Office for Nuclear Regulation

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OFFICE FOR NUCLEAR REGULATION (ONR)
NEW CIVIL REACTOR BUILD
NNB GENCO - WORKSTREAM 1 – MANAGEMENT SYSTEMS
LICENCE CONDITION 17 COMPLIANCE ARRANGEMENTS

Assessment Report: ONR-CNRP-AR-12-087
Revision 1
7 February 2013

Site:		Qube London
Project:		New Civil Reactor Build EDF Energy NNB GenCo
1	**Title:**	NNB GenCo – Work stream 1 – Management System Compliance Arrangements
2	**Licence Number:**	N/A (Pre licence granting)
3	**Licence Condition(s):**	LC 17 Management Systems
IIS Rating:		3
COIN Service Order:		N/A

Document Identifier

Identifier	Revision	TRIM Reference(s)
ONR-CNRP-AR-12-087	1	2012/332993

Step-based Document Review

Step	Description	Role	Name	Date	TRIM Revision[1]
1	Initial draft, including identification and mark-up of SNI/CCI	Author	[redacted]	15/08/12	
2	Main editorial review	Author	[redacted]	16/08/12	
3	Peer Review in accordance with AST/005 Issue 1	Peer Reviewer			
4	Assessor update / sentencing of comments and return to Peer Reviewer	Author			
5	Final editorial / clean draft review	Author			
6	Acceptance review in accordance with AST/003 Issue 4	AUH	[redacted]	20/8/12	
7	Report Sign-off	Author / Peer Reviewer / AUH	[redacted]	22/8/12	

Document Acceptance (Revision 0)

Role	Name	Position	Signature	Date
Author	[redacted]	HM Inspector	[redacted]	22/08/12
Acceptance	[redacted]	HM Superintending Inspector	[redacted]	22/8/12

[1] TRIM revision to be identified upon completion of activity and incorporation of any changes to document.

Document Acceptance (Revision 1)

Role	Name	Position	Signature	Date
Author	[redacted]	HM Inspector	[redacted]	07/02/2013
Peer Review for Publication	[redacted]	HM Inspector	[redacted]	18/02/2013
Acceptance for Publication	[redacted]	HM Superintending Inspector	[redacted]	27/2/13

Revision History

Revision	Date	Author(s)	Reviewed By	Accepted By	Description Of Change
0	22/08/2012	[redacted]		[redacted]	First formal issue.
1	07/02/2013	[redacted]	[redacted]	[redacted]	Review for Publication

Circulation (latest issue)

Organisation	Name
ONR	[redacted]
ONR	[redacted]
ONR	[redacted]
ONR	[redacted]
ONR	[redacted]
ONR	[redacted]
ONR	[redacted]
ONR	[redacted]
EA	[redacted]
CNS	[redacted]

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EXECUTIVE SUMMARY

Background

EDF Energy Nuclear New Build Generation Company Ltd (NNB GenCo) has applied for a nuclear site licence to install and operate a twin European Pressurised Reactor (EPR) nuclear power reactor at Hinkley Point C (HPC) in Somerset. As part of ONR's assessment of this application, a review of the prospective licensee's arrangements for compliance with the conditions to be attached to the nuclear site licence has been conducted. This report presents the findings of ONR's assessment of NNB GenCo's compliance arrangements for Licence Condition 17 (LC17) 'Management Systems'. The assessment informs a judgement on whether a nuclear site licence should be granted to NNB GenCo to construct, commission and operate a power reactor at Hinkley Point C in Somerset.

The assessment considers the adequacy of NNB GenCo's arrangements, and their implementation, for the stage of development that NNB GenCo has reached at this point. It is recognised that the arrangements will continue to evolve as the project proceeds, and continuing ONR interaction with NNB GenCo is anticipated to gain assurance that the arrangements remain fit for purpose and that they are implemented effectively.

Assessment and Inspection work carried out by ONR

This assessment has been informed by a number of level 4 (working level) meetings plus a targeted intervention which took place in July 2012. The level 4 meetings provided a forum for dialogue and for influencing the development of NNB GenCo's LC17 compliance arrangements.

NNB GenCo were able to demonstrate during the targeted intervention that their arrangements for compliance with LC17 have the essential elements of an effective management system as defined in international management system requirements for example, BS-EN-ISO 9001:2008 "Quality Management Systems – Requirements" and IAEA standard GS-R-3 "The management system for facilities and activities Safety Requirements".

The on going dialogue ONR and NNB GenCo have had in support of this work over the past year has yielded positive benefits in terms of the approach adopted by NNB GenCo and the design of their arrangements.

This assessment concentrated on the development stage of the project management systems to seek assurance that they meet international management system standards and expectations. The assessment also took into account the level of implementation of the developed assurance and business architecture group processes. The processes reviewed were: internal independent and self assessment; development and implementation of company processes; non conformance process; management review; and management of the independent third party inspection agency (ITPIA). Objective evidence of compliance to management systems requirements was sought to confirm that key elements of the processes are, or can be, implemented. Other processes that form part of management systems also inform this assessment for example, interfaces with the architect engineer (AE), procurement of goods and services, manufacturing inspection, records management (LC 6), and document control.

The HPC project is in its early phases and the arrangements are still being refined and developed. NNB GenCo's management systems arrangements are still evolving and completion of a full cycle of implementation is several months away for many of the systems. The management systems most developed are those to control and manage production of Long Lead Items (LLI) large forgings for the Nuclear Steam Supply System (NSSS). This is sensible, noting the safety significance and scheduling of these activities. An interim licensee certificate for management

systems has been issued by external certification body Bureau Veritas. This is a limited scope for LLI only, with full scope certification scheduled to be completed by end of 2013.

This assessment, and our level 4 interventions and meetings, found the NNB GenCo management systems arrangements to be adequate for this stage of the project. Processes developed so far have started to be implemented and are controlled within business collaborator (BC), the document control process. The assurance and business architecture processes have been developed and have started to be implemented. Although implementation is not yet fully mature NNB GenCo have made significant progress and have established key attributes of an effective management system.

NNB GenCo's LC17 compliance arrangements will need to be robust enough to cope with the varying demands of scale, complexity and technological challenges throughout the HPC lifecycle. As the project advances there will be increased users across a range of different geographical locations: ONR will need to seek assurance that arrangements continue to develop appropriate to project lifecycle and that they are implemented effectively.

NNB GenCo needs to ensure that it learns the lessons of findings from internal reviews and assessments. Although such findings are recorded in Organisational Learning Reports (LR), at the moment this is currently an immature process. Further development is needed, in particular, to ensure that actions raised have been satisfactorily completed.

Matters arising from ONR's work

I have not identified any significant findings that I consider must be completed prior to nuclear site licence (NSL) granting. However, I have identified a number of observations for consideration by NNB GenCo, and these will be followed up as part of ONR's continued oversight of NNB GenCo's development and implementation of its management system.

Conclusion

This report presents the findings of ONR's assessment of NNB GenCo's compliance arrangements for Licence Condition 17 'Management Systems'.

To conclude, I am broadly satisfied that NNB GenCo's compliance arrangements for LC17 have adequately addressed the expectations of relevant international standards. The arrangements and implementation are still evolving, but outstanding issues have been recognised and there is a strong forward momentum within the company to carry this forward. This gives me confidence that NNB GenCo are sufficiently well advanced for this stage of the project.

I am satisfied that the prospective licensee has identified all the processes which at this point in the life cycle are pertinent to all matters which may affect safety and has process management arrangements in place for managing them.

Recommendations

My recommendations are as follows:

1. NNB GenCo's arrangements for compliance with LC17, and their implementation of these arrangements, should be considered adequate to support a decision by ONR to grant a nuclear site licence for Hinkley Point C.
2. ONR should continue to monitor and influence the continued development of NNB GenCo's arrangements.

List of Abbreviations

LIST OF ABBREVIATIONS

ALARP	As low as is reasonably practicable
BSL	Basic Safety level (in SAPs)
BSO	Basic Safety Objective (in SAPs)
BMS	(ONR) How2 Business Management System
HSE	Health and Safety Executive
IAEA	International Atomic Energy Agency
LC	Licence Condition
ONR	Office for Nuclear Regulation (an agency of HSE)
PCER	Pre-construction Environment Report
PCSR	Pre-construction Safety Report
PID	Project Initiation Document
PSA	Probabilistic Safety Assessment
PSR	Preliminary Safety Report
RGP	Relevant Good Practice
SAP	Safety Assessment Principle(s) (HSE)
SFAIRP	So far as is reasonably practicable
SSC	System, Structure and Component
TAG	Technical Assessment Guide(s) (ONR)
TSC	Technical Support Contractor
WENRA	Western European Nuclear Regulators' Association

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1 INTRODUCTION

1.1 Background

1 This report presents the findings of the assessment of EDF Energy Nuclear New Build Generating Company Ltd's (NNB GenCo) Management Systems as presented in their Management Systems Manual (MSM), (Ref. 8), and supporting documentation provided by the prospective licensee. Assessment was undertaken in accordance with the requirements of the Office for Nuclear Regulation (ONR) How2 Business Management System (BMS) procedure reference; PI/FWD, (Ref. 1). The ONR Safety Assessment Principles (SAP), (Ref. 2), together with supporting Technical Assessment and Inspection Guides (TAG) & (TIG), (Ref. 3), has been used as part of this assessment.

1.2 Scope

2 This report considers the adequacy of NNB GenCo's arrangements for compliance with licence condition 17. The assessment has been undertaken before the NNB GenCo arrangements are fully developed but at a point when sufficient progress has been made to be able to assess their adequacy for this stage of the project. The report sets out the activities that ONR has carried out associated with this work stream, number 1 (WS 1) "Management System" (MS) up to present. The conclusions and work stream findings will contribute to informing ONR's decision on whether to grant a nuclear site licence for Hinkley Point C (HPC).

1.3 Methodology

3 The methodology for the assessment follows ONR BMS document PI/FWD, (Ref. 1), in relation to mechanics of assessment within the ONR.

4 This assessment has been focussed primarily on seeking assurance that NNB GenCo management systems meet established requirements as detailed in, for example; IAEA GS-R-3 (ref 5) management system for facilities and activities, BS-EN-ISO 9001:2008 (Ref 06) on management systems for quality, BS-EN-ISO 14001:2004 (Ref 7) management systems for environmental.

5 An important consideration during ONR's assessment is our expectation that the applicant licensee should be able to demonstrate that it has robust processes which enable it to manage for safety effectively and have adequate quality management arrangements at the point when it is granted a nuclear site licence.

2 ASSESSMENT STRATEGY

6 The intended assessment strategy for management systems is set out in this section. This identifies the scope of the assessment and the standards and criteria that have been applied.

7 ONR and NNB GenCo have been engaged in a series of Level 4 meetings to discuss the arrangements NNB GenCo have been developing to comply with the requirements of LC17 (see annex 2). These culminated in an ONR intervention to assess the status of the arrangements and their implementation as part of the licensing process. This intervention was an opportunity for NNB GenCo to demonstrate how their arrangements are structured and how the discussions at the Level 4 meetings have influenced their development.

8 This assessment judged NNB GenCo's management systems arrangements using established standards and guidance as outlined in several international standards and supported by ONR guidance. The NNB GenCo management system identifies that they comply with several international standards which are taken into account in their documented processes. Compliance to NNB GenCo's own management system processes as documented in their management systems manual, procedures and instructions was also assessed. (See section 6, references)

2.1 Standards and Criteria

9 The relevant standards and criteria adopted within this assessment are principally the Safety Assessment Principles (SAP), (Ref. 2), internal ONR Technical Guides, (Ref. 3), relevant national and international standards and relevant good practice informed by existing practices adopted on UK nuclear licensed sites. The key SAPs and relevant technical guides are detailed within this section. National and international standards and guidance have been referenced where appropriate within the assessment report. Relevant good practice, where applicable, has also been cited within the body of the assessment.

2.2 Safety Assessment Principles

10 The key SAPs applied within the assessment are included within Table 1 of this report.

- SAP MS.1 to MS.4 "Leadership and management for safety"
- SAP EMC 18 "Engineering principles: integrity of metal components and structures: manufacture and installation" Third-party inspection.
- SAP EMC 19 "Engineering principles: integrity of metal components and structures: manufacture and installation" & Non-conformities.

2.2.1 Technical Assessment Guides

11 The following Technical Assessment and Inspection Guides have been used as part of this assessment, Ref. 3:

- TAG T/AST/077 "Procurement of Nuclear Safety Related Items or Services"
- TIG T/INS/017 "Quality Assurance".

2.2.2 National and International Standards and Guidance

12 The following international standards and guidance have been used as part of this assessment (Refs 4, 5):

- IAEA GS-R-3 “The management system for facilities and activities”;
- IAEA GS-G-3.1 “Application of the management system for facilities and activities”;
- IAEA S-G-3.5 “The management system for nuclear installations”;
- BS-EN-ISO 9001:2008 “Quality Management Systems – Requirements”;
- BS EN ISO 14001:2004 “Environmental management systems. Requirements with guidance for use”;

2.3 Use of Technical Support Contractors

13 No supporting contractors were used.

2.4 Integration with other Assessment Topics

14 Management systems are address within GS-R-3 ‘The Management System for facilities and Activities’ and BS-EN-ISO ISO9001 ‘Quality management systems – Requirements’. This report contains an assessment of the adequacy of NNB GenCo’s management arrangements to comply with the requirements of Licence Condition 17 ‘Management Systems”. The adequacy of NNB GenCo’s arrangements to comply with Licence Condition 17, management systems, covers all process that they will implement to manage the HPC project. This work also contributes to other ONR assessment activities including design management, procurement of goods and services, manufacturing inspection, document and records management.

2.5 Out-of-scope Items

15 No out of scope items have been included.

3.0 LICENSEE’S SAFETY CASE

16 NNB GenCo has not provided its compliance arrangements for Licence Condition 17, management systems as a formal safety case; rather they have been presented as a suite of documentation to support the targeted intervention carried out in July 2012. That intervention, plus the series of Level 4 meetings, has formed the basis for the overall assessment. Documents provided by NNB GenCo are recorded in the reference section 6 and are accessible to ONR on the NNB GenCo BC system.

4.0 ONR ASSESSMENT

17 This assessment has been carried out in accordance with ONR How2 BMS document PI/FWD,(Ref. 1).

4.1 Scope of Assessment Undertaken

18 The aim of my assessment was to confirm the adequate development of the project management systems and implementation of the developed assurance and business architecture departmental processes. The assessment of the management system arrangements sought assurance that adequate arrangements that meet international standards are in place for this stage of the project. My review of process implementation covered the following: internal independent and self assessments, implementation of company process; non conformance process; periodic management review and management of the independent third party inspection agency (ITPIA).

4.2 Assesment strategy

19 The strategy during this period has been to continue to adopt an open and transparent working relationship, offering constructive advice and guidance in line with ONR's guidance to its Inspectors and commensurate with any requirements of national and international standards and good practice. This has been achieved via Level 4 meetings, which have been held at NNB GenCo's London office. (See Appendix 1 for details of meetings held so far). These meetings have been scheduled in conjunction with representatives of the Environment Agency (EA).

20 A targeted inspection was carried out between the 17 and 19 July 2012 at NNB GenCo London office to confirm adequacy of processes and to sample compliance, refer to report reference: ONR-NNB-GenCo IR-12-112, trim reference 2012/315564.

4.3 Assessment

21 Objective evidence of compliance to management systems requirements was sought to confirm that key elements of the processes are, or can be implemented when required.

4.3.1 Management Systems (MS)

22 The level 4 meetings with NNB GenCo have provided updates on the development of the management system (MS). The current version of the management system manual reference; NNB-OSL-MAN-000004 version 2, (Ref 08), is a typical manual which generally meets the management system requirements identifying project document structure, accountability, authority and responsibilities along with the main twenty one processes which are required to run a project of this complexity. An audit trail has been identified from the manual to the main process document which in turn cascades down to a number of procedures and instructions that identify the detail of the individual process steps.

23 The integrated management system (IMS) tool called MEGA is currently being populated with process procedures and appears to be a very useful tool as a document control system allowing easy access to processes and associated linked procedures, instructions and template data. Not all project documents will be controlled on this tool so business collaborator (BC) will control other project documents, for example, drawings and technical procedures, quality plans etc. A key element of any IMS is the current management systems manual as required by international standards which on first look appears to have been isolated outside of the IMS. A DRAFT issue of MSM document available on BC seems to compound this isolation by the removal of unique process

procedure references for the twenty one main process documents. I have raised this matter for consideration by NNB GenCo and will pursue it in subsequent interventions, but I do not consider it should be a barrier to the granting of a nuclear site licence.

4.3.1.1 Assessment Findings

24 I recognise that the documented processes have been developed in a relatively short time in an atmosphere of project resource build up and changing organisational responsibilities. This phase is likely to continue for some time and may become more settled with the issue of the project implementation plan (PEP) towards the end of this year (2012). The interfaces between internal projects groups and the architect engineer (AE) have also been under development resulting in the issue of interface agreements. As a consequence, the management system processes as developed at this time have not been fully stressed; however, sufficient objective evidence has been available to confirm they exist, are adequate for the stage of the project and are being used.

25 The risk register entry reference, A27H, identifies a risk if NNB fails to develop a coherent IMS. The inspector considers that this risk is reducing as more processes are produced, approved and implemented, giving more clarity on process interfaces and the IMS structure.

26 From the level 4 meetings and the compliance inspections I have not found any systematic problems or major shortfalls in the documented management system or the processes that assurance and business architecture are responsible for. My assessment at this moment in time confirms that adequate systems processes are in place. Most processes have only recently been implemented and thus have not been exercised through a full cycle . As these are fully exercised, lessons will be learnt that will need to be captured in the relevant process updates.

27 Production of an induction training package for management systems (over and above that which enables issue of an access pass) and the self assessment pre job brief are positive developments that are very important for the project and site teams both for people already resident on the project and those that join from very different industries. These inductions are considered to be a first step in identifying the project culture and process compliance training of people working on the project.

28 NNB GenCo are now considering how they can expand the scope of their limited Licensee Certificate to other project areas. The original certificate was issued by Bureau Veritas to cover a limited scope for Long Lead Items (LLI) associated with large forgings for the Nuclear Steam Supply System (NSSS). Enhanced scope will cover all Primary Circuit Pressure Boundary Components.

29 Recent interventions in connection with early forgings of NSSS components have not revealed any significant gaps in the associated NNB GenCo management system arrangements. A number of procedures have been produced, reviewed and approved by NNB GenCo that make up the LLI support processes and work control documents.

4.3.2 The Quality Assurance Department

Within the assurance department function they are responsible for six processes as follows;

- Process Development & Process Implementation: – Documented in process procedures; NNB-FIN-PRO-000031 & NNB-FIN-PRO-000014 both version 2 (see reference 9 & 10). These are well-written procedures which require, among other things, impact assessments identifying for example training requirements. Reviews

of output processes by key stakeholders and interface groups are recorded currently on BC. Good compliance to this process was identified in our sample. Process documents will eventually be controlled on MEGA, the IMS. Consideration will have to be given to identifying how process owners will sentence review comments and record approval of their processes in this tool which is currently done within BC.

- Self Assessment: - is adequately addressed in procedure, NNB-OSL-PRO-000026 version 2 (Ref 11) plus guidance document NNB-OSL-GUI-000163 version 1 (Ref 15) on "How to conduct a self assessment". A training package for each assessment is performed effectively as a pre job brief to prepare people in auditing techniques. These briefs are attended by a representative of IACO. I consider this training very useful in promoting a consistent quality of self assessment.

  There is an annual programme of self assessments of process areas plus capacity for reactive assessments as required. Self assessments are being done more or less to programme, with reports being recorded on business collaborator (BC). The self assessment process is in its infancy and still has to be proved fully.

  An important contribution to the success and continued effectiveness of any process is the way in which learning opportunities are captured and acted upon. Findings are currently being put into organisational learning reports on a system called OLIM. At present this is an immature process which still has to be proved to ensure that actions placed are tracked to closure.

- Management Review: - Procedure NNB-OSL PRO-000027 version 1 (Ref 12) identifies the current process. A management review (MR) for 2011/12 has been completed which has served to provide an early demonstration of the process. The MR results have been submitted to the senior management board for consideration. The scope of the MR needs developing to take account of the wider considerations referred in for example,GS-R-3 and BS-EN-ISO 9001:2008. At the moment there is rightly a dominant focus on process development and not on procedural adherence however future MRs need to consider these wider issues as the processes are stressed and become more mature. OLIM reports are being used to record findings from the MRs, and as a result the process procedure needs refinement to take account of this. This process needs more time to demonstrate its effectiveness.

  An approach is being developed for rolling reviews to be done quarterly to support the annual review. There is also a move to get MR considerations put onto the monthly management board meeting agenda. I regard both approaches as the right way to deal with this subject as a single once a year review on its own is too coarse for this type of project

- Independent Assessment and Challenge Oversight (IACO): - There is a procedure for carrying out independent assessments, challenge and oversight (IACO) NNB-OSL-PRO-000025 version 1 (Ref 13) which is being updated to take account of operating experience. There are two IACO programmes, one of which is aligned to the twenty one (21) main project processes with reserve capacity for reactive assessments; with the other programme covering assessment of the architect engineer (AE) interfacing process implementation. Both programmes have now started to be implemented, with several reports being witnessed by the inspector, and are on currently on schedule. Again the independent assessment process is in its infancy and has not completed a full cycle yet.

  The assessments are conducted against a range of standards and non compliance reports raised which are entered on to OLIM as organisational learning report. The

IACO group have recently made arrangements to track and verify the close out of actions they have raised on other groups where that have been some poor results. The IACO group attend the daily screening meeting that assigns all actions to challenge incorrect interpretation of their findings or the assigned action holder from their assessment close out process.

IACO have arrangements for assessing the competency of their assessors identifying a level of training qualification required for each individual. I am satisfied with these arrangements.

- Management of Non Conformance: - This process is documented in procedure NNB-OSL-PRO-000028 version 2 (Ref 14). Records of non conformances (NC) have been entered onto BC, however due to the stage the project is at there has been limited information so far on this subject. There are three categories of non conformance defined in the process; major, significant and minor.

  Major/Significant findings only will be recorded on the OLIM action tracking system. I consider that NNB should use the totality of information received more proactively and include low level minor NC to identify trends and potential methodology and organisational difficulties. They are all non compliance to process or product contract requirements.

- ITPIA management: - The management of the ITPIA is via a contract and thus a contract specification which defines the scope of deliverables of the contract and the interactions between each group. This is being managed within the assurance group but is scheduled to move to the manufacturing inspection department MID post-approval of a management of change (MOC) application. The changes to the contract management are in anticipation of the forecast increase of activity on the project when the arrangements will be more stressed as the project develops and the amount of work and number of safety significant contractors involved increases.

  Objective evidence of inspection involvement on LLI was witnessed and monthly progress contract meetings between NNB GenCo and Lloyds-APAV. Actions and identified non acceptance notes were reviewed for close out of the identified action. I consider the management of the ITPIA to be adequate.

4.3.2.1 Assessment Findings

30 I have identified no formal findings that should be completed prior to the licence granting milestone. The following observations are noted and are recorded as a flag to ONR to review in future interventions. These observations were relayed to NNB GenCo's assurance management during the targeted intervention in July.

- During the assessment several minor wording inconsistencies were noted between the documented process associated forms and actual practice. Also, quite often records from a process have been designated as permanent when they would fit better as project life cycle records. It was noted that several process documents included in this assessment were under review with draft copies on the control system.
- The management systems manual currently identifies an audit trail by unique number from the main process description to the process procedures. This audit trail appears to have been removed from the draft copy of the next revision.

- IMS (Mega) tool is almost ready for full launch. This tool seems to isolate the MSM as it does not appear to be part of this system. However management systems requirements see a MSM as a key document in any integrated management system.
- The future strategy for process document management control is on the IMS product and not on BC. The objective evidence of review and approval by a process lead of the documented process on the IMS prior to issue was not evident. Note; BC for process documents will run in parallel with IMS for six months. Review close out of comments and approval to issue is evident on BC the current document control process.
- Self-assessment reports do not consistently identify the following;
  1. The person or people who carried out the assessment,
  2. What processes were being assessed,
  3. What standards were used to assess the process against to gauge compliance to those requirements,
  4. The printed name of the approver - the template needs updating.
- Observation of minor non-compliance to the current documented version of the self-assessment process – i.e; the head of QA/IAC should sign approval of the SA reports prior to issue. This is currently not being done and the SA report template does not identify this requirement either.
- OLIM action tracking tool. It was noted that very few assessment actions are on OLIM currently but some difficulty was experienced with finding particular self-assessment findings. I suggest that either the SA report is not issued as approved until the unique OLIM number can be recorded against each action raised or an assessment unique action number is assigned and a tracking document or schedule is developed linking this and the OLIM number. A review of a sample of assessment findings found that although several months had gone by actions were not always evident. For example, a person assigned an action on an environmental issue was no longer in that area of responsibility. Handover of actions when people move or leave may be problematical. I also noted that manufacturing inspection department (MID) self assessment findings were not being tracked to completion on OLIM but internally by the MID group.
- The Management Review MR process, perhaps naturally at this stage, concentrates on process development as it is early days in their implementation. Future MRs should assess process compliance and include findings issued by internal and external assessment groups.
- Process NNB-OSL- PRO-000027 for MR does not identify that outputs from the MR will be assigned and tracked to completion on OLIM or who will be responsible for verifying that the actions assigned have been completed.

4.3.3 General Quality Assurance Specifications (GQAS)

31 No issues were identified with GQAS during this period up to licence granting. Cascade of GQAS requirements to contractors has been witnessed in proposed contracts for safety significant plant.

4.3.4 Licensee Certificate

32 The Licensee Certificate is referenced in ONR's TAG on "Procurement of Nuclear Safety Related Items or Services" (T/AST/077) and derives from a requirement in the ASME III standard. The French code RCC-M does not describe the owner's/licensee's responsibilities in the same manner as ASME III. NNB GenCo has produced a UK EPR RCC-M adaptation document which gives a full picture of the arrangements to procure safety related items.

33 NNB GenCo currently have a limited scope Licensee Certificate for LLI large forgings for the NSSS system, and are now considering how they can expand the scope of this to cover all the Primary Circuit Pressure Boundary Components. The current certificate was issued by Bureau Veritas.

4.3.4.1 Assessment and Findings

34 The assurance group have updated ONR with regard to the next phase to extend the scope and thus the time scale of the Licensee Certificate beyond the current limited scope certification for phase 1 (NSSS pouring of forgings only). This will be developed further during the coming year (2013).

35 I do not consider there to be any ONR work stream findings in this area at the moment. Independent assessment by another external group and the issue of findings for non conformances and shortfalls are considered to be helpful in shaping NNB GenCo processes and their implementation to ensure they are robust and fit for purpose.

4.4 Comparison with Standards, Guidance and Relevant Good Practice

36 NNB GenCo's arrangements for Licence Condition 17 Management Systems have been assessed against the requirements of the standards and the associated guidance identified in paragraph 2.2 and section 6. Technical Inspection Guide for LC 17, T/INS/017 "Quality Assurance" was used to inform and guide the assessment.

37 I consider that NNB GenCo's processes are clearly defined and documented and have the essential features expected from a management system as defined in Technical Inspection Guide T/INS/017 "Quality Assurance".

38 The Licence Certificate is identified in Technical Assessment Guide T/AST/077 "Procurement of Nuclear Safety Related Items or Services". NNB GenCo have adequately met this expectation for this phase of the project.

5.0 CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

39 NNB Generation Company Ltd (NNB GenCo) has applied for a nuclear site licence to install and operate a twin EPR nuclear power reactor at Hinkley Point C in Somerset. As part of ONR's assessment of this application, a review of the prospective licensee's arrangements for compliance with the conditions to be attached to the nuclear site licence has been conducted. This report presents the findings of ONR's assessment of NNB GenCo's compliance arrangements for Licence Condition 17(LC17) 'Management Systems'. The assessment considers the arrangements themselves, which are documented in process and procedural documentation; and the level of implementation up to the end of July 2012. The assessment has been based on the requirements set out

in established standards and guidance including GS-R-3, BS-EN-ISO ISO 9001 and the ONR Technical Guides T/AST/077 and T/INS/017.

40 The assessment considers the adequacy of NNB GenCo's arrangements, and their implementation, for the stage of development that they have reached at this point. It is recognised that the arrangements will continue to evolve as the project proceeds, and continuing ONR interaction with NNB GenCo is anticipated to gain assurance that the arrangements remain fit for purpose and that they are being implemented effectively.

41 NNB GenCo were able to demonstrate during the intervention that their arrangements for compliance with LC17 have the essential elements of management systems as defined in GS-R-3, BS-EN-ISO 9001 and T/INS/017. The ongoing dialogue ONR and NNB GenCo have had in support of this work stream over the past year has yielded positive benefits in terms of the approach adopted by NNB GenCo and the design of the arrangements.

42 The HPC project is in its early phases and the arrangements are still being refined and developed. Implementation has not yet matured however NNB GenCo has made significant progress and has established adequate processes for their management system.

43 The HPC project lifecycle has a number of key phases such as: design, manufacture, construction, commissioning and operation, shutdown and decommissioning. NNB GenCo's LC17 compliance arrangements will need to be continually reviewed and revised in order to cope with the varying demands of scale, complexity and technological challenges throughout the HPC lifecycle. As the project advances there will be increased users across a range of different geographical locations; ONR will need to seek assurance that arrangements continue to develop appropriate to project lifecycle and that they are implemented effectively.

IIS Rating LC17 Management Systems

44 NNB GenCo has made significant progress over the past year which has been reflected in the Level 4 meetings and the recent targeted intervention in July. Assurance and business architecture processes are now in place and have started to be implemented. In recognition of the progress that has been achieved, the fitness for purpose of the current arrangements and their implementation, and the strong positive forward momentum an **IIS rating of 3 adequate is allocated**.

Concluding Remarks

45 NNB GenCo have made significant progress in building up resource and processes in the last year or so. They have designed, documented and are beginning to implement adequate arrangements for this stage of the project. They are aware of the need to review and develop arrangements as the project progresses. The requirement to develop new arrangements, as opposed to keeping exiting arrangements under review, should reduce in time as the HPC project reaches maturity.

46 During the July targeted intervention I examined samples of a vertical slice of NNB GenCo's management system from the management systems manual (MSM) to process procedures and instructions and probed their commitment to developing adequate arrangements that are fit for purpose.

47 The granting of a site licence will enhance rather than diminish ONR's ability to influence future progress on developing further the arrangements. The arrangements are judged to be adequate for this stage of the project and will provide a sound platform for development as the project proceeds.

48 To conclude, I am broadly satisfied that NNB GenCo's compliance arrangements for LC17 are addressing the expectations of relevant ONR and international standards. The arrangements and their implementation are still evolving, but outstanding issues have been recognised by NNB GenCo and there is a strong forward momentum within the company to carry this development forward. This gives confidence that they are sufficiently far advanced for this stage of the project.

5.2 Recommendations

49 My recommendations are as follows;

- NNB GenCo's arrangements for compliance with LC17, and their implementation of these arrangements, should be considered adequate to support a decision by ONR to grant a nuclear site licence for Hinkley Point C.
- ONR should continue to monitor and influence the continued development of NNB GenCo's arrangements.

6 REFERENCES

1 *ONR How2 Business Management System. Permissioning - Purpose Scope of Permissioning* PI/FWD Issue 3. HSE. www.hse.gov.uk/nuclear/operational/assessment/index.htm.

2 SAP MS.1 “Leadership and management for safety”
Safety Assessment Principles for Nuclear Facilities. 2006 Edition Rev1. HSE. January 2008. www.hse.gov.uk/nuclear/SAP/SAP2006.pdf.

3 Technical Inspection Guide: T/INS/017 “Quality Assurance”.

Technical Assessment Guide: T/AST/077 “Procurement of Nuclear Safety Related Items or Services”
www.hse.gov.uk/nuclear/operational/tech_asst_guides/index.htm.

4 *Western European Nuclear Regulators’ Association. Reactor Harmonization Group. WENRA Reactor Reference Safety Levels.* WENRA. January 2008.
www.wenra.org.

5 GS-R-3 “The management system for facilities and activities Safety Requirements”;

GS-G-3.1 “Application of the management system for facilities and activities”;

GS-G-3.5 “The management system for nuclear installations Safety Guide”;

. www.iaea.org.

6 BS-EN-ISO 9001:2008 “Quality Management Systems – Requirements”;

7 BS EN ISO 14001:2004 “Environmental management systems. Requirements with guidance for use”;

8 NNB-OSL-MAN-000004. Version 2. “Management Systems Manual”.

9 NNB-FIN-PRO-000031. Version 2. NNB GenCo company procedure: “Develop Company Processes and Procedures”.

10 NNB-FIN-PRO-000014. Version 2. NNB GenCo company procedure: “Implement Company Procedures”.

11 NNB-OSL- PRO-000026. Version 2. NNB GenCo company procedure: “Perform Self Assessment”.

12 NNB-OSL- PRO-000027. Version 1. NNB GenCo company procedure: “Management Review”.

13 NNB-OSL--PRO-000025. Version 1. NNB GenCo company procedure: “Independent Assessment”.

14 NNB-OSL- PRO-000028. Version 2. NNB GenCo company procedure: “Manage Non-Conformance”.

15 NNB-OSL-GUI-000163. Version 1. NNB GenCo company guidance instruction: “How to Conduct a Self Assessment”.

Table 1

Relevant Safety Assessment Principles Considered During the Assessment

SAP No.	SAP Title	Description
MS.1	Leadership and Management for Safety Paragraph 51: The QMS should be based on national and international standards or other defined documents and should be reviewed periodically. Consideration should be given to the adoption of a single company wide management system ensuring that the principle of continuous improvement is maintained.	**Leadership** Directors, managers and leaders at all levels should focus the organisation on achieving and sustaining high standards of safety and on delivering the characteristics of a high reliability organisation.
MS.2	Leadership and Management for Safet Paragraph 55: Processes and systems should secure and assure maintenance of the appropriate technical and behavioural competence of directors, managers and leaders and all other staff relevant to their safety roles and responsibilities.	**Capable organisation** The organisation should have the capability to secure and maintain the safety of its undertakings.

Table 1

Relevant Safety Assessment Principles Considered During the Assessment

SAP No.	SAP Title	Description
MS.3	Leadership and Management for Safety Paragraph 65: Active challenge should be part of decision making throughout the organisation. This may have different forms and functions in different areas, but all aspects of challenge should be part of an integrated process for the whole organisation, including the most senior levels of management. This should ensure that active challenge: a) occurs by design in all key decision making and for processes that may affect safety; b) does not originate solely from independent nuclear safety assessment or peer review; c) has a preoccupation with failure and actively looks for ways that things could go wrong; d) applies to technical/plant-based and management	**Decision making** Decisions at all levels that affect safety should be rational, objective, transparent and prudent.

Table 1

Relevant Safety Assessment Principles Considered During the Assessment

SAP No.	SAP Title	Description
MS.4	Leadership and Management for Safety Paragraph 66: An organisation should have effective processes for seeking out, analysing and acting upon lessons from a wide range of sources. A learning organisation should challenge established understanding and practice by reflecting on experiences to identify and understand the reasons for differences between actual and intended outcomes. An absence of major accidents and incidents alone does not indicate that safety risks are being adequately controlled and should not breed complacency. Near misses are opportunities to learn. Leading and lagging indicators should be used to monitor performance over time to track the effectiveness of the control of risks. Paragraph 69: The lessons derived from learning should be embedded through a structured system for implementing corrective actions that is rigorously applied and actively followed up to completion. Effectiveness reviews should be undertaken to confirm that the changes have delivered the desired improvements.	**Learning from experience** Lessons should be learned from internal and external sources to continually improve leadership, organisational capability, safety decision making and safety performance.
EMC.18	Engineering principles: integrity of metal components and structures: manufacture and installation	**Third-party inspection** Manufacture and installation operations should be subject to appropriate third-party independent inspection to check that processes and procedures are being carried out as required.

Table 1

Relevant Safety Assessment Principles Considered During the Assessment

SAP No.	SAP Title	Description
EMC.19	Engineering principles: integrity of metal components and structures: manufacture and installation	**Non-conformities** Where non-conformities with the procedures are judged to have a detrimental effect on integrity or significant defects are found and remedial work is necessary, the remedial work should be carried out to an approved procedure and should be subject to the same requirements as the original.

Annex 1 Summary of Meetings (inc teleconferences) Held

Date	Location	Topic	Contact Report TRIM Ref no
03/02/10	Qube	Level 4 Quality Assurance (CR09020)	2010/60404
06/03/10	Qube	Level 4 Quality Assurance (CR10016)	2010/149800
07/04/10	Qube	Level 4 Quality Assurance (CR10016)	2010/211496
12/05/10	Qube	Level 4 Quality Assurance Procurement (CR10018)	2010/224192
22/06/10	Qube	Level 4 LC17 Quality Assurance (CR10033)	2010/280659
24/08/10	Qube	Level 4 LC17 Quality Assurance (CR10077)	2010/395142
09/09/10	Qube	Level 4 LC17 GQAS (CR10089)	2010/448949
21/10/10	Qube	Level 4 LC17 Quality Assurance (CR10131)	2010/555625
13/12/10	Qube	Level 4 Licensee Certificate (CR10177)	2011/29768
14/02/11	Qube	Level 4 LC17 Quality Assurance (CR11031)	2011/122397
27/04/11	Qube	Integrated Management System (LC17) (CR11090)	2011/256768
03/05/11	Qube	Integrated Management System (LC17) (CR11092)	2011/258193
29/06/11	Qube	Integrated Management System (LC17) (CR11125)	2011/358871
25/08/11	Qube	Integrated Management System (LC17) (CR11162)	2011/461277
13/10/11	Qube	Integrated Management System (LC17) and Construction and Installation of New Plant (LC19)	2011/581870
04/11/11	Qube	Integrated Management System (LC17)	2011/618174
03/02/12	Qube	Integrated Management System (LC17)	2012/163067
09/03/12	Qube	Pre Licence Certificate meeting to appraise inspector of their proposed way forward	Informal Meeting
03/04/12	Qube	Integrated Management System (LC17)	2012/197285
30/04/12	Qube	Integrated Management System (LC17)	2012/201154
31/05/12	Qube	Integrated Management System (LC17)	2012/279144
17 to 19 July/12	Qube	Integrated Management Systems (LC17) Compliance Assessment	2012/315564

Annex 2 Licence Condition 17 Management Systems

17	**Licence Condition 17 Management Systems**
17(1)	Without prejudice to any other requirements of the conditions attached to this licence, the licensee shall establish and implement management systems which give due priority to safety.
17(2)	The licensee shall, within its management systems, make and implement adequate quality management arrangements in respect of all matters which may affect safety.
17(3)	The licensee shall submit to the Executive for approval such part or parts of the aforesaid management systems or part or parts of the aforesaid quality management arrangements as the Executive may specify.
17(4)	The licensee shall ensure that once approved no alteration or amendment is made to the approved management systems or approved quality management arrangements unless the Executive has approved the alteration or amendment.
17(5)	The licensee shall furnish to the Executive such copies of records or documents made in connection with the aforesaid quality management arrangements as the Executive may specify.