

**JOINT PROGRAMME OFFICE**

**REPORT ON THE JOINT REGULATORS' TEAM INSPECTION OF  
EDF/AREVA's ARRANGEMENTS AS PART OF THE GENERIC DESIGN  
ASSESSMENT  
(QUALITY MANAGEMENT ARRANGEMENTS)**

**July 2009**

<b>REQUESTING PARTY:</b>	EDF/AREVA	<b>FILE REF.:</b>	
<b>SITE:</b>	Paris	<b>CC:</b>	
<b>DATE:</b>	April 21-23 April 2009		
<b>INSPECTION No.:</b>	02/09		
<b>SUBJECT</b>	Inspection of EDF/AREVA quality management arrangements in support of GDA process.		
<b>INSPECTION OBJECTIVES:</b>	<p>Joint HSE/EA Inspection objectives:</p> <ul style="list-style-type: none"> <li>• to assess adequacy of EDF/AREVA GDA QA arrangements for safety, security and environment submission documentation and procurement in particular for; <ul style="list-style-type: none"> <li>○ Configuration control</li> <li>○ Control of modifications</li> <li>○ Internal audit</li> <li>○ Selection and oversight of suppliers and manufactures</li> </ul> </li> </ul> <p>To inform the UK Nuclear Regulators' assessment of EDF/AREVA GDA submission.</p>		
<b>INSPECTION BACKGROUND:</b>	<p>As part of the GDA process, the UK Nuclear Regulators carried out an inspection of EDF/AREVA QMS and in particular those arrangements relating to the development of the submission (environmental, safety, security report). Ms J Fourche, an inspector from the French Nuclear Safety Authority (ASN-DEP), attended throughout the inspection as an observer and through her input provided the UK regulators with useful insight into the French regulatory process.</p>		
<b>FACILITY/AREA:</b>	EDF CNEN offices Montrouge Paris, Areva offices La Defense Paris		

## **INSPECTION FINDINGS**

### **Summary**

The organisational and quality assurance arrangements for the UK EPR GDA Project Team have been operating throughout STEP 2 and STEP 3 of GDA and are well established. The joint project arrangements are supported and supplemented within EdF and Areva by well developed QA arrangements. The Project Specific Quality Plan is supported by a number of procedures which have been implemented to a large degree.

As identified during the previous joint regulators' inspection during 2007 the UK EPR GDA project has a well defined organisational structure with clear roles and responsibilities identified.

The inspection provided evidence that the UK EPR GDA project is well managed and the elements important to effective interfaces between the Joint Programme Office and EdF and Areva are well controlled.

The April 2009 inspection has raised a number of aspects for consideration by EdF/Areva including clarification of the role of INSA as applied to design changes and its application to environmental aspects of the design. Additionally EdF/Areva should consider extending auditing programmes to cover all GDA support contractors. The joint inspection team also suggested that both EdF and Areva should consider reviewing their current arrangements for managing and tracking non-conformances arising from their auditing activities.

The joint inspection identified the need for further discussions, probably through QA Topic Meetings, on submission tracking sheets, design change controls and INSA arrangements.

### **The UK Regulators' Conclusion is that:**

EdF/Areva continue to manage and operate joint activities in support of GDA in a professional manner. These joint activities are defined in the UK EPR Project Quality Plan and are implemented through the related procedures. The joint project arrangements are supported by well established quality management systems operated separately by EdF and Areva. There were no major issues identified during the joint inspection and as such the joint regulators have confidence in EdF/Areva GDA project arrangements.

### **EdF/Areva Organisational Overview**

The inspection addressed interfaces between the joint RPs applicable to the UK EPR project and described in the dedicated Quality Plan. It also addressed processes such as auditing and procurement that are embedded in EdF and Areva as part of their QA programmes. There is clear evidence of a professional approach to the organisation and management of the UK EPR project and the support provided by the sponsoring organisations. Since the joint regulators' initial inspection in 2007, both EdF and Areva

have developed additional resources and processes in support of the UK GDA project including additional project specific procedures bringing the total to 35 specific to the project.

The UK EPR Project has clear safety, security and environmental objectives ie design acceptance confirmation from HSE (NII), a positive conceptual security plan statement from HSE (OCNS) and a statement of acceptability from the Environment Agency. These clear and concise objectives have focused the RP to develop processes to achieve the objectives. This provides the joint regulators with confidence of the intent of the UK EPR project to achieve its objectives and respond to the joint regulators comments.

It is evident that the Requesting Party wishes to de-risk aspects associated with the procurement of the NSSS and construction works.

The design freeze of December 2008 aligned the UK EPR design with the FA3 design. There have been around 12 modifications since the last design freeze which are fully documented and recorded. Changes to the GDA EPR design, incorporated after the December 2008 freeze date, will be subject to formal change control arrangements.

Topic meetings were discussed and it was agreed that issues such as the use of tracking sheets, the revised design change process and in particular the application of INSA should be discussed.

**Recommendation:** The RP and joint regulators to consider holding QA topic meetings to discuss, amongst other things, tracking sheets, design change processes and INSA.

The RP has a clear vision on the focus of interest on supply chain controls, how EdF and Areva will specify work and the transition between the UK EPR project and the future operating organisation. It was evident that EdF/Areva have considered and are preparing for the future stages of GDA and the transition into construction and operation.

With regard to Project Organisation and decision making there is strong evidence of the presence of governance by the Joint Steering Committee. Additionally through the Joint Project Team (EdF/Areva), the Project Quality Plan and related dedicated procedures, control and review of communications by both project managers, the operation of a joint public website, the use of Sharepoint for all project information and records there is an obvious commitment to management and control of UK EPR project joint functions. The project is supported by a number of contractors. One audit of Amec (provision of technical support services) has been carried out. The joint regulators suggested that other contractors supporting the project should be considered for audit.

**Recommendation:** EdF/Areva should consider auditing all UK EPR project contractors.

**Submission Control** (Configuration/Modification Controls)

The RP has reviewed and revised the project instructions for the PCSR and PCER submissions. It was noted however that the 2008 PCER was not subjected to INSA review. The joint regulators suggested that the INSA process be applied to the PCER as this provides an additional and independent review which in turn increased the joint regulators' confidence in the report. The joint regulators understood from the previous inspection (December 2007) that an independent review was applied to the environment submission. Additionally the joint regulators suggested that the INSA panel for future reviews of the PCER should include appropriate environment expertise.

**Recommendation:** EdF/Areva should consider the application of INSA reviews to future updates to the PCER and that such review panels should have appropriate environment expertise.

During discussions on INSA it became clear that the level of application of the INSA process was more restricted than the joint regulators had realised. This was a genuine misunderstanding. The current position is where ASN has considered information as part of the licensing review for FA3 this information although applicable to the UK EPR design will not be subject to INSA. Where information is applicable to the UK EPR design but not part of the FA3 safety report eg the ALARP chapter of the PCSR, this has been subject to INSA. There is a logic to this approach, however, the joint regulators considered this policy should be discussed further as part of a QA topic meeting.

Submission Configuration Control appears to be well managed. The basis of the UK EPR design is FA3 with all recorded design changes applicable to the UK. There is an EPR Configuration Management Board (ECMB) which has responsibility for overseeing the configuration control of the generic EPR design. One of its key objectives is the standardisation, as far as possible, the EPR design but giving consideration to national codes, standards and regulations.

Submission tracking sheets are updated when revised submissions are forwarded to JPO and all revisions have unique identifiers. Sharepoint, based on the Areva secure server, is used as the application to share information between EdF Areva and the joint regulator via JPO. This appears to operate effectively.

There is an established, structured UK EPR project database and a related user guide including rules for use. This database contains the project quality plan related procedures and instructions. An example of a design change folder was inspected which was found to be consistent with the procedures with change forms, listings and design information available.

EdF/Areva are considering a potential improvement for sharepoint to be used for the co-applicant approvals process. Lifetime archiving of project data is carried out by each co-applicant organisation.

The procedures for transmission of submission documents to the joint regulators are now well established. There are formal instructions for the transmission of letters and other documents, and the maintenance of records. The UK EPR project Front Office co-ordinates a review of UK EPR documentation before final approval and authorisation for use.

The control of design modifications is seen as fundamental to the UK EPR project's effectiveness. The current project procedure is UK EPR-I-003 rev 03 issued 20-03-2009. This issue introduced new definitions including the Design Change Screening Group, the Design Change Master List and a new paragraph on informing the JPO of changes and followed a review carried out in December 2008.

There are currently no differences identified between the UK EPR and the reference design although this may occur in the future. The joint regulators suggested that the logic behind any design change should be incorporated in the procedure. EdF/Areva explained that the next revision will include this information. All changes will be notified to the regulators even if not applicable to UK EPR.

There is a Design Change Screening Group which is responsible for screening FA3 design changes and making recommendations on FA3 change categorisation and implementation schedule for the UK. The DCSG includes technical managers with backgrounds in safety and environment from both EdF and Areva. The DCSG screens requests for modifications arising in order to determine the possible applicability to UK EPR and relevance to the GDA phase. Design Change Management forms are used to track the change status and to formalise the decisions for A1 type modifications to FA3 and for all UK specific changes. The Design Change Management form is recorded by the Design Change Process Co-ordinator in the Project share drive at the stages of processing the change status. There are periodic meetings of the UK Design Change Committee which has the responsibility of deciding whether to accept or reject changes for the UK EPR. The Design Change Management form provides the Change Committee with a description of the design changes, justification and an impact analysis and it recommends whether a more detailed impact study is required and gives an indication of which organisations should carry this out. The particular good element to the form is the identification list of documents that must be updated and verification of this prior to close out.

An example of a modification was examined. This dealt with changes to the fuel pond purification system (UK EPR-CMF-002). An impact study was requested and carried out. The study concluded there would be no increase in releases during normal operations or accident conditions as a result of a transient within design basis. The study found no impact on PCSR Chapter 9.

An example FA3 modification was examined. The documentation included the proposal, decision, approvals verification, potential impacts including radiological and environmental protection considerations. The current design change list indicated that there are 12 modification forms open for implementation of FA3 changes on UK EPR. The current design change process commenced at the December 2008 design freeze.

In summary the control of submission documents and related design configuration and modification control is well documented and managed. The application of the INSA process requires more discussion. The regulators have confidence in the co-applicants and UK EPR project with respect to these aspects.

### **Auditing**

The Joint Regulator's inspection in 2007 confirmed that both EdF and Areva have well established internal and external processes which continue to operate using qualified auditors, to formal procedures. Of particular relevance for this inspection is the status of close outs of non compliances and the programming of Joint GDA activity audits. With respect to the latter, a 3 day audit took place in May 2008 involving the front office and back offices of EdF and Areva. The audit team represented both EdF (CNEN) and Areva (NPP) which covered the management of interfaces between EdF and Areva and front and back offices in London and Paris.

Three findings were identified and satisfactorily closed out by October 2008. Of particular relevance was finding No 3 from this audit which identified an occurrence where UK EPR-I-003 (Design Change) was not being implemented fully with respect to the frequency of Design Change Committee meetings. The corrective actions put into place address this and the other 2 issues adequately. There is another EDF/AREVA joint audit planned for 4th quarter of 2009 to focus on configuration management and design change relating to UK EPR.

Both Rolls Royce Associates and AMEC have been used by the UK EPR project to carry out pre-joint regulator inspection reviews. The regulators consider this good practice.

The Joint Regulators suggested to both EdF and Areva separately that their individual internal and external audit programmes could be shared with ASN to establish any involvement from ASN eg observing audits.

Although both co-applicant organisations operate audit processes in line with general good practices, the regulators considered that the tracking and closure of corrective actions arising from internal, second party (excluding suppliers) and third party audits, which may impact on the UK EPR GDA process, could be more transparent. Management reviews in both EdF and Areva do consider outstanding corrective action status and require appropriate action.

**Recommendation:** EdF/Areva should consider a review of their current arrangements for the tracking and close out of non conformances arising from internal, second party (excluding suppliers) and third party audits which may impact on the UK EPR GDA process (including activities associated with the procurement of long lead items).

## **Procurement Arrangements**

The inspection scope included presentations and questions relating to EdF and Areva procurement arrangements in light of the need to consider these aspects for long-lead items alter in GDA and into Phase 2. The joint regulators also wished to initiate discussions on how the design intent is achieved via procurement, contracting and supply chain processes within the UK context. This will need to include vendor/licensee oversight, inspections and testing.

Both EdF and Areva are large complex organisations with numerous operational units, a number operating independently.

It was evident that both organisations have well established procurement arrangements including contract definition, supplier selection, in process inspection and surveillance and final acceptance. The level of controls applied to any contract is related to a number of factors including safety significance of the items/services being procured.

With respect to NSSS, Areva explained that ESPN French Order dated 12/12/005, applicable to nuclear pressure equipment had to be complied with. This is based on the European Pressure Equipment Directive with additional requirements to reflect nuclear risk aspects. It is also clear that DEP (part of the French Nuclear Safety Authority) carried out by law, a number of assessment, inspection and test activities on primary pressure components. Under these arrangements, the manufacturer is responsible for obtaining from DEP a certificate of conformity, this requires that the manufacturer must apply an acceptable quality management system, provide all the technical documentation for assessment and organise inspection at all sub-contractors works.

It is clear that there are a number of elements of this process that align with models described in T/AST/077, which is a draft guidance document for NII inspectors, entitled Procurement of Items and Services significant to Nuclear Safety. However, due mainly to the different regulatory regimes in the UK and France further discussions with respect to procurement and in particular long-lead items will take place during Step 3.

In summary: EdF and Areva have well established procurement processes that have been applied directly to contracts for the construction of nuclear power plants. Quality and environmental considerations are factored into the contracting processes. Both organisations pre qualify contractors and operate approved suppliers lists which are reviewed periodically. A number, or combination, of standard devices are used by the co-applicants including questionnaires, audit and technical assessments to qualify supplier organisations. We examined an example of a technical supplier evaluation questionnaire (Areva) for a supplier in Scotland. The questionnaire contained questions on organisation, control of document, competence, environment and health and safety (including quality levels). Both organisations recognise the use of quality plans and have ongoing inspection and surveillance programme using competent inspection bodies, eg. CEIDRE for EdF.

## **Learning from Experience**

Areva explained its policy of LFE which applies to all regions, eg. France, Germany, USA. There are processes in place to capture lessons learned from the construction of EPRs being built in France (FA3), Finland, China (Taishan) and USA. There is an internal network of staff responsible for LFE and a dedicated IT application to allow staff to input and access information. Currently there are around 400 lessons learned in the database, many of these from Finland (OL3). EdF is currently implementing a LFE process for 1400 and 900 MW plants using FA3 as a reference. There are, at present, 20 EdF staff who provide details of operating experience from French and German plants to the FA3 team. Both EdF and Areva are considering the use of LFE within the UK EPR project.

### **Environmental Programmes**

#### **EPR EdF Environment Programme**

The environment review took place in October 2004 before a site had been chosen. The purpose was to confirm performance and limits for EPR and improvements that were reasonably achievable.

The review meeting considered BAT, comparison with existing fleet and potential improvements. Recommendations included:

- 1 Reduction of Tritium in Liquid Discharges
- 2 Reduction and Control of Carbon14 in Liquid Discharges
- 3 Reduction of discharges of Radionuclides other than C14 and Tritium
- 4 Tanks to be added for Boron Recycling. This was presented at the March waste topic meeting in Paris attended by the UK Regulators
- 5 Reduction of Discharges containing Nitrogen
- 6 Chemical conditioning of secondary circuit and steam generator blowdown circuit resins
- 7 Confirmation of solid waste inventory for EPR using feedback experience from existing fleet; Taskforce in place 2004-5 using feedback from French fleet (see PCSR Chapter 6.3)

The presentation provided information on consideration of potential environmental improvements and how these might be incorporated in the EPR design. Further specific information may be required by the Environment Agency in this area. A TQ was issued to request further information on this topic.

#### **Areva NP Environmental Programme**

The EPR was designed before the Areva NP EMS was introduced and there has been no specific environmental improvements introduced to the UKEPR. Lessons learned

from OL3 were fed into the Areva EMS and there are monthly teleconferences and reports on environmental issues for OL3. The same process will be implemented for the UK project and an environmental management plan will be written for the UK project.

### **Observations**

1. EdF/Areva operate well defined UK EPR joint project activities which appear to be effectively managed. In addition to the QA arrangements that exist within the co-applicants organisations the joint project is controlled through arrangements detailed in a project specific quality plan which is supported by a number of procedures that are increasing in number and being further developed as the project progresses.
2. The UK EPR GDA Project has operated an independent nuclear safety assessment (INSA) process as part of design change since Step 2. This was seen as a very positive step and reflected future requirements for a licensee during construction, commissioning and operation of nuclear plant. However its application appears to be more limited than the regulators thought and also it has been applied in an inconsistent manner to the PCER.
3. Of increasing interest is procurement and the delivery of design intent through the supply chain of structures, systems and components significant to nuclear safety. Both EdF and Areva have established procurement arrangements that include supplier selection contract controls and inspection and surveillance. Further discussions will take place between EdF and Areva and the UK joint regulators with regard to the controls applicable to long lead items.

### **Recommendations**

Recommendation 1: The RP and Joint Regulators to consider holding QA topic meetings to discuss, amongst other things, tracking sheets, design change processes and INSA.

Recommendation 2: EdF/Areva should consider auditing all UK EPR project contractors.

Recommendation 3: EdF/Areva should consider the application of INSA reviews to future updates of the PCER and that such review panels should have appropriate environment expertise.

Recommendation 4: EdF/Areva should consider a review of their current arrangements for the tracking and close out of non conformances arising from internal, second party (excluding suppliers) and third party audits which may impact on the UK EPR GDA process (including activities associated with the procurement of long lead items).

