

NUCLEAR DIRECTORATE

GENERIC DESIGN ASSESSMENT – NEW CIVIL REACTOR BUILD

**STEP 3 MANAGEMENT OF SAFETY AND QUALITY ASSURANCE ASSESSMENT OF THE
WESTINGHOUSE AP1000**

DIVISION 6 ASSESSMENT REPORT NO. AR 09/022-P

HSE Nuclear Directorate
Redgrave Court
Merton Road
Bootle
Merseyside L20 7HS

EXECUTIVE SUMMARY

This report presents the findings of the Quality Assurance assessment (including inspection) of the Quality Assurance (QA) arrangements implemented by Westinghouse (WEC) to deliver the UK AP1000 safety case as presented in the Westinghouse AP1000 Pre-Construction Safety Report (PCSR) (Ref. 1) undertaken as part of Step 3 of the HSE Generic Design Assessment (GDA) process. Discussions are ongoing with WEC to update the QA related sections of the current PCSR which is scheduled for re-issue during December 2009.

This report for the AP1000 presents the results of Nuclear Directorate's (ND) GDA Step 3 assessment (including inspection) of the application of WEC's established QA arrangements and those developed specifically to support the UK GDA AP1000 project. It provides an overview of the WEC's organisational and procedural arrangements to deliver a safety case as presented in the PCSR; the standards and criteria adopted in the assessment; and the joint inspection by HSE Nuclear Directorate / Environment Agency of the application of WEC's declared QA arrangements.

Scope of Assessment

A joint regulators' inspection of WEC's QA arrangements, carried out during Step 2 of GDA, established that WEC operates a QMS designed to meet the requirements of 10CFR50 Appendix B (Ref. 10) and as such satisfies the requirements of the USNRC for this discipline and provides a sound basis of control for the UK project. In response to a recommendation made by the joint regulators in the published inspection report in November 2007 (Ref. 4) WEC developed a specific Project Quality Plan (PQP) (UKP-GW-GAH-001 Rev. 1) for the UK AP1000 GDA project which describes the organisational and procedural arrangements to deliver the submission documents for GDA. This Project Quality Plan references a number of established WEC procedures covering aspects such as design and document controls and introduces additional project specific arrangements including the transmission of submission documents and control of joint regulator queries resulting from assessment.

During Step 3 ND's assessment of WEC's application of quality assurance principles to the project included the preparation of comments on the PQP and project specific procedures and also involved carrying out an inspection, in conjunction with Environment Agency, of the implementation of selected WEC procedures in Pittsburgh. Of particular interest were the WEC processes for the selection and use of supply organisations especially when related to the supply of long lead items such as those related to the Nuclear Steam Supply System (NSSS). Additionally the joint regulators critically assessed WEC review and audit and Learning from Experience (LFE) procedures applied to the UK AP1000 GDA project as part of the joint inspection scope.

Conclusion

WEC operates a quality programme to meet the requirements of 10CFR50 Appendix B. In addition, a specific Project Quality Plan GDA-UKP-GW-GAH-001 Rev. 1 has been issued in March 2009 and is currently being updated taking into account comments from HSE Nuclear Directorate and the Environment Agency. This provides a top level quality management document for the UK AP1000 GDA project which heads a number of project specific procedures and cites those procedures within WEC's QMS that are to be applied to the project, e.g. receipt and processing of Technical Queries (TQ) from the UK Regulators (procedure UKP-GW-GAP-012 Rev. 0).

The inspectors confirmed that configuration control/change management processes within WEC are well established and there is evidence that these documented arrangements are implemented. There is an obvious strong ownership of these processes which provides additional levels of assurance to the established review and the use of a properly constituted change committee.

WEC operates well established arrangements for the selection and surveillance of suppliers as part of its procurement activities. Particular attention is given to the controls applied through the procurement stages for safety related items and services.

It is noted that WEC has experienced and knowledgeable staff and a commitment to retain adequate technical resources.

However, the joint regulators' confidence in the arrangements for the delivery of the GDA programme by WEC could be improved by the clear application of all elements of the WEC quality programme to the UK AP1000 GDA project. Through a number of targeted initiatives organisational learning and continuous improvement have been addressed. However, the full benefit of these initiatives had not been realised for the project at the time of the joint regulators' inspection as the level of application to the UK AP1000 GDA project was not comprehensive. This leads to some doubt regarding the effective application of the wider WEC processes to the UK AP1000 GDA project.

Regulatory Observations RO-AP1000-17, RO-AP1000-33 and RO-AP1000-35 (Ref 15) have been raised and WEC has proposed and implemented a number of measures to address the issue of a wider application of its Quality Management System to the UK AP1000 GDA project. These address, in part, a number of the aspects raised by the ROs. However, it is not yet fully evident that WEC apply the full breadth and depth of their QA arrangements to the UK AP1000 GDA project. In addition WEC has yet to fully demonstrate the reliability of its procedures for the preparation of documents for the GDA process.

Some progress has been made, for example a comprehensive internal audit specific to the WEC UK AP1000 GDA project has already been carried out since the joint regulators' inspection with a number of areas for improvement being identified.

Work is ongoing with respect to updating of the PQP and related procedures. WEC has not always responded in a timely manner to UK Regulator queries, however, this is being addressed and should improve during Step 4. The application and adequacy of WEC's proposals will be closely monitored during GDA Step 4 including further regulator inspections.

LIST OF ABBREVIATIONS

ALARP	As Low As Reasonably Practicable
BAT	Best Available Techniques
BMS	(Nuclear Directorate) Business Management System
CAPS	Corrective Action Programme System
CCB	Change Control Board
DCD	Design Control Document
DCP	Design Change Process
DRP	Design Reference Point
EA	The Environment Agency
EDMS	Electronic Document Management System
GDA	Generic Design Assessment
HSE	The Health and Safety Executive
IAEA	The International Atomic Energy Agency
LFE	Learning From Experience
MDEP	Multi-national Design Evaluation Programme
ND	The (HSE) Nuclear Directorate
NSSS	Nuclear Steam Supply Systems
OEF	Operation Experience Feedback
PCER	Pre-construction Environment Report
PCSR	Pre-construction Safety Report
PQP	Project Quality Plan
QA	Quality Assurance
QMS	Quality Management System
TAG	(Nuclear Directorate) Technical Assessment Guide
TDC	Technical Document Control
TQ	Technical Query
RO	Regulatory Observation
RP	Requesting Party
RPV	Reactor Pressure Vessel
SAP	Safety Assessment Principle
SG	Steam Generator
SSC	System, Structure and Component
SQEP	Suitably Qualified and Experienced Personnel
USNRC	The United States Nuclear Regulatory Commission
WEC	Westinghouse Electric Company LLC

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Annex 1: Management of Safety and Quality Assurance – Status of Regulatory Issues and Observations

1 INTRODUCTION

- 1 This reports presents the findings of the Quality Assurance (QA) assessment (including inspection) of the Quality Assurance arrangements implemented by Westinghouse (WEC) to deliver the UK AP1000 safety case as presented in the AP1000 Pre-Construction Safety Report (PCSR) (Ref. 1) undertaken as part of Step 3 of the HSE Nuclear Directorate's (ND) Generic Design Assessment (GDA) process. This assessment has built on the work carried out in Step 2 and has taken into account the requirements of the Business Management System (BMS) document AST/001 (Ref. 2) and its associated guidance document G/AST/001 (Ref. 3), and has been carried out on a sample basis. It has focused on those arrangements that are operated by WEC to deliver a fit for purpose PCSR. It has relied in significant part on the Step 3 joint regulators' inspection of April 2009 (Ref. 4) which examined the adequacy and implementation of a sample of the RP's arrangements. The Safety Assessment Principles (SAPs) (Ref. 5) have been used as the basis for the assessment of the quality assurance arrangements associated with AP1000 design. The SAPs require that arrangements for quality assurance, based on national and/or international codes and standards, on a nuclear power plant or nuclear chemical plant site be identified and considered in safety assessments. Ultimately, the goal of assessment is to reach an independent and informed judgment on the adequacy of a nuclear safety case.
- 2 The developing generic design and related safety case requires the application of Quality Assurance (QA) arrangements by the Requesting Party (RP) to manage the process. These are designed to provide organisational and procedural arrangements to deliver a fit for purpose PCSR. It is in the development of the site specific PCSR, to be developed during Phase 2 (site licensing), that detailed and specific QA and Management of Safety arrangements will describe the organisational and procedural arrangements to procure and construct in order to realise the design intent. The means by which the design and safety case are developed does require the application of well established QA principles supported by procedures that detail aspects such as Design Control, GDA Document Change Management and Document Control. Specific interface arrangements have been established between the RPs and the UK Nuclear Regulators in the form of an Interface Protocol (Ref. 13). Interface arrangements have been established, for example to deal with Technical Queries and Regulatory Observations.
- 3 Work on this topic area was initiated during the early stages of Step 2 and a formal joint regulators' inspection was carried out and reported on during Step 2 (Ref. 4). 5 recommendations were made in the Step 2 joint regulators' inspection report. WEC has considered these and undertaken a number of actions to close out findings. The 2007 inspection findings were for Westinghouse to:
- Develop a quality plan / programme for the UK GDA process with clearly defined responsibilities, processes and procedures.
 - Produce a history of the development of the AP Series design, showing the design options considered and the reasons for those adopted. This would support application of BAT and ALARP principles.
 - Develop awareness and understanding for chapter leads of the UK regulatory process with emphasis on ALARP and BAT.
 - Formalise the existing arrangements for the capture of Operational Experience Feedback (OEF) and other sources of feedback.
 - Finalise the waste and decommissioning strategy submission and submit to the UK Regulators prior to the start of Step 3.
- 4 Westinghouse documented these recommendations as part of its established Corrective Action Programme System (CAPS) to enable these to be managed to close out as part of

WEC's existing quality arrangements. One issue that remains outstanding is uncertainty of the effectiveness of the awareness training provided to WEC GDA 'Chapter Leads' with respect to ALARP and BAT. It is intended to examine this as part of the Step 4 assessment.

- 5 ND's Generic Design Assessment (GDA) process calls for a step-wise assessment of the Requesting Party's safety submission. With respect to the assessment and inspection of the RP's QA arrangements these have focussed on the RP's arrangements to deliver and control the safety submission. In addition arrangements for the provision of long-lead items, procurement and internal monitoring and review have been examined. A significant element of ND's assessment of the QA discipline has been a planned inspection of the implementation of RP's arrangements in WEC's offices in Pittsburgh. This Step 3 inspection was carried out in conjunction with the Environment Agency (Ref. 4).
- 6 It was established during Step 2 that the organisation and quality assurance arrangements for the WEC UK AP1000 GDA Project Team which have been developed rely greatly on the well established Quality Management System (QMS) (Ref. 11) which has been accepted by the US NRC as meeting 10CFR50 Appendix B (Ref. 10). The WEC QMS also describes the company's commitment to meeting the requirements of ISO9001 and the IAEA Quality Assurance Codes and Guides. In addition a GDA specific Project Quality Plan (PQP) (UKP-GW-GAH-001 Rev. 1 March 2009) has been issued and implemented. This is supported by numerous referenced, well established WEC procedures which are a part of the WEC QMS. Collectively, these provide a basis for the operation of arrangements in support of the GDA process. A number of WEC UK GDA project specific procedures have been developed which provide for controlled flows of information between WEC and the UK nuclear regulators.
- 7 There is a defined and dedicated team responsible for interfacing with the UK Regulators and for developing and maintaining the AP1000 documentation to support the GDA process. There are identified roles and responsibilities and a structured hierarchy of documents that are pertinent to the activities of the joint project team.
- 8 The Step 2 assessment findings concluded that WEC operates a well developed set of quality arrangements and has experienced and knowledgeable staff and a commitment to retain adequate technical resources. On that basis a recommendation was made that WEC should proceed to Step 3 of the GDA process.

2 NUCLEAR DIRECTORATE'S ASSESSMENT

2.1 Requesting Party's Safety Case

- 9 Section 3 of the AP1000 PCSR describes WEC's approach to the management of safety which clearly states its policy to design, produce, market and distribute WEC's products and services and to conduct its operations in an environmentally sound and socially responsible manner. WEC also considers as part of this policy the impact of its actions on the health and safety of its employees, its subcontractors, customers and the public. WEC clearly states that compliance with management of safety codes, standards and other publications including IAEA GS-R-3 (Ref. 12) as well as ND SAPs is an essential component to achieving adequate levels of safety management.
- 10 There is clear commitment to the integration of safety into the design process and to safety during construction and commissioning. In particular, WEC recognises its principal duties as the design organisation as providing a design that meets performance specifications whilst controlling the risks of all phases of the plant to meet the requirement that risks are reduced to levels which are As Low As Reasonably Practicable (ALARP). The PCSR cites its design process including design review and design change management procedures and their importance to the achievement of safety.

- 11 Section 3 of the PCSR recognises the need for Suitably Qualified and Experienced Personnel (SQEP) designers and the transfer of Design Authority status to the operating organisation as well as its role as the concept of 'intelligent customer' all of which indicate an understanding of the management of safety. These concepts will be assessed in more detail during Step 4.
- 12 Section 3 introduces Quality Assurance into the PCSR. It refers to the Design Control Document Chapter 17 which describes WEC's Quality Management System (Ref.11).
- 13 In addition to the PCSR, the PQP describes organisational and procedural arrangements to control the work associated with the GDA project. The PQP is underpinned by the WEC Quality Management System (QMS). The PQP illustrates a tiered documentation system and references the policies, procedures and work instructions applicable to the delivery of GDA. The coverage of these second and third tier documents is appropriate to the development of a complex design and the control of its associated documents.

2.2 Standards and Criteria

- 14 The main standards and criteria used are ND's Safety Assessment Principles (SAPs) (Ref. 5), in particular MS.1 *Leadership and management for safety* which requires the application of a quality management system that is based on national and international standards. The assessment and inspection activities by the regulators during Step 2 confirmed compliance with this SAP for WEC. A check of implementation of the RP's arrangements was undertaken as part of the assessment activities during Step 3 by a joint regulators' inspection.
- 15 For Step 3 it is important to note that the QA arrangements applicable to the WEC UK GDA project are subject to ongoing review and improvement. Changes can be initiated through internal and external review by WEC, certification bodies or the UK nuclear regulators. Additionally the organisational and procedural arrangements will be further developed and detailed in the PCSR as part of Phase 2 (site licensing).

2.3 Nuclear Directorate Assessment

- 16 Assessment and inspection of the WEC project activities as detailed in the PQP and a sample of related aspects of the QMS provided evidence of a structured and documented approach to the application of QA principles to the project. Since Step 2 WEC has produced a number of GDA specific processes, referenced in the PQP, in order to formalise interfaces defined in the joint regulator's Interface Protocol (Ref. 13).
- 17 The UK AP1000 GDA Project has clear safety, security and environmental objectives i.e. design acceptance confirmation from HSE (ND), a positive conceptual security plan statement from the HSE Office for Civil Nuclear Security (OCNS) and a statement of acceptability from the Environment Agency. These clear and concise objectives have focused WEC to develop processes to achieve the objectives. This provides the joint regulators with confidence of the intent of the UK AP1000 GDA project to achieve its objectives and respond to the joint regulators' comments.
- 18 WEC operates a quality programme designed to meet the requirements of 10CFR50 Appendix B (Ref. 10). In addition, a specific Project Quality Plan for GDA-UKP-GW-GAH-001 Rev. 1 was issued in March 2009. This provides a top level quality management document for the UK AP1000 project which heads a number of project specific procedures (e.g. Receipt and Processing of Technical Queries (TQ) from the UK Regulators UKP-GW-GAP-012 Rev. 0), and cites those procedures within WEC's QMS that are to be applied to the UK GDA project.

- 19 Since the GDA Step 2 joint regulators' inspection there have been a number of quality initiatives set up across WEC e.g. the carrying out of self assessments. These initiatives support the concepts of a learning organisation and continuous improvement and as such are seen as a positive development by the regulators. However, it is not clear how the UK AP1000 GDA project has benefitted, as yet, from these initiatives.
- 20 The inspection confirmed that the configuration control/change management process within WEC is well established and there is evidence that these documented arrangements are implemented. There is strong ownership of the process which provides additional levels of assurance to the more formal means of review and the use of a properly constituted change committee. WEC has agreed to amend its design change proposal procedure to ensure that both WEC and UK Safety Categorisations are fully taken into account.
- 21 WEC continues to operate a matrix management structure. The UK AP1000 GDA project organisation is established under the banner 'Nuclear Power Plant's' (NPP). There has been a significant pan-WEC initiative to achieve integration of processes and procedures with the WEC 'Nuclear Services' and 'Fuel Division' which both provide resource and technical expertise to the AP1000 programme.
- 22 The Step 2 joint regulators' inspection, carried out during November 2007, considered that WEC has a strong focus on learning and development in the organisation which through the implementation of a number of specific quality related initiatives has been reinforced (Ref. 4). The scope of the Step 3 joint regulators' inspection included the RP's audit and continuous improvement processes viewing these as one indicator of the health of the QMS.
- 23 Since the previous joint regulators' inspection during Step 2 of GDA it is apparent that WEC has continued to recruit personnel and the number working within the quality management discipline has increased. Although the Step 2 inspection established that WEC operate a mature, well-documented Quality Management System (QMS), there appears to be a more obvious commitment to its review and application which enhances the established quality ethic.
- 24 The application of WEC QMS NSNP 18.2 Self Assessment/Continuous Improvement is designed to review levels of compliance at the procedure and work instruction levels. These assessments have resulted in improvements being made. Each department within the Nuclear Power Plants Division is required to carry out one self assessment per year with this target generally being achieved. The target has been exceeded during 2009; with 23 self assessments being carried out against a target of 12. Self-assessments are conducted by personnel that have no direct involvement in the work being assessed but who may work in the same department. The process is seen as an element of WEC's monitoring and review of quality activities. It was clear that individuals' time to participate in a self-assessment was allocated in a planned way and sanctioned by management. Findings from self-assessments are entered into and controlled by the CAPs process. A number of findings could be applicable to the WEC UK GDA project but because the self-assessment process had not been extended to the WEC UK GDA project any benefits had not been realised. A recommendation was made for WEC to consider the application of the self-assessment process to the WEC UK GDA project.
- 25 WEC continues to operate a well-established procedure for internal audits – WEC QMS, Section 18.1. A team of six dedicated internal auditors provide the core resource to deliver the internal audit programmes. These are supplemented by trained individuals that have the requisite technical skills to support the audit programme when necessary. During 2008, six internal audits were carried out in WEC Nuclear Power Plants, 12 within WEC Nuclear Fuels and 30 within WEC Nuclear Services. During 2008, approximately 45 of the 50 audits planned were carried out. A number of reactive audits were completed. This is a reasonable outcome for a realistic programme. 50 internal audits

are planned for 2009. As with the self-assessment process, corrective actions are entered into and controlled by the established CAPs process which is described in the WEC QMS, Section 22.2. The closeout of corrective actions is formalised requiring adequate justification. The closeout rate, within planned timescales, is good and management of outstanding actions is closely controlled.

- 26 There were three internal audits carried out during 2008 on New Plants AP1000 but none was carried out on the WEC UK GDA project. A management review is under way of self-assessments, internal and external audits. The output of this review will assist in the planning of the 2009 audit programmes. The intention is to ensure that the combination of review and audit processes provides a balanced approach and makes best use of resources. The audits planned for 2009 include aspects relating to AP1000 US contracts and International projects; even though these may not be directly applied to the WEC UK GDA project these may well cover related and applicable issues.
- 27 CAPs are reviewed on a weekly basis by the issues review board, chaired by the Vice President, Quality Assurance. Engineering, supply chain and quality are represented at senior level. There has been a concerted and targeted initiative (Global Growth Initiative) to reduce duplication and overlap between WEC Nuclear Power Plants, Nuclear Fuels and Nuclear Services and to optimise the interactions of these elements of the WEC organisation. The area of monitoring and review (i.e. self-assessment, internal and external auditing) has been a productive area. There is a stated intention within WEC to self identify issues rather than have customers, third parties or the US Nuclear Regulator, the US Nuclear Regulatory Commission (USNRC) find these first.
- 28 Of specific relevance to GDA, an analysis of internal and external audits and self-assessments from 2008 identified an issue relating to the Design Change Proposal process and a 'stop work' notice was issued. This was in relation to the submittal of the US Design Control Document (DCD) Revision 17 to the USNRC. The 'stop work' notice required that certain criteria be met before restart. Significant scrutiny was applied prior to restart. This action indicated to the inspection team that elements of monitoring and analysis is being carried out.
- 29 WEC has been requested to consider carrying out a review of effectiveness of the self assessment programme as part of the 2009 internal audit programme and to include directly the WEC UK GDA project and to consider covering all aspects of the WEC UK GDA project in the internal audit programme. Progress has been made.

2.3.1 Configuration Control/Change Management

- 30 Central to the processes that will deliver an effective GDA are the configuration control and change management processes.
- 31 It was a US legal requirement demanded by 10CFR50 (Ref. 10) to have configuration control. WEC QMS Section 6.1 Document Control is the high level procedure that details how configuration management is managed throughout WEC. This top level procedure is supported by a number of lower level detailed procedures (e.g. covering the development of P&IDs). Procedures for issuing and modification of documents are mandatory with this being made clear in the documents. This approach reflects the status of configuration/document control within the company with the requirements being imposed on WEC's vendors and suppliers through the mandatory use of specific procedures.
- 32 The Technical Document Control (TDC) system is at the centre of document control within WEC Nuclear Power Plants. This system tracks document revisions and issues unique numbers. Document cover sheets are controlled by the QA department within alphabetic issue indicators for drafts / unreviewed documents followed by numeric when the document is issued for use. The TDC is arranged such that it is possible to identify

any document (e.g. drawing), the revision and the applicable site on any particular day. The system retains records of all revisions.

- 33 The Electronic Document Management System (EDMS) is the master repository for all records relating to AP1000. The same document numbers are used as in the TDC, providing the functional relationship between the two systems (EDMS and TDC). Examples of documents were presented from the system and there are authorisation levels, requiring specific training, to access, enter and archive information held on the system. These controls are considered adequate. A Design Reference Point (DRP), effectively a design freeze, date of 31 December 2009 has been agreed with WEC. Westinghouse has been asked to consider the installation and use of a data centre (termed a 'jackbox') dedicated to the WEC UK GDA project to facilitate the DRP. In the event WEC has introduced the use of a dedicated eRoom which will provide a more focused approach to the joint regulators for documentation requests. This is a satisfactory solution and is now in place.
- 34 WEC operates a mature design change process which is applied to design/safety documentation. These arrangements are fully described in WEC QMS Section NSNP 3.4.1 which applies within NPP and to design partners and contractors. The change classification is based on the impact (including safety) of the changes. The Document Change Proposal (DCP) form (which is required for all proposed changes) is used to indicate the nature and class of change. There is a policy to minimise the number of changes to technical documents e.g. by grouping a number of changes where appropriate. The criteria for change are that the design is unsafe; the design doesn't work as intended or for design finalisation or additions. Specific training sessions to reinforce the policy of the allowed reasons for change proposals are carried out. Examples of DCPs were examined from which it was clear that the arrangements to ensure those disciplines that may be affected are required to comment, and where there is an impact this must be fully assessed (nil returns required) are implemented. The joint regulators' inspections during Step 4 will closely examine significant changes that have an impact on the UK AP1000 project.
- 35 The Chairman of the Change Control Board (CCB) has to agree with the classification of the change proposal. In addition to the assessment of the impact on the standard UK Regulator 15 technical assessment areas, comments are requested from an external Builders Group. The form requesting comments now also includes the UK Safety Categorisation for changes. The current WEC DCP procedure applies UK modification categorisation after the standard WEC modification categorisation has been applied. This 2 stage approach may exclude some items that should be categorised under the UK process. WEC has agreed to modify its DCP procedure to ensure that the possibility of such an exclusion is removed. WEC has taken steps to address this as part of its actions to address RO-AP1000-35.
- 36 There is currently a significant backlog of unincorporated DCPs (uDCPs), approximately 10,000 many of which are for very minor changes, e.g. spelling or pagination. All have been through the assessment and justification stages of proposed changes and a system is in place which will identify to the designated WEC Lead Engineer(s) the existence of unincorporated DCPs. There is a concerted effort within the RP's organisation to significantly reduce this number. The RP has been requested to inform the UK regulators of progress with this task by November 2009.
- 37 Changes to documents are subject to levels of verification. It requires the verifier to be independent of the work in question and technically competent. The arrangements detail the responsibilities of the verifier which includes the resolution of all comments received and these must be documented. Managers allocate verification work with knowledge provided on individuals through the annual review process and the WEC training intranet site, of a verifier's competency. A course on DCP verification is a standard element of

the WEC training portfolio. Examples were examined and found to be procedure compliant.

2.3.2 Organisational Learning

- 38 WEC has formed a new organisation within Nuclear Power Plants to manage continuous improvement. There are a collection of 'learning' programmes including organisational learning, project excellence, 'Customer First' and 'Human Performance'. These supplement and support existing 'learning' programmes within Operational Excellence and Quality; Self Assessment, CAPs and Supplier Quality. A dedicated 'iKnow' database has been constructed to collect information on lessons learned. New employees are made aware of the organisation learning initiatives and the 'iKnow' database. It is evident that there has been a concerted effort to capture relevant information, e.g. collection of issues on containment vessel manufacturing and nuclear island base-mat preparation issues and to enable employees, via 'iKnow' to access these.
- 39 The organisational learning programme is well thought out and important to continuous improvement. The examples of information shown were relevant to GDA. The work that has been carried out in this area adequately addresses the recommendation made in the November 2007 inspection report with regard to the development of a formal system to capture learning from experience.

2.3.3 Control of Procurement Activities

- 40 As the GDA process advances, there is increasing interest in the RP's procurement arrangements, particularly with respect to long lead items. This subject is of more importance to ND than the Environment Agency in order to assess the quality arrangements applied to the realisation of design intent. WEC has an established history of dealing with suppliers through the supply chain. 10CFR50 Appendix B (Ref. 10) requires processes on procurement document control and control of material, equipment and services. WEC operates a quality system compliant with 10CFR50 Appendix B and therefore is required to control these activities.
- 41 WEC has a strategy on the supply of long lead items which include RPV forgings, SG forging and tubing, reactor cooling pump, structural modules and forgings for the main turbine generator. No purchase orders have been placed for any components to be supplied to the UK market and no procurement activity will take place until an agreement is signed with a customer (i.e. a prospective operator). There is preparatory work taking place with WEC including assessing suppliers for the UK market and a number of memoranda of understanding have been agreed with potential UK contractor organisations. The WEC procurement function is formalised with arrangements for supplier qualification, control of purchased items and services, supply chain management, and supplier oversight.
- 42 There is a clear distinction between WEC selection of suppliers for 'safety related' items/services than for commercial grade items. However, where appropriate, WEC supplements the quality assurance/control processes of a supplier of commercial grade items in order to provide appropriate levels of assurance for their use in a safety related application. WEC operates a witness and hold point surveillance programme which is applied based on the safety significance, contract cost/risk and reliability of the items/service being procured. In some instances e.g. NSSS items, WEC inspectors are resident at manufacturers for the duration of the supply contract
- 43 WEC has an organised approach to procurement, operating quality planning and inspection and surveillance activities, safety is one of the criteria used to decide on levels

of control of suppliers. USNRC has planned to carry out an inspection of WEC procurement arrangements during 2009.

44 WEC is conversant with the owner's responsibility under ASME III and the delegation/non-delegation aspects. WEC has an established position with operators and suppliers with respect to design authority and the practical application of the ASME Code requirements. Further discussions will take place during Step 4 to establish a planned way forward on the application of controls to the procurement, manufacture, fabrication and testing of nuclear pressure vessels. WEC outline, in Section 3 of the PCSR, its understanding of the 'intelligent customer' concept as applied to operators.

45 Section 3 of the PCSR also recognises the need to transfer sufficient and appropriate information to the operator such that the latter can function as an effective design authority. A TQ has been raised to seek more information from the RP on how this will be achieved.

2.3.4 Observations

46 **Recommendations arising directly from the Step 3 Joint Regulators' Inspection.** Seven recommendations resulted from the inspection of the RP's arrangements as follows:

- *Recommendation 1:* WEC should consider the application of the self-assessment process to the UK-GDA project.
- *Recommendation 2:* WEC should consider covering all aspects of the UK-GDA project in the internal audit programme.
- *Recommendation 3:* WEC should consider the application of the organisational learning initiative to the UK GDA project.
- Recommendations 1, 2 and 3 have been incorporated into RO-AP1000-35 which requires WEC to apply all the rigours of its QMS to the UK GDA Project.
- *Recommendation 4:* WEC should consider carrying out a review of effectiveness of the self assessment programme as part of the 2009 internal audit programme and to include directly the UK GDA project.
- *Recommendation 5:* WEC should inform the Joint UK Regulators of progress with the closeout of unincorporated DCPs by the end of November 2009.
- *Recommendation 6:* WEC should consider the installation and use of a data centre dedicated to the UK-GDA project.
- *Recommendation 7:* WEC should consider the amendment of its DCP procedure as related to the UK GDA project to ensure that both the WEC and UK categorisations are fully taken into account.

47 WEC letter reference UN WEC 00088 (Ref. 18) identifies the corrective actions that WEC has initiated to address these recommendations the majority of which are covered in RO-AP1000-35 (Ref. 15). Progress has been made and implementation will be examined by UK regulators early in Step 4.

48 WEC will need to ensure that future revisions of the PCSR demonstrate the full application of the WEC QA arrangements.

49 **Requirements of GDA guidance.** The guidance to RPs on GDA required them, at Step 3 and Step 2, to submit a description of its QA arrangements for the GDA project. Additionally information regarding the RP's strategy regarding long-lead items was requested. WEC's strategy, expressed during the joint regulators' inspection, with regard to long lead items is to progress the procurement of these items when there is a contract

with a potential operator. WEC will notify the UK regulators prior to procurement of long lead items.

50 **Use of other regulators information.** Although no direct use has been made of overseas regulators' assessment information the joint regulators' inspections carried out during Steps 2 and 3 were attended by representatives of the United States Nuclear Regulatory Commission (USNRC). This interaction has been found to be very useful and will continue in Step 4. Additionally the joint regulators' work has been reported to the Multinational Design Evaluation Programme working group on Vendor Inspection.

51 **Related research.** No QA related research requirements at this stage.

52 **Technical Queries (TQs).** During GDA, 4 TQs (Ref. 14) have been raised relating to QA, 3 of which have been closed. TQ-AP1000-330 remains open and deals with WEC's arrangements for knowledge transfer to potential operators.

53 **Regulatory Observations (ROs).** Two ROs have been raised relating to QA throughout Step 3, RO-AP1000-17 and RO-AP1000-35 (Ref. 15). The application of the RP's corrective actions for both of these aspects will be inspected as part of the planned inspections for Step 4.

54 **Regulatory issues (RIs).** In the QA area there have been no failings or shortfalls of sufficient magnitude to warrant the issue of an RI.

55 **Potential exclusions.** There are no QA based Exclusions at this time.

3 ASSESSMENT AREAS FOR STEP 4

56 **Plans for Step 4 assessment.** It is intended that our Step 4 assessment will look in detail at all of the areas reviewed at a high level in Step 3 using the additional information received as a result of the TQs and ROs as a basis together with any further planned submissions from WEC. The first stage of Step 4 will be a Step 3 assessment 'wrap up meeting' with WEC which will summarise the work done so far, and aim to agree and assign priorities to the work needed to address the TQs and ROs.

57 Our Step 4 assessment will therefore include the following:

- The application of the full breadth and depth of the Westinghouse QMS applicable to the UK GDA Project.
- Further demonstration of the adequacy of the quality arrangements describing and being applied to the UK GDA Project as part of the safety case development.
- The justification of the approach, strategy and procedure that will be applied during any eventual construction and installation to result in a plant which meets the requirements of the safety case.
- The development of an outline commissioning and installation schedule which demonstrates that the as-built plant will meet the design intent.
- Demonstration of the adequacy of the arrangements for the future production of operational documentation, for establishing a Design Authority (including Knowledge Transfer) and for the control of site-specific activities including design changes.

58 In Step 4 we will carry out one or more targeted inspections to establish the consistent and comprehensive application of adequate quality assurance arrangements.

59 During Step 4 we will also focus on those aspects important to the development of a licensee that is sufficiently knowledgeable with respect to the design and safety case, paying particular attention to the management of safety arrangements, design change and document configuration control. Particular emphasis will be placed on the interfaces

with prospective operators and their involvement in design and safety case development and control.

4 CONCLUSIONS AND RECOMMENDATIONS

- 60 WEC continues to operate a well developed set of quality arrangements which include sub-tier procedures which are periodically reviewed and audited. A GDA specific Project Quality Plan (PQP) was developed and first issued in March 2008 and a revision issued in March 2009. This is supported by a number of related GDA procedures, also issued in March 2009, that are designed to formalise the interface between the Joint Programme Office (JPO) and WEC. The PQP and procedures have been reviewed by the joint regulators and comments were provided formally by letter (WEC 70080R and WEC70081R, Refs 16 and 17). This work is progressing.
- 61 It is acknowledged that WEC has experienced and knowledgeable staff and a commitment to retain adequate technical resources. Through a number of targeted initiatives organisational learning and continuous improvement have been addressed. However, the full benefit of these initiatives had not been realised for the UK GDA AP1000 project, at the time of the joint regulators' inspection, as the level of application to the project appears to be minimal. This leads to some doubt regarding the commitment to apply WEC established processes to the GDA project.
- 62 There is strong leadership and ownership of the design configuration and change processes, however, there remains a significant workload to clear the backlog of unincorporated DCPs. WEC has recognised the challenge and has plans in place to address this situation.
- 63 WEC operates well established arrangements for the selection and surveillance of suppliers as part of its procurement activities. Particular attention is given to the controls applied through the procurement stages for safety related items and services.
- 64 WEC has not always responded in a timely manner to questions, Technical Queries and Regulatory Observations, however, this is being addressed and should improve during Step 4. Of particular significance is the need for WEC to address RO-AP1000-35 fully and demonstrate to application of applicable elements of the WEC QMS to the GDA process. A comprehensive audit has been undertaken by WEC on the applicability of the WEC QMS to the UK AP1000 GDA project and a number of corrective actions have been identified. On that basis ND sees no reason why the UK AP1000 GDA project should not proceed to Step 4 of the GDA process on Quality Assurance grounds providing there is a clear and sustained commitment to the application of the full rigours of the WEC QMS to the UK AP1000 GDA project. This is of particular relevance to the update and control of the PCSR. The application and adequacy of WEC's proposals will be closely monitored during Step 4 and this will include further joint regulators' inspections.

5 REFERENCES

- 1 *AP1000 Pre-construction Safety Report UKP-GW-GL-732* Revision 1 Westinghouse Electric Company LLC March 2009.
- 2 *ND BMS, Assessment Process AST/001* Issue 2 HSE February 2003.
- 3 *ND BMS, Guide: Assessment Process G/AST/001* Issue 2 HSE February 2003.
- 4 Joint Regulators' Team Inspections:
Report on the Joint Regulators' Team Inspection of Westinghouse's Arrangements as part of the Generic Design Assessment (Quality Management Arrangements) November 2007.
Report on the Joint Regulators' Team Inspection of Westinghouse's Arrangements as part of the Generic Design Assessment (Quality Management Arrangements) April 2009.
- 5 *Safety Assessment Principles for Nuclear Facilities* 2006 Edition, Revision 1 HSE January 2008.
- 6 Not used.
- 7 Not used.
- 8 Not used.
- 9 Not used.
- 10 US Nuclear Regulatory Commission Regulations: *Title 10, Code of Federal Regulations, Part 50, Domestic licensing of production and utilization facilities.*
- 11 *Westinghouse Electric Company Quality Management System (QMS)* Revision 5 October 2002.
- 12 *The Management System for Facilities and Activities. Safety Requirements* IAEA Safety Standards Series No. GS-R-3 International Atomic Energy Agency IAEA Vienna 2006.
- 13 *Nuclear Power Station Generic Design Assessment. Interface Protocol Between HSE Nuclear Directorate / Environment Agency and Requesting Parties* JPO/003 Issue 2 August 2008. TRIM Ref. 2008/41861.
- 14 *Westinghouse AP1000 - Schedule of Technical Queries raised during Step 3* HSE-ND. TRIM Ref. 2009/358248.
- 15 *Westinghouse AP1000 - Schedule of Regulatory Observations raised during Step 3* HSE-ND. TRIM Ref. 2009/358257.
- 16 *Regulator Comments on UKP-GW-GAH-001 Revision 1 - Project Quality Plan for the UK Generic Design Assessment. (Regulatory Observation RO-AP1000-17)* HSE Nuclear Directorate UN WEC 70080R 27 May 2009. TRIM Ref. 2009/201724.
- 17 *Regulator Comments on UKP-GW-GAP-011 to UKP-GW-GAP-016 Inclusive - Project Quality Procedures for the UK Generic Design Assessment. (Regulatory Observation RO-AP1000-17)* HSE Nuclear Directorate UN WEC 70081R 29 May 2009. TRIM Ref. 2009/201726.
- 18 *Westinghouse letter - Regulatory Observation Actions RO-AP1000-35.A1 and RO-AP1000-35.A2 – QMS* Westinghouse Electric Company LLC UN REG WEC 00088 31 August 2009. TRIM Ref. 2009/342722.

Annex 1 – Management of Safety and Quality Assurance – Status of Regulatory Issues and Observations

RI / RO Identifier	Date Raised	Title	Status	Required timescale (GDA Step 4 / Phase 2)
Regulatory Issues				
None.				
Regulatory Observations				
RO-AP1000-17	3 Oct 2008	<p>A number of documents comprising the Westinghouse Step 3 submission received to date (as of 19 August 2008) contain a variety of minor errors, or have not included changes which have been discussed and agreed between the Regulators and Westinghouse.</p> <p>Examples include poor cross-referencing of documents, omission of SI unit conversions and omission of agreed changes reflecting the Environment Agency's role in the GDA process. More latterly, a document appears to have been modified without re-issue (UKP-GW-GL-730 Rev 2). This indicates that there may be a deficiency in the quality assurance arrangements being applied to document production and review for the UK AP1000 GDA process. This would undermine the quality of the submissions, and could reduce Regulators' confidence in the safety claims, arguments and evidence being provided for Steps 3 and 4.</p>	An outstanding action relates to the wider application of the WEC QMS to the UK GDA project. WEC's proposals are currently being evaluated.	By commencement of Step 4
RO-AP1000-33	1 June 2009	Quality Assurance issues for the Environment Report and supporting documents	WEC has responded with proposals which are being considered by the Environment Agency. The resolution will be the delivery of an updated and accurate Environment Report and supporting documents.	Start of Step 4

RI / RO Identifier	Date Raised	Title	Status	Required timescale (GDA Step 4 / Phase 2)
RO-AP1000-35	12 Jun 2009	Westinghouse need to demonstrate that the full rigour of its Quality Management System is being applied to the UK GDA process, for example the application of self-assessments, internal audit, learning from experience and document verification procedures. This includes the development of adequate procedures for a UK specific context where necessary.	A detailed internal audit of WEC's application of its QMS has been undertaken and a number of findings have been highlighted. Discussions are ongoing with respect to WEC's response to fully address the RO.	Early in Step 4