

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

**Assessment report
Management systems**



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Published by:

Environment Agency
Rio House
Waterside Drive, Aztec West
Almondsbury, Bristol BS32 4UD
Tel: 0870 8506506

Email: enquiries@environment-agency.gov.uk

www.environment-agency.gov.uk

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Generic design assessment

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

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	Dr Colette Grundy

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 inspection of EDF and AREVA's management systems at their main offices in Paris.
- 2 The Joint Regulators for GDA, the HSE 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 Quality Plan and supporting procedures. We have carried out our inspections jointly with HSE 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 Project Quality 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 concluded from our assessment detailed herein that EDF and AREVA has 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 has 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 findings on the wider environmental impacts and waste management arrangements for the UK EPR reactor may be found in our Consultation Document (Environment Agency, 2010a).

2 Introduction

- 8 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.
- 9 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.
- 10 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.
- 11 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.
- 12 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).
- 13 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.
- 14 We assessed information contained in the PCER and supporting GDA submission documents. We raised two management related Regulatory Observations (ROs) 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
- 15 We raised 31 Technical Queries (TQs) on EDF and AREVA during our assessment. One raised jointly with HSE was relevant to this report:
- a) TQ-EPR-523 Expectations of Operating Utility Management System.
- 16 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.

3 Assessment

3.1 Assessment Methodology

- 17 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 HSE 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) decide on any GDA Issues or other issues to carry forward from GDA.
- 18 Our Consultation Document (Environment Agency, 2010a) provides more detail on the assessment process, including how any issues remaining at the end of GDA in June 2011 could be taken forward.

3.2 Assessment Objectives

- 19 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?
- 20 We have examined EDF and AREVA's GDA submissions, and jointly with HSE 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

21 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	02

22 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

23 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.

24 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.

25 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.

26 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.

27 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.

28 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.

29 A project quality assurance plan (PQAP) was produced for the UK GDA project by EDF and AREVA [we have accepted the PQAP as commercially confidential information]. The plan was revised in November 2008 and in September 2009, to reflect developments in the project organisation and associated documents and instructions. A joint project team was established by EDF and AREVA, the joint Requesting Parties 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.

30 The project is resourced by the licensing teams drawn from EDF and AREVA and their sub-contractor, Amec, for design activities, and production of submission

documents and related information for GDA. The PQAP is supported by the Quality and Environmental Management Systems of the co-applicant organisations, namely EDF and AREVA, and their sub-contractor, 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.

- 31 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 QA manuals, organisation documents including project organization, 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, including a specification for the PCER.
- 32 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.
- 33 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.
- 34 EDF and AREVA have a specific UK GDA procedure for design change. 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 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 arising from Flamanville 3, and from UK regulations or interactions with UK Regulators, 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. The process for changes to submission documents is set out in PCERsc2.2 Quality and Environmental Management. Details of the design change management process are also set out here.
- 35 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).
- 36 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.
- 37 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.
- 38 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.
- 39 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.
- 40 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 Quality and Environmental Management 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.
- 41 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 Quality Plan and supporting procedures.
- 42 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 HSE.
- 43 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.
- 44 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.
- 45 One aspect of particular interest to HSE 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.
- 46 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.
- 47 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.
- 48 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).
- 49 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.
- 50 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.
- 51 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).
- 52 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 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

- 53 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 suggested that both EDF and AREVA should consider reviewing their current arrangements for managing and tracking non-conformances arising from their auditing activities which may impact on the UK EPR GDA process.
- 54 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. 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.
- 55 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.
- 56 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.
- 57 A general discussion was held concerning AREVA's response to RO-UKEPR-31. There is a cross audit system in AREVA NP which has been in place for around 5 years in order to ensure that arrangements deployed in various sectors and regions (France, Germany, US) of AREVA NP remain consistent across the entire company. There are effectively four sub-management systems in place, though they are well integrated across AREVA NP. The cross audit system is centrally managed by "Corporate" and takes auditors independent of the region/sector being audited and carries out audits using two lead auditors. In addition, third party audits are carried out on the 4 sectors of activity in the various countries.
- 58 AREVA's Corporate level procedure, Q105 Performance and Evaluation of 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. Procedure 105 has a standard checklist. For example, compliance with the Corporate level Procedure Q102 "internal and supplier audits" is included on the checklist. An example cross audit was seen; 2008 cross audit report. This

- report contained one observation and no findings, and some positive observations were made. The report includes information on certification of auditors, audit plan and audit checklist. There is a quarterly meeting between the four sector heads, plus the two regional managers for Germany and US, and the corporate function to review cross audits. There are formal training sessions on the cross audit process to establish a framework for consistent practice across AREVA. Non conformances are followed up as part of the internal audit plan so that responses are followed up to close out.
- 59 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.
- 60 The new AREVA tracking system was presented as detailed in the response to RO-UKEPR-31, in Appendix 2. The system is called MAEVA, Managing Events and Actions in a common way. This is a common global database tracking all quality events, audit findings, non-compliances, and was due go live on 1 August 2009 in AREVA. A plants pilot of MAEVA was tested by key users in France and Germany. AREVA noted there is a need for integrated tracking, not least due to the increasing number of external audits with the global growth in business in new nuclear build. There is a module for "event and assessment" which was due to be in place by October 2009 and which covers planning, execution and reporting of audits.
- 61 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. This is an area that HSE will examine again in Step 4 of their process as noted in their Step 3 Assessment Report for Management of Safety and QA (HSE, 2009), and this information will be used by Environment Agency to inform our decision document for GDA.
- 62 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.
- 63 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 will be examined by HSE in their planned Step 4 inspection, as noted in their Step 3 assessment report (HSE, 2009).
- 64 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.
- 65 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 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, specifically including Chapter G on

- Environment. This was not strictly within the scope of the INSA review but was provided to INSA to aid understanding.
- 66 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 persons 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.
- 67 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-1-004 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.
- 68 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.
- 69 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. 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 (1000MWe) developed by AREVA and Mitsubishi, and how potentially the integrated management system applied. Environment Agency noted that our focus was GDA and in terms of independent peer review (IPR), AREVA might consider the role of the AREVA Environment Committee in contributing to IPR for GDA.
- 70 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.

71 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 will be examined during HSE's planned Step 4 Inspection, including one issue in regard to EDF's integrated oversight of issues arising from audits. We will continue to work with HSE on this matter and this will inform our decision and statement of design acceptability in June 2011.

3.6 Expectations for the Operator's Management System

72 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.

73 The EDF and AREVA submission addresses these matters in the PCER, Chapter 2 Quality and Project Management at Sub-chapter 2.1 Project Organisation.

74 PCERsc2.1s3 sets out the responsibilities of the post GDA organisation. This is defined according to the Plant Owner and 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.

75 Reference 1.1 of Table 1 of the 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 intends to facilitate the required knowledge transfer and the arrangements to provide ongoing support to the potential Operator.

76 The EDF and AREVA submission addresses these matters in the PCER at sub-chapter 2.1 'Project Organisation'.

77 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.

78 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.

79 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.

80 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.
- 81 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.
- 82 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.
- 83 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.
- 84 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.
- 85 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

4 Public comments

86 We received no relevant public comments on management systems before the end of 2009. Any comments received after that time will be addressed in our final decision to be published in June 2011.

5 Conclusion

87 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 inspection 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.

88 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 will be examined during HSE's planned Step 4 Inspection, including one aspect in regard to EDF's integrated oversight of QA activities. We will continue to work with HSE on this matter and this will inform our decision in June 2011.

89 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.

90 We concluded that EDF and AREVA has 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.

91 We conclude that EDF and AREVA has 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.

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Abbreviations

ALARP	As Low As Reasonably Practicable
ASN	Autorité de Sûreté Nucléaire, the French Nuclear Safety Authority
BAT	Best available techniques
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
MAEVA	Managing Events and Actions in a common way (AREVA system)
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
QP	Quality Plan
REPs	Radioactive substances environmental principles
RGN	Regulatory Guidance Note
RGS	Regulatory Guidance Series
RO	Regulatory Observation
SODA	Statement of Design Acceptability
TQ	Technical Query

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