the activity or process from one stage to the next without the **consent** of ONR. 22(4)

- 7) The requirement to halt the modification if **directed** by ONR, and not to recommence without ONR **consent**. 22(5)
- 5.6 The arrangements should identify the person(s) responsible for responding to any specification, direction, approval or consent, and also identify the person responsible for reporting any non-compliance with the arrangements to ONR.
- 5.7 The arrangements should include a classification system for the proposed modification based on safety significance of the proposal taking into account potential as well as likely consequences. This should also take due cognisance of the works being inadequately conceived or executed as well as any additional hazards / faults associated with the change itself and the novelty of the proposal. The system should include a review process for each classification commensurate with safety significance i.e. comprehensive and independent review / assessment for the highest safety classification and referral to relevant Safety committee(s) or Nuclear Safety Committee for consideration and advice, as appropriate (further guidance is provided in Appendix 1).
- 5.8 The licensee's classification system for the safety significance of modifications should be consistent with that used for LC 19, 20, 21 and 35.
- 5.9 The licensee's arrangements should include a procedure with roles and responsibilities for the design, review, control and implementation of all permanent and temporary modifications.
- 5.10 The arrangements should require that no modifications are implemented until an adequate safety assessment has been produced to underpin the safe implementation of the proposal and that this is agreed by the licensee's responsible person (and as appropriate, independently assessed, considered by the licensee's nuclear safety committee and submitted to ONR, if appropriate).
- 5.11 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.
- 5.12 The arrangements should provide for the proportionate consideration of the safety impact of the modification in areas such as:
- Claims and substantiation of Structures Systems and Components (SSC) important to safety and their performance requirements for all operating and fault conditions.
 - Potential for impairment of the safety functionality or reliability of other SSCs on plant, or in other plants due to the proposal that may be realised during installation, commissioning or subsequent operation e.g. increase in internal hazard potential, increased cable inventories, excavations, vibrations etc.
 - Human-based safety claims and their substantiation, where the modification may change operational philosophy and context, change plant and task design and assumptions about plant and equipment on which human reliability claims are based.
- 5.13 The arrangements should require feedback from operational experience to be captured and reviewed for each modification.
- 5.14 The licensee's arrangements should include a documented systematic process that covers the following, as appropriate to the category of the modification:
- Determining the problem, solution and relevant nuclear safety issues.

- Preparing the modification proposal in summary, including division into any stages.
 - Classification of the proposed modification.
 - Preparation of relevant safety documentation to justify the modification
 - Production of the modification submission.
 - Verification the modification submission.
 - Ratification of the category.
 - Identification of all claims and proposals made by the safety case which need to be implemented (safety case intent).
 - Obtaining approval from authorised person/body, including ONR as necessary.
 - Implementation of the modification – including as necessary construction, installation, commissioning/testing arrangements.
 - Close out and review of efficacy.
 - Record keeping.
- 5.15 The licensee's arrangements should include a revision process for controlling any further amendment(s) to an already approved modification. The expectation is that such a revision will be categorised and managed by the licensee raising an amended submission. Any modification made to the design of plant under construction must be compliant with the licensee's LC 20 arrangements.
- 5.16 The arrangements should include a process to avoid two or more potentially conflicting modifications being implemented coincidentally on the same part or interrelated parts of plant(s). This is facilitated by maintaining a clear understanding of plant configuration and the status of other ongoing LC 22 activities. The arrangements should therefore include a requirement for the licensee to compile and maintain a list of all modifications implemented or intended to be implemented on its plants that clearly shows the status of each modification.
- 5.17 The licensee should have arrangements for capturing, progressing, recording and sentencing issues arising from modification(s) including the management of technical queries, concessions, design changes and partial omissions or omissions. Compliance with LC 20 arrangements must be maintained in this regard. [NB. A concession may only be used for acceptance of an *existing, unplanned* variation of installed equipment against the original design; any intentional configuration change should be handled as a design change].
- 5.18 The arrangements should identify requirements for the licensee's design/ construction/ installation programme(s) for modifications to include adequate time for assessment of safety submissions by ONR and/or other regulators. This time should be independent of that required for the licensee's own internal peer review processes, which should be complete before submission to ONR.
- 5.19 The arrangements should describe how the modification is to be implemented with reference to compliance with the existing Management System requirements for design, procurement, manufacture, installation, commissioning.
- 5.20 The arrangements should include as part of the implementation phase for a modification, consideration of amendments to other related arrangements as applicable and preferably before normal operation is authorised. These may include the following:
- Updates to safety case documentation and identification of changes to or new operating limits and conditions (OLC).
 - Updating or producing new operating and maintenance instructions, including incorporation of changes to or new OLC.
 - Updates to the plant maintenance schedule.

- Updating or providing new training for operators and maintenance personnel.
 - Updating emergency arrangements.
 - Updating the plant as-built drawings.
 - Updating and archiving records, plans, authorities and certificates.
 - Updating plant configuration schedules.
 - Updated decommissioning arrangements.
 - Updates to security arrangements
 - Updates to environmental arrangements.
- 5.21 The arrangements should clearly identify criteria for invoking related licence condition arrangements such as LC 20 and LC 21. Where configured designs have been changed, for instance following findings from commissioning activities, the requirements of LC 20 must be met; where safety systems have been temporarily disabled to facilitate the modification it is likely that re-commissioning will be required under LC 21.
- 5.22 It is not unusual for licensees to wish to implement part of a modification before the full modification activities are complete. If the licensee chooses to do this then their arrangements should specify the criteria for allowing this to occur, how configuration control will be maintained and how they will ensure that safety is not compromised.
- 5.23 The arrangements should include an adequate and robust process for confirmation of modification closure and associated sign-off.
- 5.24 The arrangements should identify an adequate process for the licensee to monitor and evaluate the effectiveness of their LC 22 process.

Temporary modifications

- 5.25 LC 22 does not distinguish between 'temporary' or permanent modifications. Therefore the licence condition and arrangements apply to both types. The licensee may wish to have arrangements that differentiate modifications which are implemented for a limited period of time i.e. 'temporary modifications'. These must provide for an appropriate safety justification and control over the modification. The arrangements should adequately cover the control of temporary modifications, emergency and urgent plant modifications, including their installation and return to pre-modification status and should allow for rapid review, assessment and independent verification of any such modifications.
- 5.26 Roles, responsibilities and designations to initiate, approve, perform and remove temporary modifications should be clearly defined, including the need to interface with and take action in accordance with the licensee's arrangements made under LC 7, 11 and 13 as appropriate.
- 5.27 The arrangements should include a requirement for plant management to periodically review temporary modifications to consider:
- If they are still needed.
 - Whether they conform to the correct configuration.
 - If operating procedures, instructions and drawings and operator aids conform to the approved configuration.
 - Whether they should be converted to a permanent modification.
 - The impact of any planned permanent modifications against existing temporary modifications and the effects of the proposed change considered.

Decommissioning

- 5.28 The definitions in LC 1 include key aspects of decommissioning. Therefore, the licensee's arrangements for decommissioning should refer to and be based on the same principles

as those for controlling plant modifications. Inspectors should check that the LC 22 arrangements cross refer to the licensee's LC 35 arrangements and vice versa. Specific proposals for decommissioning activities should be controlled in accordance with the licensee's arrangements for modifications. However, the management systems and procedures for controlling the decommissioning and its staging should be defined within the licensee's arrangements made under LC 35.

ONR Permissioning of Modifications

- 5.29 Arrangements should include provisions for the permissioning of modifications by ONR through issue of Primary Powers licence instruments under LC 22 and define the persons within the licensee organisation responsible for this.
- 5.30 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 LC 22 arrangements may include agreement, notification, acknowledgement and specification but not approval, consent or direction. However, derived powers have no formal legal basis and constitute administrative arrangements agreed between ONR and the licensee. Inspectors should note that inclusion of derived powers are not a prerequisite for the licensee's LC 22 arrangements to be considered as adequate, nor does their use preclude the use of primary powers to exercise regulatory control over modifications.
- 5.31 The licensee's arrangements may also include provision for enhanced implementation monitoring and control of a modification by ONR, where ONR considers that the use of primary or derived power LIs may not be appropriate or proportionate to exercise regulatory control and oversight of a licensee's modification proposal. Where this is the case, the inspector should check that such arrangements are consistent with the expectations set out in NS-PER-GD-001 Rev 2.

6. GUIDANCE ON INSPECTION OF IMPLEMENTATION OF LC 22 ARRANGEMENTS

- 6.1 This section provides guidance to inspectors on what to consider when they are on-site inspecting compliance with the modification arrangements. This guidance is subject to review and revision in light of operational inspection experience.
- 6.2 Inspectors should check that all the relevant elements outlined in Section 5 above are included in the licensee's arrangements for plant modifications, where appropriate. The modification should at all times be under the control of plant management and managed in accordance with the established arrangements.
- 6.3 Confirm that safety functions associated with a modification have been appropriately identified and categorised and the associated SSCs classified according to their nuclear safety significance. This should also include the impact of connecting / interfacing the modification with existing safety functions / SSC.
- 6.4 Check that the effect of a modification / series of modifications on common cause failure potential, internal hazard potential, human error potential to compromise safety system 'independence' has been adequately assessed. Also, that the modification has not compromised the validity of previous system substantiation and qualification conditions.
- 6.5 Verify that where a modification is preceded by a paper justifying changes to the safety case only, which may not require ONR agreement, that sufficient reference is made in the original paper to any subsequent planned changes to the plant, which may be justified by lower category submissions, to allow the ONR assessment to include a complete appreciation of all of the consequences of the safety case change. The licensee's

- arrangements should require an assessment of the cumulative effect on safety of separate modifications. This should interface with the requirements for the licensee to have an adequate safety case under LC 23, 21(7) and for the periodic and systematic review and reassessment of safety cases under LC 15. In addition, inspectors should verify that where staged or a series of modifications are proposed, the licensee's rationale for this is appropriately justified and does not result in a high category modification proposal being dissected into a series of lower category modifications.
- 6.6 Where staged modifications are planned, check that these are / have been implemented in the correct sequence. In such cases, an overarching or 'master' modification proposal should be prepared that assesses and categorises the overall safety impact and potential interactions of the changes.
- 6.7 Confirm that there is a procedure in place for tracking all modifications and linkages between them (supported by register(s) as appropriate).
- 6.8 Evaluate whether revision of procedures, training material and any provisions for plant simulators as part of the implementation of the modification has been appropriately assessed and implemented by the licensee. Any modifications to training and operating procedures should be made in accordance with the licensee's arrangements made under LC 10 and 24.
- 6.9 Check that an adequate process is in place and being followed for sentencing, aggregating, recording, tracking and progressing technical queries, concessions, design changes and partial omissions or omissions on all modifications.
- 6.10 Check whether relevant Operating Experience Feedback (OEF) has been reviewed and used to inform the modification design and its implementation.
- 6.11 Verify that a suitable implementation Quality Plan or other control document for each modification is in place, which outlines or references:
- All hazards during design, construction and installation (nuclear, conventional, environmental).
 - Applicable procedures, instructions or method statements - what needs to be done - how it is done - how it is closed out?
 - Any hold-points and their means of release (including those agreed with or specified by ONR).
 - Safety/ technical issues tracking and close-out arrangements.
 - Responsibilities and how the licensee controls the work of any contractors involved.
 - The requirement for contractors to comply with licensee's arrangements and system of work.
 - The safety case intent i.e. identification of all claims and proposals made by the safety case which need to be implemented.
- 6.12 Select a representative sample from the open modifications as the basis for the inspection. The inspector should then carry out checks including those identified below, where applicable:
- The licensee's safety classification for selected modifications is appropriate.
 - The licensee's control of implementation of a sample of modifications, including:
 - In instances where modifications have been partially implemented prior to full modification closeout check that controls in place are adequate to maintain a clear understanding of plant configuration and plant safety.

- Whether work has been approved before commencement.
 - Specification, recording and evidence of closure / completion of any regulatory and / or internal hold-points clearance criteria and decisions.
 - Whether appropriate liaison has taken place to meet other regulatory requirements. (ONR may not be the lead regulator in all areas e.g. planning approval, CDM regulations, and environmental aspects.)
 - Whether responsibilities are clearly defined and recognised, including interfaces between licensees and contractors. Persons have been trained and are demonstrably SQEP for their roles associated with the modification (implementation and subsequent operation).
 - Whether instructions have been written for significant on-site activities.
 - Application of the licensee's safe system of work process for control of construction/installation hazards (conventional, nuclear, environmental).
 - Implementation of plant modifications, including necessary testing, commissioning and verification has been / is being performed or completed in accordance with the licensee's arrangements for control and supervision of work, commissioning and quality assurance procedures.
 - Whether appropriate commissioning activities have been implemented for safety systems reinstated (without modification themselves) following implementation of an associated modification.
 - Whether control and supervision of staff and contractors is adequate.
 - Whether adequate segregation is in place to limit interaction with other operational plant and appropriate plant configuration controls have been put in place.
 - Whether adequate radiological protection measures have been put in place to meet IRR requirements e.g. temporary containment, shielding etc.
 - That appropriate contingency measures and conservative decision-making procedures exist to deal with unexpected or abnormal occurrences during implementation of the modification.
 - Temporary changes to enable the modification have been controlled, and then removed following completion of the modification.
- 6.13 Verify that there are appropriate links to the safety case requirements (and any interfacing safety cases) for every stage of development of the design, construction and installation of the modification and that those responsible for undertaking and implementing these activities are aware of and have access to the safety case requirements. Where a modification package includes construction, installation and commissioning activities, inspectors should also check evidence of clear linkage with supporting LC arrangements e.g. LC 19, 20, 21.
- 6.14 Check time limits for completion of modifications and that there are no undue delays. The period where the plant is partially modified and/or drawings and other documents have not been updated, represents a challenge to configuration control. Progress on some activities may be critical to the success of others. The knock-on effects of delays should be recognised by the licensee and appropriate interim safety cases may need to be established.
- 6.15 Verify the close-out of modification sample(s) to ascertain whether activities associated with the modification have been completed or adequate progress made/ is being made to enable the facility or process to move to the next stage or be fully implemented. Areas to consider here should include:
- Adequate training (SQEPs) and its assessment has been completed.

- Completion of documentation including, drawings, site schedules, plant configuration schedules.
 - Maintenance schedule and instructions updated and implemented to reflect new status.
 - Operating rules and or instructions updated and implemented to reflect new status as appropriate.
 - Adequate controls are being exercised over removal of any temporary plant / construction aids e.g. Hardwired links for C&I, defeat of interlocks, spades in process lines.
 - As built modification is verified as designed and specified and / or there is a robust process in place to substantiate this.
 - All regulatory and other hold point points have been demonstrably complied with and have received authorisation from SQEP personnel.
- 6.16 Check the overall number of modifications that remain open and for how long to ascertain whether there is a systemic issue with the licensee's ability to effectively close out modifications in accordance with the arrangements. Experience shows that this is a useful indicator of safety performance in this regard. Inability to close modifications can reveal issues related to other aspects of the licensees' arrangements such as training and management system controls.
- 6.17 Verify the accuracy of the list of all modifications implemented or intended to be implemented by the licensee on its plants. Maintaining plant configuration in accordance with the safety case intent is an important aspect of modification control.
- 6.18 For temporary modifications, inspectors should check that plant documentation such as operating flow-sheets, operating manuals, rules, instructions, and maintenance manuals, emergency procedures etc. accurately reflect the plant state during any temporary modifications. Other aspects to verify are:
- Logging, labelling and tagging of temporary modifications is distinctive.
 - Communication with the operating personnel, involvement of the operating personnel in the implementation process at the initial stage, and control of the temporary modifications by the operators.
 - The lifetime of a temporary modification and the procedure to extend this lifetime and decisions on when modification becomes permanent.
 - Adequate checking of configuration recovery and communication with personnel when a temporary modification is removed.
 - Temporary modifications are clearly identified at the point of application and at any relevant control position.
- 6.19 Verify that changes to safety-related software are appropriately controlled within the licensee's LC 22 arrangements. This should include procedures for configuration management, validation and verification of software modifications. (There is a wide variety of software used on nuclear plants ranging from plant control and safety systems, to safety-related applications such as software tools that maybe used to gather data and perform calculations to check compliance with operating rules, through to software used in the safety analyses which support plant modifications and safety cases).

Licensee Organisation for control of modifications

- 6.20 Maintaining the high levels of safety expected of nuclear installations requires that changes to it must be made with full knowledge of the design and the safety functions that need to be provided. ONR expects licensees to have a suitable and sufficient Design Authority service to review, assess, advise and authorise, as appropriate, proposed modifications.
- 6.21 Inspectors should verify that arrangements include a requirement for modification proposals to be proportionately and systematically compiled, reviewed, assessed, revised, extended, validated, verified, approved or cancelled by staff who are SQEP/DAP. This should include as a minimum, multiple agreement by relevant and independent authorisations prior to implementation.
- 6.22 Where the licensee relies upon a Responsible Designer(s) or other contractor(s), its Design Authority acts as an Intelligent Customer by specifying requirements, supervising the work and technically reviewing the output before, during and after implementation. ('Intelligent Customer' is defined and described in T/AST/049 'Licensee use of contractors and intelligent customer capability').
- 6.23 Inspectors should check relevant Design Authority intervention has confirmed the effectiveness of a modification after its implementation to ensure that the original objectives and intent have been achieved.

7. SAFEGUARDS REQUIREMENTS

- 7.1 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 following plant modification. 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. Inspectors should contact ONR Safeguards to ensure that the requirements for BTCs in NSR19 have been complied with in the event of a plant modification.

8. FURTHER READING

- 8.1 Further useful information can be found in:
 - 1) IAEA Safety Guide NS-G-2.3 Modifications to Nuclear Power Plants.

APPENDIX 1 – GUIDANCE TO INSPECTORS ON MODIFICATION CLASSIFICATION

1. The following list outlines some of the elements that may feature in the licensee's classification/categorisation arrangements for modifications. Inspectors should check whether the hierarchy included in the arrangements is proportionate to the safety significance of the proposal.

- **Category 1/A**

Modifications in Category 1/A may have a significant effect on the magnitude of the radiological hazard / release (and hence risk), or may involve an alteration of the principles and conclusions on which the design and the licensing of the plant were based. Such modifications may involve changes in the set of design basis accidents, or they may alter the technical solutions adopted for meeting the safety goals, performance of safety functions or lead to changes in the operating rules. Modifications in Category 1/A necessitate thorough analysis and usually prior approval by ONR, and may require amendment to the operating/design basis.

A proposal affecting nuclear safety, which, if inadequately conceived or executed, might lead to a serious increase in the risk of a radiological hazard; or which involves significant alteration to the principles on which safety arguments have been based.

Potential for significant off-site hazard (e.g. > 5 mSv).

Significant changes to high category safety functions and systems and operating conditions and limits that protect against off-site hazards.

- **Category 2/B**

Modifications in Category 2/B include changes in safety related items or systems and in operational approaches and/or procedures, and usually necessitate an update of the safety case or other licensing documents. Modifications in Category 2/B are characterised by a lesser influence on safety and no significant alteration to the principles on which plant licensing has been based. There should be no changes to the conclusions in the licensing documents. In the design phase for modifications in Category 2/B, it should be determined whether there are negative side effects, such as degradation of safety features, ability to affect the performance of safety functions or an expectation of causing significant radiation exposure in making the modification. For modifications in Category 2/B, the operating organisation should inform ONR, in accordance with established procedures.

A proposal affecting nuclear safety, which, if inadequately conceived or executed, might lead to a significant but less serious increase in the radiological hazard / release; and which involves no significant alteration to the safety principles on which safety arguments have been based.

Significant on-site hazard, or in-building hazard; with low off-site hazard.

Changes to safety systems and operating limits and conditions that protect against significant on-site hazards.

■ **Category 3/C**

Modifications in Category 3/C are minor modifications that can be characterised in one of the following ways:

- The modification has minor or no consequences for safety;
- The items to be modified are classified as items not important to safety and are not mentioned in the licensing documents; and
- The modification, even if ill-conceived or implemented incorrectly, could not lead to a significant increase in risk or create a significant hazard.

Modifications in this category should not normally require consideration by ONR.

Minor in-building hazard; very low off-site hazard.

■ **Category 4/D**

A proposal which, even if inadequately conceived or executed, could not affect nuclear safety or lead to a radiological hazard.

Radiological hazard confined to local work area; negligible off-site hazard.

2. Safety classification is aimed at determining the potential hazard from making a modification and therefore what level of control the proposal and its safety justification should receive. Inspectors should therefore check that a licensee's classification process is based on unmitigated consequence (those in the absence of safety systems or other interventions). By-passing sufficient challenge and advice has been identified as the root cause of a number of major accidents.
3. Inspectors should note that some licensee's classification arrangements may state that for an existing facility with proven safety systems, allowance can be made for reasonable mitigation provided that any safety systems for which the credit is claimed will clearly and demonstrably be unaffected by the modification or its implementation. Inspectors should also verify that such safety systems have a valid engineering substantiation and where engineered safety systems are claimed for mitigation, their efficacy is guaranteed, their integrity is demonstrated to be invulnerable to the fault and they achieve their safety function simply by being present.
4. Lower hazard sites may be expected to have different criteria for the classification of modifications. Such sites will not have potential for the high hazards that are typically equated to the highest category modifications. However, it is still important that proportionate oversight and control of radiological safety is provided through consideration of modifications by the licensee's own internal challenge processes and nuclear safety committee. This should ensure that modifications will still receive appropriate internal scrutiny and challenge, without the need to submit proposals to ONR.