

JOINT PROGRAMME OFFICE

**REPORT ON THE JOINT REGULATORS' TEAM INSPECTION OF
WESTINGHOUSE'S ARRANGEMENTS AS PART OF THE GENERIC DESIGN
ASSESSMENT
(QUALITY MANAGEMENT ARRANGEMENTS)**

March – April 2009

REQUESTING PARTY:	Westinghouse Electric Company (WEC)	FILE REF.:	
SITE:	Pittsburgh	CC:	
DATE:	March 31 – April 3 2009		
INSPECTION No.:	01/09		
SUBJECT	Inspection of selected WEC quality management arrangements in support of GDA process.		
INSPECTION OBJECTIVES:	<ul style="list-style-type: none"> -To check that WEC is applying its Quality Management Systems to the UK GDA process. - Through inspection, to establish that WEC has implemented and continue to review arrangements that adequately control their GDA related activities. - To inform the UK Nuclear Regulators' assessment of WEC's submission. 		
INSPECTION BACKGROUND:	<p>As part of the GDA process the UK Nuclear Regulators carried out a second inspection of a selected number of aspects of WEC's QMS and in particular those arrangements relating to the control of the submission (environmental, safety, security report). Mr J Nakoski, an inspector from the United States Nuclear Regulatory Commission (USNRC), attended throughout the inspection as an observer. He asked questions and sought clarification on a number of issues and provided the UK regulators with useful insight into the US regulatory process. Also present were representatives of potential UK operators EON, Iberdrola and RWE at the invitation of WEC</p>		
FACILITY/AREA:	NPP WEC Monroeville Pittsburgh PA		

SUMMARY OF INSPECTION FINDINGS

SUMMARY

WEC continues to operate a quality programme to meet the requirements of 10CFR50 Appendix B. In addition, a specific Project Quality Plan for GDA-UKP-GW-GAH-001 Rev1 has been issued in March 2009. This provides a top level quality management document for the UK-AP 1000 project which heads a number of project specific procedures (for example. Receipt and processing of TQ's from the UK regulators UKP-GW-GAP-012),. and cites those procedures within WEC's QMS that are to be applied to the UK GDA project.

Since the GDA Step 2 inspection, by the joint regulators, in late 2007 there have been a number of quality initiatives set up across WEC e.g. Self assessment. These initiatives support the concepts of a learning organisation and continuous improvement and as such are seen as positive by the inspection team. However, because of the WEC established way of working the UK-AP1000 project has not benefitted, as yet, from these initiatives.

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

WEC continues to operate a matrix management structure. The AP1000 project organisation is established under the banner Nuclear Power Plants (NPP). There has been a significant pan-WEC initiative to achieve integration of processes and procedures with Nuclear Services and Fuel Division which both provide resource and technical expertise to the AP1000 programme.

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.

The UK Regulators' conclusion is that:

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 Quality Plan 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, issued in March 2009, that are designed to formalise the interface between the Joint Programme Office (JPO) and WEC. The Quality Plan and procedures were reviewed by the joint regulators and comments were provided formally by letter (WEC 70080R and WEC70081R). The Inspection Team considers that the joint

regulators' confidence in the arrangements for the development of the Step 3 submission could be improved by the application of all the elements of the WEC quality programme to the UK GDA project (the Step 3 GDA report will comment on the effectiveness of this). 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 has not been realised for the GDA project as the level of application to the project appears to be minimal. This leads to some doubt regarding the effective application of WEC processes to the UK GDA project.

There is evident 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. The Joint Regulators require to be updated on progress with regard to the closeout of unincorporated DCPs.

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.

Recommendation: WEC should inform the Joint UK Regulators of progress with the closeout of unincorporated DCPs by the end of November 2009.

ASME III Responsibilities

Westinghouse explained its position with regard to ASME owners' responsibilities as part of the Step 3 assessment process. There was clear commitment to ISO 9001; ISO 9003; 10CFR 50 Appendix B, ASME NQA-1 and IAEA 50-C-Q. WEC recognised that the latter code has been replaced by GS-R-3 and consideration was being given to its application. As a minimum quality standard ISO 9001 is applied for items and services that are designated as non-safety related. It is very clear that WEC operates its quality system in line with US Regulatory Requirements and in particular 10CFR 50 Appendix B (as described in US NRC Regulatory Guide 1.28) and the applicable ASME Boiler and Pressure Vessel Code.

WEC provided a clear overview of its quality programme identifying the legal requirements and the resultant Level 1, 2 and 3 management system and Procedures to ensure compliance. It was evident from discussions and inspection that WEC has a mature and highly codified Quality Management System.

WEC has developed its QA programme, via the Quality Assurance Programme Manual (WCAP -12308) to satisfy the requirements of ASME Section III, division 1 – NQA1 – 10CFR-50 Appendix B. This Programme applies to all ASME Code related activities performed under ASME Code, Section III, Division 1.

WEC described the owner's responsibility under ASME III and emphasised the delegation/non-delegation aspects. It was clear that WEC has an established position with operators and suppliers with respect to design authority and the practical application of the ASME Code requirements. It was suggested that further discus-

sions take place during Steps 3 and 4 to establish a planned way forward on the application of controls to the procurement, manufacture, fabrication and testing of nuclear pressure vessels. WEC demonstrated a good understanding of the 'intelligent customer' concept as applied to operators and fully accepted responsibility to ensure planned transfer of technical knowledge.

Self- Assessments

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, there appears to be a more obvious commitment to its review and application which enhances the established quality ethic. The introduction of the self-assessment process provides an indication of the commitment to continuous improvement.

The application of NSNP 18.2 Self Assessment/Continuous Improvement is designed to review levels of compliance at the procedure and work instruction levels. From the evidence provided during the inspection, these assessment have enabled improvements to be 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 Joint Regulators understand the target was exceeded this year; 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 WECs monitoring and review of quality activities. It was clear that individuals' time to participate in a self-assessment was allocate in a planned way and sanctioned by management. Findings from self-assessments are entered into and controlled by the CAPs process. It was noted that a number of findings could be applicable to the UK-GDA project, however. It was noted that the self-assessment process had not been extended to the UK GDA project.

Recommendation: WEC to consider the application of the self-assessment process to the UK-GDA project.

Internal and External Auditing

WEC operates a well-established procedure for internal audits – WEC 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 Nuclear Power Plant, 12 within Nuclear Fuels and 30 within Nuclear Services. During 2008, approximately 45 of the 50 audits planned were carried out. A number of reactive audits were completed. The inspection team considers this to be a reasonable outcome for a realistic programme. Fifty 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 WEC 22.2. The closeout of corrective actions is formalised requiring adequate justification. The closeout rate, within planned time-

scales, is good and management of outstanding actions is closely controlled.

There were three internal audits carried out during 2008 on New Plants AP1000 but none was carried out on the 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. WEC explained that audits planned for 2009 include aspects relating to AP 1000 US contracts and International projects; even though these may not be directly applied to the UK GDA project these should cover related and applicable issues.

CAPs are reviewed on a weekly basis by the issues review board, chaired by the VP QA. 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 NPP, NF and NS and to optimise the interactions of these elements of the WEC organisation. The area of monitoring and review (ie self-assessment, internal and external auditing) has been a productive area.

WEC wish to self identify issues rather than have customers, third parties or the US Nuclear Regulator find these first.

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 DCD 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 effective monitoring and analysis is being carried out and more importantly that senior management scrutiny is being carried out and appropriate sanctions applied.

It was noted that in 2008 there were five external audits by; NUPIC, USNRC, Duke Energy, LRQA and JPMO (China).

Recommendation: WEC 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 UK GDA project.

Recommendation: WEC to consider covering all aspects of the UK-GDA project in the internal audit programme.

Configuration Control/Change Management

WEC explained that it was a legal requirement demanded by 10CFR 50 to have configuration control. WEC 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 (eg 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 importance of configuration/document control within the com-

pany and the requirements are imposed on WEC's vendors and suppliers (GEP 001 outlines technical and administrative requirements on vendors and suppliers, with an appendix stating which procedures are mandatory).

At the centre of the control of documents is the Technical Document Control system (TDC). 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. WEC stressed that the TDC is arranged such that it is possible to identify any document (eg drawing), the revision, the applicable site on any particular day. The system retains records of all revisions.

The 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 enter, access and archive information held on the system. It was not entirely clear how the EDMS relates to the TDC.

WEC described its well-established change process which is applied to design/safety documentation. These arrangements are fully described in NSNP 3.4.1 which applies within NPP and to design partners and contractors. The change classification is based on impact of the changes. The Document Change Proposal 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 eg by grouping a number of changes. The criteria for change are that the design is unsafe; the design doesn't work as intended or for design finalisation or additions. There were recent training sessions to reinforce the policy of the allowed reasons for change proposals. The inspection team was shown examples of DCPs, and the arrangements to ensure those disciplines that may be affected are able to comment, and where there is an impact this must be fully assessed (nil returns required). There is currently a significant backlog of unincorporated DCPs (uDCPs), approximately 10,000. WEC explained that many of these are for very minor changes, eg spelling or pagination. WEC recognises that the criteria for incorporation has not been achieved for many of these changes, however all have been through the assessment and justification stages of proposed changes. A system is in place which will identify to the Engineer the existence of unincorporated DCPs..

The Chairman of the Change Control Board has to agree with the classification of the change proposal. In addition to assessment of impact on the standard 15 internal technical areas comments are requested from the 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. On this basis the WEC DCP procedure should be modified to ensure that the possibility of such an exclusion is removed.

Recommendation: WEC should inform the Joint UK Regulators of progress with the closeout of unincorporated DCPs by the end of November 2009.

Recommendation: WEC should consider the installation and use of a data centre (jackbox) dedicated to the UK-GDA project to facilitate a GDA design freeze.

Recommendation: WEC should consider the amendment of its DCP procedure as related to the UK GDA project to ensure that both the WEC and UK categorisation are fully taken into account.

Organisational Learning

WEC has formed a new organisation within Nuclear Power Plants to manage, through a number of new and existing initiatives, Continuous Improvement. There are a collection of “learning” programmes including organisational learning, project excellence, I³, Customer 1st and Human Performance. These supplement and support existing “learning” programmes within Operational Excellence and Quality; Self Assessment, CAPs and Supplier Quality. The “i know” database has been constructed to collect information on lessons learned. New employees are made aware of the organisation learning initiatives and the “i know” database. It is evident that there has been a concerted effort to capture relevant information, eg collection of issues on containment vessel manufacturing and nuclear island base-mat preparation issues and to enable employees, via “i know” to access these for consideration.

The inspection team considered the Operational Learning programme to be well thought out and important to continuous improvement. The examples of information shown were relevant. The joint regulators were satisfied that one of the recommendations made in the November 2007 inspection report with regard to the development of a formal system to capture learning from experience has been adequately addressed.

Recommendation: WEC should consider the application of the organisational learning initiative to the UK GDA project.

Document Modification Process

WEC explained that all changes to documents must subject to proper levels of verification. APP GW-GAP 100 Rev O NSNP 3.3.3 – Design Verification by Independent Review or Alternative Calculations was tabled and discussed. 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 by individuals 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.

WEC tabled an example of a DCP verification. DCP APP-GW-GEE-586 Rev 0 entitled “Main Steam Safety Valve Material Change”. This is a WEC Class 2 change. All checks for impact on potentially affected areas had been carried out and verification was completed in accordance with the governing procedure. A second example relating to the verification of a design calculation was also in line

with the prescribed arrangements with a completed verification checklist and close out of comments.

There was some discussion relating to document protective markings and whether these constituted a formal change. WEC's legal department had informed the UK GDA project that changes to protective markings are modifications and should be treated as such.

Transmission of Documents to UK Regulators

WEC has issued a UK GDA project specific procedure which describes the production and distribution of UK licensing documents. UKP-GW-GAP-011. The UK regulators have separately provided review comments to WEC on this procedure, and the procedures and quality plan produced for the UK AP1000 (WEC 70080R and WEC70081R).

Control of Procurement Activities

As the GDA process advances, there is increasing interest in vendor'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 explained that it has a long established history of dealing with suppliers through the supply chain.

10CFR50 Appendix B requires processes on procurement document control and control of produced material, equipment and services. WEC operate a quality system compliant with 10CFR50 Appendix B and therefore control these activities.

WEC confirmed that there is a strategy of the supply of long lead items which include RPU forgings, SG forging and tubing, Reactor cooling pump, Structural modules, forging 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. There is preparatory work taking place with WEC including the soliciting of quotes from suppliers for the UK market and a number of memoranda of understanding have been agreed with potential UK suppliers. The WEC procurement function is highly proceduralised with arrangement for supplier qualification, control of purchased items and services, supply chain management, and supplier oversight.

There is a clear distinction between the selections of suppliers for "safety related" items/services than for commercial grade items. However commercial grade items can be purchased and used in "safety related" applications, provided WEC has applied additional self imposed inspections/tests/verifications to provide levels of assurance consistent with the intended use of the item. Of particular interest is the established WEC witness and hold point surveillance programme which is applied based on the safety related, 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

It was evident that WEC has a number of functions that provide support to the pro-

curement activities and much of this is formally documented. The purchase order execution and subsequent supplier contract management are examples of the importance WEC places upon supply chain arrangements. The inspection team explained that there would be increasing interest in WEC arrangements for procurement and inspections of that function specifically would be planned when UK related procurement activity begins. The inspection team consider that WEC has an organised approach to procurement, operates quality planning and inspection and surveillance activities, and has safety as one of the criteria used to decide on levels of control of suppliers. USNRC is to carry out an inspection of WEC procurement arrangements during 2009. This provides NII with an opportunity to obtain the report or even take part in the inspection.

Observations

1. WEC has developed and issued a quality plan specifically for the UK GDA project (first issued March 2008 and revised and reissued March 2009). This is supported by a number of UK GDA project specific procedures issued March 2009 . These documents have been reviewed by the joint regulators, and formal comment has been provided (WEC70080R and WEC 70081R).
2. WEC through a number of quality related initiatives has focused on establishing WEC as a learning organisation and implementing processes directed towards continuous improvement. These initiatives are to be welcomed. However, the UK GDA project has not benefitted from these initiatives as they have not been applied.
3. There remains strong leadership and ownership of the design change and configuration processes. WEC has recognised the challenge of the significant number of unincorporated DCPs and has decided on a course of action to reduce and ultimately reduce these to more acceptable levels.

Recommendations

4. Recommendation 1: WEC should consider the application of the self-assessment process to the UK-GDA project.
5. Recommendation 2: WEC should consider covering all aspects of the UK-GDA project in the internal audit programme.
6. Recommendation 3: WEC should consider the application of the organisational learning initiative to the UK GDA project.

Recommendations 1, 2 and 3 will be incorporated into a Regulatory Observation which requires WEC to apply all the rigours of its QMS to the UK GDA Project.

7. 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.

8. Recommendation 5: WEC should inform the Joint UK Regulators of progress with the closeout of unincorporated DCPs by the end of November 2009.
9. Recommendation 6: WEC should consider the installation and use of a data centre (jackbox) dedicated to the UK-GDA project.
10. 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.