

Generic design assessment

**UK EPR™ nuclear power plant design by
AREVA NP SAS and Electricité de France SA**

Final assessment report

Management systems



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Final Assessment report - Management Systems

Protective status	This document contains no sensitive nuclear information or commercially confidential information
Process and Information Document¹	The following sections of Table 1 in our Process and Information document are relevant to this assessment: 1.1 – description of the management system for the development of the design and production of the submission for GDA
Radioactive Substances Regulation Environmental Principles²	The following principles are relevant to this assessment: MLDP1 Establishing and Sustaining Leadership and Management MLDP2 High Standards of Environment Protection MLDP3 Capability MLDP4 Decision Making MLDP5 Learning from Experience
Report author	Grundy, Dr. C. L.

1. Process and Information Document for Generic Assessment of Candidate Nuclear Power Plant Designs, Environment Agency, Jan 2007.

<http://publications.environment-agency.gov.uk/pdf/GEHO0107BLTN-e-e.pdf>

2. Regulatory Guidance Series, No RSR 1: Radioactive Substances Regulation - Environmental Principles (REPs), 2010.

<http://publications.environment-agency.gov.uk/pdf/GEHO0709BQSB-e-e.pdf>

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1 Summary

- 1 This report presents the findings of our assessment of the adequacy of EDF and AREVA's management systems based on information submitted by EDF and AREVA in their Pre-Construction Environmental Report (PCER) and supporting documents. In particular, the management arrangements that EDF and AREVA implement to control the development of the UK EPR design, and the production of submission documents for GDA. It is based upon our inspections of EDF and AREVA's management systems at their main offices in Paris.
- 2 The Joint Regulators for GDA, the [Office for Nuclear Regulation¹ \(ONR\)](#) and the Environment Agency, have worked together closely to review the adequacy of EDF and AREVA's management arrangements in GDA. Our assessment of management arrangements has involved review of EDF and AREVA's GDA submissions and arrangements for quality management, in particular the overarching project quality plan and supporting procedures.
- 3 A significant part of our assessment activity has involved inspection to review the application of EDF and AREVA's arrangements to the UK GDA project, and to identify evidence of the effective implementation of EDF and AREVA's management arrangements to GDA, including EDF and AREVA's GDA Project Quality Assurance Plan and supporting procedures. We have carried out our inspections jointly with ONR and published our findings.
- 4 The Joint Regulators conclusion from the 2009 Inspection was that:
- a) EDF and AREVA continue to manage and operate joint activities in support of GDA in a professional manner.
 - b) These joint activities are defined in the UK EPR GDA Project Quality Assurance Plan and are implemented through the related procedures.
 - c) The joint project arrangements are supported by well established quality management systems operated separately by EDF and AREVA
 - d) There were no major issues identified during the joint inspection and as such the joint regulators have confidence in EDF and AREVA's GDA project arrangements.
- 5 We have concluded from our assessment that EDF and AREVA have an appropriate management system in place to:
- a) control the content and accuracy of the information provided for GDA;
 - b) maintain records of design and construction;
 - c) control and document modifications to the design.
- 6 We conclude that EDF and AREVA have adequately specified:
- a) its expectations for any operating utility's management system;
 - b) how it expects to transfer knowledge and provide continuing support to any operating utility.
- 7 [Our conclusions remain unchanged since our consultation. However, they are subject to a GDA Issue which reflects that EDF and AREVA will need to continue to control changes to GDA submission documents, resulting from the management of design changes, until the issue of final design acceptance confirmation \(DAC\) / statement of design acceptability \(SoDA\) from the Regulators.](#)

¹ The Office for Nuclear Regulation (ONR) was created on 1st April 2011 as an Agency of the Health and Safety Executive (HSE). It was formed from HSE's Nuclear Directorate and has the same role. In this report we therefore generally use the term "ONR", except where we refer back to documents or actions that originated when it was still HSE's Nuclear Directorate.

- 8 The GDA Issue is: Consolidated Final GDA Submission, including agreed design change for the UK EPR :
- a) EDF and AREVA to continue to control, maintain and develop the GDA submission documentation, including the Safety, Security and Environmental Report (SSER), Submission Master List (SML) and design reference document and deliver final consolidated versions of these as the key references to any Design Acceptance Confirmation (DAC) / Statement of Design Acceptability (SoDA) ONR or Environment Agency (the joint Regulators) may issue at the end of GDA. These should include the management and acceptance of changes to GDA submission documentation impacted by design changes agreed for inclusion in GDA. (GI-UK EPR-CC-02)
- 9 In response to the GDA Issue, EDF and AREVA have provided a detailed Resolution Plan that identifies the details of how they intend to respond to the Issue. We have reviewed the Resolution Plan and discussed it with EDF and AREVA and we agree that it is credible.
- 10 Our findings on the wider environmental impacts and waste management arrangements for the UK EPR reactor may be found in our [Decision Document \(Environment Agency, 2011\)](#).

2 Introduction

- 11 We originally published this report in June 2010 to support our GDA consultation on the UK EPR design. We received additional information from EDF and AREVA after June 2010 and also undertook additional assessment in response to consultation responses, and taking into account matters arising from ONR's Step 4 activities including planned inspections. This report is an update of our original report covering assessment undertaken between June 2010 and the end of March 2011 when EDF and AREVA published an update of their submission. Where any paragraph has been added or substantially revised it is in a blue font.
- 12 We set out in our Process and Information Document (P&ID, see Environment Agency, 2007) the requirements for a Requesting Party to provide a description of the management system for the development of the design and production of the submission for GDA. This information should include identification of management responsibilities for both development of the design and the submission. The management arrangements should include those for:
- a) Maintaining records of design and construction, and;
 - b) Control and documentation of modifications to the submitted design.
- 13 Our (P&ID) also requires a description of the requesting party's expectations of the operating utility's management system to cover the reactor's operations throughout its lifecycle.
- 14 In our Radioactive Substances Regulation Environmental Principles (Environment Agency, 2010b), principles MLDP1-5 on management and leadership for the environment refer to this topic. We consider that management systems and the leadership shown by senior management have key roles in ensuring that business and other users use radioactive substances in a way that fully protects people and the environment. We expect an operator to manage its business and provide that leadership to ensure that the business minimises its impact on people and the environment from the use of radioactive substances.
- 15 This assessment aims to establish the adequacy of EDF and AREVA's management arrangements, and to identify demonstrable evidence that these arrangements are effectively implemented by EDF and AREVA, both to control changes to the UK EPR design, and for the production of submission documents for GDA.
- 16 This assessment comprises a review of EDF and AREVA's submission on management arrangements, together with inspections to assess the implementation of arrangements to control the production of submission documents for GDA, and the development of the design, including design changes. Our assessment is performed on a sampling basis, and a significant part of our assessment has focused on the findings of the Joint Regulators Inspection carried out in 2009 (see Joint Regulators, 2009).
- 17 During the Environment Agency's detailed assessment stage, we have kept EDF and AREVA's management arrangements under review. The Joint Regulators have worked closely to review the adequacy of EDF and AREVA's management arrangements in GDA. Our assessment of management arrangements has involved review of EDF and AREVA's GDA submissions and arrangements for quality management, in particular the overarching project quality plan and supporting procedures.
- 18 We assessed information contained in the PCER and supporting GDA submission documents. We raised two management related Regulatory Observations (ROs), jointly with ONR, on EDF and AREVA:
- a) RO-UKEPR-31; Tracking and closure of audit non-conformities;

b) RO-UKEPR-34 Quality Assurance –Issues for the PCER and Supporting Documents

19 We refer to regulatory observations raised by ONR during their Step 4 assessment where relevant to our assessment in this report.

20 We raised 33 Technical Queries (TQs) on EDF and AREVA during our assessment. One raised jointly with ONR was relevant to this report:

a) TQ-EPR-523 Expectations of Operating Utility Management System.

21 EDF and AREVA responded to all the ROs and TQs. They reviewed and updated the PCER in March 2010 to include all the relevant information provided by the ROs and TQs.

22 On 28 June 2010, our consultation began on our preliminary conclusions following our detailed assessment of this submission. This consultation closed on 18 October 2010.

23 In March 2011, EDF and AREVA provided an updated PCER.

24 Our detailed assessment of EDF and AREVA's management systems is documented within this assessment report. This is essentially the same as that provided in the first issue of this assessment report but updated, where appropriate, to reflect:

a) Our assessment of any further information provided by EDF and AREVA since the consultation date.

b) Any further work that we said, in the consultation document, that we intended to do.

c) Any matters arising from ONR's GDA Step 4 work, including their further inspections, that are relevant to our assessment.

d) Our consideration of any consultation responses relevant to this topic.

e) Our consideration of any comments from our 6 July GDA stakeholder seminar relevant to this topic.

25 We have published the consultation responses submitted in regard to our preliminary conclusions for the UK EPR design on our website (see: <https://consult.environment-agency.gov.uk/portal/ho/nuclear/gda>).

26 The questions raised at our stakeholder seminar have also been published (see: <http://www.hse.gov.uk/newreactors/seminar-060710.pdf>).

3 Assessment

3.1 Assessment Methodology

27 The basis of our assessment was to:

- a) review appropriate sections of the PCER and its supporting documents including the project quality plan and supporting procedures for UK GDA;
- b) carry out inspections jointly with ONR to assess the implementation of EDF and AREVA's management systems;
- c) hold technical meetings with EDF and AREVA to clarify our understanding of the information presented and explain any concerns we had with that information;
- d) raise Regulatory Observations and Technical Queries where we believed information provided by EDF and AREVA was insufficient;
- e) [consider consultation responses and comments from our stakeholder seminar relevant to this topic](#);
- f) decide on any GDA Issues;
- g) identify assessment findings to carry forward from GDA.

3.2 Assessment Objectives

28 We started our assessment with some key questions to answer:

- a) Are adequate management systems and arrangements in place to control design changes, and to control the production of submission documents for GDA?
- b) Are management arrangements being effectively implemented for the GDA project?
- c) Have EDF and AREVA adequately specified its expectation for any operating utility's management system?
- d) Have EDF and AREVA provided information on how it expects to transfer knowledge and provide continuing support to any operating utility?

29 We have examined EDF and AREVA's GDA submissions, and jointly with ONR we have carried out inspections to assess their management systems, processes and documentation, and held topic specific discussions on areas where we required further information and clarity. We carried out a Joint Regulators Inspection of EDF and AREVA at their main offices in Paris in April 2009. The purpose of the inspection was to examine in more detail areas such as design change control and submission configuration control, and to clarify progress on implementation of recommendations made during the initial Joint Regulators inspection visit carried out in December 2007. This initial inspection was part of our preliminary assessment, and was reported in our Public Statement in March 2008 (Environment Agency, 2008).

3.3 EDF and AREVA documentation

30 We referred to the following documents to produce this report:

Document reference	Title	Version number
UKEPR-0003-020	PCER – Chapter 2 – Quality and Project Management	03
UKEPR-O-001	UK EPR GDA Project Quality Assurance Plan	04
UKEPR-I-002	Reference Design Configuration	10
UKEPR-I-003	Design Change Procedure	08

31 We use short references in this report, for example:

- a) PCER sub-chapter 6.2 section 1.2.1 = PCERsc6.2s1.2.1;
- b) PCSR.

3.4 Detailed Assessment of EDF and AREVA Management Systems

32 We examined EDF and AREVA's management system in some detail during our preliminary assessment and concluded that it was suitable for controlling the content and accuracy of the information EDF and AREVA has provided to us for GDA (Environment Agency, 2008). There were, however, some matters that we felt could be improved and we made the following recommendations in our Joint Regulators Inspection in December 2007:

- a) The EDF and AREVA Project Team should consider, as part of its restatement of the role of the GDA Steering Committee, the role the latter plays in providing Governance to the process.
- b) The EDF and AREVA Project Team should consider the formal tracking of Regulatory Issues possibly by using the existing action tracking database.

33 EDF and AREVA responded positively to the recommendations of the Joint Regulators Inspection of December 2007. EDF and AREVA's progress in implementation of the recommendations was discussed during the Joint Regulators Inspection in April 2009. EDF and AREVA have advised the Joint Regulators of appropriate changes to the Project Organisation and supporting instructions and procedures.

34 The role of the GDA Steering Committee in providing governance to the GDA committee was presented by EDF and AREVA, and discussed during the Joint Regulators Inspection in April 2009. PCER Sub-Chapter 2.1, Project Organisation, describes the role of the Steering Committee and shows the interfaces in relation to the Project Organisation.

35 The EDF and AREVA Project Team considered the formal tracking of Regulatory Issues. The project instruction for Management of Regulatory Issues for the UK EPR GDA project has been regularly reviewed and updated by EDF and AREVA, and outlines roles and responsibilities for responding to and progressing Regulatory Issues.

36 Our conclusion is that EDF and AREVA responded positively to the Joint Regulator's inspection recommendations and have implemented changes to reflect the suggested improvements.

37 Our assessment of management arrangements has involved review of EDF and AREVA's GDA submissions and arrangements for quality management, in particular the overarching Project Quality Assurance Plan and supporting arrangements.

- 38 A Project Quality Assurance Plan (PQAP) ([UKEPR-O-001](#)) was produced for the UK GDA project by EDF and AREVA. The plan was revised in November 2008, in September 2009, in 2010 and most recently in 2011 ([revision 4](#)) to reflect developments in the project organisation and associated documents and instructions.
- 39 A joint project team was established by EDF and AREVA, the joint Requesting Party for the UK EPR design, to manage and deliver the UK GDA project. The PQAP describes the arrangements in place to deliver the GDA submissions including the PCER and PCSR, and the development of responses to Regulatory Issues, Regulatory Observations, and Technical Queries, and for responding to the public involvement process.
- 40 The project is resourced by the licensing teams drawn from EDF and AREVA and their sub-contractors, for example AMEC, for design activities, and production of submission documents and related information for GDA. The PQAP is supported by the management systems of the co-applicant organisations, namely EDF and AREVA, and their sub-contractors, such as AMEC. The management systems comply with recognised international standards and are externally audited. The PQAP is supported by a number of joint project instructions and procedures that were specifically developed for the UK EPR GDA project.
- 41 [One respondent \(GDA123\) to our consultation queried 'what standard is each management system based on....Have the management systems been third party assessed by a recognised accreditation body?'](#)
- 42 [Information is provided in the PQAP \(revision 4, 2011\) to indicate that EDF and AREVA management systems applied to the UK EPR project comply with international standards, for example ISO 9001 \(2008\) Quality Management Systems - Requirements. There are external audits carried out, including assessments by recognised accreditation bodies. This information has been discussed with the joint Regulators during the GDA inspections, and QA topic meetings, and the inspection reports are available on the joint website.](#)
- 43 [AREVA's organisation changed in 2010, during GDA, and supporting information was provided to the Regulators; the Head Procedure to the Integrated Management Manual \(QM DC 55 J,20 January 2010\). This confirmed that AREVA's existing integrated management system continued to apply to the new organisation during the transition stage.](#)
- 44 [The structure and interfaces for the new AREVA organisation were finalised and included in the new management system manual, as described in the revised PCSR and PCER. The GDA submission documents \(PCSR Chapters 21.1 and 21.2, PCER Chapter 2\) were updated to reflect this change.](#)
- 45 The PQAP outlines the organisation of the QA documentation at 3 levels:
- a) level 1 PQAP provides the overarching description of the structure, organisation, responsibilities, processes and lines of communication between the co-applicants and their sub-contractor;
 - b) level 2 documents include the management manuals, management documents including project organisation, and scope of work and division of responsibilities, and procedures and processes, such as the design change procedure, and the process for management of formal letters; and
 - c) level 3 documents comprise the detailed working documents such as project instructions and guidelines developed by the Project, including a specification for the PCER.
- 46 The PQAP describes the arrangements for control of documents and data including technical reports and submission documents, and references the relevant procedures. It also describes the arrangements for control of quality and

- environment records issued during GDA, such as reports and specifications, and review records, with reference to relevant procedures. [The PQAP was revised throughout the GDA project to reflect developments in the project organisation and associated documents and instructions, most recently in March 2011.](#)
- 47 Our P&ID requires the Requesting Party's management system to identify management responsibilities for development of the design and the submission documents. The arrangements for management responsibility are outlined in the PQAP with the commitment of the project, in line with the overall policy deployed by senior management of AREVA and EDF, to develop and implement a quality and environmental management system which complies with UK regulations and international codes and standards. It sets out arrangements for interactions between the Regulators and UK EPR Project Staff with reference to a number of procedures such as management of submissions, and management of meetings with Regulators.
- 48 EDF and AREVA have a specific UK GDA procedure for design change ([UKEPR-I-003](#)). There is a change process for design and submission documents. The UK EPR reference design configuration is based on the Flamanville 3 EPR design at a given point in time. This reference design is formally defined and recorded in a document [Reference Design Configuration \(UKEPR-I-002\)](#) used by the Project team as design input data in preparing submission documents for UK GDA. There is a Design Change Committee in place which meets on a regular basis to review potential design changes for their applicability to the UK EPR design, for controlled implementation of design changes identified for the UK EPR, and for impact on the UK submission. Design changes may arise from Flamanville 3, from UK regulations or interactions with UK Regulators, [and UK EPR specific changes proposed by EDF and AREVA based on feedback from other EPR construction projects](#). The process for changes to submission documents is set out in PCERsc2.2 [Management System](#). Details of the design change management process are also set out here.
- 49 The control of design modifications is seen as fundamental to the UK EPR projects effectiveness. There was a review of this approach in December 2008, and a revised project procedure was issued in 2009 including, for example, a paragraph on informing the Joint Programme Office (JPO) of changes. In summary the control of submission documents and related design configuration and modification control is well documented and managed as evidenced by our joint Regulators inspection report in 2009 (Joint Regulators, 2009). [Further inspections carried out by ONR in Step 4 in regard to design change and configuration control are discussed later.](#)
- 50 The project planning arrangements are set out in the PQAP. The arrangements for delivery of UK submission documents are described here. This includes details of the change process for design and submission documents. Arrangements for other UK GDA activities are described such as project meetings, and specialist topic meetings.
- 51 The project organisation is set out with a description of roles and responsibilities for each of the Co-Applicants including their interfaces with the Regulators, and the arrangements for independent nuclear safety assessment (INSA), and design safety review.
- 52 The PQAP sets out arrangements for resource management to deliver the UK EPR GDA project, and all the procedures and processes that are in place to support the delivery. The details of the process for development and review of technical reports and submission documents are set out.
- 53 Arrangements to review and improve the effectiveness of the management systems and processes for the project are implemented, for example through audit and close out of any audit actions identified, including the identification and incorporation of improvements.

- 54 PCERsc2.1 Project Organisation sets out details of the EDF and AREVA organisational arrangements for the GDA project. It also sets out information on the organisation at the stage following GDA. This is defined in terms of plant owner and or operator, the architect engineer and suppliers. Subchapter 2.2 [Management System](#) sets out the management arrangements for quality and environment during GDA. The particular quality management arrangements for GDA include document and data control, records, design control, independent reviews and design change management. The Sub-Chapter also provides an overview of the arrangements for quality and environment management in EDF and AREVA, and AMEC, a UK company providing sub-contractor support services to the UK GDA project.
- 55 A significant part of our assessment activity has involved inspection to review the application of EDF and AREVA's arrangements to the UK GDA project, and to identify evidence of effective implementation of EDF and AREVA's management arrangements to GDA, including EDF and AREVA's GDA [PQAP](#) and supporting procedures.
- 56 The purpose of the inspections was to assess EDF and AREVA's systems, processes and documentation, including specific discussions on areas where we required further information and clarity for the UK EPR Project. The inspections were carried out jointly with ONR.
- 57 A further inspection was carried out by the Joint Regulators during the detailed assessment stage of GDA in April 2009, and was followed by a QA topic specific meeting in July 2009. The inspection focused on control of modifications to the UK EPR design, configuration control for GDA submission documents and arrangements for transmission of submission documents to the regulators, internal, external and third party certification audits, learning from experience, and procurement arrangements.
- 58 In particular, during the inspection, we re-examined the arrangements for:
- a) Control of Modifications to the Design;
 - b) Arrangements for Transmission of Submission Documents to the Regulators;
 - c) Learning from Experience;
 - d) Effectiveness of Auditing Arrangements-Internal, External and Third Party Audits;
 - e) Procurement.
- 59 One aspect of particular interest to ONR is in relation to procurement of "long lead items". These are items that need to be procured some time in advance of construction of new nuclear powers stations such as reactor pressure vessels. Our discussions covered arrangements for inclusion of operators in the design and manufacturing activities, including inspection, for long lead items. [Procurement of long lead items was subsequently agreed to be out of scope for GDA.](#)
- 60 The scope and details of the inspection were agreed in discussions held with EDF and AREVA in advance of the inspection. We also agreed that recommendations made by the Regulators during the inspection would be set out in the form of Regulatory Observations, and their progress tracked by the Regulators to satisfactory completion.
- 61 The inspection was attended by a member of the French Nuclear Safety Authority, Autorité de Sureté Nucléaire, ASN who acted as an observer, at the invitation of the UK Joint Regulators. The findings of the inspection were discussed with EDF and AREVA at the close of each day, and at the closing session of the inspection.
- 62 A copy of the Joint Regulators Inspection findings was issued to EDF and AREVA shortly after the inspection. The Joint Regulators Inspection report was published on the Joint Regulators website in 2009 (Joint Regulators, 2009).

- 63 The Joint Regulators findings from the April 2009 inspection were:
- a) that the organisational and quality assurance arrangements for the UK EPR GDA Project Team have been operating throughout GDA and are well established;
 - b) that the joint project arrangements are supported and supplemented within EDF and AREVA by well developed QA arrangements; and
 - c) that the PQAP is supported by a number of procedures which have been implemented to a large degree.
- 64 We had identified during the previous Joint Regulators' inspection in December 2007 that the UK EPR GDA project has a well defined organisational structure with clear roles and responsibilities identified. The inspection carried out in April 2009 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.
- 65 The following recommendations were made by the Joint Regulators and discussed with EDF and AREVA at the Inspection in April 2009:
- a) EDF and AREVA and Joint Regulators to consider holding QA topic meetings to discuss, amongst other things, tracking sheets, design change processes and INSA.
 - b) EDF and AREVA should consider auditing all UK EPR project contractors.
 - c) EDF and AREVA should consider the application of INSA reviews to future updates of the PCER and that such review panels should have appropriate environmental expertise.
 - d) 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). [As noted previously procurement of long lead items was subsequently agreed to be out of scope for GDA.](#)
- 66 The Joint Regulators conclusion from the Inspection was that:
- a) EDF and AREVA continue to manage and operate joint activities in support of GDA in a professional manner.
 - b) These joint activities are defined in the UK EPR Project Quality Assurance Plan and are implemented through the related procedures.
 - c) The joint project arrangements are supported by well established quality management systems operated separately by EDF and AREVA.
 - d) There were no major issues identified during the joint inspection and as such the Joint Regulators have confidence in EDF and AREVA GDA project arrangements.

3.5 Regulatory Observations

- 67 The recommendations from the inspection were followed up by the Regulators and discussed in subsequent meetings. We issued two Regulatory Observations following our inspection in April 2009 on areas where we required EDF and AREVA to address specific issues. These related to clarification of the role of Independent Nuclear Safety Assessment (INSA) as applied to design changes, and its application to environmental aspects of the design. The Regulators also recommended that both EDF and AREVA should consider reviewing their current

- arrangements for managing, tracking and close out of non-conformances arising from their auditing activities which may impact on the UK EPR GDA process.
- 68 [The inspection suggested that EDF and AREVA should consider extending auditing programmes to cover all UK GDA support contractors.](#)
- 69 A Regulatory Observation, RO-UKEPR-31 was issued in May 2009, concerning audit arrangements, in particular tracking and closure of audit non-conformances. At the time of the inspection, neither EDF nor AREVA could provide evidence to demonstrate that non-conformances were subject to adequate tracking. Both EDF and AREVA have established auditing and review systems. Internal, Customer and Third Party findings are part of these processes. The Joint Regulators consider it would be beneficial to develop integrated systems for capturing non-compliances, and tracking processes that would provide improved management information to support close outs and system improvements, and strengthen the well being of the management system. [The published Joint Regulators Inspection report stated that '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.](#)
- 70 [The joint inspection identified that further discussions were needed on issues including submission tracking sheets, design change controls and INSA arrangements \(RO-UKEPR-31\).](#)
- 71 The joint Regulators and EDF and AREVA held a quality assurance topic specific meeting in July 2009. There was further discussion on the inspection recommendations including RO-UKEPR-31 and RO-UKEPR-34 and the proposed responses from EDF and AREVA
- 72 In accordance with the first recommendation from the April 2009 inspection, a QA topic specific meeting was held in July 2009 between the Joint Regulators and EDF and AREVA at their offices in Paris. Further discussion was held on the inspection recommendations, the associated regulatory observations and the proposed responses from EDF and AREVA.
- 73 The Regulators reviewed the information supplied by EDF and AREVA in response to RO-UKEPR-31, and supporting discussions were held, both in July 2009 at a topic specific meeting, and in teleconference discussions between the Joint Regulators and EDF and AREVA.
- 74 [A general discussion was held concerning AREVA's response to RO-UKEPR-31. There is a cross audit system in AREVA NP to ensure that arrangements deployed in various sectors and regions of AREVA NP remain consistent across the entire company. In addition, third party audits are carried out.](#)
- 75 [AREVA's corporate level procedure on cross audits, which is used to check consistent application of the QMS across the organisation, and the 2009 cross audit plan were shown to the UK Joint Regulators. An example cross audit was seen; 2008 cross audit report. This report contained one observation and no findings, and some positive observations were made. Non conformances are followed up as part of the internal audit plan so that responses are followed up to close out.](#)
- 76 The UK Regulators examined details presented in the response to RO-UKEPR-31 where audits remained open with AREVA after some time. AREVA explained the reasons the audits had not been closed out. The Regulators suggested that close out could be considered if no response was received within 6 months despite provision of a response from AREVA to external audit findings.
- 77 [The new AREVA tracking system project, managing events and actions in a common way, was presented as detailed in the response to RO-UKEPR-31. This](#)

- system is a common global database tracking all quality events, audit findings, and non-compliances. The module for 'event and assessment' covers planning, execution and reporting of audits.
- 78 EDF provided information on the global evaluations carried out on the engineering business to evaluate performance, to identify areas for improvement and to promote best practice. These are carried out every 3 years, with follow ups to assess progress against action plans. EDF gave commitments to complete further actions in auditing arrangements and implementation of associated learning by the end of 2009.
- 79 Evidence provided and discussions held in response to RO-UKEPR-31 on oversight satisfied the Regulators that AREVA has an integrated oversight and review process in place for its quality assurance audit activities.
- 80 The Regulators considered the responses from EDF and AREVA provided sufficient information and were satisfactory. The closure of RO-UKEPR-31 was agreed between the Regulators and EDF and AREVA in September 2009. The implementation of the corrective actions associated with RO-UKEPR-31 were examined by ONR in their planned Step 4 inspection, as noted in their Step 3 assessment report (HSE, 2009).
- 81 ONR examined this area again in Step 4 during planned inspections in April 2010 and September 2010. We continued to work closely with the ONR and the findings from ONR's inspections, and their Step 4 reports were used to inform our decision for GDA. ONR examined the management of non-conformances in software control supporting design development, and non-conformances arising from supplier audits during its Step 4 inspections. A regulatory observation RO-UKEPR-66 was issued with actions A1, A2, A3 in regard to supply chain and follow up of findings from supplier audits.
- 82 Audit reports and summaries were examined by ONR during its inspection in April 2010 that focused on the management arrangements for procurement of GDA services. Some repeat non-conformances were noted with no evidence of the original non-conformances being closed-out through EDF's tracking systems. As a result ONR raised regulatory action RO-UKEPR-66 action A2, requiring EDF and AREVA to ensure that any non-conformances or actions arising from GDA supplier assessment activities are controlled and managed appropriately.
- 83 In response to RO-UKEPR-66, action A2, EDF amended the EDF Project Quality Plan to clarify responsibility for managing GDA supplier audits and non conformances, and provided evidence of audit action follow-up with AMEC and Rolls Royce. ONR found that AMEC's progress on action close-out appeared reasonable and Rolls Royce's progress was not yet completed but progressing; EDF are able to track these actions to completion.
- 84 During the April 2010 inspection, ONR found that the management by EDF of non-conformances associated with SOFINEL (SOFINEL was created to support EDF and AREVA in design activities) deliverables was not consistent with EDF's own arrangements, and issued RO-UKEPR-66 action A3. In response to RO-UKEPR-66.A3, EDF updated its internal surveillance process and provided evidence of adequate control and management of the 2008 SOFINEL audit actions.
- 85 ONR closed out RO-UKEPR-66 based upon the improvements implemented to address the regulatory observation and the information and evidence provided.
- 86 In its Step 4 report, ONR found that internal audit actions were managed appropriately (ONR, 2011). There are systems in place for reporting non-conformances. ONR found that EDF improved their internal processes and followed up on the outstanding supplier audit corrective actions in response to a regulatory action resulting from HSE's April 2010 inspection.

- 87 The management of non-conformances associated with software was considered by HSE in their inspection in September 2010. For example non-conformances are raised associated with software errors, No trending on software errors was made available during the inspection. Information was been provided in June 2011 however, this was too late for consideration in ONR's assessment. ONR has raised an assessment finding in their step 4 report for the future licensee to have adequate arrangements in place to address learning from all sources of non-conformances.
- 88 A second Regulatory Observation RO-UKEPR-34 was issued in June 2009 which required EDF and AREVA to clarify the role of independent nuclear safety assessment, INSA and to consider the application of the INSA process to changes to environmental aspects of the design, and the environment submission. This will provide confidence to the Regulators in the application of an independent review process.
- 89 The recommendation RO-UKEPR-34 on INSA was discussed in the QA topic meeting held with EDF and AREVA and the Regulators in July 2009. The rationale has been to only apply INSA to parts of the safety submission produced uniquely for UK GDA, e.g. on aspects such as Probabilistic Safety Analysis and ALARP. It was confirmed, as understood by the Joint Regulators Inspection of December 2007, that INSA was applied to Volume 1 of the Safety Security and Environment Report, that is the initial GDA submission made in 2007, including Chapter G on Environment. This was not strictly within the scope of the INSA review but was provided to INSA to aid understanding.
- 90 External reviews are documented in the UK EPR GDA project instructions 19 and 29. Instruction 19 was developed as a result of the project responding to the Regulatory Issue raised by the Environment Agency in February 2008. This regulatory issue required the GDA submissions to be updated to provide further information to satisfy Environment Agency's process and information document requirements for GDA. Instruction 29 was issued as a result of the project team updating the PCER submissions in June and November 2008. There was a technical review for all chapters with review from two individuals in the licensing teams (one from each Co-Applicant organisation) and one third party review. The AMEC review process was discussed. The environmental impact studies commissioned by EDF and AREVA were carried out by AMEC. As this was an area of new technical work (not required in France) unfamiliar to the Co-Applicants, an independent peer review was commissioned of the work carried out by AMEC.
- 91 For future submissions, and design changes related to environment, such as the planned update to the PCER in March 2010, the Co-Applicants proposed to maintain the independent review process applied to previous submissions with added formalisms. Procedure UKEPR-I-004 on document production notes that INSA is only applicable to certain aspects of the submission and was updated in July 2009 to address the need for independent reviews. Specific instructions were to be developed for future updates of the PCER with identification of specific items for which an extended review panel will be needed. Instructions for specification for the PCER at various update stages in GDA have subsequently been produced, and are referred to in the PQAP.
- 92 A number of report reviews were requested and examined during the July 2009 QA topic meeting. Evidence seen included work orders containing detailed specification of the level of technical review required by a third party, AMEC. Evidence included PCER review records detailing review comments and how they have been addressed by EDF and AREVA, and reports updated in accordance with such reviews.
- 93 We also suggested in the inspection that AREVA should consider how its integrated management system (integrated to include management of quality and environment) can be applied to the UK GDA project going forwards to the end of GDA. In regard to design, the environmental programme presented by AREVA is

being applied to conceptual design activities for new plants, but does not address the EPR as the design was complete before the integrated management system was introduced. Prior to the development of the integrated management system, AREVA did develop environmental improvements for the EPR such as reduction in cobalt and reduction in uranium use but these improvements were not formalised in a management system. AREVA discussed the improvements for the new 3 loop PWR design, ATMEA1 developed by AREVA and Mitsubishi, and how the integrated management system applied.

94 We have assurance from evidence reviewed and discussions held in July 2009 that an independent peer review process has been applied to production of the PCER. A number of report reviews were requested and examined during the July meeting. EDF and AREVA formally responded to provide a summary of information discussed at the July meeting, and proposals for application of independent peer review for future PCER submissions made during GDA. The Regulators were satisfied with the review arrangements that had previously been applied to GDA documents on the basis of evidence seen in the inspection, and further topic meeting. The Regulators were also satisfied with the plans for future reviews which were formally documented in revised versions of project instructions. [The closure of RO-UKEPR-34 was agreed in August 2009.](#)

95 EDF and AREVA has responded to those recommendations that were raised following the Joint Regulators inspection in April 2009, and we are satisfied that their responses fully address the issues we raised. The implementation of corrective actions associated with EDF and AREVA responses to the regulatory observations and inspection recommendations [were examined during ONR's planned Step 4 inspections, and were generally found to be satisfactory.](#)

96 [In its Step 4 report, ONR found that internal audit actions were managed appropriately, and concerns raised in regard to the management of non-conformances from supplier audits were satisfactorily addressed by EDF and AREVA during step 4. A number of assessment findings were raised by ONR and are required to be addressed by the future licensee. We will expect the future operator to address such matters as part of their management arrangements at the site-specific stage.](#)

97 [We concluded from our assessment that EDF and AREVA have an appropriate management system in place to:](#)

- a) [control the content and accuracy of the information provided for GDA;](#)
- b) [maintain records of design and construction;](#)
- c) [control and document modifications to the design.](#)

3.6 Ongoing work since our Consultation proposals were published

98 [ONR has continued to assess EDF and AREVA management systems in its Step 4 of GDA. We have continued to work closely with ONR, and we reviewed new information on management systems and participated in selected meetings with EDF and AREVA and ONR. More details are presented below.](#)

99 [ONR carried out further planned inspections in Step 4. They carried out a further inspection of EDF and AREVA procurement arrangements in Step 4 in April 2010. The scope was limited to procurement arrangements for delivering the design presented in the GDA submission including the PCSR. The inspection findings are discussed in ONR's Step 4 report on MSQA \(ONR, 2011\) and in this document where relevant to our decision.](#)

100 [EDF and AREVA provided information to the Regulators to confirm they carried out audits of the UK GDA project as part of their planned internal audit activities in 2010. There was an audit of the GDA project carried out jointly by EDF and](#)

AREVA in November 2010, and separate internal audits of the GDA project were carried out by EDF and AREVA where they examined their own arrangements for the project. ONR found that actions arising from these audits have been followed up and the learning used to improve the procedures, and demonstrate continuous improvement.

3.6.1 Management of Design Changes during GDA including changes to the Design Reference Point (DRP)

- 101 One of the questions raised at our GDA Stakeholder Seminar in regard to management systems was '*Once the design is approved to what extent is the design frozen?*' EDF and AREVA are required to submit a design reference point (DRP) as the basis for GDA; effectively the design is frozen at the time of the DRP. All GDA submissions made to the Regulators should be based solely on that defined design. Supporting procedures are in place for DRP and changes to the DRP for GDA can only be made by submission to the Regulators joint Assessment Review Group (ARG).
- 102 As a general principle, EDF and AREVA wish to keep the UK EPR design as close as possible to the Flamanville 3 (FA3) design, that is the reference design. The design freeze (DRP) was established at December 2008. The GDA UK EPR design reference is described in UKEPR-I-002 'Reference Design Configuration'.
- 103 Cumbria County Council (GDA166) commented on our consultation in regard to the UK EPR design querying how the joint Regulators plan to manage changes to the design in GDA, specifically design improvements arising from construction of new reactors in France and Finland.
- 104 There is an EDF and AREVA process for changes in design, resulting from design improvements or regulatory requirements, to be taken into account during GDA; this is described in more detail below.
- 105 An MSQA topic meeting took place on 21 May 2010 between EDF and AREVA, and HSE, where arrangements for the management of design change proposals within the GDA process were discussed. This was followed by correspondence and discussions in June 2010 between EDF and AREVA and the Regulators in regard to arrangements for control of proposed design changes to UK EPR for inclusion in GDA.
- 106 HSE outlined its six step change control process to EDF and AREVA, for consideration of design changes for inclusion in Step 4 of GDA. EDF and AREVA are required to notify the Regulators of the proposed design change, and the rationale and description for the design change, and to provide confirmation of the design change categorisation and impact assessment.
- 107 EDF and AREVA's project instruction on design change for GDA (UKEPR-I-003) defines the design change control process for the UK EPR during GDA. Proposed changes are specified using the UK EPR Reference Design Configuration (UKEPR-I-002) as the baseline. The instruction mirrors the ONR/EA six step change process. EDF and AREVA apply a three stage design change process, including a system of categorisation with three categories, A1, A2 and B based on impact of the change on the GDA submission. A1 and A2 changes are modifications related to nuclear safety, environment and security; A1 changes have, or potentially have, a significant impact, while A2 changes have a minor impact in regard to GDA submissions. Category B changes are not related to nuclear safety, environment and security.
- 108 Design changes originating from FA3 are largely A2 or B changes associated with detailed design finalisation during the construction phase of FA3.

- 109 The proposed changes to the design are considered by the joint Regulators ARG. The regulators then provide formal agreement (or not) in writing to EDF and AREVA in regard to inclusion of the change proposal for assessment in GDA. The design changes proposed for inclusion during GDA, originated from one of the following possible sources:
- a) FA3 design changes, which take international experience feedback into account.
 - b) UK specific changes proposed by EDF and AREVA.
 - c) UK specific changes resulting from UK regulation or interactions with the UK Regulators during GDA.

3.6.1.1 Incorporation of Flamanville 3 (FA3) Design Changes

- 110 A meeting was held between EDF and AREVA and the Regulators in September 2010 where proposals for incorporation of design changes from FA3 were presented. A proposal was made by EDF and AREVA to update the UK EPR design reference point to end 2010, to include design changes originating from FA3, in Design Freeze 2010, DF2010.
- 111 EDF and AREVA proposed to include a number of category A2 and B FA3 design changes in GDA in the DF2010. For the regulators to agree in principle with EDF and AREVA's proposals we would need to be satisfied on a number of issues. These assurances would include that the list of low or non safety significant changes (A2 and B) considered for inclusion in DF2010 is fixed, that an appropriate categorisation process has been applied to all the design changes, that a description of the proposed design change is clear and explicit regarding the proposed change on safety, environment or security. Also that an appropriate impact assessment has been undertaken and affected documents such as the PCER and PCSR have been clearly identified and the scope defined etc.
- 112 Subject to appropriate assurances being received, a process could be agreed for inclusion of A2 and B design changes within GDA, and this would include a sampled assessment of these changes within GDA by both regulators. This would enable the Regulators to gain confidence in the application of the categorisation system. The design change procedure I-003 has been updated by EDF AREVA to reflect the process arrangements to manage the inclusion of these A2 and B changes, see next section.
- 113 However, although the Regulators have agreed to sample the FA3 originated changes proposed for DF2010 these have not yet been agreed for inclusion in GDA.

3.6.1.2 HSE Inspection on Design Development

- 114 An inspection was carried out by HSE in September 2010 of EDF and AREVA's arrangements for design development, design change control and configuration control. HSE found well established arrangements in EDF and AREVA for design development, design change control and configuration control. Two inspection recommendations were made as the scope of the project specific procedure for managing design changes within GDA was found to be limited.
- 115 The inspection recommendations were identified in a regulatory observation issued by HSE in October 2010, RO-UKEPR-81 Inclusion of design changes in EPR GDA post December 2008 design freeze, containing two actions. One action was for a process to be developed and documented for identification, control, review and acceptance and implementation of changes to all supporting documentation for design changes to be included in GDA. The second action required a process to be

- developed and documented by EDF and AREVA for transferring the information associated with incomplete design changes from GDA to phase 2 site-specific.
- 116 EDF and AREVA responded to RO-UKEPR-81 with an action plan in November 2010. The action plan included planned updates to the design change procedure/instruction.
- 117 EDF and AREVA updated their design change procedure and provided a copy to the Regulators in February 2011 in response to RO-UKEPR-81. The updated procedure includes new sections on management of UK specific changes originating from the Regulators assessment, and a section on management of changes post GDA. The revised procedure also includes the transfer of incomplete design changes agreed for inclusion in GDA to phase 2 site specific activities.

3.6.1.3 GDA Issue: Consolidated Final GDA Submission, including agreed design change for the UK EPR

- 118 We participated in ONR's MSQA convergence meeting for Step 4 with EDF and AREVA on 27 October 2010. We discussed with EDF and AREVA that we might raise an issue in regard to design reference, which is proposed to change to Design Freeze DF (end 2010) with the incorporation of FA3 design changes, since this will be the reference for any final Statement of Design Acceptability we might issue for the UK EPR. Our consultation on our preliminary conclusions for the UK EPR was based on the design described in the 2008 design freeze. We require that a description of any proposed design change to be incorporated in DF2010 is clear and explicit regarding the impact of the proposed change on environment, and that an appropriate impact assessment has been undertaken and affected documents such as the PCER have been clearly identified, as described previously.
- 119 EDF and AREVA wrote to the Regulators on 10 December 2010 in regard to the proposed update of the GDA Design Reference for the final DAC/SoDA to include FA3 design changes. This letter was prepared in response to the expectations of the Regulators, as discussed in 3.6.1.1, seeking a number of assurances in regard to a list of fixed design changes for A2 and B changes originating from FA3, requiring appropriate categorisation, description, justification etc. It provided further information to support the proposal.
- 120 The tool proposed for control of the A2 and B design changes within EDF AREVA GDA submissions was presented to ONR at a QA topic meeting on 13 December 2010.
- 121 ONR responded by letter to confirm the proposal to update the GDA EPR design reference to include FA3 design changes was discussed by the joint Regulators ARG at a meeting on 16 December 2011. The ARG agreed in principle to the update to the GDA Design Reference post Step 4 to include FA3 design changes, subject to ONR and Environment Agency:
- a) Agreeing a programme with EDF and AREVA for the submission of information for each design change to be considered, including description, impact assessment and justification for the proposed design change categorisation
 - b) Developing an appropriate sampling process for FA3 design changes
 - c) Developing a process for acceptance/rejection of sampled design changes in GDA.
- 122 HSE's letter of January 2011 confirmed the need for an agreed programme from EDF AREVA as described in a) above. Also, HSE's letter confirmed that the tool presented at 13 December meeting appeared to be satisfactory for proposed control of design changes.

- 123 Proposals to update the GDA Design Reference beyond June 2011 to include FA3 A2 and B design changes were set out in a letter from EDF and AREVA in February 2011. EDF and AREVA set out in a separate letter in February 2011 their proposals for A2 and B changes arising from FA3 that they propose to include in the design freeze for the end of GDA (DF2010). EDF and AREVA indicated that the assessment of the full impact of the modifications on all reference documents will be completed by the end of June 2011.
- 124 EDF and AREVA will produce a consolidated PCSR and PCER in 2012 that will include all changes to reflect the revised DRP.
- 125 It is our expectation that EDF and AREVA will continue to control, maintain and develop the GDA submission documentation including the SSER, SML and design reference and deliver final consolidated versions of these documents as the key references to any SoDA we may issue, and DAC that ONR may issue at the end of GDA. These should include the management and acceptance of changes to GDA submission documentation impacted by design changes agreed for inclusion in GDA.
- 126 EDF and AREVA shall ensure that these key deliverables are subject to appropriate review and that the review comments are included, as appropriate, in the final consolidated submission.
- 127 This is the basis for our GDA issue, jointly with ONR 'Consolidated Final GDA Submission, including agreed design change for the UK EPR'
- 128 The GDA issue has three actions:
- a) EDF and AREVA to fully implement its processes to manage the implementation and acceptance of amendments to documentation impacted by design changes agreed for inclusion in GDA, including any other additionally agreed design changes associated with other GDA Issues Resolution Plans. This should involve the incorporation of all relevant amendments into the impacted documentation associated with design changes, including the Reference Design Configuration Document UKEPR-I-002, the PCSR and the PCER.
 - b) EDF and AREVA to apply the revised Design Change procedure in order to identify and transfer all relevant agreed incomplete GDA design changes into Nuclear Site Licensing and permissioning activities, and Environmental Permitting.
 - c) EDF and AREVA shall continue to control, maintain and develop the GDA submission documentation, including the SSER, SML and design reference document and shall deliver final consolidated versions of these as key references to any DAC/SoDA we may issue at the end of GDA.
- 129 To enable the final consolidation of the GDA submission documentation, it is our expectation that the design changes agreed during GDA Step 4 will be fully implemented and the change details incorporated into the supporting level 2 design documentation scheduled to be updated before end of GDA. It is also our expectation that the scope of any design changes agreed for inclusion in GDA are clearly identified in EDF and AREVA's GDA Reference Design Configuration and that these design changes are supported by adequate safety justifications and design detail.
- 130 It is recognised that EDF and AREVA has developed arrangements for the control, review, acceptance and implementation of amendments to documentation impacted by GDA design changes agreed for inclusion in GDA. However the application and suitability of this process was not be fully available for testing by 31 March 2011. Hence the GDA Issue in this area. Additionally, the arrangement for transfer of incomplete design changes from GDA to site specific activities will need to be examined more fully in GDA.

- 131 The scope of design changes included in this GDA issue includes those incomplete design changes already agreed for inclusion in GDA and any additional design changes arising as part of the Resolution Plans associated with other ONR GDA issues.
- 132 It is also recognised, due to the existence of GDA issues and incomplete design changes that the GDA submission documentation, including the SSER, SML and design reference will need to be updated to reflect this outstanding work and will require final consolidation prior to submission and referencing against any DAC/SoDA we may issue.
- 133 During the site specific phase, further design changes may be proposed for the UK EPR design as a result of learning from experience on EPR construction projects. ONR raised an assessment finding in their step 4 report for the future licensee to manage and control design changes as a result of learning from experience during construction. We would expect the future operator to have appropriate arrangements in place to control and manage such design changes at the site specific stage.

3.7 Expectations for the Operator's Management System

- 134 Before a site-specific application for a UK EPR can be made, the potential operator will need to begin establishing its management system, including organisational structure and resources, and there will need to be considerable knowledge transfer about the design. We thus require a requesting party to address, in its GDA submission, the implications of the design for the potential operator's management system, and how it intends to facilitate the required knowledge transfer and provide ongoing support to the potential operator.
- 135 Issues concerning the transfer of knowledge about the design between the vendor and the future operator were examined by the Regulators in GDA and are discussed below. Respondents to our consultation also raised the issue of knowledge transfer as discussed in our decision document (Environment Agency, 2011). We assessed evidence provided by EDF and AREVA against our expectations for the operators management systems.
- 136 The EDF and AREVA submission addresses these matters in the PCER, Chapter 2 Quality and Project Management at Sub-chapter 2.1 Project Organisation.
- 137 PCERsc2.1s3 sets out the responsibilities of the post GDA organisation. This is defined according to the Plant Owner or Operator, the Architect Engineer and suppliers. It is recognised in the submission document that the Plant Owner (Operator) will have safety and environmental responsibilities in relation to plant operation, including waste and effluent management.
- 138 Reference 1.1 of Table 1 of our P&I Document requires EDF and AREVA to set out their expectations of the Operator's Management System to cover the reactor's operations throughout its lifecycle. The Regulators asked EDF and AREVA to provide further information in TQ-UKEPR-523, specifically to address in their GDA submission, the implications of the UK EPR design for the potential Operator's management system. In particular, how AREVA and EDF intend to facilitate the required knowledge transfer and the arrangements to provide ongoing support to the potential Operator.
- 139 The EDF and AREVA submission addresses these matters in the PCER at sub-chapter 2.1 'Project Organisation'.
- 140 The operator is required to establish a design authority, with arrangements in place to make sure that enough information and knowledge about the design is transferred from EDF and AREVA, as the design organisation, to the operator so

- that it can act as an effective design authority. EDF and AREVA are a unique requesting party in GDA as co-applicants.
- 141 EDF and AREVA provided information to suggest a number of possible approaches to transferring knowledge and developing an 'intelligent operator' (we use the term to describe the capability of an operator to have a clear understanding and knowledge of the reactor design being supplied), given that, at this stage, the future operating organisation is not known.
- 142 EDF set out principles in regard to responsibilities and management systems aligned with the principles set out in International Nuclear Safety Advisory Group, INSAG 19 "Maintaining the Design Integrity of Nuclear Installations throughout their Operating Life" 2003. The Design Authority and Responsible Designer being implemented within the EDF organisation.
- 143 For development of intelligent operator, EDF participate in a knowledge transfer programme which takes account of EDF operating experience feedback. EDF are the world's largest nuclear operator, and currently operate 58 nuclear power plants (CEA Nuclear Power Plants in the World 2008 Edition). The Operator will be integrated into the engineering design, operation and procurement processes with specific responsibilities for specification of UK requirements, and the final stage of design reference and safety case.
- 144 AREVA's approach as the vendor, to facilitate knowledge transfer and to provide ongoing support to the potential operator, will depend upon the future owner / operator organisation. AREVA set out their expectations and how they can be achieved. AREVA will use their knowledge based on 35 years experience in building nuclear power plants and organising the associated knowledge transfer to the plant owner and operator to allow for safe and efficient operation of the plant.
- 145 AREVA discussed at the Joint Regulators Inspection in April 2009 that several Utilities were integrated in the EPR basic design phase, participating in technical and project working groups. In addition, studies were carried out under the responsibility of the Utilities in areas such as overall operation policy, and availability and maintenance analysis. AREVA also reference the European Utility Requirements (EUR) document, specifically the EPR sub-set to illustrate the ongoing Utility-Vendor interface for the EPR.
- 146 AREVA recognise that knowledge transfer to Operators is important to ensure the future owner / operator has the capability to secure and maintain the safety and environmental performance for the EPR. AREVA organise workshops and seminars with potential utility customers to provide technical information on the EPR design and to exchange information on the technical scope, and knowledge transfer.
- 147 The knowledge transfer stage includes both handover of technical data and information, and also training programmes. Interfaces with sub-contractors and Utilities are detailed in configuration and design change management procedures for each project. AREVA also set out their training programme information in order to facilitate the development of the knowledge, skills and behaviours required for safe operation of the EPR. The Owners group has arrangements in place to facilitate experience feedback from operating plants between the Utility and the Vendor.
- 148 AREVA and EDF demonstrate their understanding of the requirement to establish arrangements to maintain design integrity, and to preserve the necessary detailed and specialised knowledge generated over the plants' operational life for the EPR. AREVA and EDF have arrangements in place to facilitate the knowledge transfer and to fully support the plant owner / operator at all phases of the nuclear new build project, through the provision of training programmes and data and document and technical information transfer.

149

We conclude that EDF and AREVA have adequately specified:

- a) its expectations for any operating utility's management system;
- b) how it expects to transfer knowledge and provide continuing support to any operating utility.

4 Public comments

150 We received no relevant public comments on management systems before the end of 2009. Comments made in response to our public consultation in regard to management systems for the UK EPR design were considered in our decision document (Environment Agency, 2011), and herein where relevant to our assessment.

151 Questions were also raised and published from our 6 July GDA stakeholder seminar and are considered in our decision document.
<http://www.hse.gov.uk/newreactors/seminar-060710.pdf>

5 Conclusion

- 152 On the basis of our assessment, including review of submissions, inspection activities and discussions with EDF and AREVA, we conclude that the quality assurance arrangements for the UK EPR project are well established and effectively implemented. The UK EPR GDA project has a well defined organisational structure with clear roles and responsibilities, and is supported by a comprehensive set of project procedures and instructions. Our inspections provided evidence the UK EPR project is well managed, and the elements important to effective interfaces between the Joint Programme Office and EDF and AREVA are well controlled. There is a professional approach from EDF and AREVA to project control and interface with the Regulators. There are high levels of control for configuration management and modifications.
- 153 We issued Regulatory Observations following our inspection in April 2009 on areas where we required EDF and AREVA to address specific issues. These related to clarification of the role of Independent Nuclear Safety Assessment, INSA as applied to design changes, and its application to environmental aspects of the design. 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. These Regulatory Observations were fully addressed by EDF and AREVA and closed out by the Regulators in 2009. The implementation of EDF and AREVA responses to the Regulatory Observations and Inspection recommendations was examined during ONR's planned Step 4 Inspection, including one aspect in regard to EDF's integrated oversight of QA activities. We continued to work with ONR on this matter to inform our decision, and [based upon the improvements implemented and the information and evidence provided we consider that arrangements in place for GDA are satisfactory](#).
- 154 EDF and AREVA have given consideration to transfer of knowledge about the design to the future operating organisation, and have provided supporting information. We are satisfied that AREVA and EDF have arrangements in place to facilitate the knowledge transfer and to fully support the plant owner / operator at all phases of the nuclear new build project, through the provision of training programmes and data and document and technical information transfer.
- 155 We concluded that EDF and AREVA have an appropriate management system in place to:
- a) Control the content and accuracy of information provided for GDA.
 - b) Maintain records of design and construction.
 - c) Control and document modifications to the design.
- 156 We conclude that EDF and AREVA have adequately specified:
- a) its expectations for any operating utility's management system;
 - b) how it expects to transfer knowledge and provide continuing support to any operating utility.
- 157 [Our conclusions remain unchanged since our consultation. However, they are subject to a GDA Issue which reflects that EDF and AREVA will need to continue to control changes to GDA submission documents, resulting from the management of design changes, until the issue of final design acceptance confirmation/statement of design acceptability from the Regulators.](#)
- 158 [The GDA Issue is; 'Consolidated Final GDA Submission, including agreed design change for the UK EPR':](#)
- a) [EDF and AREVA to continue to control, maintain and develop the GDA submission documentation, including the Safety, Security and Environmental](#)

Report (SSER), Submission Master List (SML) and design reference document and deliver final consolidated versions of these as the key references to any Design Acceptance Confirmation (DAC) / Statement of Design Acceptability (SoDA) ONR or Environment Agency (the joint Regulators) may issue at the end of GDA. These should include the management and acceptance of changes to GDA submission documentation impacted by design changes agree for inclusion in GDA (GI-UK EPR-CC-02).

- 159 In response to the GDA Issue, EDF and AREVA have provided a detailed Resolution Plan that identifies the details of how they intend to respond to the Issue. We have reviewed the Resolution Plan and discussed it with EDF and AREVA and we agree that it is credible.

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- (ONR, 2011) Assessment Report No AR11/029 Step 4 Management of Safety and Quality Assurance Assessment of the EDF and AREVA UK EPR
<http://www.hse.gov.uk/newreactors/reports.htm>

While every effort has been made to ensure the accuracy of the references listed in this report, their future availability cannot be guaranteed.

Abbreviations

ALARP	As Low As Reasonably Practicable
ASN	Autorité de Sûreté Nucléaire, the French Nuclear Safety Authority
BAT	Best Available Techniques
DAC	Design Acceptance Confirmation
EPR 10	Environmental Permitting (England and Wales) Regulations 2010
EPRI	Electrical Power Research Institute – an independent USA organisation
GDA	Generic Design Assessment
HSE	Health and Safety Executive
IAEA	International Atomic Energy Agency
INSA	Independent Nuclear Safety Assessment
INSAG	International Nuclear Safety Advisory Group
IPR	Independent Peer Review
JPO	Joint Programme Office
MSQA	Management of Safety and Quality Assurance
NSL	Nuclear Site Licensing
ONR	Office for Nuclear Regulation, an Agency of the HSE (formerly HSE's Nuclear Directorate)
P&ID	Process and Information Document
PCER	Pre-Construction Environmental Report
PCERsc3.3s4.1	PCER sub-chapter 3.3 section 4.1 (example reference)
PCSR	Pre-Construction Safety Report
PQAP	Project Quality Assurance Plan
PWR	Pressurised water reactor
QA	Quality Assurance
QMS	Quality Management System
REPs	Radioactive substances environmental principles
RGN	Regulatory Guidance Note
RGS	Regulatory Guidance Series
RO	Regulatory Observation
SML	Submission Master List
SoDA	Statement of Design Acceptability
SOFINEL	French Society of Nuclear Power Engineering and Assistance for Export
SSER	Safety, Security and Environmental Report
TQ	Technical Query

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