

Office for Nuclear Regulation

An agency of HSE

Generic Design Assessment – New Civil Reactor Build

Step 4 Management of Safety and Quality Assurance Assessment of the EDF and AREVA UK EPR™ Reactor

Assessment Report: ONR-GDA-AR-11-029

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PREFACE

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 (ND) and has the same role. Any references in this document to the Nuclear Directorate (ND) or the Nuclear Installations Inspectorate (NII) should be taken as references to ONR.

The assessments supporting this report, undertaken as part of our Generic Design Assessment (GDA) process and the submissions made by EDF and AREVA relating to the UK EPR™ reactor design, were established prior to the events at Fukushima, Japan. Therefore, this report makes no reference to Fukushima in any of its findings or conclusions. However, ONR has raised a GDA Issue which requires EDF and AREVA to demonstrate how they will be taking account of the lessons learnt from the events at Fukushima, including those lessons and recommendations that are identified in the ONR Chief Inspector's interim and final reports. The details of this GDA Issue can be found on the Joint Regulators' new build website www.hse.gov.uk/newreactors and in ONR's Step 4 Cross-cutting Topics Assessment of the EDF and AREVA UK EPR™ reactor.

EXECUTIVE SUMMARY

This report presents the findings of the Management of Safety and Quality Assurance Assessment of the UK EPR reactor undertaken as part of Step 4 of the Health and Safety Executive's (HSE) Generic Design Assessment (GDA). The assessment has been carried out on the Pre-construction Safety Report, its supporting documentation and the processes applied by EDF and AREVA to maintain and develop the GDA submission during Step 4.

In addition to the review of EDF and AREVA's processes to maintain and develop the GDA submission this assessment has followed a step-wise-approach in a claims-argument-evidence hierarchy. In Step 2 the claims made were examined, in Step 3 the arguments that underpin those claims were examined.

The scope of the Step 4 assessment was to review EDF and AREVA's processes to maintain and develop the GDA submission and the safety aspects of the UK EPR reactor in greater detail, by examining and inspecting the evidence, supporting arguments and claims made in the safety documentation, building on the assessments and inspections already carried out for Steps 2 and 3, and to make a judgement on the adequacy of the Management of Safety Quality Assurance (MSQA) control arrangements and information contained within the Pre-construction Safety Report and supporting documentation.

It is seldom possible, or necessary, to assess a safety case in its entirety, therefore sampling is used to limit the areas scrutinised, and to improve the overall efficiency of the assessment process. Sampling is done in a focused, targeted and structured manner with a view to revealing any topic-specific, or generic, weaknesses in the safety case. To identify the sampling for the MSQA an assessment plan for Step 4 was set-out in advance.

My assessment has focused on:

- Management System, including audit and assessment, non-conformance and records management.
- Training and competency of personnel.
- Audit and Assessment, including non-conformance reporting.
- Quality Assurance arrangements for control of design development.
- Quality Assurance arrangements for software control supporting design development.
- Quality Assurance arrangements for control of design changes.
- Quality Assurance arrangements supporting the procurement of GDA services.
- Configuration control of GDA submission documentation (Safety Case, Design Reference and Submission Master List).

A number of items have been agreed with EDF and AREVA as being outside the scope of the GDA process and hence have not been included in my assessment. For example, the Quality Assurance (QA) arrangements for all manufacturing activities have been agreed as being outside the scope of GDA and will be addressed during the site specific phase.

From my assessment, I have concluded that:

- EDF and AREVA have developed and applied suitable Quality Management System arrangements to the UK EPR project and these have included adequate project controls and suitable execution of audit and assessment activities. The management of non-conformances was revisited in my Step 4 assessment, internal audit actions were managed appropriately however concerns were raised by Nuclear Directorate (ND) associated with the management

of non-conformances arising from supplier audits. These were satisfactorily addressed by EDF and AREVA during Step 4.

- EDF and AREVA have well established arrangements for the development and maintenance of technical competency and have demonstrated adequate competency of project personnel involved in the UK EPR project.
- The Step 4 inspection on procurement (Ref. 37) identified areas of concern associated with the GDA supplier assessment and selection process and the surveillance and action follow up of suppliers. These were adequately addressed in response to a Regulatory Observation, and the application of these processes will be revisited post Step 4 during the assessment of the GDA Issue associated with updating impacted submission documentation. The assessment of the QA arrangements supporting the procurement of all manufactured items such as long lead items, are out of scope for the Step 4 assessment and have been captured as an Assessment Finding (Annex 1).
- The UK EPR design was frozen in December 2008 based on Flamanville 3 (FA3) reference design configuration. Design changes arising from FA3, those proposed by EDF and AREVA for inclusion in the UK EPR and those arising from the UK regulatory assessment agreed for inclusion into GDA have been adequately controlled, impact assessed and the details successfully incorporated into the relevant Pre-construction Safety Report Chapters. The design change details will be incorporated into the consolidated Pre-construction Safety Reports, however the impacted supporting documentation contained in the design reference is yet to be updated to reflect these design changes. Therefore the implementation of these design changes and any other changes arising from GDA resolution plans will be followed up by the joint GDA Issue with the Environment Agency.
- EDF and AREVA have established arrangements for design engineering within their respective organisations. AREVA has demonstrated adequate application of controls for the development of the design. EDF has provided adequate evidence on the control of software use for design in the areas we sampled; however for the overall controls for design detail the evidence presented has been limited and will be assessed further through the GDA Issue on design change implementation and the Assessment Finding associated with control of design changes (Annex 1).
- Configuration control of the GDA submission document by EDF and AREVA has been good and the controlled update of the Pre-construction Safety Report Chapters has been demonstrated on a number of occasions and found to be robust. The tools used to control the submission, the Submission Master List and Pre-construction Safety Report Route Map, have been independently reviewed and the completeness and accuracy assured.

In some areas there has been a lack of detailed information which has limited the extent of my assessment. As a result HSE ND will need additional information to underpin my conclusion and these are identified as Assessment Findings to be carried forward as normal regulatory business. These are listed in Annex 1; an example of an Assessment Finding is given below:

AF-UKEPR-QA-01: Licensee must have adequate arrangements for the capture of Generic Design Assessment submission documentation into their records management system, in order to support the further development of the Pre-construction Safety Report.

This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

One observation identified within this report is of particular significance and will require resolution before HSE ND would agree to the commencement of nuclear safety related construction of a UK EPR reactor in the UK. It is identified in this report as a GDA Issue. However, due to the fact that this will affect many topic areas, this GDA Issue will be reported in and progressed under the Cross-cutting topic area. The GDA Issue requires:

GI-UKEPR-CC-02: EDF and AREVA to continue to control, maintain and develop the Generic Design Assessment submission documentation, including the Safety, Security and Environmental Report, Submission Master List and design reference document and deliver final consolidated versions of these as the key references to any Design Acceptance Confirmation/Statement of Design Acceptance the Regulators may issue at the end of Generic Design Assessment. These should include the management and acceptance of changes to Generic Design Assessment submission documentation impacted by design changes agreed for inclusion in Generic Design Assessment.

Overall, based on the sample undertaken in accordance with ND procedures, I am broadly satisfied that the processes applied by EDF and AREVA to maintain and develop the GDA submission during Step 4 and the MSQA claims, arguments and evidence laid down within the Pre-construction Safety Report and supporting documentation submitted as part of the GDA process present an adequate safety case for the generic UK EPR reactor design. The UK EPR reactor is therefore suitable for construction in the UK, subject to: satisfactory progression and resolution of the GDA Issue which is to be addressed during the forward programme for this reactor; and assessment of additional information that becomes available as the GDA Design Reference is supplemented with additional details on a site-by-site basis.

LIST OF ABBREVIATIONS

AE	Architect Engineer
ALARP	As Low As Reasonably Practicable
ASN	Autorité de Sûreté Nucléaire (French nuclear safety authority)
BMS	(Nuclear Directorate) Business Management System
BTS	Book of Technical Specifications
BTR	Book of Technical Rules
CAD	Computer-aided Design
CATHARE	Code for Analysis of THERmalhydraulics during an Accident of Reactor and safety Evaluation
C&I	Control and Instrumentation
CMF	Change Management Form
CTS	Contract Technical Specifications
DA	Direction des Achats (EDF's Procurement Division)
DAC	Design Acceptance Confirmation
DCC	Design Change Committee
DCML	Design Change Master List
DCSG	Design Change Screening Group
DIN	EDF's Nuclear Engineering Division
DSRC	Design Safety Review Committee
EDF and AREVA	Electricité de France SA and AREVA
FA3	Flamanville 3
FM	Modification Request
GDA	Generic Design Assessment
GQAS	General Quality Assurance Specification
HSE	The Health and Safety Executive
IAEA	The International Atomic Energy Agency
INSA	Independent Nuclear Safety Assessor / Assessment
IRSN	Institut de Radioprotection et de Sûreté Nucléaire (French Institute for Radiological Protection and Nuclear Safety)
ITT	Invitation to Tender
JPO	Joint Programme Office
LOCA	Loss of Coolant Accident
MDEP	Multi-national Design Evaluation Programme

LIST OF ABBREVIATIONS

MSQA	Management for Safety and Quality Assurance
NEA	Nuclear Energy Agency (of OECD)
NC	Non Conformance
ND	The (HSE) Nuclear Directorate
OECD	Organisation for Economic Cooperation and Development
ON	Observation Notices
PCER	Pre-construction Environment Report
PCSR	Pre-construction Safety Report
PQAP	Project Quality Assurance Plan
PSA	Probabilistic Safety Analysis
QMS	Quality Management System
RAS Export	EDF's Regulatory Correspondence Tracking System
RI	Regulatory Issue
RO	Regulatory Observation
ROA	Regulatory Observation Action
SAP	Safety Assessment Principles
SDM	System Design Manuals
SMD	System Detailed flow diagram
SMF	System Functional flow diagram
SML	Submission Master List
SODA	Environment Agency Statement of Design Acceptance
SSC	Systems, Structures and Components
SSER	Safety, Security and Environmental Report
STUK	Säteilyturvakeskus (Finnish Radiation and Nuclear Safety Authority)
TAG	(Nuclear Directorate) Technical Assessment Guide
TQ	Technical Query
US NRC	Nuclear Regulatory Commission (United States of America)

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Annex 1: Assessment Findings to be Addressed During the Forward Programme as Normal Regulatory Business - Management of Safety and Quality Assurance – UK EPR

Annex 2: GDA Issues - Management of Safety and Quality Assurance – UK EPR

1 INTRODUCTION

- 1 This report presents the findings of the Step 4 Management of Safety and Quality Assurance (MSQA) assessment of the UK EPR reactor under the Health and Safety Executive's (HSE) Generic Design Assessment (GDA) process. The assessment has been carried out on the Pre-construction Safety Report (PCSR) (Ref. 13) and supporting documentation derived from the Submission Master List (Ref. 14) and the MSQA processes applied by EDF and AREVA to deliver maintain and develop the GDA submission during Step 4. The approach taken was to assess the principle submission and the supporting documentation on a sampling basis in accordance with the requirements of Nuclear Directorate's (ND) Business Management System (BMS) procedure AST/001 (Ref. 2). The Safety Assessment Principles (SAP) (Ref. 4) have been used as the basis for this assessment. Ultimately, the goal of assessment is to reach an independent and informed judgment on the adequacy of a nuclear safety case.
- 2 During the assessment a number of Technical Queries (TQ) and Regulatory Observations (RO) were issued and the responses made by EDF and AREVA assessed. Where relevant, detailed design information from specific projects for this reactor type, in particular from the reference design plant FA3, has been assessed to build confidence and assist in forming a view as to whether the design intent proposed within the GDA process can be realised.
- 3 A number of items have been agreed with EDF and AREVA, confirmed in letter EPR00836N (Ref. 29), as being outside the scope of the GDA process and hence have not been included in this assessment. These are recorded in the Design Reference document UKEPR-I-002 (Ref. 51).

2 NUCLEAR DIRECTORATE'S ASSESSMENT STRATEGY FOR MANAGEMENT OF SAFETY AND QUALITY ASSURANCE

4 The intended assessment strategy for Step 4 for the MSQA topic area was set out in an assessment plan that identified the intended scope of the assessment and the standards and criteria that would be applied. This is summarised below:

2.1 Assessment Plan

5 The assessment plan for Step 4, AR09070 (Ref. 1) followed on from the Step 3 assessment report findings. It addresses the findings from Step 3 and it planned to assess the UK EPR project deliverables and the supporting quality assurance (QA) arrangements applied by EDF and AREVA.

2.2 Standards and Criteria

6 The main standards and criteria used are ND's Safety Assessment Principles (SAP) (Ref. 4) which take cognisance of The International Atomic Energy Agency (IAEA) guidance, including GS-R-3 The Management System for Facilities and Activities Safety Requirements (Ref. 16) and ISO 9001:2008 Quality Management Systems (Ref. 17) in particular:

- Leadership and management for safety, MS.1 Leadership. This principle requires the adequate, proportionate monitoring and auditing of implementation and effectiveness of the safety policies, strategies, plans, goals and standards, systems and procedures through the application of a Quality Management System (QMS). The QMS should be based on national and international standards or other defined documents and should be reviewed periodically (Ref. 16 and 17).
- Leadership and management for safety, MS.2 Capable organisation. This principle requires an intelligent capability should be maintained to ensure that the use of contractors in any part of the business does not adversely affect the ability to manage safety. There should be provision for identifying, updating and preserving documents and records relevant to safety. Document and records should be stored securely and should be retrievable and readable throughout their anticipated useful life.

7 In addition to ND's SAPs, elements of the following Technical Assessment and Inspection Guides have been used, where appropriate.

- T/INS/017 – LC 17 Quality Assurance (Ref. 18).
- T/AST/027 – Training and Assuring personnel Competence (Ref. 19).
- T/AST/057 – Design safety assurance (Ref. 20).
- T/AST/077 – Procurement of Nuclear safety related items or services (Ref. 8).

2.3 Assessment Scope

8 The objective of the Step 4 assessment was to review the safety aspects of the UK EPR design by examining the claims, arguments and evidence made in the EDF and AREVA safety documentation, building on the assessment already carried out for

-
- Steps 2 and 3 and make a judgement on the adequacy of the MSQA arrangements supporting the delivery of the Step 4 Submission and the consolidated PCSR.
- 9 For MSQA “evidence” is broadly interpreted as being the demonstrable application of the policies and procedures, and confirmation that the final outputs of the project meet the UK Regulator’s requirements as defined in the GDA guidance.
- 10 The scope of the MSQA assessment in GDA Step 4 was:
- Management System, including records management, audit and assessment and non-conformance reporting.
 - Training and Competency of personnel.
 - QA arrangements for the control of design development.
 - QA arrangements for software control supporting design development.
 - QA arrangements for the control of design changes.
 - QA arrangements supporting the procurement of GDA services.
 - Configuration control of GDA Submission Documentation.
- 11 The conclusion of my assessment in GDA Step 4 will include:
- Verification that all questions and queries that I raised have been resolved and are suitably dealt with in the Submission / consolidated PCSR.
 - Where there has been a lack of detailed information which has limited the assessment, further information has been requested through a number of Assessment Findings to underpin the conclusions.
 - If full resolution of Regulatory queries has not been achieved during Step 4 a GDA Issue will be raised detailing the remaining action(s) to be taken. These GDA Issues will require EDF and AREVA to submit a Resolution Plan detailing the approach to be taken to resolve the issue prior to nuclear island safety-related construction.

2.3.1 Findings from GDA Step 3

- 12 The conclusions of the Step 3 assessment as detailed in the Step 3 Assessment Report AR09032 (Ref. 6) were as follows:
- The organisational and QA arrangements for the UK EPR GDA project have been operating throughout GDA Step 2 and GDA Step 3. The joint project arrangements are supported and supplemented within EDF and AREVA by well developed QA arrangements. The Project Quality Assurance Plan (PQAP) is supported by a number of joint procedures which have been appropriately implemented.
 - The UK EPR GDA project has a well defined organisational structure with clear roles and responsibilities.
 - The Step 3 inspection provided evidence that the UK EPR GDA project is well managed and the elements important to effective interfaces between the Joint Programme Office (JPO) and EDF and AREVA are defined and controlled.

- The UK EPR design was frozen in late 2008 based on the FA3 design at that time. Design changes since then arising from FA3, or proposed by EDF and AREVA for the UK EPR or those arising from the UK Regulators' assessment will be considered for inclusion in the UK EPR, with the highest category changes subjected to Independent Nuclear Safety Assessment (INSA) or Independent Peer Review (IPR) processes. A joint inspection of the QA arrangements by ND and Environment Agency raised a number of aspects for consideration by EDF and AREVA including clarification of the role of INSA as applied to design changes and its application to environmental aspects of the design.
- EDF and AREVA have been requested to consider extending auditing programmes to cover all GDA support contractors. The Regulators also suggested that both EDF and AREVA should consider reviewing their current arrangements for managing and tracking non-conformances arising from their auditing activities. This issue was raised as a specific Regulatory Observation (RO) which has now been fully addressed. It was suggested that this would be revisited during Step 4.
- With regard to the control of design changes, the development of design detail and cut-off dates for information that can be included in the scope of GDA, discussions are ongoing with EDF and AREVA and will be finalised and assessed during Step 4.
- On the basis of the Step 3 assessment and EDF and AREVA's application of quality management principles to the UK EPR GDA project, there was no reason why the UK EPR should not proceed to GDA Step 4.

2.3.2 Additional Areas for Step 4 Management of Safety and Quality Assurance Assessment

13 For the most part the MSQA areas, or topics, assessed in Step 4 are broadly the same as those in Step 3. That said Step 4 has been focused on obtaining evidence on the application of these arrangements to control, develop and deliver the Step 4 Submission and the consolidated PCSR. Two areas that are new to the Step 4 assessment are the QA arrangements for managing training and competency of EDF and AREVA's staff and for software control.

2.3.3 Use of Technical Support Contractors

14 No Technical Support Contractors were used in the MSQA assessment.

2.3.4 Cross Cutting Topics

15 MSQA is cross-cutting in nature; therefore information has been shared and integrated within all the technical areas assessments as and when appropriate. The following 'cross-cutting' sub-topics have been identified as being particularly relevant in the MSQA topic area:

- Design Change.
- Function categorisation and classification of Systems, Structures and Components, as it feeds into the graded approach adopted for procurement and design change assessment.

- 16 For these instances information has been shared with the topic leads for these areas and the work reported in the Cross-cutting topic report (Ref. 42).

2.3.5 Out of Scope Items

- 17 The following items have been agreed with EDF and AREVA as being outside the scope of GDA.
- QA arrangements for all manufacturing activities, these will be addressed during the site specific phase.
 - Post GDA UK EPR Project organisation, as it is project specific.
 - Details of processes to be applied during UK EPR project execution, to take account of UK and customer requirements site specific needs.
 - Project specific QA arrangements for knowledge transfer between designer and operator. The general approach was defined and assessed during Step 3 and will be developed further with the operator in the licensing phases.
 - Documentation listed in the Submission Master List (SML) as Level 4; this information was submitted to HSE-ND for information purposes only, for example, detailed design information, site and operator specific information. Level 4 information is included in our assessment but excluded from the submission listing for any IDAC / DAC we may issue.
 - 3D modelling of design layouts (process and outputs), as it is site and operator specific. Some information was however provided in GDA to give confidence in design realisation.

3 REQUESTING PARTY'S SAFETY CASE

18 The MSQA arrangements for the GDA project overall are described in the PCSR within Chapter 21, which is split into the following sub-chapters:

- Sub-chapter 21.1 – Project Organisation (Ref. 24).
- Sub-chapter 21.2 – Management System (Ref. 25).

19 The Project Organisation sub-chapter (Ref. 24) provides a detailed description of the whole UK EPR project organisation, including the organisational structure, interfaces and responsibilities. The document is focussed on the scope of the GDA process however, high level principles of a post-GDA organisation is proposed in Section 3 and EDF and AREVA recognise that the post GDA organisation will depend on the plant owner, so will need to be revisited and defined further after GDA.

20 The Management System sub-chapter (Ref. 25) provides a detailed description of the Management System in place to deliver the UK EPR GDA project. The document explains how the key processes are controlled and managed in order to deliver the project such as Document and data control, Records, Design change management process. The Management System is supported by a UK EPR GDA Project Quality Assurance Plan (PQAP) (Ref. 23) and a number of joint management procedures.

21 The PQAP describes the processes used for GDA and references out the joint project procedures to be followed. The structure and content of the PQAP aligns to the requirements set out in ISO 9001:2008 – Quality Management System requirements (Ref. 17) such as Management System, Management Responsibility, Resource Management, Product Realisation; and Measuring, Analysis and Improvement.

22 The GDA submission includes the Safety, Security and Environmental Report (SSER), supporting documents referenced in the SSER, Design Reference, and responses to regulatory queries, e.g. documents submitted in response to TQs, ROs, RIs and meeting actions. However, any project or site specific information included in responses to regulatory actions / requests may be considered within the assessment but would be excluded from the GDA submission referenced in the DAC.

23 A review of the March 2011 consolidated PCSR Chapters is being conducted to confirm the factual accuracy and completeness of the chapter's technical content, ensuring that the relevant commitments in response to regulatory queries have been captured correctly. For MSQA assessment, sub-chapters 21.1 and 21.2 have been reviewed and no significant findings were identified; minor comments will be progressed through the Cross-cutting GDA Issue action associated with submission of a final consolidated PCSR at the end of GDA.

4 GDA STEP 4 NUCLEAR DIRECTORATE ASSESSMENT FOR MANAGEMENT OF SAFETY AND QUALITY ASSURANCE

4.1 Management System (Including Audit and Assessment, Non-Conformance and Records Management)

24 Building on the Step 3 assessment, I have based the Step 4 assessment on the application of EDF and AREVA's QMS to the UK GDA project. EDF and AREVA have developed and implemented a set of joint project procedures to control, develop and deliver the GDA safety submission, and I have sampled these. The joint procedures have been continuously improved during Step 4 in response to both internal learning and regulatory feedback.

25 The joint project procedures are supported by the QMS arrangements within each co-applicant organisation and the delivery of the design engineering is performed using these intercompany arrangements. Therefore, my assessment has sampled, where appropriate, the co-applicants internal QMS arrangements against the principles of T/INS/017 (Ref. 18) and international management system standards (Ref. 16 and 17).

26 To ensure that the updated PCSR meets the regulatory requirements and captures all the agreed changes, a specification for the 2009 PCSR update and a specification for the Consolidated Step 4 PCSR have been written as EDF and AREVA joint procedures (UKEPR-I-030 and UKEPR-I-031 respectively). These documents capture and provide visibility of the changes triggered by the regulatory assessment and INSA review which EDF and AREVA have committed to implement. EDF and AREVA have used these specifications to clarify the scope of the Step 4 and Consolidated Step 4 PCSR and have made amendments during Step 4 to ensure that these specifications are kept up to date with respect to current commitments.

27 A major reorganisation of the AREVA group was announced in early 2010 following the withdrawal of the Siemens shareholder from AREVA NP. The new organisational structure is based on the creation of Business Groups supported by an Engineering and Projects Organisation, all of which support the following objectives:

- Finalise the alignment of the organisational structure with the group's strategy.
- Better support the nuclear renaissance and the development of renewable energies.
- Allow a better optimisation of resources and increase quality and efficiency in project delivery.

28 During the transition phase in 2010, the quality management unit implemented a Head Procedure to the Integrated Management Manual – QM DC 55 J (NQ/2009.040 Revision A) defining the way the existing Plants Sector Integrated Management System continued to apply to the new AREVA organisation. This Head Procedure ensured the continuity of service and project delivery. The AREVA UK EPR GDA project and Licensing Team have continued to apply the existing AREVA Plants Sector Integrated Management System, as demonstrated in the Step 4 MSQA Inspections. The new organisational structures and interfaces have now been finalised and the relevant PCSR Chapters and the PQAP have been updated to reflect this.

4.1.1 Assessment

4.1.1.1 Records management

- 29 Records produced during the GDA project are registered and filed by each co-applicant in accordance with their QMS requirements and loaded onto their IT systems. Both EDF and AREVA use Electronic Document Management Systems to capture and securely store records allowing easy retrieval.
- 30 GDA records are regarded by EDF and AREVA as lifetime records and will be retained as per customer contract requirements in electronic form.
- 31 Documents and records submitted to the Regulators are done so by loading them into SharePoint as and when required. This has provided a useful tool to collate, file and transfer information between EDF and AREVA and the Regulator but also has enabled knowledge capture and share between the co-applicants, EDF and AREVA. For security marked documents and records, these are submitted to the Regulators securely via CDs. The folder structure in SharePoint has been developed to mimic the records types for the GDA project. The lifetime archiving of the project data is the responsibility of each co-applicant organisation in accordance with its own QMS arrangements.
- 32 At the end of GDA, EDF and AREVA's intention is to download the information into each of the co-applicants records management systems. The controls and arrangements to be applied to this transfer of documentation are yet to be defined. The principles to be applied to the process are defined within letter EPR00878N (Ref. 48) which includes:
- Application of internal procedures for document and data transfer and storage.
 - Identification of records to be transferred.
 - Sample transfer to test arrangements.
 - Verification check after transfer to ensure completeness of record and data capture.

4.1.1.2 Audit and assessment

- 33 It is noted that it is EDF and AREVA's practice not to distribute internal audit reports to outside parties, but these have been made available for review by the Regulators during inspections and meetings. Each co-applicant has an annual audit program (Ref. 31 and 32), and the GDA project is included in the schedule. The programs are held and monitored by the relevant internal audit departments and the expectation, within each co-applicant, for responding to any corrective actions is four weeks.
- 34 A joint internal audit was performed by EDF and AREVA in November 2010 on the Management of the Consolidated Step 4 PCSR update process; the scope of this audit included:
- UKEPR-I-031 Revision 2, Specification – Consolidated Step 4 PCSR.
- Other relevant GDA Project procedures considered in this audit were:
- UKEPR-O-001 Revision 3, UK EPR GDA QA Plan.
 - UKEPR-O-002 Revision 5, Project Organisation.
 - UKEPR-I-003 Revision 7, Design Change Procedure.

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- 35 No non-conformances were raised as a result of this audit. One observation was raised associated with the content and scope of the PCSR Route Map. The initial intent of the PCSR Route Map was to record only the changes which have been made to the PCSR. However, it was considered more beneficial to include all the changes which EDF and AREVA intended in making to the PCSR prior to the end of Step 4. This action has been completed and the PCSR Route Map has been updated.
- 36 In addition to this joint audit, each co-applicant has conducted an internal audit within their respective organisations in accordance with their audit programmes. The scope of the internal audits covered the management of TQs and ROs, including the performance of engineering work.
- 37 The EDF audit conducted in November 2010 reviewed the adequacy and application of the relevant joint project procedures plus resource management and EDF's regulatory correspondence tracking system (RAS Export). The audit report, ECMT100135 Revision A, was reviewed by ND during a QA topic meeting in January 2011 and the report structure and content was considered to be adequate. The audit identified two observations, one associated with the volume of GDA Step 4 exchanges with respect to resource planning and one associated with the RAS Export system. EDF did not accurately anticipate the resource required in responding to the GDA assessment, this has been captured as a lesson learnt from GDA. For regulatory interaction, EDF has an internal system RAS Export however, for the GDA, EDF have been using SharePoint to transmit information to the ND according to the joint GDA instructions. An observation was raised confirming that SharePoint is the key tool to use with respect to GDA and information will continue to be uploaded to RAS Export for records management purposes.
- 38 The AREVA audit conducted in December 2010 reviewed the adequacy of how information relating to TQs/ROs is issued to the teams and how the technical work is performed in order to respond to the regulatory action. The audit report PQ/2010.092 was reviewed by ND during a QA topic meeting in January 2011. The report was found to be well structured and a good level of detail provided with a large list of sampled documents indicating a suitable level of breadth and depth. The audit identified that the organisation demonstrated a strong commitment to the regulatory actions and that SharePoint, as a tool, was being used effectively. During AREVA's audit, a number of design files could not or only partially be made available, therefore an observation was raised requiring AREVA to provide and ensure all validation files were stored correctly. Action taken by AREVA to address this observation has been completed.

4.1.2 Findings

- 39 From my assessment of QMS arrangements the following strengths were identified:
- Document submission is achieved by the use of SharePoint, but this is limited to non security marked documents. SharePoint has been a useful tool to enable capture and transfer of information to both Regulators and between co-applicants.
 - Records generated in support of the GDA project are regarded as lifetime quality records and will be controlled as such.
 - Annual audit programmes are in place and the GDA project is included. Learning from these audits has been fed back into the project QMS and resulting actions are being monitored.

40 From my assessment of QMS arrangements the following observations were identified:

- It is not fully defined how SharePoint documentation will be downloaded into the co-applicants record management IT systems and what QA arrangements will be applied to ensure accurate identification and retrieval of all GDA safety submission documentation, including protectively marked documents post-GDA. Principles have been defined and will be applied within each co-applicant organisation at the end of GDA.
- EDF and AREVA's practice is not to distribute internal/third party audit reports to outside parties, including Regulators, as advanced information. Arrangements were made at EDF and AREVA's offices to select a sample of documents for review. It is recognised that GDA is a voluntary process however, for nuclear site licensing and permissioning activities, the Regulators will require unrestricted access to relevant internal and third party audit reports.

4.2 Training and Competency

41 EDF and AREVA's training and competency arrangements were sampled during a MSQA inspection in September 2010 (Ref. 26) to ascertain the adequacy of the arrangements for the GDA project. For my assessment, I have used parts of the Technical Assessment Guide (TAG) for Training and Assuring Personnel Competency (Ref. 19). The TAG states that a systematic approach should be taken to the identification and delivery of personnel competence. It also assists in the application of other SAPs including MS.2 which set out expectations for training processes and arrangements for assuring competence. It is this area of the TAG which has been used in this assessment.

4.2.1 Assessment

42 EDF conducted a capability review in 2004 that identified six technical competences which were considered to be under threat and becoming scarce such as, Civil Engineering and Control & Instrumentation. For each technical competency, a leader was nominated and was tasked with establishing a development plan and competency levels in order to strengthen the capability.

43 This capability review in EDF has been repeated and resource forecasts provide management information to enable mobility, succession planning and recruitment to be planned and acted upon. The reviews used information from individual performance appraisals undertaken within the technical teams. An example of a resource forecast completed in 2010, covering the next three years, was presented during an inspection (Ref. 26). This illustrated in manhours how much work is estimated against each technical area against a project. It was noted that Human Factors was not mentioned in the first capability review however, it has been introduced in future lists. This process demonstrates good arrangements for identification and development of key competencies in EDF.

44 In AREVA, the technical competencies are split into three levels - basic knowledge, solid practice and specialist. Skills mapping performed in 2006 support these competencies and for each division or department within the organisation the skills have been identified. In some cases the skill has been further sub divided for example, Thermo-mechanical is split into Fracture Analysis and Welding Simulation.

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- A spreadsheet populated with the skills and sub-skills was observed. This demonstrates good identification and allocation of competency within AREVA.
- 45 In both organisations, role descriptions are in place and performance appraisals are conducted periodically, which meet the requirements of the TAG (Ref. 19). The descriptions are set at a role level; therefore the responsibilities are consistent across the projects for example, junior engineer and senior engineer. The role descriptions cover responsibilities, performance measures, experience and qualification profile, behavioural competency and career pathway. The appraisals in both organisations cover the technical competency levels achieved, work performance, development actions and career aspirations, meeting the requirements of T/AST/027 (Ref. 19).
- 46 With respect to the UK GDA Project, individuals have been identified within the relevant technical areas of expertise to support the project. The records to demonstrate responsibility on the GDA project is through the individual's performance appraisal, three names were picked by the Regulators from the list of technical correspondents and sampled. The performance appraisal records were found to be satisfactory and clearly identified their objectives in relation to the GDA project.
- 47 For the GDA project, Technical Correspondents were nominated to support the requirements set out in procedure UKEPR-I-023 (Ref. 27). The AREVA Project Manager issued a calling notice to the AREVA Department Managers for GDA support. To test the process of nomination of technical leads for GDA, names were chosen and the paperwork requested by the Regulators. Suitable paperwork was presented for the sample taken.
- 48 The technical competency framework has been developed at a generic level and the technical skills should be the same whatever Project an individual is allocated to. It is the responsibility of the project to provide any specific training needs, therefore for GDA no further specific technical training was conducted. However, the nominated leads were given information on UK regulation, codes and standards and the Project quality management system procedures. This was achieved through a seminar launching the Project, to ensure common understanding of procedures and the UK regulation approach. To maintain this focus regular Project meetings are held to discuss current organisation and management system arrangements, minutes and slides are produced and sent out to all technical leads. Examples of material used were made available during the inspection and were found to be satisfactory.

4.2.2 Findings

- 49 From my assessment of training and competency arrangements, the following strengths were identified:
- EDF and AREVA have both recognised the importance of developing and maintaining key competencies and have established arrangements for the management of training and competency.
 - With respect to the GDA Project, there are no additional technical skills required over and above an individual's technical competency, therefore only awareness training was given at the launch of the Project. This was considered to be adequate.

4.3 Control of Design Development

50 I have assessed the arrangements for control of development of design documentation including System Design Manuals and other relevant documents. This assessment area looked at EDF and AREVA's arrangements for controlling input data and information, application of design codes and standards, and review and verification activities in accordance with T/AST/057 (Ref. 20).

4.3.1 Assessment

51 The Engineering support to the UK EPR GDA Project is provided by the engineering organisations of EDF and AREVA. In addition, further supplier organisations are contracted by EDF or AREVA for engineering or project support as needed.

52 The engineering support for the UK EPR GDA Project from EDF is provided by the EDF Nuclear Engineering Division (DIN). The Nuclear Engineering Division covers the activities of plant design, construction and commissioning of installations and comprises of the following six organisations:

- CNEN for nuclear design engineering.
- CNEPE for electricity production engineering.
- CIPN for nuclear base engineering.
- CIDEN for decommissioning and environmental engineering.
- SEPTEN for thermal and nuclear engineering and projects.
- CEIDRE for inspection and testing appraisal.

53 The CNEN, CNEPE, CIDEN and SEPTEN engineering centres are involved in the pre-licensing phase of the UK EPR project. The EDF UK EPR GDA Project Team belongs to CNEN.

54 Within AREVA, the Reactors and Services Business Group is organised into six business units:

- Products and Technology.
- New Builds.
- Equipment.
- Installed Base.
- Nuclear Measurements.
- Propulsion and Research.

55 In particular, the Products and Technology Business Unit is responsible for 'ensuring licensing and technical performance of Reactors and Services products, and providing advanced, high performance products and necessary technologies'. The New Build Business Unit is responsible for 'delivering new nuclear reactors, from proposal phase until commissioning and hand-over to the client'.

56 Engineering and Projects, a resource organisation, has been created within AREVA with the purpose of providing the business units with design, construction and commissioning and inspection services. In addition, Engineering and Projects provide Reactors and Services Business Group with engineering and project management

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- resources and develops project methods and tools. For the UK EPR GDA Project, the AREVA project team belongs to the Products and Technology Business Unit and is supported by the Engineering and Projects organisation.
- 57 The UK EPR is designed against a set of design codes issued and approved by the industry. The design codes are:
- ETC-C (Ref. 54).
 - ETC-F (Ref. 55).
 - RCC-C (Ref. 56).
 - RCC-M (Ref. 57).
 - RCC-E (Ref. 58).
 - RSE-M (Ref. 59).
- 58 Within my assessment I sampled the QA arrangements for controlling the development of the design codes but did not technically assess the adequacy of the codes, this has been done in the technical topic assessment areas. Each code has been developed using information from both the industry and the Regulators in France, taking into account the relevant rules, regulations and practices. The maintenance and further development of these codes is undertaken by a set of Working Groups, Committees and Sub-committees. For the RCC codes, the AFCEN organisation (French Society for Design & Construction Rules for Nuclear Island Components) is the code owner and governing body and generally every year, the code is updated to the next edition through a set of sub-committees. The maintenance of these codes was presented during the MSQA inspection in September 2010 (Ref. 26) and was found to be adequate.
- 59 It was explained by EDF and AREVA that if a change to a code is required, a change request will be sent to the dedicated Working Group or Subgroup, who will be tasked with reviewing the change request and raising recommendations to resolve the issue identified. The change request can be originated from a user of the code, a customer or a Regulator. The members of the dedicated Working Group or Subgroup include external organisations such as Rolls Royce, French Atomic Bureau, etc. Recommendations from the Working Group or Subgroup are passed to a sub-committee for consideration. After consideration, a modification sheet is generated and the action to be taken is forwarded to the Editorial Committee for approval, copying to the originator for information. Note the structure and attendance of the working groups, sub-committees and committees may vary depending on the technical area of the code however, the principles for development are the same.
- 60 To support the codes, EDF have developed equipment technical standards in the form of a Book of Technical Specifications (BTS) and Technical Rules (BTR). These standards support the Technical Codes and Standards, Guides and Laws. BTS provide further technical requirements, e.g. for a piece of equipment, the BTR detail the welding and examination requirements for that equipment. The BTS / BTRs supporting FA3 are used to develop the Contract Technical Specifications (CTS) and aid in the development of the System Design Manuals (SDM). The development of the CTS is conducted under a Quality Plan and Principles document as they are project specific. The equipment technical standards will have to be reviewed and, where required, amended for application to the UK on a site/fleet specific basis. Therefore the QA arrangements for the development of these standards were not sampled during Step 4.
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61 Technical specifications and rules (BTS / BTR) evolutions are analysed by the project, which will decide whether to adopt the modification dependent on the impact. Modification of the Technical Specifications may also result from the output of the design change process. The BTS / BTR requirements are cascaded through the contract documentation so, if a modification is required, the change is applied to the project through a contract amendment. The quality assurance arrangements for modification and application were not tested during the GDA assessment and will need to be considered once these BTS / BTRs are reviewed and amended for the UK site specific project. This will be followed up by Assessment Finding **AF-UKEPR-QA-02**.

AF-UKEPR-QA-02: *The Licensee shall make and implement adequate QA arrangements for the control of detailed design activities. This will include the QA arrangements supporting the use of 2D and 3D modelling tools in design development and the QA arrangements for the control of site specific design documentation, such as Stage 2 and 3 SDMs, BTS / BTRs and FMEA analysis.*

62 This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

63 AREVA explained how they use the RCC-M code in the development of the design and purchase specifications. RCC-M is regarded as input data into the design and design development is prescribed in the generic engineering work process P08 WW - Perform engineering works.

64 As the RCC-M is a large complex code there is a requirement to select the right rules applicable to the design task. This is done through an Initiation Notice document, so for the FA3 Pressuriser, which is a class 1 item, the Initiation Notice references RCC-M, class 1 and therefore specifies volume B is to be used for the minimum thickness design calculations. All design calculations are reviewed to check that the code and standard versions used are correct and the rule is appropriate. This record of the review is kept in the review sheet.

65 The Perform engineering works process is the high level process in AREVA for planning and performing engineering activities. The process covers a number of steps including gathering input data, validation of the data and verification. The validation step is performed through the use of rules and assessments. All the information generated during the engineering design activity is recorded within the Design File. Design development for the FA3 Pressuriser was examined during the September MSQA inspection (Ref. 26) to demonstrate the use of the RCC-M code and the prescribed QA arrangements were applied.

66 As an example of the engineering work performed in AREVA, the response to RO-UKEPR-057 was presented live through the IT system during the inspection. The Design File for this engineering work was sampled. It was in 13 parts and held information supporting the design work such as:

- LOCA analysis.
- Correspondence, e.g. the minutes from a meeting with EDF and ND.
- Software tools used, e.g. CATHARE.
- Independent verification sheets.

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- 67 I found that the information was well structured and filed and was easily retrieved, demonstrating the application of the QA arrangements for design development. The file included evidence on the independent verification performed. Records sampled were found to be adequate and meet the principles of T/AST/057 (Ref. 20).
- 68 For EDF, EDF CNEN procedure B4.5 – Organisation of design (ECDQS020045 Revision C) defines the design activities and the quality plan requirements. The EPR engineering process is based upon the FA3 design and one of the main products is a set of SDMs. The SDMs are developed through three stages: SDM stage 1 (includes functional requirements); stage 2 (updated with supplier information); and stage 3 (updated with commissioning data). Within the SDM Stage 1 there are five parts.
- Part 1 of the SDM lists the updates to all parts of the SDM.
 - Part 2 provides the technical specification on the system, main description and the safety, operational and design requirements.
 - Part 3 involves sizing of the system and its components.
 - Part 4 involves the functional and detailed flow diagrams and their interactions (SMFs and SMDs).
 - Part 5 details the functional instrumentation and control and description of location/architecture.
- 69 A number of the SDMs are developed for EDF by a supplier, SOFINEL. EDF has oversight of the development activities, which is achieved in accordance with the EDF CNEN procedure B5 – Surveillance of subcontractors (ECDQS020005 Revision E). The documents used for SDM production are the system specifications, safety reports and safety function requirements. Parts 1 to 5 are reviewed throughout stage 1 using the B5 surveillance process. Once the surveillance of Parts 1 to 5 has been completed, a System Review is undertaken. The System Review integrates the comments from the surveillances and modifies the scope if required. An example was cited during a MSQA inspection. This provided a limited view of the process.
- 70 Modifications to the SDMs are managed through a Modification Request (FM). They are generally performed in Stage 2. Prior to the modification being made, a decision on the approach needs to be made and the change controlled. An example of a FM being implemented on a stage 1 SDM was provided however, it was post the GDA design freeze and no examples for recent FMs were available. Therefore modifications to SDMs relevant to the GDA project could not be tested. The QA arrangements for GDA will need to be assessed during design change implementation work post GDA Step 4 and followed up by the GDA issue **GI-UKEPR-CC-02** (Ref. 42) Annex 2.
- 71 Design development and review is achieved via surveillances conducted by EDF. The design studies with respect to fault studies were presented. These are based upon the French regulatory requirements of 1984 which require surveillance focusing on technical and quality assurance arrangements. For this example, the surveillance is conducted by EDF SEPTEN in accordance with the internal EDF SEPTEN procedure 4.4 – Surveillance of subcontractors (ENDAM070046 Revision B). The surveillance of services describes the organisation and who is responsible for what. There are three levels for the surveillance of technical studies.
- L1 – verification of data, structure and methodologies.
 - L2 – as per L1 plus calculations, if necessary.
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- L3 – as per L2 plus detailed analysis.
- 72 The level required is based on risk analysis and experience feedback, so takes into consideration the potential consequences of an error in the study on the safety or availability of plant. The surveillance schedule describes the organisation of the project, the documents to be sampled, level of surveillance to be applied and the level of competence to be used. Once the surveillance has been initiated, a surveillance folder is set up and contains all the records generated during the surveillance such as correspondence, reference documents, findings and any non conformances (NCs) identified. If a NC is identified an assessment of impact is performed.
- 73 For example, the fuel management project for N4 (the N4 is the most modern reactor design in France; there are four N4 reactors in operation) discovered a problem in an AREVA code. Surveillance picked this up and the mistake was corrected. As a consequence, recalculations were performed on all reactors covered by the project. This information has been archived against the station.
- 74 The application of the design development and surveillance process described above was presented for Fault Studies FA3 project during a MSQA inspection. The documentation observed, included an engaging letter from AREVA and a results letter. The engaging letter requested the input data and information required to perform the study. The results letter recorded the calculations and conclusions from the study. At the time of the inspection the results had not been validated.
- 75 Within EDF the 2D modelling CAD tool is used in support of the design development, providing functional diagrams, detail design information and layouts. The process and arrangements presented were limited to functional and detailed flow diagrams – System Functional Flow Diagram and System Detailed Flow Diagram (SMFs and SMDs) and to functional C&I diagrams (DFE) which support stage 1 System Design Manuals (SDM). The quality assurance arrangements supporting this activity were not tested during Step 4. These may need to be considered when changes to Stage 1 SDMs and supporting documentation are made to update the Design Reference within GDA.
- 76 The tools used within the 2D modelling include a Unified user data model, which ensure the data is unified and consistent throughout the SDM lifecycle and can be shared and transferred to other users without transcription or translation errors. A set of instructions are in place for users to work and refer to, which cover the process on development and maintenance of the CAD tools. The software is based on proprietary product that has been adapted for specific EDF applications. So the instructions cover validation, customer acceptance and testing strategies. EDF monitors the performance of the software through a number of metrics, such as number of poor quality instances and errors identified during validation. EDF will also perform audits to check consistency of application and data.
- 77 EDF and AREVA have established QA arrangements for controlling design development. The arrangements used to develop the design detail for FA3 has not been assessed during the MSQA assessment as it is out of scope. That said, the arrangements have been sampled during the Civil Engineering assessment (Ref. 47). The Civil Engineering assessment has identified a number of concerns relating to the QA arrangements for the control of contractors and the QA practices applied by the supply chain in developing the design detail. The Cross-cutting GDA Issue **GI-UKEPR-CC-02** (Ref. 42) is requesting EDF and AREVA to apply adequate arrangements to manage and accept changes to GDA submission documentation,

impacted by design changes, agreed for inclusion in GDA. It is the intention to confirm that the lessons learnt from the Civil Engineering assessment have been applied as part of this GDA Issue.

4.3.2 Findings

78 From my assessment of control of design development the following strengths were identified:

- EDF and AREVA actively participate in the development of the design codes used for the EPR design. Within EDF, these codes are complemented by internal technical standards in the form of books of technical specifications and technical rules. The QA arrangements for the control and development of the technical specifications and rules for UK project specific requirements has not been assessed during Step 4, so will need to be considered when UK versions are being developed. This requirement for the licensee is identified as an Assessment Finding **AF-UKEPR-QA-02** (Annex 1).

AF-UKEPR-QA-02: *The Licensee shall make and implement adequate QA arrangements for the control of detailed design activities. This will include the QA arrangements supporting the use of 2D and 3D modelling tools in design development and the QA arrangements for the control of site specific design documentation, such as Stage 2 and 3 SDMs, BTS/ BTRs and FMEA analysis.*

This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.
- The QA arrangements for the design development process in AREVA were found to be suitable and sufficient. The use of the design files by AREVA provided structure and easy retrieval of design documentation including calculations, demonstrating a good auditable trail.
- A robust approach to verification is performed by AREVA, this approach is applied to all engineering work regardless of safety significance.
- EDF applies an appropriate graded approach to their review process for technical studies.

79 From my assessment of control of design and development the following observations were identified:

- The development of some SDMs for EDF is performed by SOFINEL and EDF's surveillance process provides the QA arrangements to support the design development. As the SDMs are still yet to be adapted for the UK, no recent examples for modification of these documents or for oversight and acceptance by EDF and AREVA for inclusion in GDA, were available for examination. This will be captured as part of the GDA Issue (**GI-UKEPR-CC-02**) requesting a process to manage and accept changes to the GDA submission documentation impacted by design changes agreed for inclusion in GDA.
- The QA arrangements supporting the 2D modelling tools were not assessed by ND. These may need to be considered when changes to Stage 1 SDMs and supporting documentation are made to update the Design Reference within GDA.

4.4 Software Control Supporting Design Development

80 My assessment has sampled the QA arrangements for the control of software in design development. My sample included the validation of software codes, user controls and training in accordance with ISO 9001:2008 requirements (Ref. 17).

4.4.1 Assessment

81 Within EDF, the qualification process for scientific software is through computer validation and physical validation. The computer validation checks that the tool is working; the physical validation checks if the tool is right for the task. The process for scientific lifecycle management is described in EDF SEPTEN procedure 9.4 – Cycle de vie des applications scientifiques et techniques (ENDAM030303 Revision B).

82 Each software version is qualified for a given scope of use on a given IT system. The details of this qualification are held within the Software Qualification File. Guides are available when using qualified and unqualified software, plus there is an EDF users club for scientific software. Software users are authorised but this authorisation is recorded at an organisation/entity level, not at an individual level. If work is to be carried out by a supplier involving software codes, EDF may specify the software to be used dependent upon supplier competence and/or creditability.

83 AREVA defines verification as checking the functionality of the software; and validation as the physical checking using known standards to test the calculations sometimes referred to as qualification. Validation is only performed for software with physics.

84 The validation work is presented in a formal report which is reviewed by the Commission de Qualification (appointed by the engineering vice president of AREVA). For each code assessment, the Commission's board invites a set of relevant technical members not involved in this specific code development to participate and to rule on. The assessment is required for new codes and existing codes, if modified, or the scope of use is to change. For purchased software, the software is verified and validated as per in-house developed software but AREVA may use the vendor's test calculations.

85 As per EDF, AREVA controls access to users via the role of the Software Manager. The users are trained using a mix of CEA training, in-house training and specific study. The management of CATHARE2 V2.5 code was presented to demonstrate the appropriate validation and control of user documentation. This is a CEA code sponsored by EDF and AREVA and is the main code used for Thermal hydraulics during loss of coolant accident analysis. Regarding user support and training, AREVA cited that there is a CATHARE users club, which includes approximately 10 organisations including CEA, EDF AREVA, IRSN and University members.

86 Within both EDF and AREVA, the details on the software can be found on the IT system to help users locate, access and use the correct and valid code for the task. These systems include:

- Current version.
 - Purpose and scope of application.
 - Who's in charge, the Software Manager.
 - Operating platform the code is available on.
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- Version history, confirms or otherwise if validation still applies and how to use the software.
 - Documentation, user manual and guides.
 - Qualification / validation status and results.
- 87 EDF and AREVA were questioned on how they manage software errors or non-conformances. They cited that if an error is identified during use of the software, the details are recorded on a sheet and sent to the Responsible Engineer to investigate and correct. An impact assessment is performed and, if the resolution involves revising the version or creating a new version, then validation will need to be completed prior to use. No trending on software errors was made available during the MSQA inspection (Ref. 26). Information has been provided in June 2011 however, this was too late for consideration in this assessment. An Assessment Finding, **AF-UKEPR-QA-05**, has been raised to ensure that adequate arrangements are in place to trend learning opportunities and NCs.

AF-UKEPR-QA-05: *The Licensee shall make and implement adequate arrangements for trending information, such as events and non-conformances, in a timely manner and format to allow identification of learning opportunities and implementation of the necessary improvements to realise the learning opportunity benefits.*

- 88 This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:
- Long lead items and SSC procurement specifications.
- 89 Examples of software code non-conformance reporting were cited during the inspection (Ref. 26). Evidence could not be provided during the visit and was provided at a later date under the cover of letter EPR00615N – MSQA Inspection Actions A2 and A3 – Non-Conformances in CATHARE and COCCINELLE Codes (Ref. 40). This letter provided information on the number of non-conformances raised within a 24-month period associated with the CATHARE and COCCINELLE codes. An example of a non conformance provided in the letter (Ref. 40) was examined further, to review the adequacy of the investigation performed and the action taken. The additional information on this non conformance was assessed by ND’s Fuel Design assessor and was found to be satisfactory and demonstrated adequate investigation and impact analysis.

4.4.2 Findings

- 90 From my assessment of the control of software used in design development, the following strengths were identified:
- There are robust processes for controlling the development and application of software codes within both organisations.
- 91 From my assessment the following observations were identified:
- Both co-applicants report software errors. The number of errors raised was quoted in letter EPR00615N for software codes CATHARE and COCCINELLE within the last 24 months. EDF and AREVA claim that trending is performed by the co-applicants as part of their management review activities. Evidence of trending of

software errors could not be provided at the time of the inspection and was subsequently sent in June 2011. This information was provided too late for assessment..

- As this will continue to be important in the site specific phase an Assessment Finding, **AF-UKEPR-QA-05**, was raised to capture the requirement for the implementation of adequate arrangements for trending errors, so that the opportunity for learning and implementation of potential preventive measures can be achieved in a timely manner (Annex 1).

AF-UKEPR-QA-05: *The Licensee shall make and implement adequate arrangements for trending information, such as events and non-conformances, in a timely manner and format to allow identification of learning opportunities and implementation of the necessary improvements to realise the learning opportunity benefits.*

This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

4.5 Control of Design Changes

92 My assessment sampled the QA arrangements for controlling the identification, impact assessment and implementation of design changes against T/AST/057. I have sampled a number of design changes during this assessment in order to test the application and adherence of EDF and AREVA's QMS arrangements for change control. The management arrangements and tracking of individual design changes is covered by ND's Cross-cutting assessment report (Ref. 42).

4.5.1 Assessment

93 The GDA UK EPR Design Reference was frozen in December 2008 based upon the FA3 design at that time. The Design Reference provides information on the key technical functions and safety parameters of the design. The design reference is composed of supporting Elementary Systems, defined and specified by a SDM, complemented by a number of agreed design changes. The Design Reference Configuration is described in the GDA UK EPR project joint procedure UKEPR-I-002 (Ref. 51).

94 The arrangements for the inclusion of design changes in the GDA submission post the December 2008 design freeze, have been discussed with EDF and AREVA on several occasions. The Regulators' defined a six step process for the progress and agreement of design changes into GDA. This was detailed in letter EPR70197R dated 7 June 2010 (Ref. 41) and has been incorporated into EDF and AREVA project procedure UKEPR-I-003 (Ref. 30).

95 This process may be used to propose and control any category of design change into GDA. The design changes proposed for inclusion during GDA, originated from one of the following possible sources:

- FA3 design changes, which take international experience feedback into account.

- UK specific changes proposed by EDF and AREVA.
 - UK specific changes resulting from UK regulation or interactions with the UK Regulators during GDA.
- 96 In GDA, this process has been limited to a small number of category A1/A2 design changes which have been assessed on a case by case basis and the application of the GDA categorisation system was not assessed in Step 4. Further details on GDA design changes are given in the Cross-cutting EPR technical report (Ref. 42).
- 97 EDF and AREVA design change procedure UKEPR-I-003 (Ref. 39) outlines EDF and AREVA's three stage design change management process, including design changes categorisation based on impact on the GDA submission. Under its arrangements, EDF and AREVA are required to submit (monthly) an updated submission program for those design changes agreed to be included in the GDA. The submission program identifies the schedule for delivery of the supporting documentation for each design change, including the safety justification, description and supporting analysis.
- 98 Within EDF and AREVA, the FA3 proposed design changes are reviewed at the Design Change Screening Group (DCSG) for their application to the UK and are allocated an initial category. The group includes the two GDA technical managers, the design change coordinators and appropriate technical support. The change is categorised into one of three levels, Category A1, A2 or B, based on the impact on the GDA submission. Information on the design changes, as well as the proposed categorisation of the changes, is recorded in the Design Change Master List (DCML). The DCML is then passed onto the GDA Design Change Committee (DCC) for approval. The decision on whether to propose a change for inclusion in GDA is made by the DCC depending on the impact of the change on the GDA submission. The key project personnel and DCC members are listed in joint procedure UKEPR-O-005 (Ref. 36).
- 99 Once a potential design change has been identified by the DCC as applicable to the UK, it is proposed for inclusion in GDA. The confirmation that the change is included within GDA scope and agreement for full assessment of the change is reached by using the Regulators' six step process. The potential design change is discussed with the relevant assessors and then formally issued for agreement to the Joint Regulators' Assessment Review Group via the JPO. The changes are documented in a Change Management Form (CMF) identifying the change description, rationale and impact analysis on the safety submission. The status of these agreed design changes is summarised in the Cross-cutting topic report (Ref. 42).
- 100 Joint procedure UKEPR-I-002 (Ref. 35) includes at Annex 2, a set of design changes which were included in the 2008 design freeze but are yet to be incorporated fully in the supporting documentation. Annex 3 of the document references the design changes agreed with the Regulators for inclusion into GDA since the Design Freeze 2008. The design reference has been regularly updated to include any new design changes agreed for inclusion in GDA. The joint procedure UKEPR-I-002 was updated in May 2011 to reflect the completion status of CMFs and the arrangements for tracking outstanding changes to reference design documents, for example SDMs, has been included in UKEPR-I-003 (Ref. 39).
- 101 During the inspection in September 2010 (Ref. 26) the DCML was sampled. At the time of the inspection, there were 865 changes triggered by FA3, of which 550 have been identified as potentially applicable to the UK GDA. The design change for the protection for the iodine filters (CFSE0346) was selected as an example and it was

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- noted that this design change had been proposed as A2 by the DCSG but was then re-categorised to B by the DCC. However, the justification for this change in categorisation was not explicit on the DCML and did not appear to be supplemented by additional information to support the decision to change the candidate design change from A2 to B. This was fed back to EDF and AREVA who took an action to improve the justifications for categorisation of the changes and rationale for the changes in the DCML.
- 102 The joint design change procedure UKEPR-I-003 (Ref. 30) and the change submission schedule indicated that changes to the consolidated PCSR will be achieved within the GDA Step 4 timeframe. However, the GDA supporting documentation such as SDMs will be updated incorporating the design changes after GDA Step 4. This was confirmed by a TQ response and the process for capturing and controlling the transfer of outstanding work post Step 4 at the time of raising the TQ was unclear. To address this concern, RO-UKEPR-081 (Ref. 11) was raised requesting EDF and AREVA to:
- Develop and document processes for identifying, control, review, acceptance and implementation of changes to all supporting documentation for design changes to be included in GDA (including SDMs).
 - Develop and document a process for transferring the information associated with incomplete design changes from GDA to licensing activities.
- 103 EDF and AREVA shared with ND their plans to respond to this RO and have since developed and documented the processes to manage design changes within GDA post Step 4. Design Change joint procedure UKEPR-I-003 (Ref. 39) was amended to incorporate the RO requirements. This has been presented for comment to ND and the principles and key steps within the processes meet ND expectations. However, sampling the application of these processes cannot be conducted until the new parts of this procedure have been implemented in GDA post Step 4. This will be followed up under the GDA Issue (**GI-UKEPR-CC-02**) (Ref. 42).
- 104 EDF and AREVA have proposed to update the UK EPR Design Reference to a December 2010 status. This updated design freeze will include a certain number of category A2 and B design changes. The Regulators have agreed in principle to consider the inclusion of these changes in GDA. However, the suitability of these changes, the application of the design change categorisation system and the implementation of the change in the safety submission will need to be sampled post GDA Step 4 so that the Regulators gain confidence in the application. This will be followed up under GDA Issue **GI-UKEPR-CC-02** (Ref. 42).
- 105 It is recognised that during site specific design development or construction the number of design changes may increase as a result of operating experience during construction. The QA arrangements to manage this flow of information will need to be considered to ensure that the design documentation reflects as built. This has been raised as an Assessment Finding **AF-UKEPR-QA-04** (Annex 1).
- AF-UKEPR-QA-04:** *The Licensee shall make and implement adequate arrangements for managing and controlling design changes triggered by learning from experience activities during construction, including suitable records management arrangements to ensure the plant design documentation reflects as built status.*
- 106 This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:
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- First structural concrete.

4.5.2 Findings

107 From my assessment of the control of design changes the following strengths were identified:

- EDF and AREVA froze the design reference in 2008 and have an established joint procedure (Ref. 39) in place to control changes to the design reference. This procedure has been updated a number of times to take account of improvements identified by the requesting party and the Regulators during Step 4, and incorporates ND's six step design change control process.
- Design change modifications are graded against the impact to the GDA submission and only changes which are of the highest category (proposed by EDF and AREVA), or other specific changes proposed by EDF and AREVA were presented to ND for inclusion into GDA in Step 4. This process and the supporting tools have provided adequate visibility and control of the design reference.

108 From my assessment of the control of design changes the following observations were identified:

- EDF and AREVA have established a process to control, review, accept and implement changes to supporting design documentation impacted by design changes agreed within GDA. This activity will not be fully implemented until after Step 4, so the adequacy of these arrangements will need to be assessed. This will include the identification and transfer of incomplete design changes from GDA to Nuclear Site Licensing and permissioning. This will be progressed by the GDA Issue, **GI-UKEPR-CC-02** (Ref. 42).
- It is recognised that during site specific design development or construction the number of design changes may increase as a result of operating experience during construction. The QA arrangements to manage this flow of information will need to be considered to ensure that the design documentation reflects as built, this has been raised as an Assessment Finding **AF-UKEPR-QA-04** (Annex 1).

AF-UKEPR-QA-04: *The Licensee shall make and implement adequate arrangements for managing and controlling design changes triggered by learning from experience activities during construction, including suitable records management arrangements to ensure the plant design documentation reflects as built status.*

- This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:
 - First structural concrete.

4.6 Procurement Arrangements

109 We have assessed the QA arrangements for the procurement of services supporting the GDA project. Our assessment sampled supplier selection, specification,

performance monitoring and non-conformance management against T/AST/077 (Ref. 8) and Safety Assessment Principles (SAP) MS.2 (Ref. 4).

110 The UK EPR GDA design is based on FA3 EPR project as the reference design. The design information was procured by EDF and AREVA using their respective procurement arrangements. For GDA, the MSQA assessment has focussed on the arrangements developed and used by EDF and AREVA to procure services specific to the delivery of the UK EPR GDA safety submission.

4.6.1 Assessment

111 An MSQA inspection in April 2010 (Ref. 37) examined the QA arrangements supporting the procurement activities for GDA. EDF and AREVA explained their generic procurement arrangements and how they have been implemented for the FA3 EPR project in France. In both organisations the arrangements cover the following areas:

- Supplier selection.
- Supplier surveillance (both documentation and manufacturing processes).
- Acceptance of product.
- Release of product for use.
- Non conforming product.
- Evaluation of supplier performance.

112 For the UK EPR GDA project, EDF is the lead for GDA suppliers, AMEC and Rolls Royce. AMEC provides support to level 1 and some level 2 design activities, whilst Rolls Royce provides INSA services.

113 A number of Stage 1 System Design Manuals (SDMs) contained in the GDA submission were essentially products procured by EDF for the French FA3 EPR project from SOFINEL. Although SOFINEL is an EDF and AREVA jointly owned company, it is regarded by EDF as an external supplier and is subject to management system audit and surveillance.

4.6.1.1 AREVA

114 AREVA's procurement process is documented in procedure, P09WW – Purchase Products, Revision A1. This process includes supplier assessment, documentation surveillance, manufacturing surveillance and final release and engineering activities. AREVA's overarching procurement process was seen to contain all of the components required to ensure compliance with national and international standards and industry good practice.

115 The UK EPR GDA project is covered by a Management System which is common to all the divisions of AREVA that contribute to it. AREVA operate an audit system across all divisions and audits carried out are systems based and designed to check that each operating division's QMS align with the same corporate principles.

116 For AREVA, the process for the selection of suppliers is specified in procedure P09-01-02F-TRA-EN (Consulter et sélectionner le fournisseur, Revision A1). A pre-assessment process is carried out, which includes an audit of the perspective

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- suppliers QMS. This process is applied to all new suppliers irrespective of the grade of product to be supplied.
- 117 The process for supplier assessment in AREVA is documented in P16-01-02F (Ensure assessment follow-up, Revision A). This process implements a graded approach to the assessment of suppliers. It clearly states the requirement that an assessment of the QMS of the potential system must be carried out prior to selection. This graded approach is also applied to the specification arrangements. The quality level requirement is specified in the purchase order. There are three levels of quality specified:
- N100 - Items important for safety - applicable quality standards GS-R-3 and ISO -9001.
 - ISO – Items not important for safety but important for other reasons, e.g. availability – quality standards ISO 9001.
 - NC – Items not classified – no quality standards applied.
- 118 AREVA operates an approved vendor list, each supplier having a Quality Inspection Record (QIR). This shows the assessments carried out and the grade of goods or services that the supplier is authorised to provide. Orders can only be placed in accordance with the information contained within the suppliers QIR. The QIR is reviewed and updated including re-assessment on a periodic basis. This provides a physical control on the placing orders with suppliers not qualified to provide specific goods or services.
- 119 An example of a completed assessment for the appointment of Risk Management Consultancy (RMC) by AREVA, was examined during the MSQA inspection April 2010 (Ref. 37). RMC was selected to provide licensing advice to the GDA project. The quality requirement for this contract was ISO9001 (Ref. 2009 12 NP 2383 E). Evidence was sampled of the pre assessment audit of RMC's QMS. This audit identified one non conformance and two observations. Evidence of the tracking of these findings was provided and the use of AREVA's tracking system to progress issues was found to be adequate. A further example of the application of this process by AREVA was examined for the procurement of a small tank at FA3 for the RPE system. All documentation was present and in good order and was seen to be fully within the process. This appears to be a thorough and comprehensive process for the identification, assessment and selection of suppliers.
- 120 The procurement process within AREVA is a linear process with inputs from several departments, resulting in a single specification for large components, or for small components, a generic specification plus a data sheet. These specification documents contribute to a requisition specification for purchasing, which includes the quality management system requirements. Examples of the documents produced by specific departments including MSIV (VVP) on the secondary side were sampled during the April inspection (Ref. 37). The requisition for a MSIV was examined (N1-1-4232); the quality level requirements specified were N100.
- 121 An example was also examined that demonstrated the procurement of engineering services in support of the GDA submission. This covered the procurement of the seismic margins assessment. The pre selection process used was minimal as the supplier, as the provider, was an existing AREVA supplier. The technical specification and scope of services were examined and were seen to be fully within process. The product was a report which was seen to have been reviewed and accepted by a SQEP
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- resource within AREVA and subsequently EDF. The report forms a stand alone reference to the GDA PCSR.
- 122 A graded approach to QA is applied, using the three levels identified previously (N100, ISO and NC). This graded approach informs the required level of surveillance (S1-S4) and documentation (D1-D4) necessary to demonstrate QA and applies to both supplier documentation and the manufacturing process:
- Q-N-100 (generic requirements for suppliers' quality management systems plus project specific as an annex).
 - Q-N-200 (generic requirements for surveillance plus special).
 - Q-N-300 (general documentation requirements).
- 123 EIRA is that part of AREVA which is responsible for surveillance of manufacturing activities. The aim of surveillance is to build confidence that the entire supply chain is producing goods and services which meet all technical and regulatory requirements. AREVA's surveillance organisation, EIRA, is accredited to EN17020 as a type B organisation by COFRAC which is the French equivalent of the UK Accreditation Service. It is independent of the purchasing department and has a measure of autonomy in how it operates. All EIRA inspectors are qualified to international standards (EN ISO/CEI 17020) and authorised annually identifying any training experience requirements.
- 124 The surveillance plan is based on the quality requirements specified in the purchase order, which as already described, relates to the safety significance of the goods or services being procured. The EIRA inspector assigned is then responsible for implementing the surveillance plan, identifying witness or hold points for inspection. The inspection is reported in a standard format, Observation Notices (ONs) and NCs are issued to the supplier. The ONs and NCs are reviewed and trended for each supplier; this could result in additional surveillance requirements for a supplier. During the inspection (Ref. 37) examples of this review and trending were examined and examples of vertical slices of the supply chain were provided, where the main supplier and their sub-contracts were assessed.
- 125 All NCs are transmitted to the relevant technical department to be assessed and classified. Non conforming goods or services can be accepted, rejected or reworked to meet specification. An example of a NC deviation report 10/13600 associated with the manufacture of a valve body was provided during the inspection (Ref. 37). The conclusion was "use as is" dated 2 April 2010 based upon the fact the deviation leads to bigger wall thickness but does not change significantly either the mass of the body or the position of the COG. Based upon the sample taken, the application of the surveillance process and NC management were found to meet the requirements of T/AST/077 (Ref. 8).

4.6.1.2 EDF

- 126 For the FA3 EPR project, procurement is jointly carried out by EDF's Engineering (DIN) and Procurement Divisions (DA). EDF presented an overview of the procurement arrangements, which involved a pre-qualification phase incorporating identification of suppliers, interviewing and completion of a pre-qualification questionnaire prior to the final qualification phase. The final qualification phase includes Invitation to Tender (ITT), evaluation and final selection of suppliers. The

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- technical and commercial aspects of each tender are assessed in parallel respectively by DIN and DA.
- 127 The EDF procurement process places significant responsibility for Quality Management on the individual suppliers. This is specified through the General Quality Assurance Specification (GQAS), which expects the supplier to identify all of the quality related activities (QRA) within its own processes. The list of QRA identified by the supplier within its own processes is then transmitted to EDF for acceptance. This means the list of QRA is subject to surveillance according to the B5 process.
- 128 EDF explained that within the GDA project, the suppliers AMEC and Rolls Royce, were appointed directly through senior management intervention activities, based on predefined criteria identified in the relevant process EDF CNEN Procedure B3.2 – Evaluation et surveillance du couple fournisseur/produit Revision D. However, this means of appointment is less rigorous than that normally applied for the selection and assessment of suppliers.
- 129 As EDF did not audit the management system of AMEC and Rolls Royce before placing a contract, it was not evident how EDF had assured and tested the suitability of AMEC and Rolls Royce in terms of experience, supplier quality assurance arrangements and expertise and demonstrable delivery. This led to the Regulatory Observation Action (ROA) RO-UKEPR-66.A1 (Ref. 11) which required EDF and AREVA to provide assurance that the procurement process for GDA services, prior to supplier selection, includes assessment of supplier capability with respect to competency, knowledge and experience appropriate to the service deliverables.
- 130 With regard to the monitoring of GDA suppliers, EDF has carried out assessments of AMEC and Rolls Royce's management systems after contracts were awarded. These were of limited scope against the requirements of ISO 9001; evidence examined during the inspection noted the corrective actions resulting from the 2008 audit at AMEC have not been adequately monitored and closed out. The audit reports and draft summaries were examined and some repeat NCs were noted with no evidence of the original NCs being closed-out through EDF's tracking systems. This led to Regulatory Action RO-UKEPR-66.A2 (Ref. 11) being raised, requiring EDF and AREVA to ensure that any non-conformances or actions arising from GDA supplier assessment activities are controlled and managed appropriately.
- 131 SOFINEL is an engineering organisation which has produced some of the Stage 1 SDMs for FA3 and these constitute part of the submission for the UK GDA. Based on the fact that SOFINEL was created to support EDF and AREVA in design activities for nuclear installations, in particular for EPR, and that SOFINEL is widely staffed by AREVA and EDF engineers, EDF considered that it was not relevant to apply a contractor selection process to SOFINEL. Although the activities assigned to SOFINEL are contracted and subject to surveillance, during the April 2010 MSQA inspection (Ref. 37) the management by EDF of non-conformances associated with SOFINEL deliverables was not consistent with EDF's own arrangements. This led to Regulatory Action RO-UKEPR-66.A3 (Ref. 11) being raised requesting EDF to ensure that any NCs or actions arising from audits of SOFINEL associated with the production of Stage 1 SDMs included in the GDA submission are controlled and managed appropriately.
- 132 EDF's process for developing the system safety requirements and the production of technical and equipment specifications for procurement was assessed. Technical specifications are produced by the engineering function within the Architect Engineer's (AE) organisation. There are three levels of engineering within the AE;
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- Level 1 covers activities such as project management and concept design;
 - Level 2 covers detailed design development; and
 - Level 3 covers activities undertaken by suppliers.
- 133 As a general rule, the surveillance of each level is carried out by the level above. There is no surveillance carried out on Level 1 activities; assurance at this level is achieved through management system audits.
- 134 From the information provided during the MSQA inspection in April 2010 (Ref. 37) it was not clear whether EDF adopt a graded approach to procurement, which is commensurate with the safety classification of the product. With respect to the UK GDA project, it is acknowledged that services provided by AMEC and Rolls Royce have limited scope however, it remains unclear how EDF apply a graded approach commensurate with safety classification of manufactured items. As QA arrangements supporting the procurements of manufactured items is out of scope of GDA, this will need to be addressed by future licensee/operator during the procurement and construction stages of new nuclear build and is identified in this report as an Assessment Finding (**AF-UKEPR-QA-03**) in Annex 1.
- AF-UKEPR-QA-03:** The Licensee shall make and implement adequate QA arrangements for the procurement of all manufactured items including long lead items. These arrangements shall include a suitable and sufficient quality graded approach which is commensurate with safety significance of the goods or items being procured. The arrangements must be based upon the principle that the responsibility for supply chain quality is retained with the Licensee. Therefore the Licensee will be required to have appropriate oversight of all supply chain activities to ensure quality of supply.*
- 135 This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:
- Long lead items and SSC procurement specifications.
- 136 EDF surveillance arrangements for manufacturing activities comprise of two parts: documentation and manufacturing activities. There are three levels of surveillance dependant on the quality and safety requirements of the items being manufactured. Surveillance is on a sampling basis, which covers as a minimum but is not limited to the Quality Related Activities identified by the supplier as specified by the GQAS. The surveillance programme is subject to change based on feedback, knowledge of supplier and foreseen difficulties.
- 137 EDF demonstrated during the inspection (Ref. 37) the implementation of the procurement and surveillance processes for design activities using the following examples: Steam Generator supplied by AREVA, Heat Exchanger supplied by ACCP and the Stage 1 SDM for JPV system supplied by SOFINEL.
- 138 The JPV fire fighting system Stage 1 SDM for the FA3 project was sampled. Information was provided to demonstrate the EDF surveillance programme and how EDF's comments on the developing SDM were captured in the revision made by SOFINEL. The examples provided demonstrated good document control and visible surveillance planning however, it is unclear how EDF can demonstrate oversight of suppliers and sub-contracts throughout the supply chain using the current surveillance levels. This will need to be tested as SDMs are updated and this requirement was
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captured within GDA Issue **GI-UKEPR-CC-02** (Ref. 42) on inclusion of design changes post Step 4.

- 139 EDF has a system for controlling non-conforming product. The assessment of NCs is carried out at Level 1 by CNEN with support being provided as necessary by CEIDRE and SEPTEN. This assessment then guides the decision taken to accept, reject or rework to specification of the non conformance. Manufacturing products are released for use after a review of the procurement and the decision to release for use is taken at Level 1 by CNEN.

4.6.1.3 GDA Supplier Capability (RO-UKEPR-66 Response)

- 140 EDF and AREVA responded to the regulatory actions associated with RO-UKEPR-66 (Ref. 11) in letters EPR00460R and EPR00579R, providing additional details and evidence. In response to RO-UKEPR-66 Action 1, EDF and AREVA have reviewed an assessment of supplier capability for the GDA suppliers: AMEC and Rolls Royce. This has confirmed the suitability of the suppliers to meet the GDA UK EPR project requirements. For RO-UKEPR-66. Action 2, EDF has amended the EDF Project Quality Plan to clarify responsibility for managing GDA supplier audits and non conformities and have provided evidence of audit action follow-up with AMEC and Rolls Royce. AMEC's progress on action close-out looks reasonable and Rolls Royce's progress is not yet completed, but progressing. EDF claim they are able to track these actions to completion.
- 141 For RO-UKEPR-66.A3, EDF have updated their internal surveillance process B5 to respond to the requirements and provided evidence of adequate control and management of the 2008 SOFINEL audit actions. Based upon the information and evidence provide in the letters (EPR00460R and EPR00579R) the RO was closed out.

4.6.2 Findings

- 142 From our assessment of the QA arrangements supporting procurement, the following strengths were identified:
- EDF and AREVA have well established arrangements within their respective organisations for the procurement of design and manufacturing activities.
 - EDF and AREVA have established processes for the production, review and approval of technical specifications within their respective procurement arrangements.
 - AREVA has an approved vendor list and its use was demonstrated.
 - AREVA are applying a graded approach to its procurement activities, including surveillance of manufacturing. Surveillance of manufacturing is conducted by an independent team (EIRA) of qualified inspectors against a surveillance plan. The inspections are recorded and NCs are tracked and trended to inform future surveillance plans.
 - EDF and AREVA have appointed specific GDA suppliers and the outputs from these suppliers are reviewed jointly by EDF and AREVA in accordance with GDA project governance arrangements.
 - EDF and AREVA have adequate arrangements for controlling non-conforming products, including decision points on accept, reject and re-work.

143 From our assessment of the QA arrangements supporting procurement, the following observations were identified:

- The assessment and selection of the GDA suppliers (AMEC and Rolls Royce) by EDF was not conducted in accordance with its documented arrangements for supplier selection. The rigour applied in this assessment and selection process was limited, which resulted in a Regulatory Observation Action (RO) (Ref. 11). This RO action was closed out following submission of satisfactory evidence to demonstrate the adequate assessment of supplier capability.
- It was not clear how EDF apply a graded QA approach to procurement commensurate with the safety significance of all systems, structures or components (SSCs). The QA arrangements supporting procurement of manufactured items is out of scope for GDA and this will need to be addressed by the future licensee/operator during the procurement and construction stages of new nuclear build. It is identified in this report as an Assessment Finding (**AF-UKEPR-QA-03**).

AF-UKEPR-QA-03: *The Licensee shall make and implement adequate QA arrangements for the procurement of all manufactured items including long lead items. These arrangements shall include a suitable and sufficient quality graded approach which is commensurate with safety significance of the goods or items being procured. The arrangements must be based upon the principle that the responsibility for supply chain quality is retained with the Licensee. Therefore the Licensee will be required to have appropriate oversight of all supply chain activities to ensure quality of supply.*

- This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:
 - Long lead items and SSC procurement specifications.
- Evidence was seen that EDF does not have an adequate system for recording, tracking and resolving corrective actions identified during supplier assessments. However, EDF improved their internal processes and followed up on the outstanding supplier audit corrective actions in response to a regulatory action resulting from ND's inspection.
- The surveillance approach to engineering services, where each level performs surveillance on the one below, is limited as it does not enable EDF to achieve full oversight of the design activities, if an external supplier sub-contracts work out to other organisations. No SDMs have been updated for the UK as yet, therefore this observation will be considered as part of GDA Issue **GI-UKEPR-CC-02** see Cross-cutting report (Ref. 42) Annex 2.

4.7 Configuration Control of GDA Submission Documentation

144 I have assessed the arrangements for controlling the GDA submission documentation, sampling the control and tracking of information and safety submission development against the requirements in T/INS/017, SAP MS.1 and the international standards.

4.7.1 Assessment

145 The production of the safety submission is governed by EDF and AREVA's joint procedures UKEPR-I-004 GDA Document Production and UKEPR-I-012 Management of Submissions. The configuration is managed through UKEPR-I-033 Submission Structure and Submission Document Lists. The input material to the safety submission includes the following:

- Regulator guidance.
- Design reference configuration.
- TQs/ROs/RIs plus technical meeting discussions.
- Pre-construction Environment Report (PCER) and PCSR specifications.
- SML.

4.7.1.1 Design Reference

146 The Design Reference is based upon the FA3 EPR design at a given point in time. To maintain a stable design reference point to allow assessment by the Regulators, EDF and AREVA chose to 'freeze' the FA3 EPR design in December 2008 as documented in UKEPR-I-002. At the start of Step 4, Revision 5 of the Design Reference was submitted (Ref. 34). Changes to the Design Reference have been adequately controlled by EDF and AREVA; refer to Section 4.5 for details of my assessment. To ensure that the Design Reference document aligns to the GDA and the consolidated PCSR, the document has been amended to identify the out of scope items and the design changes impacting the design reference documentation (Ref. 51).

147 The QA arrangements for amending the Design Reference are documented in the joint project document control procedure, UKEPR-I-004 (Ref. 45). One organisation takes the lead to amend the document, suitable technical representatives from each co-applicant are assigned to review the document on behalf of the project and then the Project Managers approve the document prior to submission to the Regulators.

148 Although category A1 design changes require INSA in accordance with EDF and AREVA joint project procedure UKEPR-I-003, INSA reviews have not been completed for all applicable design changes included in GDA. The inclusion of outstanding Design Safety Review Committee (DSRC) recommendations in the GDA submission will not be achieved until post Step 4, therefore will be followed up as part of GDA Issue **GI-UKEPR-CC-02** (Ref. 42).

4.7.1.2 Submission Master List

149 The GDA project working tools established by EDF and AREVA are supported by the project organisation and project interfaces defined in the PQAP (Ref. 23). They include the use of SharePoint, a project database on a single secured server which allows controlled transfer of information between Regulator and EDF and AREVA and supports the exchange of information between co-applicant organisations. The access rights are managed by EDF and AREVA Project Managers and a user guide has been written to ensure effective use of the system, UKEPR-I-021 (Ref. 43).

150 The Submission Tracking Sheet (STS) is another tool utilised by EDF and AREVA to meet the requirements of the JPO Interface Protocol (Ref. 9) and its maintenance is governed by procedure UKEPR-I-033 (Ref. 38). The STS records all documents

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- submitted to the Regulators, including their revision status and submission status. The STS is issued periodically to the Regulators and the changes to the sheet are visibly communicated through the use of a colour coded system. In addition to the STS, a submission master list (SML) is transmitted regularly to the JPO.
- 151 The SML is split into four levels of documentation and lists all the documents and records which support the GDA submission and has been included in our assessment. The four levels are described below:
- Level 1 – safety, security and environmental reports.
 - Level 2 – documents referenced in the safety, security and environment reports, such as the design reference and Stage 1 SDMs.
 - Level 3 – submission supporting documents provided to the Regulator for assessment, supporting TQ, RO, Regulatory Issues (RI) and meeting action responses.
 - Level 4 – project or site specific documents for information only, which have been used in the assessment to achieve regulatory confidence that the design outline in GDA can be developed to the construction stage, such as Stage 2 SDM.
- 152 The Level 4 documents are project or site specific documents that are provided for information only. They have been used in the assessment to achieve regulatory confidence that the design outline in GDA can be developed to the construction stage, for example, the Stage 2 SDMs. This Level 4 information will not be included in the scope of the GDA submission for any iDAC/DAC we may issue.
- 153 The STS, SML and PCSR Route Map are all spreadsheet based documents and require a high level of manual input, therefore data errors are likely. To guard against this, EDF and AREVA have performed a number of self assessments to identify any errors, trend errors and rectify. An independent sample review was performed in January 2011 on the PCSR Route Map to assess consistency between the RO action plans, TQ impact Sheets, Change Specification and the PCSR Route Map. A number of minor errors were identified on the PCSR Route Map and these have subsequently been resolved.
- 154 An independent administrative review was also conducted on the SML in January 2011. The review involved taking a 5% sample of the submission documents and checking for completeness, correctness and duplication. The data from this review was analysed and trended to identify key themes. From the 250 documents sampled, 220 were found to be correct, one document was found on the STS but omitted from the SML. Omissions were regarded as a serious concern, even though the errors found were small. A 100% cross check was performed by EDF and AREVA on the STS and SML as a result of this finding. The remaining errors were associated with duplicates, typographical errors and inconsistency of information recorded on the lists.
- 155 For the end of Step 4 prior to submitting the SML, EDF and AREVA have commissioned an external review conducted by AMEC. This external review involved a 100% check of the SML to ensure that the data is accurate prior to submission. This review was performed in two phases to allow early review of findings and discharge of corrective actions. No significant errors such as omissions were identified. The reviews performed have demonstrated adequate controls and have given the regulators greater confidence in the robustness of the information held in the SML.
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156 EDF and AREVA have placed Levels 1, 2 and 3 of the SML under configuration control and issued the list as a controlled document with its own unique number so that it can be referenced on the iDAC/DAC. This SML includes all the submission documentation considered as part of ND's Step 4 assessments (Ref. 60).

4.7.1.3 Safety Case

157 The development of the PCSR Chapters through Step 4 has been in accordance with UKEPR-I-031 Specification – Consolidated Step 4 PCSR (Ref. 28). Detailed specifications for PCSR updates during Step 4 are included in Appendix B and the template for the PCSR Route Map is provided in Appendices D and E. This process for updating the PCSR Chapters is used in conjunction with project Procedure UKEPR-I-004, which defines the formal requirements for the production and approval of the UK EPR PCSR and underlying Technical Reports.

158 UKEPR-I-004 (Ref. 45) GDA Document Production identifies the scope and roles within the Project Master lists including the Project working tools. The preliminary technical report, once drafted, is reviewed by the co-applicant technical correspondent, the GDA front office and, if required, is subject to review by INSA. The review comments and DSRC recommendations, if applicable, are tracked and incorporated where appropriate. These technical reports are assembled into the submission chapters by a nominated Chapter Pilot who is responsible for the generation of the chapter and ensuring technical consistency. The link between the SSER documents and the technical reports are managed through a Linking Table, described in joint procedure UKEPR-I-028 Revision 7 sampled during a MSQA Technical topic meeting.

159 To reduce the impact on the Chapter Pilots at the end of Step 4, EDF and AREVA have introduced change specification sheets to capture amendments to the chapters triggered by internal reviews or Regulatory requests (TQs/ROs/RIs/Technical meetings). Due to the large volume of TQs (Ref. 10) a process has been developed to optimise the efficiency of incorporating TQs into the safety submission. So an impact sheet is attached and requests the Technical correspondent to assess the impact of the TQ on the submission documentation. This information is recorded in the PCSR Route Map and any amendments are documented within the PCSR Chapter Revision Tracking Sheet. Each entry on the Revision Tracking Sheet is reviewed by the co-applicant Technical correspondent and approved by the Pilot of the Chapter it supports. The PCSR Route Map and Revision Tracking Sheets were sampled and two TQs were picked and were successfully followed through to completion on the change specification record during an inspection in September 2010 (Ref. 26).

160 PCSR revision tracking is conducted live within SharePoint using the windows word "track changes" functionality. Examples of this continuous amendment process, triggered by a TQ impact sheet and incorporation into the Safety, Security and Environment Report, was examined for TQs 467 and 569 (Ref. 10) and the impact on PCSR sub-chapter 11.5. The amendment details matched across the different tools and the safety and environment reports.

161 Several TQ examples, including two in the Probabilistic Safety Analysis (PSA) topic area numbers TQ718 and TQ520 (Ref. 10) were sampled and the tracking sheet was seen to be completed satisfactorily by the technical correspondents. Additionally, TQ 520 has been included in the 'live' draft PCSR triggered by the change identified in the impact sheet. The change was to add a reference to PCSR chapter 15.1.

- 162 We looked at TQ 146 in the civil engineering technical area as an example of a TQ impacting on more than one PCSR subchapter. In fact, this TQ impacted on subchapters 1.4 and 3.3. The amendments made to the sub-chapters to incorporate the TQ information was associated with correct referencing of safety rules. The sub-chapters were sampled and the amendment details captured on the PCSR Route Map and the Revision Tracking Sheet records matched.
- 163 For ROs / RIs the responses are generally included in PCSR. A status sheet is used to track completion and impact against the PCSR; each RO has a technical lead identified. This initial impact assessment process then inputs into the change specifications in order to manage the update to the relevant PCSR chapters. This creates a strong link to convergence while TQs and ROs are still being generated. This impact assessment and amendment process has been included within the joint project procedure UKEPR-I-031 (Ref. 28).
- 164 During the final stages of consolidation of the PCSR, each technical topic has generated an action plan, which includes all the outstanding TQs, ROs, RI updates. The Technical and Project Correspondents reviewed the action plans for completeness and sufficient clarity of responsibilities prior to approval. The action plan for Fault Studies signed 08/01/2011 was sampled in January 2011. The information contained therein, listed the commitments by EDF and AREVA and appears to be in sufficient detail. The details from the change specifications and action plans are updated into the PCSR Route Map, so that the commitments for PCSR update at the end of Step 4 can be tracked. This review and action planning exercise helped towards ensuring that the PCSR chapters have been amended in line with one another, so that such characteristics as the technical assumptions and document references are aligned.
- 165 The alignment between the PCSR, the SML, STS and PCSR Route Map were tested by comparing a sample of ROs and TQs and checking on the updates. RO-UKEPR-30, 35 and 43 were sampled and the information on the PCSR Route Map matched the PCSR. The impact sheets for TQs 332, 772, 1303 and 1327 were also sampled. Where updates to the PCSR were identified as for TQ 332, the details had been recorded in the PCSR Route Map.
- 166 In accordance with the joint project procedure UKEPR-I-003 and PQAP, category A1 design changes require INSA and relevant sections of the PCSR are subject to an independent review. Not all the INSA and independent reviews have been completed, therefore the resulting DSRC recommendations have not been addressed in the consolidated Step 4 GDA submission. The inclusion of outstanding DSRC recommendations in the GDA submission will not be addressed until post Step 4. Therefore they will be followed up as part of GDA Issue **GI-UKEPR-CC-02** (Ref. 42).

4.7.2 Findings

- 167 From my assessment of the configuration control of the GDA submission documentation the following strengths were identified:
- EDF and AREVA have established joint procedures for the controlled development and tracking of the GDA submission documents. Evidence has been presented which demonstrates good configuration control.

- The PCSR Route Map and tracking sheets are effective tools and provide good evidence of action tracking and traceability of updates made on the submission documentation.
- To aid the consolidation of the PCSR, impact assessment of TQs, ROs and RIs responses was performed during Step 4. The intention was to ensure adequate assessment and capture within the relevant chapters and secure timely delivery of the PCSR in March 2011.
- Action plans have been developed and have gone through a process of review and approval to ensure all outstanding work is captured and tracked.
- EDF and AREVA have conducted a review on their tracking sheets and the PCSR Route Map. Both reviews have checked the completeness and accuracy of the data held within these tools. The results from the reviews have been acted upon and an external 100% check has been completed successfully to support the Step 4 submission.

168 I have identified no significant observations associated with configuration control of GDA submission documentation. That said, the GDA safety submission will need to be updated at the end of GDA to reflect any resolution plans executed together with the implementation of outstanding design changes. So the following observations associated with the GDA submission documentation content were identified:

- In accordance with the joint project procedure UKEPR-I-003 and PQAP, category A1 design changes require INSA and relevant sections of the PCSR are subject to an independent review. Not all the INSA and independent reviews have been completed, therefore the resulting DSRC recommendations have not been addressed in the consolidated Step 4 GDA submission. The inclusion of outstanding DSRC recommendations in the GDA submission will not be addressed until post Step 4. These will be followed up as part of GDA Issue **GI-UKEPR-CC-02** (Ref. 42).
- EDF and AREVA will have to continue to control, maintain and develop the GDA submission documentation, including the SSER, SML and design reference document and deliver final consolidated versions of these as the key references to any DAC/SODA the 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. This will be progressed post Step 4 as a GDA Issue **GI-UKEPR-CC-02** (Ref. 42).

4.8 Overseas Regulatory Interface

169 HSE's Strategy for working with Overseas Regulators is set out in (Ref. 52) and (Ref. 53). In accordance with this strategy, HSE collaborates with Overseas Regulators, both bilaterally and multinationally.

4.8.1 Bilateral Collaboration

170 HSE's Nuclear Directorate (ND) has formal information exchange arrangements to facilitate greater international co-operation with the Nuclear Safety Regulators in a number of key countries with civil nuclear power programmes. These include:

- The US Nuclear Regulatory Commission (NRC).

- The French L'Autorité de Sûreté Nucléaire (ASN).
- The Säteilyturvakeskus (Finnish Radiation and Nuclear Safety Authority) (STUK).

4.8.2 Multilateral Collaboration

171 ND collaborates through the work of the International Atomic Energy Agency (IAEA) and the Organisation for Economic Cooperation and Development (OECD) Nuclear Energy Agency (OECD-NEA). ND also represent the UK in the Multinational Design Evaluation Programme (MDEP) - a multinational initiative taken by national safety authorities to develop innovative approaches to leverage the resources and knowledge of the national regulatory authorities, tasked with the review of new reactor power plant designs. This helps to promote consistent nuclear safety assessment standards among different countries.

172 The MSQA Inspection conducted in April 2010 (Ref. 37) focused on the QA arrangements associated with Procurement activities supporting GDA. An invitation to witness this inspection was offered during an MDEP meeting and this was accepted by ASN, STUK and the US NRC, who subsequently participated in the inspection.

4.9 Interface with Other Regulators

173 The principal interface with other UK Regulators is with the Environment Agency with whom we have a close working relationship and a shared JPO for GDA. MSQA has been an area of joint regulatory responsibility with the Environment Agency so Regulator interactions and invitations to inspections and meetings have been extended and information shared. The Environment Agency has not participated in any of ND's inspections during Step 4. However it has attended a number of progress meetings, including a convergence meeting in October 2010. Inspections of EDF and AREVA's MSQA arrangements for the UK EPR GDA Project were carried out jointly between HSE ND and Environment Agency during Environment Agency's earlier assessment stages of GDA and our joint inspection reports were published on the website.

4.10 Other Health and Safety Legislation

174 There is no other Health and Safety Legislation relevant to MSQA considered in this Assessment Report.

5 CONCLUSIONS

175 This report presents the findings of the Step 4 MSQA assessment of the EDF and AREVA UK EPR reactor.

176 The Step 4 assessment in my topic area commenced with consideration of the relevant chapters of the PCSR and supporting references available at that time and is referred to as appropriate in this report. As the GDA submission developed during Step 4 in response to regulatory questions, amendments were made as appropriate to the PCSR and its supporting references. A review has been made of the updates to the GDA submission in my technical topic area and the conclusion of this review is that the updates to the GDA submission are as expected and contain no new information. The consolidated PCSR (Ref. 49) and its supporting references are therefore acceptable as the reference point for an Interim Design Acceptance Confirmation (iDAC).

177 I am broadly satisfied with the claims, arguments and evidence laid down within the PCSR (Ref. 49) and supporting documentation for the MSQA which is listed in the SML (Ref. 60). I consider that from a MSQA view point, the EDF and AREVA UK EPR design is suitable for construction in the UK. However, this conclusion is subject to satisfactory progression and resolution of GDA Issues to be addressed during the forward programme for this reactor and assessment of additional information that becomes available as the GDA Design Reference is supplemented with additional details on a site-by-site basis.

5.1 Key Findings from the Step 4 Assessment

178 EDF and AREVA have established robust joint procedures for the GDA UK EPR project; these are supported by a number of effective project tools, such as SharePoint, Submission Tracking Sheets and PCSR Route Map. To ensure that the project QMS remains suitable and sufficient, the GDA project has been subject to internal audits during Step 4. Actions arising from these audits have been followed up and the learning used to improve the procedures, demonstrating continuous improvement.

179 The GDA records are regarded by EDF and AREVA as lifetime quality records and will be retained in accordance with the customer contract. How documentation will be downloaded from SharePoint onto the co-applicants record management IT systems and what QA arrangements will be applied to ensure accurate identification and retrieval of all GDA safety submission documentation, including protectively marked documents post-GDA, is yet to be defined. However, principles to be applied to this process have been provided. For the PCSR to develop further in preparation for construction activities, the records associated with the GDA project need to be accepted and transferred into the future licencees' record management systems. To capture this requirement Assessment Finding **AF-UKEPR-QA-01** has been raised (see Annex 1).

AF-UKEPR-QA-01: *The Licensee shall make and implement adequate arrangements for the capture of the GDA submission documentation into their records management system, in order to support the further development of the PCSR.*

This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

180 EDF and AREVA have both recognised the importance of developing and maintaining key competencies and have established arrangements for the management of training and competency. With respect to the GDA project, there are no additional technical skills required over and above an individual's technical competency, therefore only awareness training was given at the launch of the project. This was considered to be adequate.

181 EDF and AREVA actively participate in the development of the design codes used for the EPR design. Within EDF, these codes are complemented by internal technical standards in the form of book or technical specification and technical rules. The QA arrangements for the control and development of the technical specifications and rules for UK project specific requirements have not been assessed during Step 4 as these will only become available at the site specific phase. So, these arrangements will need to be considered when UK versions are being developed. It is also true for the development of Stage 2, SDMs and the use of the 2D and 3D modelling tools, the QA arrangements supporting these activities were not sampled during Step 4. They will be followed up under the Assessment Finding **AF-UKEPR-QA-02** (see Annex 1).

AF-UKEPR-QA-02: *The Licensee shall make and implement adequate QA arrangements for the control of detailed design activities. This will include the QA arrangements supporting the use of 2D and 3D modelling tools in design development and the QA arrangements for the control of site specific design documentation, such as Stage 2 and 3 SDMS, BTS/ BTRs and FMEA analysis.*

This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

182 EDF and AREVA apply a graded approach for design studies and both organisations have adequate control processes for use of software codes. The QA arrangements for the design development processes in AREVA were found to be suitable and sufficient and the use of design files demonstrated a good auditable trail for design documentation and technical analysis. Non-conformances are raised associated with software errors and trending is performed. Trending information could not be provided at the time of the inspection. It was provided in June 2011, too late for adequate consideration and will be followed up under the Assessment Finding **AF-UKEPR-QA-05** (see Annex 1).

AF-UKEPR-QA-05: *The Licensee shall make and implement adequate arrangements for trending information, such as events and non-conformances, in a timely manner and format to allow identification of learning opportunities and implementation of the necessary improvements to realise the learning opportunity benefits.*

This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

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- 183 EDF and AREVA froze the UK EPR project design reference in 2008 and have a robust joint procedure (Ref. 39) in place to control changes to the GDA design reference. This procedure includes a graded approach to design change modification and incorporates the ND's six step design change control process.
- 184 The latest update to the Design Change procedure (Ref. 39) has incorporated the response to RO-UKEPR-81 (Ref. 11) on the topic of changes to GDA submission documentation impacted by design changes. However, the arrangements developed will not be fully implemented until after Step 4, so the adequacy of these arrangements will need to be assessed. The application of the arrangements for implementing the outstanding GDA agreed design changes, including the identification and transfer of incomplete design changes from GDA to Site Licensing, will be followed up by **GI-UKEPR-CC-02** (Ref. 42).
- 185 It is recognised that during site specific design development or construction the number of design changes may increase as a result of operating experience during construction. The QA arrangements to manage this flow of information will need to be considered to ensure that the final design documentation reflects the as built plant. This has been raised as an Assessment Finding **AF-UKEPR-QA-04** (Annex 1).

AF-UKEPR-QA-04: *The Licensee make and implement adequate QA arrangements for managing and controlling design changes triggered by learning from experience activities during construction, including suitable records management arrangements to ensure the plant design documentation reflects as built status.*

This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:

- First structural concrete.

- 186 EDF's surveillance approach to engineering services is limited and does not enable EDF to achieve full oversight of the design activities if an external supplier sub-contracts work out to other organisations. A number of the SDMs are produced by an external supplier and for the UK design they are yet to be modified following the GDA agreed design changes. Therefore it is the intention that the following areas are included in the scope of **GI-UKEPR-CC-02** (Ref. 42):
- Adequate oversight of the supply chain activities.
 - Robust supplier inspection and surveillance arrangements.
- 187 EDF and AREVA have well established arrangements within their respective organisations for the procurement of design and manufacturing activities, including supplier selection, performance monitoring and product acceptance. However, a number of observations were made with the application of these processes for GDA services. A regulatory observation (RO-UKEPR-66) was raised and subsequently responded to and closed out following satisfactory corrective action and assessment.
- 188 AREVA apply a graded approach to its procurement activities including surveillance of manufacturing. It was not clear how EDF apply a graded QA approach to procurement commensurate with the safety significance of all systems, structures or components (SSCs). The QA arrangements supporting procurement of manufactured items is out of scope for GDA. As it is a licensee/operator matter, it will therefore be reviewed during site specific stage. This has therefore been raised as an Assessment Finding **AF-UKEPR-QA-03** (see Annex 1).

AF-UKEPR-QA-03: *The Licensee shall make and implement adequate QA arrangements for the procurement of all manufactured items including long lead items. These arrangements shall include a suitable and sufficient quality graded approach which is commensurate with safety significance of the goods or items being procured. The arrangements must be based upon the principle that the responsibility for supply chain quality is retained with the Licensee. Therefore the Licensee will be required to have appropriate oversight of all supply chain activities to ensure quality of supply.*

This Assessment Finding should be addressed as part of the following procurement and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

189 EDF and AREVA have established joint procedures for the controlled development and tracking of the submission documents. The evidence provided, including the recent independent reviews, has demonstrated adequate configuration control. Good use of peer review and management approval has been applied on design engineering in response to regulatory queries (TQs, ROs, RIs and meeting actions) prior to incorporation into PCSR chapters.

190 In accordance with the joint project procedure UKEPR-I-003 and PQAP, category A1 design changes require INSA and relevant sections of the PCSR are subject to an independent review. Not all the INSA and independent reviews have been completed; therefore the resulting DSRC recommendations have not been addressed in the consolidated Step 4 GDA submission. The inclusion of outstanding DSRC recommendations in the GDA submission will not be addressed until post Step 4 therefore will be followed up as part of GDA Issue **GI-UKEPR-CC-02** (Ref. 42).

191 EDF and AREVA will have to continue to control, maintain and develop the GDA submission documentation including the SSER, SML and design reference. To include any updates required to address GDA Issue Resolution Plans, agreed design changes and any other updates required as agreed with the Regulators, this will be progressed post Step 4 as a GDA Issue **GI-UKEPR-CC-02** (Ref. 42).

5.1.1 Assessment Findings

192 I conclude that the Assessment Findings listed in Annex 1 should be addressed during the forward programme of this reactor as normal regulatory business with the future operator/licensee.

5.1.2 GDA Issues

193 I conclude that the GDA Issue listed in Annex 2 of the Cross Cutting report (Ref. 42) must be satisfactorily addressed before Consent can be granted for the commencement of nuclear island safety related construction.

GI-UKEPR-CC-02: *EDF and AREVA to continue to control, maintain and develop the GDA submission documentation, including the SSER, SML and design reference document and deliver final consolidated versions of these as the key references to any DAC/SODA the 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.*

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Table 1

Relevant Safety Assessment Principles for Management of Safety and Quality Assurance Considered During Step 4

SAP No.	SAP Title	Description
MS.1	Leadership and management for safety - Leadership	Directors, managers and leaders at all levels should focus the organisation on achieving and sustaining high standards of safety and on delivering the characteristics of a high reliability organisation.
MS.2	Leadership and management for safety – Capable organisation	The organisation should have the capability to secure and maintain the safety of its undertakings.

Annex 1

**Assessment Findings to be Addressed During the Forward Programme as Normal Regulatory Business
Management of Safety and Quality Assurance – UK EPR**

Finding No.	Assessment Finding	MILESTONE (by which this item should be addressed)
AF-UKEPR-QA-01	The Licensee shall make and implement adequate arrangements for the capture of the GDA submission documentation into their records management system, in order to support the further development of the PCSR.	Long lead Items and SSC procurement specifications
AF-UKEPR-QA-02	The Licensee shall make and implement adequate QA arrangements for the control of detailed design activities. This will include the QA arrangements supporting the use of 2D and 3D modelling tools in design development and the QA arrangements for the control of site specific design documentation, such as Stage 2 and 3 SDM, BTS/BTRs and FMEA analysis.	Long lead Items and SSC procurement specifications
AF-UKEPR-QA-03	The Licensee shall make and implement adequate QA arrangements for the procurement of all manufactured items including long lead items. These arrangements shall include a suitable and sufficient quality graded approach which is commensurate with safety significance of the goods or items being procured. The arrangements must be based upon the principle that the responsibility for supply chain quality is retained with the Licensee. Therefore the Licensee will be required to have appropriate oversight of all supply chain activities to ensure quality of supply.	Long lead Items and SSC procurement specifications
AF-UKEPR-QA-04	The Licensee shall make and implement adequate QA arrangements for managing and controlling design changes triggered by learning from experience activities during construction, including suitable records management arrangements to ensure the plant design documentation reflects as built status.	First structural concrete

Annex 1**Assessment Findings to be Addressed During the Forward Programme as Normal Regulatory Business****Management of Safety and Quality Assurance – UK EPR**

Finding No.	Assessment Finding	MILESTONE (by which this item should be addressed)
AF-UKEPR-QA-05	The Licensee shall make and implement adequate arrangements for trending information, such as events and non-conformances, in a timely manner and format to allow identification of learning opportunities and implementation of the necessary improvements to realise the learning opportunity benefits.	Long lead Items and SSC procurement specifications

Note: It is the responsibility of the Licensees / Operators to have adequate arrangements to address the Assessment Findings. Future Licensees / Operators can adopt alternative means to those indicated in the findings which give an equivalent level of safety.

For Assessment Findings relevant to the operational phase of the reactor, the Licensees / Operators must adequately address the findings during the operational phase. For other Assessment Findings, it is the regulators' expectation that the findings are adequately addressed no later than the milestones indicated above.

Annex 2

GDA Issues – Management of Safety and Quality Assurance – UK EPR

There are no GDA Issues for this topic area.