Health and Safety Executive

NUCLEAR DIRECTORATE

GENERIC DESIGN ASSESSMENT – NEW CIVIL REACTOR BUILD

STEP 3 MANAGEMENT OF SAFETY AND QUALITY ASSURANCE ASSESSMENT OF THE EDF AND AREVA UK EPR

DIVISION 6 ASSESSMENT REPORT NO. AR 09/032-P

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EXECUTIVE SUMMARY

This report presents the findings of HSE's assessment (including inspection) of the Quality Assurance (QA) arrangements implemented by EDF and AREVA to deliver the UK EPR safety case for Step 3 of the Nuclear Directorate's (ND) Generic Design Assessment (GDA) process.

It provides comments on the organisational and procedural arrangements to deliver EDF and AREVA's safety case as presented in the UK EPR Pre-Construction Safety Report (PCSR) (Ref. 1); the standards and criteria adopted in the assessment; and the outcome of the joint inspection by HSE and the Environment Agency.

A joint regulators' inspection of EDF and AREVA's QA arrangements, during Step 2 of GDA, established that both sponsoring organisations operate Quality Management Systems individually in line with appropriate national and/or international quality standards and as such provide a sound basis of control for the UK EPR GDA project. The co-sponsors for the UK EPR GDA Project developed a specific Project Quality Assurance Plan (PQAP) - UKEPR-O-001 (Ref. 8) which describes the joint organisational and procedural arrangements to deliver the submission documents. The PQAP defines and describes interface arrangements between the joint EDF and AREVA project organisation and the regulators' Joint Programme Office (JPO). The PQAP references a number of joint project procedures covering aspects such as submission document production, design change control and the receipt and management of Technical Queries.

Assessment of the application of quality assurance principles to the project included some assessment of the PQAP and the QA related sections of the PCSR and also involved inspecting (jointly with the Environment Agency) the implementation of selected project related EDF, AREVA and joint project arrangements at their offices in Paris. The French Nuclear Regulator ASN attended the inspection. Also of interest during GDA Step 3, were the 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 inspected both EDF's and AREVA's audit and Learning from Experience (LFE) arrangements applied to the UK EPR GDA project as part of the joint inspection (Ref. 4).

Conclusions

- The organisational and quality assurance arrangements for the UK EPR GDA Project have been operating throughout GDA Step 2 and GDA Step 3 are well established. The joint project arrangements are supported and supplemented within EDF and AREVA by well developed QA arrangements. The Project Quality Assurance Plan is supported by a number of joint procedures which have been appropriately implemented.
- The UK EPR GDA project has a well defined organisational structure with clear roles and responsibilities.
- The inspection provided evidence that the UK EPR GDA project is well managed and the elements important to effective interfaces between the JPO and EDF and AREVA are defined and controlled.
- The UK EPR design was frozen in late 2008 based on Flamanville 3 (FA3). Design changes arising from FA3 and those arising from the UK Regulators assessment will be considered for inclusion in the UK EPR, with the highest category changes subjected to Independent Nuclear Safety Assessment (INSA) or Independent Peer Review (IPR) processes. The joint inspection raised a number of aspects for consideration by EDF and AREVA including clarification of the role of INSA as applied to design changes and its application to environmental aspects of the design. Additionally EDF and AREVA have been requested to consider extending auditing programmes to cover all GDA support contractors. The regulators also suggested that both EDF and AREVA should consider reviewing their current arrangements for managing and tracking non-conformances arising from their auditing activities. This issue was raised as a specific Regulatory Observation (RO) which has now been fully addressed. We plan to re-

inspect auditing arrangements for EDF and AREVA, for the UK EPR GDA project, in GDA Step 4.

- With regard to the control of design changes, the development of design detail and cut-off dates for information that can be included in the scope of GDA, discussions are ongoing with EDF and AREVA and we will look at these in detail during GDA Step 4.

With respect to the application of quality management principles by EDF and AREVA to the UK EPR GDA project we see no reason why the UK EPR should not proceed to GDA Step 4.

LIST OF ABBREVIATIONS

ALARP	As Low As Reasonably Practicable
ASN	Autorité de Sûreté Nucléaire (French nuclear safety authority)
BMS	(Nuclear Directorate) Business Management System
CEIDRE	Centre for the Inspection and Assessment in the field of Manufacturing and Operation. (France)
CNEN	National Nuclear Facilities Centre. (France)
DCMF	Design Change Management Form
DCP	Design Change Proposal
DCSG	Design Change Steering Group
DEP	Directorate for Nuclear Pressure Vessels (France)
EA	The Environment Agency
ECMB	EPR Configuration Management Board
EDF	Electricité de France
EIRA	Equipe d'AREVA NP (AREVA NP Inspection Group)
FA3	Flamanville Unit 3
GDA	Generic Design Assessment
HSE	The Health and Safety Executive
IAEA	The International Atomic Energy Agency
INSA	Independent Nuclear Safety Assessment
IPR	Independent Peer Review
JPO	Joint Programme Office
LFE	Learning From Experience
MDEP	Multi-national Design Evaluation Programme
ND	The (HSE) Nuclear Directorate
NSSS	Nuclear Steam Supply System
OL3	Olkiluoto 3
OCNS	Office for Civil Nuclear Security
PCER	Pre-Construction Environment Report
PCSR	Pre-Construction Safety Report
PQAP	Project Quality Assurance Plan
QA	Quality Assurance
QMS	Quality Management System
SDM	System Design manual
TQ	Technical Query
RI	Regulatory Issue

LIST OF ABBREVIATIONS

RO	Regulatory Observation
RP	Requesting Party
SAP	Safety Assessment Principle

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1 INTRODUCTION

1 This report presents the findings of the Quality Assurance assessment (including inspection) of the Quality Assurance (QA) arrangements implemented by EDF and AREVA to deliver the UK EPR safety case as presented in the UK EPR Pre-Construction Safety Report (PCSR) (Ref. 1). This assessment was undertaken as part of GDA Step 3 of the HSE Nuclear Directorate's (ND) Generic Design Assessment (GDA) process. This has built on the work carried out in Step 2 by taking into account of 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 relied in significant part on the GDA Step 3 joint regulators' inspection carried out in April 2009 (Ref. 4) which examined the adequacy and implementation of EDF and AREVA's QA arrangements. The Safety Assessment Principles (SAPs) (Ref. 5) have been used as the basis for the assessment of the quality assurance arrangements associated with UK EPR design. The SAPs require that arrangements for quality assurance, based on national and/or international codes and standards be identified and considered in safety assessments.

2 The development of a generic design and a related safety case does require the application of quality assurance arrangements. These are mainly to provide project management and procedural arrangements to deliver a fit for purpose PCSR. This should also cover aspects such as Design Change Control, Document Change Management and Configuration Control. It is in the development of the site specific PCSR during Phase 2 that detailed and specific Management of Safety and Quality Assurance arrangements will describe the organisation and procedures to procure and construct equipment and hence realise the design intent.

3 Work on this topic area was initiated during the early stages of GDA Step 2 when a formal joint regulators' inspection (Ref.4) was carried out and reported on. There were 2 recommendations made in the joint regulators' inspection report that have since been addressed by EDF and AREVA (Ref. 7). These were concerned with strengthening project governance and the tracking of regulatory issues. During Step 2 it was established that the organisation and quality assurance arrangements for the UK EPR GDA Project Team have been developed in order to supplement the well established quality systems of the joint applicants.

4 The GDA process calls for a step-wise assessment of EDF and AREVA's safety submission. With respect to the assessment and inspection of QA these have focussed on EDF and AREVA'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. Unlike other GDA assessment disciplines a significant element of ND's assessment of the QA discipline has been planned inspections of the implementation of EDF and AREVA's arrangements in their main offices in Paris. The GDA Step 3 inspection was carried out in conjunction with the Environment Agency.

5 A Project Quality Assurance Plan (PQAP), UK EPR-O-001 (Ref.8) specific to joint activities has been developed and related joint procedures implemented. Collectively these provide evidence of a sound basis for the operation of arrangements in support of the GDA process. The arrangements also include the control of interfaces with the UK Nuclear Regulators.

6 There is a defined and dedicated team, established by the co-applicants, responsible for delivering the GDA process. There are clear roles and responsibilities and a structured hierarchy of documents that are pertinent to the activities of the joint project team. A number of committees have been formed to provide advice and governance as part of EDF and AREVA's joint project arrangements for GDA.

7 The supporting Quality Management Systems (QMS) of EDF and AREVA, which integrate quality and environmental management, are well established, comply with appropriate international and regulatory QA standards, are externally audited, and are inspected by the French Nuclear Regulatory Authority ASN. There are established processes in place for the control of documentation and interfaces between the co-applicant organisations. These aspects were examined during the joint regulators' inspection.

8 This report deals with HSE's GDA Step 3 assessment and inspection of a sample of the QA arrangements, related procedures and instructions and the established QMSs of both EDF and AREVA.

2 NUCLEAR DIRECTORATE'S ASSESSMENT

9 This section of the report covers 3 main areas: a short summary of EDF and AREVA's arrangements for QA as applied to GDA; identification of the standards and criteria used to assess the QA arrangements; and thirdly the assessment / inspection findings.

2.1 Requesting Party's Safety Case

10 Chapter 21 of the PCSR describes the Project Organisation and Quality and Environmental (Q&E) Management arrangements for the GDA project. It outlines the organisation for project management of GDA and identifies the organisational arrangements envisaged to control the construction of new plant in accordance with applicable standards and regulations. In addition, in line with GDA guidance, it provides a statement regarding the EDF and AREVA strategy regarding long-lead items. The quality management arrangements of EDF, AREVA and a major contractor AMEC are outlined in the submission. All of these have been developed to meet the requirements of national and international codes and standards relating to QA including IAEA GS-R-3 (Ref. 12), and ISO 9001 (Ref. 13). Chapter 21 refers to a PQAP that describes the planned project activities and specific project provisions to deliver detailed safety, security and environmental submissions.

11 The PQAP also identifies the arrangements for dealing with responses to Technical Queries (TQ), Regulatory Observations (RO) and Regulatory Issues (RI) and related actions. The PQAP references the more detailed procedures, instructions and processes for joint project activities. An indication of the organisation post GDA is presented. The exact details of the organisational arrangements will be dependent on the ultimate plant owner. EDF and AREVA's arrangements for the effective transfer of knowledge of the design and safety case will be discussed during GDA Step 4.

12 Supporting documentation to the PCSR is recognised as part of the GDA submission. Such documentation includes safety system design manuals which describe the developing design detail for important UK EPR systems. Such supporting information will be examined in more detail by the regulators as part of GDA Step 4 assessment.

2.2 Standards and Criteria

13 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 (QMS) 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 both EDF and AREVA and the joint project activities in that these were being conducted within quality management arrangements that meet international quality standards. A check of implementation of

EDF and AREVA's arrangements was undertaken as part of the assessment activities during GDA Step 3 by a joint regulators' inspection.

14 For GDA Step 3 it is important to note that the QA arrangements applicable to GDA are subject to ongoing review and improvement. Changes can be initiated through internal and external review by EDF and AREVA, the joint project team, 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 specific PCSR) by the potential operator.

2.3 Nuclear Directorate Assessment

15 Assessment of EDF and AREVA QMSs and joint project activities as detailed in the PQAP found evidence of a professional and documented approach to the application of QA principles to the UK EPR project. Interfaces between EDF and AREVA applicable to the UK EPR project are described in the PQAP and in specific arrangements as part of EDF and AREVA's QMSs. Since GDA Step 2 both EDF and AREVA have obtained additional resources and developed more processes in support of the GDA project including additional project specific procedures. These are referenced in the PQAP and controlled via a well defined Project QA Documentation Master List and Format.

16 The UK EPR GDA Project has clear safety, security and environmental objectives i.e. design acceptance confirmation from HSE (ND), 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 EDF and AREVA to develop processes to achieve the objectives. This provides the joint regulators with confidence of the intent of the UK EPR GDA project to achieve its objectives and respond to related joint regulators' comments.

17 This assessment utilises the GDA Step 3 joint UK Regulators' inspection to provide evidence of the adequacy and application of the joint project arrangements. The inspection focused on submission control, design change management and auditing, aspects that are central to the control of submission documents.

2.4 Submission Control

18 The arrangements for submission document configuration and document change control are of great significance to the project and EDF and AREVA have, during GDA Step 3, reviewed and revised the project instructions for the PCSR and Pre-Construction Environmental Report (PCER) submissions. Procedure GDA Document Production UK EPR-I-004 details the process for the production of these documents, based on the use of 'Chapter Leads' as the interface between the project and the licensing teams, and the controls applied to review the output prior to publication. Configuration control of submission documents is achieved through the application of tracking sheets, in line with the interface protocol (Ref. 6), such that there is an ongoing record of the status of all submission documents. The submission tracking sheets are updated when revised submissions are forwarded to the Joint Programme Office (JPO) and all revisions have unique identifiers. Microsoft Sharepoint™, implemented on the AREVA secure server, is used as the application to share information between EDF and AREVA and the UK Nuclear Regulators via JPO. This is operating effectively.

19 As with design change arrangements there is an Independent Nuclear Safety Assessment (INSA) process applied to certain categories of submission documents during GDA Step 3. This is seen as good practice by providing additional challenge to the established review processes. It was noted, however, that the 2008 PCER was not subjected to INSA review but the PCSR has been. The UK Regulators, at the time of the

joint inspection in 2009, suggested that the INSA process be applied to the PCER and subsequently raised RO-UKEPR-34 (Ref. 11) to this effect. In response, EDF and AREVA explained that the INSA organisation had been constituted with personnel with specific safety expertise for the PCSR review, but that an Independent Peer Review (IPR) process had also been performed on the PCER by a team with specific environmental competancies. The joint regulators considered this appropriate as this provides an additional and independent review which in turn increased the joint regulators' confidence in the report. RO-UKEPR-34 (Ref. 11) has been closed out with the issue of a revised UK EPR-I-003 which further formalises the application of IPR to the PCER.

20 Transmission of submission documents and other correspondence to the joint regulators is operating effectively and responses to regulators' queries are generally good. The PQAP, amongst other things, references instructions for the transmission of letters and other documents, and the maintenance of records e.g. UK EPR-I-013 entitled the Management of Technical Queries. The UK EPR GDA Project Front Office co-ordinates a review of UK EPR documentation before final approval and authorisation for use. From the daily interfacing with the UK Regulators via the JPO these procedures are considered adequate.

21 In summary the control of submission documents and related configuration and modification control is well documented and managed. Our understanding of the application of INSA and IPR to the PCSR and PCER respectively has been clarified and addressed in and closed out via RO-UKEPR-34 (Ref. 11). The scope of the GDA Step 4 regulatory inspection(s) may include the examination of configuration control arrangements for GDA submission documents.

2.5 Design Change Management

22 EDF and AREVA's stated principle is that the UK EPR design will be maintained as close as possible to the Flamanville (FA3) design. The December 2008 design freeze included 12 FA3 design changes that were not fully integrated in the reference design documentation at that time. Two of these changes have been designated as category A1. In addition since the design freeze, two UK specific design changes have been identified as necessary as a result of the regulatory assessment and have been agreed in principle with the UK Regulators. These relate to Control & Instrumentation architecture and fire door control measures and EDF and AREVA have started to apply the formal design change process to these modifications. These changes will be considered in depth during the Step 4 regulatory assessments. Also during GDA Step 4, EDF and AREVA may propose further changes that arise from developments of the FA3 design post the December 2008 design freeze point. These are expected to be very limited in number as only FA3 changes having a significant impact on GDA will be proposed and changes of lower categories will be stored for Phase 2. Regulatory reviews of how design changes pre and post design freeze have been incorporated into the submissions are planned for GDA step 4. It should be noted that if it is not possible to complete regulatory assessments of EDF and AREVA's proposed design changes during GDA Step 4 these would be regarded as outside the scope of GDA, and would have to be assessed as part of any site-specific submissions.

23 The reference design configuration for the UK EPR is defined in procedure UK EPR-I-002: UK EPR Reference Design Configuration. The current project Design Change Procedure (DCP) UK EPR-1-003 introduced the addition of a categorisation logic diagram; clarification of categorisation of FA3 changes in GDA; and clarification of independent review arrangements. These changes address the UK Regulators' suggestions made during the GDA Step 3 joint regulators' inspection. All potential design changes that are applicable to UK EPR are processed through this DCP and categorised with regard to degree of impact on safety, environment and security.

24 The Design Change Screening Group (DCSG) is responsible for screening FA3 design changes and making recommendations on FA3 change categorisation and developing an implementation schedule for the UK. The DCSG includes technical managers with backgrounds in safety and environment from both EDF and AREVA. Outputs from the DCSG were examined. These illustrated the application of the screening process.

25 The UK Design Change Committee (DCC) which has the responsibility of deciding whether to accept or reject changes that have been screened for the UK EPR. It is envisaged in Step 4 that the UK Regulators will critically examine the categorisation of UK EPR screened design changes either for inclusion in the GDA process or to be considered outside the scope of GDA.

26 Design Change Management Forms (DCMF) are used to track the change status and to formalise the decisions for all changes considered in GDA following the design freeze, ie A1 type modifications to FA3 and for all UK specific changes. The Design Change Management Form (DCMF) is recorded by the Design Change Process Co-ordinator (DCPC) in the Project SharePoint at the stages of processing the change status. The DCPC role is fully specified.

27 The DCMF provides the DCC 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. A particularly useful element to the form is the identification list of documents that must be updated and verified as updated prior to close out. This is considered good practice.

28 Procedure UKEPR-O-006 details, amongst other things, the joint project arrangements for the Independent Nuclear Safety Assessment (INSA) Role and Organisation. There is no regulatory requirement for INSA to be applied during the design stage however EDF and AREVA wished to apply the discipline as preparation for interfacing with a potential operator in Phase 2. There was an assumption by both HSE and the Environment Agency that INSA would be applied to all significant changes that may affect the UK EPR. The level of application of the INSA process is more restricted than the UK Regulators initially thought. This resulted in RO-UKEPR-034 being raised to reflect this. In response EDF and AREVA agreed to apply INSA to all category A1 safety related changes and IPR to all A1 environmental related changes and to provide lists of lower level changes to the JPO, in accordance with common UK practice for existing licensees. RO-UKEPR-034 has been closed out based on the agreed action.

29 During GDA Step 4 it is intended to examine the consolidation of the PCSR and PCER submissions (the latter by the Environment Agency) and the accuracy of supporting reference documents.

2.6 Internal Auditing

30 Essential elements of an effective QMS are monitoring and review of quality related activities and a positive indicator to the commitment to these functions is the application of audit activities in a planned and documented manner. 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 during the 2009 inspection was the status of close-outs of non compliances and the programming of Joint Project GDA activity internal audits. With respect to the latter, a 3 day internal audit involving the front office and back offices of EDF and AREVA took place in May 2008. The audit team represented both EDF (CNEN) and AREVA (NPP) and covered the management of interfaces between EDF and AREVA and front and back offices in London and Paris.

31 Three findings were identified and satisfactorily closed out by October 2008. Of particular relevance was one of the findings from the audit which identified an occurrence where the

design change procedure was not being implemented fully with respect to the frequency of Design Change Committee meetings. The corrective actions put into place adequately address this and the other 2 issues. There is a joint EDF and AREVA intercompany audit planned for 4th quarter of 2009 to focus on configuration control, design change management and the implementation of project procedure UKEPR-I-023 on technical assessment interface guidance.

32 It was noted that both Rolls Royce Associates and AMEC have been used by the UK EPR project to carry out pre-joint regulator inspection reviews. This approach is considered to be good practice by introducing an element of independence and indicating EDF and AREVA's commitment to effective control of joint project activities vital to the delivery of the GDA process.

33 Although both EDF and AREVA organisations operate documented audit processes in line with general good practices, the UK Regulators considered that the tracking and closure of corrective actions arising from internal, second party (excluding suppliers) and third party audits could be more transparent. These could impact on the UK EPR GDA process including activities associated with the procurement of long lead items. This finding led to a recommendation for EDF and AREVA to consider a review of their current arrangements. RO-UKEPR-31 (Ref. 11) was subsequently raised to formalise this issue (see Annex 1). This has been closed out based on explanations and commitments from EDF and AREVA. This aspect will be examined in detail as part of a GDA Step 4 regulatory inspection.

2.7 Procurement Arrangements

34 In accordance with GDA guidance EDF and AREVA are required to inform the regulator about any long-lead items that may be manufactured in parallel with the GDA process. Currently we have not been advised of any contracts for long lead items. There is a commitment from EDF and AREVA expressed in the PCSR to inform the UK Regulators of the procurement of such items and in particular of the QA arrangements associated with such contracts. Discussions regarding the QA aspects of long-lead items will continue to be discussed with EDF and AREVA and other potential operators.

35 EDF and AREVA's procurement arrangements were presented during the joint regulators' inspection and discussions were held on how the design intent can be realised through the supply chain processes within the UK context. Of particular interest were arrangements for vendor/licensee oversight, inspections and testing. Both EDF and AREVA have well developed processes in this area. These discussions further developed ND's thinking about the requirements for monitoring of EDF and AREVA's procurement activities and this has informed the development and issue of our formal guidance on this topic T/AST/077 (Ref. 9).

36 Both EDF and AREVA are large complex organisations with numerous operational units, a number operating independently. 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.

37 With respect to the Nuclear Steam Supply System (NSSS), AREVA is required to comply with the French *Nuclear Pressure Equipment (ESPN) Order* dated 12/12/005, applicable to nuclear pressure equipment. This is based on the European Pressure Equipment Directive with additional requirements to reflect nuclear risk aspects. The French Directorate for Nuclear Pressure Vessels (DEP), part of the French Nuclear Safety Authority (ASN), undertakes, by law, a number of assessment, inspection and test activities on primary pressure components for equipment to be used in France. Under these arrangements, the manufacturer is responsible for obtaining from DEP a certificate

of conformity. This requires that the manufacturer must implement an acceptable quality management system, provide all the technical documentation for assessment and organise inspection at all sub-contractors works. For items procured for the UK equivalent levels of assurance would need to be provided. ND's expectations with regard to these levels of assurance are described in T/AST/077 (Ref. 9).

38 The assessment, informed by the joint inspection, established that 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 EDF and AREVA including questionnaires, audit and technical assessments to qualify supplier organisations. From the examination of procurement documents it was evident that supplier evaluation is well established and that QA related aspects such as organisation, control of documents, competence of personnel, environment and health and safety (including quality levels) are considered.

39 Both organisations use quality plans as an integral element of their arrangements, which provide an important control mechanism which can be used by the UK Regulators. EDF and AREVA have well established ongoing inspection and surveillance programmes using competent inspection bodies, e.g. EDF's Centre for the Inspection and Assessment in the field of Manufacturing and Operation (CEIDRE) and AREVA's inspection organisation (EIRA). At this stage of the GDA process the procurement arrangements of EDF and AREVA are considered adequate. Further assessment and inspection of procurement arrangements will take place during GDA Step 4.

2.8 Learning from Experience

40 AREVA explained its policy of Learning From Experience (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 (OL3), China (Taishan) and the USA. There is an internal network of staff responsible for LFE and a dedicated IT application to allow staff to input and access information. Information on lessons learned is increasing constantly. EDF operates a LFE process which takes into account feedback from domestic and international projects involving EDF and/or AREVA as well as other international sources. Both EDF and AREVA are considering the use of LFE within the UK EPR project. This will be discussed further in Step 4.

2.9 Recommendations arising directly from the Step 3 Joint Regulators' Inspection

41 4 recommendations have been made resulting from inspection of EDF and AREVA's arrangements as follows:

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

43 **Recommendation 2:** EDF and AREVA should consider auditing all UK EPR project contractors.

44 **Recommendation 3:** EDF and AREVA should consider the application of INSA reviews to future updates of the PCER and that such review panels should have appropriate environment expertise.

45 **Recommendation 4:** EDF and 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).

46 RO-UKEPR-31 and RO-UKEPR-34 (Ref. 11) were raised as a result of recommendations 4 and 3 respectively and both have since been closed (see Annex 1). Recommendation 1 has been addressed for some aspects. Recommendations 1 and 2 will be further discussed during GDA Step 4.

47 **Requirements of GDA guidance**. The guidance to Requesting Parties on GDA required them, at GDA Step 3 and GDA Step 2, to submit a description of its QA arrangements for the GDA project. Additionally, information regarding the RP's strategy for long-lead items was requested. The PCSR and supporting documents provide this information.

48 **Use of other regulators' information**. Although no direct use has been made of overseas regulators' assessment information, the joint regulators' inspections carried out during GDA Step 2 and GDA Step 3 were attended by representatives of the French Nuclear Regulator ASN. Also, discussions on quality arrangements for NSSS components were held with DEP. The interactions between national regulators have been found to be very useful and will continue in GDA Step 4. Additionally, the work of overseas regulators has been discussed at the Multi-national Design Evaluation Programme (MDEP) working group on Vendor Inspection. As a result of these exchanges we are confident that the UK and overseas regulators are taking a similar approach in the area of quality assurance.

49 **Related research.** I have not identified any QA related research requirements at this stage.

50 **Technical Queries (TQs)**. During Step 3 no TQs (Ref. 10) have been raised relating to QA. A TQ relating to knowledge transfer to potential operators has been issued.

51 **Regulatory Observations (ROs).** Two ROs have been raised relating to QA throughout Step 3, RO-UKEPR-31 and RO-UKEPR-34 (Ref. 11), which deal with non conformance tracking and the application of INSA/IPR respectively. Responses from EDF and AREVA are considered acceptable and both ROs have been closed. A check on the application of EDF and AREVA's corrective actions for both of these aspects will be examined as part of the regulatory inspections planned for GDA Step 4.

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

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

3 ASSESSMENT AREAS FOR GDA STEP 4

54 Our GDA Step 4 assessment will include the following:

- Inspect the arrangements for control of development of design detail documentation (with specialist support as necessary – e.g. mechanical, probabilistic safety analysis, internal hazards, control and instrumentation etc).
- Inspect a sample of design changes for the application of the appropriate safety classification and subsequent processing and authorisation.
- Inspect the effectiveness of EDF and AREVA's arrangements for the evaluation of first, second and third party audit/review outputs and the management and tracking of corrective actions.
- Examine the consolidation of the PCSR and PCER submissions (the latter with the Environment Agency) and the accuracy of support reference documents.

- Further examine EDF and AREVA's arrangements for the preparation of procurement specifications and selection and control of suppliers.
- Examine EDF and AREVA's arrangements for the transfer of knowledge of the UK EPR submission, including design information, to potential operators.
- Further discuss the implementation of LFE to the GDA project (based on processes already working within EDF and AREVA)
- Further discuss EDF and AREVA's position regarding the auditing of all UK EPR project contractors.

4 CONCLUSIONS AND RECOMMENDATIONS

55 EDF and AREVA operates well defined UK EPR joint project activities which are effectively managed. In addition to the QA arrangements that exist within EDF and AREVA organisations, the project is controlled through arrangements detailed in a PQAP which is supported by a number of procedures that are periodically audited, reviewed and further developed as the project progresses.

56 The arrangements for submission document production and control and the management of changes are implemented and are seen to be operating effectively. There are established arrangements for the control of design changes, with categorisation, review and authorisation elements. The UK EPR GDA Project has operated an independent nuclear safety assessment (INSA) process since GDA Step 2 and an IPR for Environment submissions. This is seen as a positive step and reflects future requirements for a licensee during construction, commissioning and operation of nuclear plant.

57 Both EDF and AREVA operate established procurement arrangements that include supplier selection contract controls and inspection and surveillance. Further discussions will take place with EDF and AREVA with regard to the controls applicable to long lead items.

58 There remains the potential for further design changes to be identified during Step 4, either as a result of regulatory assessments or resulting from FA3 screening. Regulatory assessment of these needs to be considered GDA Step 4.

59 There are no reasons on QA grounds that the GDA process for the UK EPR should not proceed to GDA Step 4 of the GDA process.

5 REFERENCES

1 *UK EPR Pre-Construction Safety Report* UK EPR-0002-132 Issue 02 EDF and AREVA June 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:

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Report on the Joint Regulators' Team Inspection of EDF and AREVA's Arrangements as part of the Generic Design Assessment (Quality Management Arrangements) June 2009.

5 *Safety Assessment Principles for Nuclear Facilities* 2006 Edition, Revision 1 HSE January 2008.

6 *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.

7 *Response to Inspection Recommendations* EDF and AREVA letter reference ND/EA EPR 00030N 4 March 2008. TRIM Ref. 2008/89555.

8 *UK EPR GDA Project Quality Assurance Plan* UKEPR-O-001 EDF and AREVA 29 September 2009.

9 *Technical Assessment Guide Procurement of Items and Services significant to Nuclear Safety* T/AST/077 HSE 26 August 2009.

10 *EDF and AREVA UK EPR - Schedule of Technical Queries Raised during Step 3* HSE-ND November 2009. TRIM Ref. 2009/358252.

11 *EDF and AREVA UK EPR - Schedule of Regulatory Observations Raised during Step 3* HSE-ND November 2009. TRIM Ref. 2009/358253.

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 *ISO 9001:2000 Quality Management Systems – Requirements* International Standards Organisation 2000.

Annex 1 – 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-UKEPR-31	18 May 2009	Adequacy of the RP's arrangements for the tracking and closure of non-conformancies arising from 2nd party (excluding suppliers) and 3rd party audits which may impact on the UK EPR project.	Closed. The implementation of the corrective action to be inspected during Step 4. EPR70114N	See status
RO-UKEPR-34	12 June 2009	The non application of the INSA process to changes to the PCER – identified during the Step 3 joint regulators' inspection.	Closed. EDF and AREVA's explanation on the application of IPR The implementation of the action to be inspected during Step 4. EPR70112N	See status