



ONR GUIDE			
USE OF FLEXIBLE PERMISSIONING			
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1. INTRODUCTION

- 1.1 The nuclear site licence and attached licence conditions (LCs) provide the principal legal basis for regulation by ONR of nuclear safety on nuclear licensed sites. The LCs place conditions on the licence holder (licensee) that are considered necessary or desirable in the interests of nuclear safety.
- 1.2 The LCs include powers which may be used by ONR inspectors with the delegated authority to intervene and control arrangements made by the licensee in the interests of nuclear safety and operations undertaken by the licensee on their licensed site (operations are defined in LC 1).
- 1.3 These powers are known as “primary” powers as they are provided to ONR through the Nuclear Installations Act 1965 (NIA), Section 4 – *Attachment of conditions to the licences*.
- 1.4 In addition to primary powers, the NIA, the Health & Safety at Work Act 1974 (HSWA) and the Energy Act 2013 (TEA) give ONR legal powers. These powers are known as “direct powers”.
- 1.5 Using primary (or direct) powers to control arrangements and operations on a nuclear licensed site is known as “permissioning”. ONR has found over the years that it is not always appropriate to use primary powers to put into effect regulatory control of an operation. Nevertheless it remains desirable in the interests of nuclear safety for ONR to control and have oversight of some of the licensee’s arrangements and operations or proposed operations.
- 1.6 In these cases regulatory control and oversight may be achieved through the use of “flexible permissioning” via powers provided from the licensee’s arrangements for complying with the LCs.

2. PURPOSE AND SCOPE

- 2.1 The purpose of this document is to provide guidance to inspectors on the role of flexible permissioning in regulating nuclear safety on a nuclear licensed site. The scope of the document covers what arrangements should be made to allow them to work effectively and how the arrangements may be used in the interests of safety.
- 2.2 This guidance is intended to inform and promote a consistent approach to flexible permissioning given the non-prescriptive nuclear safety regulatory regime operated by ONR.
- 2.3 In developing the original version of this guidance, extensive consultation was undertaken with the Legal Advisory Team. This background information has been captured and can be referred to in Revision 0 of this guidance (Ref. 1).

3. WHAT IS FLEXIBLE PERMISSIONING?

- 3.1 The licensee is required to make and implement arrangements under many LCs. Through some of these LC arrangements, the licensee can choose to provide powers to ONR through which ONR derives power to permission selected activities on the licensed site. Such powers provided by the licensee for ONR are termed “derived powers”.
- 3.2 In particular, this is to control operations using arrangements made under LCs 19-22, 35 and 36, which may include the licensee implementing a particular proposal, undertaking an activity, or progressing from one stage of a project to the next.

- 3.3 Although construction and inactive commissioning may not pose an immediate nuclear safety hazard, ONR may choose to permission these phases of a facility's lifecycle to get regulatory control in the development of plant operations (e.g. to prevent the foreclosure of options) to ensure the licensee has reduced risks so far as is reasonably practicable at the point the hazard could be realised.
- 3.4 The main advantages of ONR using flexible permissioning are that the arrangements provide ONR with the flexibility to exercise proportionate regulatory control and to discharge this control in an efficient and effective manner. In addition, it allows the licensee (following consultation with ONR) the flexibility of updating the powers as circumstances change.
- 3.5 There are two types of flexible permissioning, which are hierarchal in approach – these are derived power licence instruments (LIs) and enhanced implementation monitoring and control (EIM&C). These are described as follows.

4. DERIVED POWER LICENCE INSTRUMENTS

- 4.1 The permissioning of activities on a licensed site using derived powers is predominantly done by ONR issuing derived power LIs, by persons with delegated authority (Ref. 2). The activities most likely to require permissioning by exercise of derived power LIs are those of greater safety significance.
- 4.2 This level of regulatory control requires a formal written response from ONR (i.e. LI letter). Agreements are the most frequently used derived power LIs, but all types of derived power LIs are set out below.
- *Agreement* - may be used, for example, to enable the ONR by LI to Agree to the commencement of an on-site activity. This activity will be justified by the licensee through the production of a safety proposal, which will be subject to ONR assessment, the level of which will be determined by the risk and potential consequence.
 - *Acknowledgement* - may be used, for example, to enable the ONR by LI to Acknowledge receipt of a licensee's proposal to implement a specified activity (and so by implication the licensee can proceed).
 - *Specification* - may be used, for example, to enable the ONR by LI to Specify an activity for its Agreement, or identify other regulatory hold-points within a proposal. If regulatory hold-points are specified, ONR must agree the release criteria for a hold-point, and the method of release of the hold-point. This power could be used, for example, if the safety significance or categorisation of the licensee's proposal did not require seeking ONR permission before proceeding, but that in any event ONR considers that the matter is of such potential safety significance that intervention is justified.
 - *Notification* - may be used for example, to enable the ONR by LI to Notify the licensee that ONR has received a safety case submission with the option of indicating that either: (a) ONR intends to take no formal action on the proposal and that by implication the licensee may proceed, or (b) ONR intends to assess the licensee's proposal in the interests of safety. In the latter case the licensee's arrangements must require that the on-site activity does not commence until ONR indicates that it is content. In addition the licensee's arrangements may provide for the ONR to notify the licensee under the arrangements of a need to take action or provide information in relation to matters affecting safety on the site.

- 4.3 Licensee's arrangements generally differ, and the derived powers conferred under them may also differ. The ONR management instruction (Ref. 3) contains standard templates agreed by the Legal Advisory Team for the types of derived power LIs most frequently employed by ONR, and referred to above. The list of persons who may exercise those powers is set out in the ONR Delegated Authorities document (Ref. 2).
- 4.4 Where it is intended to issue a LI in exercising a derived power not covered by a standard template, advice must be sought from the Legal Advisory Team before it is issued.
- 4.5 The LI and supporting project assessment report (PAR) produced to justify its issue are published on the ONR website. LIs are included in the list of instruments published in the site inspectors' quarterly reports for the nuclear licensed site's stakeholder group.

5. ENHANCED IMPLEMENTATION MONITORING AND CONTROL (EIM&C)

- 5.1 In addition to LI's, the permissioning of activities on a licensed site can also be done by "enhanced implementation monitoring and control" (EIM&C), which is a term referred to within ONR that is generally employed where:
- A derived (or primary) power LI is not deemed proportionate to control lower safety significant proposals. EIM&C may be used to permission and/or ensure that the implementation of the proposal complies with their extant arrangements;
 - A derived (or primary) power LI has been issued to initially permission an activity following assessment of the proposal and the ONR inspector determines that it should also be subject to EIM&C to ensure that the licensee's arrangements are controlling its implementation.
- 5.2 The mechanism for doing this is by defining regulatory hold points. How these hold points are established and released should be identified within the licensee's arrangements and considered fit for purpose by ONR.
- 5.3 As the use of EIM&C is generally used to permission licensee's activities that are deemed to be of lesser safety significance such that it would be disproportionate to use a LI (see Section 7 for further guidance), then the release of EIM&C hold points can also be approved by those persons with the delegated authority to exercise derived power LI's (Ref. 2).

6. LEGAL STATUS OF FLEXIBLE PERMISSIONING

- 6.1 The use of flexible permissioning using powers provided by the licensee's arrangements has no statutory basis. They are working level administrative arrangements which are put in place by a licensee as part of its LC compliance. The inclusion, or use, of derived powers in LC compliance arrangements does not limit or prevent ONR using the primary powers available to it by the wording of the LCs.
- 6.2 If the licensee does not comply with the requirements of decisions made under derived powers, or they do not provide an appropriate level of control, the ONR will consider whether action should be taken under the primary powers to ensure compliance with the LC. ONR should also consider whether it is appropriate to take other enforcement action in proportion to the safety significance of the non-compliance.

7. GENERAL GUIDANCE FOR INSPECTORS

- 7.1 Where deemed appropriate, the control of licensee's activities can be achieved through regulatory "hold-points". These define the point in a proposed activity or stage in a project beyond which the licensee shall not proceed until released by ONR. These hold-points are summarised as follows:
- Regulatory hold-points instituted by use of primary powers where ONR has Specified (e.g. LC 22(4)), Notified (e.g. LC21 (8)) or Directed (e.g. LC22 (5)) the licensee not to continue with an activity. The hold-point is only released by the use of a primary power's Consent LI issued by ONR. The list of persons who may exercise these powers is set out in the ONR Delegated Authorities document (Ref. 2).
 - Regulatory hold-points established using derived powers as set out in the licensee's arrangements. These are released through the use of a derived power LI issued by ONR. The list of persons who may exercise these powers is set out in the ONR Delegated Authorities document (Ref. 2).
 - Regulatory hold-points established using mechanisms set out in the licensee's arrangements. These are released through EIM&C measures as defined in the arrangements (e.g. letters, records of meetings or other suitable means of recording that ONR is content for the activity to proceed). Release of these hold points should be approved by those with the delegated authority to exercise derived power LI's (Ref. 2).
- 7.2 For regulatory hold-points, the ONR inspector should engage with the licensee at regulatory interface meetings at the working level (e.g. Level 4) to agree the type, scope and timing of the hold-point. This should include what evidence must be delivered to demonstrate that the basis for proceeding has been met. Consideration should also be given to the involvement and role of other regulators (e.g. Defence Nuclear Safety Regulator, Environmental Agencies and/or the licensee's internal regulator).
- 7.3 Licensees may opt to convey the above information via a site wide permissioning schedule (also known as a hold point control plan or document) to identify all forthcoming regulatory hold points. This can be used to aid discussions between the licensee and ONR and agree the permissioning requirements for each regulatory hold point.
- 7.4 The format and content of deliverables should be clear. This typically includes adequate documentation to justify the safety of the proposal in keeping with its safety significance. For large or complex submissions, an ONR assessment period of some months may be needed, and in these cases permissioning using a derived powers' LI may be appropriate.
- 7.5 Where flexible permissioning is being used to control stages of a project (e.g. construction, commissioning, modifications and decommissioning activities), any hold-points should be identified in advance, and recorded in an appropriate document by the licensee, which is made available to ONR. The document should summarise the basis for the engagement with ONR, other regulators and stakeholders as appropriate, and the licensee, and should be reviewed and revised as necessary to ensure the agreed approach provides an appropriate level of regulatory control for the duration of the project or programme. Under these arrangements the transparency and management of the regulatory hold-points can be monitored through established regulatory interface meetings.

7.6 The licensee's arrangements may provide ONR the flexibility to determine the most appropriate flexible permissioning approach (i.e. derived power LI or EIM&C). In these circumstances and in determining the most effective approach (i.e. proportionate, targeted and consistent) for a specific activity, the ONR inspector should take into consideration the:

- Risk and hazard potential
- Complexity
- Novelty
- Margins of safety
- Capability of the equipment
- Effect on any principal/significant systems, structures or components
- Previous regulatory history

7.7 In determining a specific flexible permissioning approach, the ONR inspector should record the basis of the approach) in Part 1 of a Decision Record in advance of the permissioning engagement. This should include the route and mechanism for clearance of any regulatory hold-points.

7.8 When employing EIM&C, a record of the justification for hold-point release should be recorded by the ONR inspector in Part 2 of a Decision Record to ensure a clear auditable trail for the permissioning decision. As a minimum, this can refer out to other relevant documentation that justifies the decision (e.g. Intervention/Contact Record). The regulatory decision (once approved by the delivery lead) should also be communicated to the licensee, as identified in its arrangements and may take the form of:

- Letters (not being LIs), or other written communications;
- Minutes of a quorate regulatory interface meeting(s) with appropriate terms of reference;
- Information recorded in an ONR report, which is approved for issue.

8. GUIDANCE FOR INSPECTORS ON ASPECTS OF LICENSEE'S ARRANGEMENTS FOR FLEXIBLE PERMISSIONING

8.1 Exercising flexible permissioning to permit activities is with the agreement of the licensee and at the discretion of ONR. Both ONR and the licensee must be content with the powers derived in the licensee's LC compliance arrangements, and the arrangements made by the licensee to manage and respond to interventions made by ONR as part of the accepted process.

8.2 The licensee's arrangements for the provision of flexible permissioning should be clearly described in documents, which are acceptable to ONR for the purpose of facilitating regulatory control using these powers. This should include the use of LIs and may allow for ONR to exercise EIM&C. ONR inspectors engaged in permissioning should ensure they are familiar with the licensee's arrangements.

8.3 These arrangements should include:

- A procedure for categorising modifications, experiments or change proposals according to their safety significance. Generally, ONR should permission the highest safety category change proposals prior to implementation.
- The flexibility for ONR to have the opportunity to permission proposals of lower safety significance, which ONR may decide to utilise should it be considered necessary. However, in most cases, licensees are permitted to proceed with

the lowest classification proposals under their extant arrangements, without specific intervention by the ONR under these derived powers.

- A requirement for the provision of adequate documentation to justify the safety of the proposed modification, experiment, or other change.
- A procedure to enable the identification, number and type of hold-points needed to ensure the safety of a project or activity, which may include the proposal of 'candidate' regulatory hold-points by the licensee for ONR's consideration and acceptance. The procedure should also include the mechanism for release of hold-points.
- A requirement to define the scope of an activity covered by a hold-point, and produce supporting evidence to ONR to enable release of each hold-point. The licensee should be responsible for producing the documents defining the evidence to be furnished to ONR.
- A requirement for the identification of hold-points where permissioning requires the involvement of another regulator (e.g. Defence Nuclear Safety Regulator, Environmental Agencies and/or the licensee's internal regulator).
- A procedure for the licensee's governance of the change proposal. This may include the requirement to submit to a Nuclear Safety Committee (NSC) established under LC13 (1), or other suitable body advising on safety (e.g. Independent Nuclear Safety Assessment).
- A requirement for a site-wide permissioning schedule describing the proposed regulatory hold-points across a particular site (specifically where sites are multi-facility). The schedule should cover the licensee's main activities, submission dates and evidence to be furnished to ONR and be consistent with the licensee's permissioning arrangements. Separate, more specific summary documents may also be required for large or complex projects.

9. MANAGEMENT OF PERMISSIONING WITHIN ONR

- 9.1 The management of interventions within ONR is described in Management System instructions and guides (Ref.'s. 4 and 5). Permissioning is managed within the framework outlined in these documents, and is subject to scrutiny through sub-programme board oversight and normal programme management consideration. Sub-programmes should therefore make effective use of a combination of primary powers and flexible permissioning to provide appropriate regulatory oversight of matters potentially affecting safety on the site. When considering if it is appropriate to exercise regulatory control using a primary power or flexible permissioning, persons having delegated authority for making primary power decisions (Ref. 2) should be consulted.
- 9.2 The use of primary powers and flexible permissioning hold points should be identified prior to commencement of an activity / project, to indicate points which are deemed most significant for safety (however, ONR may choose to exercise primary powers at any point). The correct balance in using primary powers and flexible permissioning will depend on specific circumstances and the licensee's extant arrangements, which will be the subject of consideration by ONR, following discussions with the licensee. This process may include advice from the Legal Advisory Team.
- 9.3 Within ONR, the sub-programme board should provide governance to ensure that activities managed using flexible permissioning provide the necessary level of

regulatory control and oversight, and deliver the planned interventions necessary to support ONR's strategies and plans for the particular sites being regulated. The sub-programme board is responsible for advising on permissioning strategies, resource allocation, ensuring adequate governance for permissioning via EIM&C and reviewing potential changes in programme milestones.

- 9.4 The lead ONR Inspector is responsible for implementing permissioning in accordance with regulatory processes (Ref.'s 6 and 7). This includes the requirement for early consultation with supporting specialist inspectors and associated professional leads to agree the required specialist output (Ref.'s 6 and 7).
- 9.5 Where permissioning is used to control a licensee's activities, the decisions made to permit the implementation of a licensee's proposal must be recorded in accordance with ONR management processes. In the case of derived power LIs, this will be in the form of a PAR and issuing a LI (Ref. 3). The authority to exercise derived (or primary) powers needing a LI is in accordance with the delegation of authorities in ONR (Ref. 2).
- 9.6 For EIM&C, the decision made by the inspector/ONR should be recorded in Part 2 of a Decision Record to ensure a clear auditable trail for the permissioning decision.

10. REFERENCES

1. Flexible Permissioning Including the use of Derived Powers – NS-PER-GD-001 Revision 0. TRIM Ref. 2013/149261.
2. Administrative Arrangements for Delegated Authorities within the Office for Nuclear Regulation – NS-PER-GD-013.
3. Preparation and Issue of Licence Instruments – NS-PER-IN-001.
4. Guidance for Intervention Planning and Reporting – ONR-INSP-GD-059.
5. Purpose and Scope of Permissioning – NS-PER-GD-014.
6. Project Inspection in ONR – ONR-INSP-GD-060.
7. Guidance on Production of Reports – NS-TAST-GD-084.