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# **Office for Nuclear Regulation**

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**CIVIL NUCLEAR REACTOR PROGRAMME**

**NEW BUILD LICENSING**

**HINKLEY POINT C NUCLEAR SITE LICENSING**

**LICENCE CONDITION 20: Modification to design of plant under construction**

Assessment Report: ONR-CNRP-AR-12-113

Revision 1

18 January 2013

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**PROTECTIVE MARKING - NONE**

# Office for Nuclear Regulation

An agency of HSE

## ASSESSMENT REPORT

<b>Site:</b>	Hinkley Point C
<b>Project:</b>	NNB Generation Company Ltd's application for Nuclear Site licence to install and operate two EPR units at Hinkley Point C.
<b>Title:</b>	Licence Condition Compliance Arrangements Intervention.
<b>Licence Number:</b>	NA (Pre-licence granting)
<b>Licence Condition(s):</b>	LC20: Modification to design of plant under construction
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# Office for Nuclear Regulation

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## ASSESSMENT REPORT

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## EXECUTIVE SUMMARY

### Background and Scope.

NNB Generation Company Ltd (NNB GenCo) has formally applied to ONR for a nuclear site licence (NSL) to install and operate two EPR™ reactor units at Hinkley Point C in Somerset.

This report presents the findings of ONR's assessment of NNB GenCo's arrangements for complying with Licence Condition 20: Modification to design of plant under construction. The assessment was informed by a programme of meetings and interventions spanning the period May 2010 to July 2012.

The scope of this report covers the adequacy of NNB GenCo's arrangements for complying with Licence Condition 20 - Modification to design of plant under construction – for the purposes of supporting its application for a nuclear site licence.

### Intervention Strategy

ONR has concluded a programme of intervention that has examined NNB GenCo's arrangements for complying with Licence Condition 20: Modification to design of plant under construction. During the course of a programme of meetings ONR has engaged in dialogue which has informed improvements to the procedures that NNB GenCo now intends to implement for managing modifications to the design arising during construction of a two unit EPR™ at Hinkley Point C. The intervention examined compliance procedures and the underlying compliance thread, training of personnel and self regulation.

### Conclusions of Intervention.

#### I conclude that:

NNB GenCo has made adequate progress with the development of its arrangements for complying with Licence Condition 20 (LC20). NNB GenCo is committed to the continued development of the arrangements, including building on the draft proposals for managing multi-stage modifications. Therefore ONR concludes that NNB GenCo's arrangements for compliance with LC20(1) are acceptable for the purposes of granting a nuclear site licence.

NNB GenCo procedure for controlling regulator approved management arrangements provides adequate control of such part or parts of the LC20 arrangements approved by the Executive.

NNB GenCo's arrangements for compliance with LC20(1) give the Executive the necessary derived powers to permission the implementation of modifications to the design of plant under construction.

NNB GenCo is implementing a programme of training in its LC20 arrangements that is targeting key personnel both within NNB GenCo and its Architect Engineer.

NNB GenCo arrangements for compliance with LC20 will be informed by a structured programme of self regulation.

### Recommendations.

I recommend that:

ONR should accept that NNB GenCo's proposed arrangements for complying with Licence Condition 20: Modification to design of plant under construction; are adequate for the purpose of granting a nuclear site licence.

Following granting of a nuclear site licence for Hinkley Point C, ONR should continue dialogue with NNB GenCo on the competence and training of personnel responsible for managing modifications to the design.

ONR continue seek opportunities to influence the continued development of NNB GenCo's arrangements.

**LIST OF ABBREVIATIONS**

<b>ALARP</b>	<i>As low as is reasonably practicable</i>
<b>BSL</b>	<i>Basic Safety level (in SAPs)</i>
<b>BSO</b>	<i>Basic Safety Objective (in SAPs)</i>
<b>BMS</b>	<i>(ONR) How2 Business Management System</i>
<b>EPR™</b>	<i>Trade Mark of European pressurised water reactor.</i>
<b>HPC</b>	<i>Hinkley Point C</i>
<b>HSE</b>	<i>Health and Safety Executive (“the Executive”)</i>
<b>IAEA</b>	<i>International Atomic Energy Agency</i>
<b>IMS</b>	<i>Integrated Management System</i>
<b>LC</b>	<i>Licence Condition</i>
<b>NNB GenCo</b>	<i>NNB Generation company Ltd</i>
<b>NSL</b>	<i>Nuclear Site Licence</i>
<b>ONR</b>	<i>Office for Nuclear Regulation (an agency of HSE)</i>
<b>PCER</b>	<i>Pre-construction Environment Report</i>
<b>PCSR</b>	<i>Pre-construction Safety Report</i>
<b>PID</b>	<i>Project Initiation Document</i>
<b>PSA</b>	<i>Probabilistic Safety Assessment</i>
<b>PSR</b>	<i>Preliminary Safety Report</i>
<b>RGP</b>	<i>Relevant Good Practice</i>
<b>SAP</b>	<i>Safety Assessment Principle(s) (HSE)</i>
<b>SFAIRP</b>	<i>So far as is reasonably practicable</i>
<b>SSC</b>	<i>System, Structure and Component</i>
<b>TAG</b>	<i>Technical Assessment Guide(s) (ONR)</i>
<b>TSC</b>	<i>Technical Support Contractor</i>
<b>WENRA</b>	<i>Western European Nuclear Regulators’ Association</i>

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Table 2: Licence Condition 20: Modification to design of plant under construction  
NNB GenCo Compliance Arrangements

## 1 INTRODUCTION

### 1.1 Background

1 NNB Generation Company Ltd (NNB GenCo) has formally applied to the Office for Nuclear Regulation (ONR) for a nuclear site licence (NSL) to install and operate two EPR™ reactor units at Hinkley Point C in Somerset (Ref 1).

2 This report presents the findings of ONR's assessment of NNB GenCo's arrangements for complying with Licence Condition (LC) 20 Modification to design of plant under construction. This assessment was informed by a programme of meetings and interventions spanning the period May 2010 to July 2012. Assessment was undertaken in accordance with the requirements of the Office for Nuclear Regulation (ONR) How2 Business Management System (BMS) procedure AST/003 (Ref. 2).

### 1.2 Scope

3 The scope of this report covers the adequacy of NNB GenCo's arrangements for complying with LC20 – Modification to design of new plant under construction – for the purposes of supporting its application for a nuclear site licence.

### 1.3 Methodology

4 The methodology for the assessment follows ONR BMS document AST/003, Assessment Process (Ref. 2), in relation to the mechanics of assessment within ONR.

5 This assessment focused upon NNB GenCo's arrangements for managing modifications to the design of a new plant during the construction and installation phases of the project. It examined: development of the arrangements; and, identification and training of key personnel.

## 2 ASSESSMENT STRATEGY

6 The assessment strategy for NNB GenCo's arrangements for complying with LC 20 – Modification to design of plant under construction - is set out in this section. This strategy identifies the scope of the assessment and the standards and criteria that have been applied.

### 2.1 Standards and Criteria

7 The relevant standards and criteria adopted within this assessment are set down in the ONR inspection guide T/INS/020 (Ref 3), which identifies relevant related inspection guidance. The assessment is also informed by relevant good practice exercised by mature licensees.

### 2.2 Intervention Strategy

8 This assessment followed ONR's Intervention Strategy (Ref 4), and was informed by a programme of level 4 dialogue which aimed to examine:

- NNB compliance matrix and compliance thread for each LC sub clause;
- communication of arrangements to relevant personnel, i.e. training;
- implementation of arrangements; and,
- dialogue on licensees self regulation activities.

9 This intervention gave particular attention to:

- the arrangements for managing design changes during construction;
- the categorisation of modifications according to safety significance;
- the management of large or complex modifications; and,
- the derived powers requiring NNB GenCo to seek ONR's permission to implement modifications to the design.

### 2.3 Integration with other Licence Conditions

10 LC10 requires the licensee to make and implement arrangements for the training of all those who have responsibility for any operations which may affect safety. LC1 – Interpretation – does not include construction and installation in the definitions of "operations" but ONR expects a licensee's arrangements for training to extend to its control of construction and installation.

11 LC19 requires the licensee to make and implement arrangements to control construction or installation of new plant. NNB GenCo's arrangements include management of non-conformances and construction changes that have the potential to generate modification to the design of the plant.

### 2.4 Out-of-scope Items

12 None identified.

**3 LICENSEE'S SAFETY CASE**

- 13 NNB GenCo is not required to present a formal safety case for its arrangements to comply with conditions attached to the nuclear site licence.
- 14 Part 4 the licence application (Ref 1) entitled " Nuclear Site Licence Compliance Matrix: Hinkley Point C" (Ref 5) identifies those procedures and documents within NNB GenCo's Integrated Management System (IMS) that achieve compliance with the licence conditions attached to the standard nuclear site licence. The Compliance Matrix identifies two groups of licence conditions.
- Group 1 – Licence conditions required for activities that NNB GenCo expect to undertake during the construction and installation phases of the project. ONR expect the arrangements for these LC to be developed sufficiently to be fit for purpose at the time of NSL granting.
  - Group 2 – Licence conditions required for activities that NNB GenCo will undertake during commissioning, operation and decommissioning phases of the project. NNB GenCo has provided a commitment to develop the necessary arrangements for complying with these LCs in the future.
- 15 LC 20 Modifications to design of plant under construction is designated Group 1 and therefore ONR expects NNB Gen Co to have fit for purpose arrangements at the time of NSL grant.

## 4 ONR ASSESSMENT

### 4.1 Scope of Assessment Undertaken

16 The aim of the intervention that informed this assessment was to judge the adequacy of NNB GenCo's arrangements for managing modifications to the design of plant under construction. The principal objective is to inform ONR's decision on whether to grant NNB GenCo a nuclear site licence. Thus ONR's intervention strategy (Ref 4) comprises the following elements.

- Development of arrangements. Examine NNB GenCo's Compliance matrix entry (procedures) and the underlying compliance thread (supporting arrangements, guidance etc.).
- Competence and Training. Examine the arrangements for developing training material and identifying the target roles and functions. Sample training packages and observe training.
- Implementation. Seek opportunities to inspect implementation of arrangements.
- Self Regulation. Discuss key findings and lessons learned from the licensee's own self assessment of its arrangements.

17 The extent of ONR's consideration of the above elements is dependent upon NNB GenCo's project schedule. In the absence of a nuclear site licence NNB GenCo is unable to start nuclear safety related construction or installation. Therefore, NNB GenCo is unable to implement its arrangements for LC20 until such time as ONR consent to start of construction. Therefore, ONR's intervention was limited to development of arrangements and a limited examination of competency and training.

18 ONR's assessment was informed by dialogue with NNB GenCo during the course of the programme of level 4 meetings listed at Table 1.

### 4.2 Assessment

#### 4.2.1 Development of Arrangements – Compliance Matrix and Compliance Thread

19 ONR guidance (Ref 3) expects a licensee's arrangements for complying with LC20 to provide a system of rigorous and appropriate control of modifications to the design of a new plant during construction. ONR guidance also expects the arrangements to give ONR derived powers to permit the implementation of modifications. Table 2 lists the NNB GenCo procedures that comprise its arrangements for complying with LC20.

##### 4.2.1.1 LC20(1)

20 The Compliance Matrix (Ref 5) identifies the NNB GenCo procedure "Procedure for Control of Modifications during Construction and Commissioning" as defining the arrangements that apply to modifications made to a design that fulfils the following criteria.

- A design declared in the Pre-Construction Safety Report (PCSR) used to support the request for ONR's permission to commence, or proceed from one stage to the next of, construction.
  - A detailed design stated at stage one of the System Design Manuals (SDM) or building design information that NNB GenCo has accepted via its Design Review and Acceptance process.
-

21 The procedure is connected by a complex compliance thread to the LC19 arrangements for controlling construction as well the arrangements for developing the design. NNB GenCo is developing a Compliance Pack for LC20 to aid its understanding of the interdependencies of this and other procedures in the construction and design processes and thus secure compliance with the arrangements.

22 LC20(4) requires that arrangements for compliance with LC20(1) shall provide for the categorisation of modifications according to their safety significance. The NNB GenCo guidance document “Modification Categorisation and Preparation of the UK Context Annex” proposes four categories of modification according to the following considerations:

- consequences of implementing the modification;
- the potential impact of the modification upon safety margin;
- the novelty of the modification; and,
- the complexity of the modification.

The resulting categories are broadly equivalent to those used by existing licences to categories modifications to existing plant (LC22).

23 Responsibility for categorising a modification lies with the proposer of the modification which may arise from a number of sources including:

- Design Evolution Notice (DEN) from the Site Engineering Team or Site Construction Team (LC19 Arrangements);
- Construction Engineering Design Evolution Notice (CEDEN) from the Construction Engineering Team
- Architect Engineer via its work instruction for the management of modifications during design, construction and commissioning.
- An update to the safety case from the NNB GenCo Design Authority.

The principal procedure for compliance with LC20 includes references to the above NNB GenCo and Architect Engineer procedures and work instructions. Typically these generate an “Information Pack” comprising the categorised modification proposal and supporting justification. Category 1 and 2 modification proposals are submitted to NNB GenCo Design Authority for assessment and approval. NNB GenCo’s Scheme of Delegated Authority delegates responsibility for approving category 3 and 4 modifications to a relevant head of the initiating organisation who has completed training and undergone a competency assessment.

24 For category 1 and 2 modifications the NNB GenCo arrangements include the following key elements.

- assess “Information Pack” which validates the quality and completeness of the proposal;
- engage with ONR;
- Design Authority (DA) assessment of proposal;
- Independent Assessment Challenge and Oversight (IACO) specified Independent Peer Review (IPR) of proposal;
- DA approval of proposal including consideration by Safety Design Change Committee (SDCC);

- Nuclear Safety Committee consultation, i.e. seek advice for category 1 and notify of category 2;
- where relevant, obtain ONR agreement or acknowledgement.

On completing the process the modification is returned to the initiating organisation for implementation.

25 LC20(4) requires that arrangements for compliance with LC20(1) shall divide the modifications into stages where deemed necessary or desirable. NNB Gen Co is proposing supplementary guidance to its principal procedure that will describe the arrangements for managing multi-stage modifications. NNB GenCo intend to adopt arrangements similar to those used by EDF Energy Nuclear Generation Ltd for existing plant, i.e. a “Paper of Principle” followed by a series of “Staged Submissions” and finally, following implementation of the change, a “Close Out Report”. The draft proposals include the option to divide complex modifications into stages and the introduction of hold points.

26 LC20(4) also expects the arrangements under LC20(1) to include the requirement for provision of adequate documentation to justify the safety of the proposed modification and shall provide for submission of this documentation to ONR. The NNB GenCo procedure includes the activity “Send modification to Regulators” which requires all category 1 modifications and, if so specified by ONR, category 2, 3 and 4 modifications to be sent to ONR together with any supporting information.

27 **ONR is satisfied that NNB GenCo has made adequate progress with the development of its arrangements for complying with LC20. NNB is committed to the continued development of these arrangements, including building upon the draft proposals for managing multi-stage modifications. Therefore ONR concludes that NNB GenCo’s arrangements for compliance with LC20(1) are acceptable for the purposes of granting a nuclear site licence.**

#### 4.2.1.2 LC20(2) and LC20(3)

28 These LCs give the Executive primary powers to approve arrangements. The compliance matrix refers to the procedure for control of regulator approved management arrangements.

29 **ONR is satisfied that the NNB GenCo procedure for controlling regulator approved management arrangements provides adequate control of such part or parts the LC20 arrangements approved by the Executive.**

#### 4.2.1.3 LC20(4)

30 In addition to requirements already discussed in section 4.2.1.1 above, this sub clause gives the Executive the primary power to specify that a licensee “...shall not commence nor thereafter proceed from one stage to the next of the modification without the consent of the Executive.” The compliance matrix entry refers to the relevant NNB GenCo procedure for responding to ONR’s use of this primary power.

#### 4.2.1.4 ONR’s use of Primary and Derived Powers to Permission Modifications.

31 In line with its regulation of operating reactors, ONR is unlikely to use the primary power embodied in LC20(4) to permission, i.e. **consent** to, NNB GenCo progressing between successive stages of a modification. However, ONR expects a licensee’s arrangements under LC20(1) to include derived powers that permit ONR to permission the implementation of modifications.

- 32 The NNB GenCo procedure for modifications includes the following derived powers:
- Category 1 Modifications – NNB GenCo to seek the Executive's **agreement** or **acknowledgment** before implementing the modification.
  - Category 2, 3 and 4 Modifications – Where the Executive so **specifies**, NNB GenCo will not implement the modification without the Executive's **agreement** or **acknowledgment**.
- 33 NNB GenCo's draft proposals for multi-stage modifications include appropriate derived powers permitting ONR to permission them to proceed from one stage to the next.
- 34 **ONR concludes that NNB GenCo's arrangements for compliance with LC20(1) give the Executive the necessary derived powers to permission the implementation of modifications to the design of plant under construction.**

#### 4.2.1.5 Comparison with Guidance and Relevant Good Practice

- 35 ONR has assessed NNB GenCo's arrangements for LC20 Modification to design of plant under construction against the requirements of the ONR Technical Inspection Guide T/INS/020 (Ref 3).
- 36 ONR judges that NNB GenCo's arrangements have addressed the expectations of the ONR guidance and are therefore adequate for the purposes of granting a nuclear site licence.

#### 4.2.2 Competence and Training.

- 37 Recognising that it will be some time before it is required to implement its LC20 arrangements; NNB GenCo completed a pilot training exercise informed by a training needs analysis. This pilot exercise informed the development of practitioner training packages which target groups of personnel according to their role in discharging the LC20 arrangements. Thus, in addition to the awareness training package, given to NNB GenCo personnel as part of its Fundamentals Training curriculum, NNB GenCo has delivered targeted training to its Architect Engineer's Technical Services Managers and Team Leaders that focused on the UK statutes behind the UK Context Guidance Document, e.g. CDM, COSHH, Environment, ALARP, etc.
- 38 During the third quarter of 2012 NNB GenCo is scheduled to deliver training to: modification categorisers in its Architect Engineer, Design Authority and Construction Engineering Team personnel in London and to the Site Engineering Team at Hinkley Point C.
- 39 **ONR concludes that NNB GenCo is implementing a programme of training in its LC20 arrangements that is targeting key personnel both within NNB GenCo and its Architect Engineer. Following granting of the nuclear site licence ONR will continue to seek dialogue on the competency and training of personnel responsible for managing modifications to the design.**

#### 4.2.3 Implementation of LC20 Arrangements.

- 40 NNB GenCo is not required to implement its arrangements for compliance with LC20 at this time but intends to introduce the arrangements two months before they are required to support construction. Therefore ONR is unable to comment on implementation at this stage. Following nuclear site licence grant ONR will look for the earliest opportunity to inspect implementation of NNB GenCo's LC20 arrangements.

**4.2.4 Self Regulation.**

- 41 NNB GenCo's arrangements for complying with LC20 have been subjected to only a limited Self Assessment. NNB GenCo recently completed a "cold eye" review of the arrangement, which informed improvements to the procedure and supporting guidance documents.
- 42 Looking forward NNB GenCo has a programme of self regulation comprising periodic assessments of implementation of its LC20 arrangements for construction or installation by both the HPC project and its Independent Assessment Challenge and Oversight (IACO) function.
- 43 **ONR concludes that the NNB GenCo arrangements for compliance with LC20 will be informed by a structured programme of self regulation.**

## 5 CONCLUSIONS AND RECOMMENDATIONS

44 ONR has concluded a programme of interventions that has examined NNB GenCo's arrangements for complying with LC20: Modification to design of plant under construction. During the course of a programme of meetings ONR has engaged in dialogue which has informed improvements to the procedures that NNB GenCo now intends to implement for managing modification to the design of a two unit EPR at Hinkley Point C. The interventions informed ONR's judgement on the adequacy of NNB GenCo's proposed arrangements and lead to the following conclusions and recommendations.

### 5.1 Conclusions

45 ONR is satisfied that NNB GenCo has made adequate progress with the development of its arrangements for complying with LC20. NNB is committed to the continued development of these arrangements, including building upon the draft proposals for managing multi-stage modifications. Therefore ONR concludes that NNB GenCo's arrangements for compliance with LC20(1) are acceptable for the purposes of granting a nuclear site licence.

46 ONR is satisfied that the NNB GenCo procedure for controlling regulator approved management arrangements provides adequate control of such part or parts of the LC20 arrangements approved by the Executive.

47 NNB GenCo's arrangements for compliance with LC20 (1) give the Executive the necessary derived powers to permission the implementation of modifications to the design of plant under construction.

48 NNB GenCo is implementing a programme of training in its LC20 arrangements that is targeting key personnel both within NNB GenCo and its Architect Engineer.

49 NNB GenCo arrangements for compliance with LC20 will be informed by a structured programme of self regulation.

### 5.2 Recommendations

50 This intervention makes the following recommendations.

- ONR should accept that NNB GenCo's proposed arrangements for complying with Licence Condition 20: modification to design of plant under construction; are adequate for the purpose of granting a nuclear site licence.
- Following granting of a nuclear site licence for Hinkley Point C, ONR should continue dialogue with NNB GenCo on the competence and training of personnel responsible for managing modifications to the design.
- ONR to continue seek opportunities to influence the continued development of NNB GenCo's arrangements.

**6 REFERENCES**

- 1 NNB GenCo letter ONR-OSL-RIO-000061 dated 29 July 2012. Application for Nuclear Site Licence for Hinkley Point. TRIM 2011/442090
- 2 *ONR How2 Permissioning Reports*. AST/003 Issue 5. HSE. July 2012.  
[www.hse.gov.uk/nuclear/operational/assessment/index.htm](http://www.hse.gov.uk/nuclear/operational/assessment/index.htm).
- 3 T/INS/020 Issue 2 LC20: Modifications to design of plant under construction.
- 4 CNRP New Civil Reactor Build. NNB GenCo Ltd's Application for a Nuclear Site Licence to Install and Operate Two EPR Reactor Units at Hinkley Point. ONR Intervention Strategy. TRIM 2012/61973.
- 5 NNB GenCo Company Document Nuclear Site Licence Compliance Matrix: Hinkley Point C. NNB-OSL-PRO-000046, (Part 4 to Ref1).

**Table 1**

**Level 4 Meetings and Interventions to Discuss LC20:  
Modification to design of plant under construction**

<b>Date</b>	<b>Location</b>	<b>Topic</b>	<b>CR/IR No.</b>	<b>TRIM Ref.</b>
Pre-NSL Application				
13/05/10	London	L4 NNB Work stream 9, design Change and Change Control	CR10028	2010/271579
21/10/10	London	L4 Work stream 9 LC20	CR10129	2010/555423
20/05/11	London	LC20 Modification to design of plant under construction.	CR11101	2011/334491
Post-NSL Application				
25/10/11	Bootle	LC20 Management of design changes during construction	IR11201	2011/647581
19/12/11	Gloucester	LC20 Management of design changes during construction	IR11244	2012/68944
22/03/12	HPC	LC20 Management of design changes during construction	IR12052	2012/176797
22/07/12	Bristol	LC20 Management of design changes during construction – Intervention conclusion.	IR12172	2012/250311

<b>Table 2</b>		
<b>Licence Condition 20: Modification to design of plant under construction NNB GenCo Compliance Arrangements</b>		
<b>LC Clause</b>	<b>NNB GenCo Procedure</b>	<b>Document Reference</b>
20(1)	Procedure for Control of Modifications During Construction and Commissioning.	NNB-OSL-PRO-000033
20(2)	Control Regulator Approved Management Arrangements	NNB-FIN-PRO-000079
20(3)	Control Regulator Approved Management Arrangements	NNB-FIN-PRO-000079
20(4)	Company Guidance: Modification Categorisation and Preparation of the UK Context Annex	NNB-OSL-GUI-000038
	Procedure for Control of Modifications During the Construction and Commissioning.	NNB-OSL-PRO-000033