Generic design assessment

AP1000® nuclear power plant design by Westinghouse Electric Company LLC

Final assessment report

Management systems

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Final Assessment report - Management Systems

Protective status	This document contains no sensitive nuclear information or commercially confidential information.
Process and Information Document[1]	The following sections of Table 1 in our Process and Information document are relevant to this assessment: 1.1 – description of the management system for the development of the design and production of the submission for GDA
Radioactive Substances Regulation Environmental Principles[2]	The following principles are relevant to this assessment: MLDP1 Establishing and Sustaining Leadership and Management MLDP2 High Standards of Environment Protection MLDP3 Capability MLDP4 Decision Making MLDP5 Learning from Experience
Report author	Grundy, Dr C. L.

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

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

2. Radioactive Substances Regulation Regulatory Environmental Principles, RGS, No RGN RSR 1, Environment Agency, 2010.

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

Table of Contents

1 Summary

1 This report presents the findings of our assessment of the adequacy of Westinghouse's management systems based on information submitted by Westinghouse in its Environment Report (ER) and supporting documents. In particular, the management arrangements that Westinghouse implements to control the development of the AP1000® design, and the production of submission documents for Generic Design Assessment (GDA). It is based upon our inspections of Westinghouse's management systems at its Head Office in Pittsburgh, USA. Additionally, on our inspections at the Westinghouse UK GDA Project Office in Chorley, UK carried out after our Consultation, in July and December 2010.

2 The Joint Regulators for GDA, the Office for Nuclear Regulation[1] (ONR) and the Environment Agency, have worked together closely to review the adequacy of Westinghouse's management arrangements in GDA. Our assessment of management arrangements has involved review of Westinghouse's GDA submissions and arrangements for quality management, in particular the overarching project quality plan and supporting procedures.

3 A significant part of our assessment activity has involved inspection to review the application of Westinghouse's arrangements to the UK GDA project, and to identify evidence of the effective implementation of Westinghouse's management arrangements to GDA, including Westinghouse's GDA Project Quality Plan and supporting procedures. We have carried out our inspections jointly with ONR and published our findings.

4 The Joint Regulators conclusion from the 2009 Inspection was that

a) Westinghouse continues to operate a well developed set of quality arrangements which include sub-tier procedures which are periodically reviewed and audited.

b) A GDA specific Quality Plan was developed, supported by a number of related GDA procedures, that are designed to formalise the interface between the Joint Programme Office (JPO) and Westinghouse.

c) The Inspection Team considers that the Joint Regulators' confidence in the arrangements for the remainder of GDA could be improved by the application of all the elements of the Westinghouse quality programme to the UK GDA project.

d) It is acknowledged that Westinghouse has experienced and knowledgeable staff and a commitment to retain adequate technical resources. Westinghouse has established a number of targeted initiatives such that organisational learning and continuous improvement have been addressed. However, the full benefit of these initiatives has not been realised for the UK GDA project as the level of application to the project appears to be minimal. This leads to some doubt regarding the effective application of Westinghouse processes to the UK GDA project.

e) There is evident strong leadership and ownership of the design configuration and change processes, however, there remains a significant workload to clear the backlog of unincorporated Design Change Proposals (DCPs). Westinghouse has recognised this challenge and has plans in place to address this situation. The joint regulators require to be updated on progress with regard to the closeout of unincorporated DCPs.

f) Westinghouse operates well established arrangements for the selection and surveillance and suppliers as part of its procurement activities.

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

5 At the time our consultation was published in June 2010, there remained outstanding matters for Westinghouse to resolve and close out during GDA in agreement with the Regulators. Westinghouse submitted a letter to the Joint Programme Office, JPO on 14 April 2010 in regard to its quality assurance (QA) improvement plan including specific commitments. We reviewed this information and continued with the planned meeting programme on QA matters with Westinghouse. ONR examined the application of the full breadth and depth of the Westinghouse QMS applicable to the UK GDA project during its Step 4. ONR carried out targeted inspections to establish the consistent and comprehensive application of adequate quality assurance arrangements by Westinghouse.

6 Following the publication of our consultation, the Environment Agency carried out, jointly with ONR, two further inspections of Westinghouse management arrangements including matters relating to our consultation reservation on Westinghouse QA. We continued to work closely with ONR in regard to the satisfactory resolution of the outstanding Westinghouse QA matters during GDA and our decision document was informed by this.

7 Thus, the following reservation was resolved and closed out by Westinghouse to the satisfaction of the UK Joint Regulators before the end of GDA:

a) Westinghouse has still to demonstrate to the UK Regulators the application of the full rigours of its Quality Management System (QMS) to the UK GDA project.

8 ONR concluded in their Step 4 report that the QMS for the GDA project, and its application, had developed considerably during Step 4, and the revised project quality plan provides clarity and guidance on the QA arrangements supporting the project. ONR also noted that in some cases the processes were under development whilst the project was being delivered.

9 We conclude from our assessment detailed herein that Westinghouse has an appropriate management system in place to:

a) control the content and accuracy of the information provided for GDA;

b) maintain records of design and construction;

c) control and document modifications to the design;

10 Westinghouse have given consideration to transfer of knowledge about the design to the future operating organisation, and have provided supporting information. We are satisfied that Westinghouse have arrangements in place to facilitate the knowledge transfer and to fully support the plant owner/operator at all phases of the nuclear new build project, through the provision of training programmes and data and document and technical information transfer.

11 We conclude that Westinghouse has adequately specified:

a) its expectations for any operating utility's management system;

b) how it expects to transfer knowledge and provide continuing support to any operating utility.

12 Our conclusions remain unchanged since our consultation. However, they are subject to a GDA Issue, joint with ONR which reflects that Westinghouse will need to control changes to GDA submission documents, resulting from the management of design changes, until the issue of final design acceptance confirmation/statement of design acceptability from the Regulators. The GDA issue is:

a) Westinghouse to submit a safety case to support the GDA Design Reference and then to control, maintain and develop the GDA submission documentation, including the Safety, Security and Environment Report, SSER, the Master Submission List, MSL 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. (GI-AP1000-CC-02).

13 The GDA Issue has three actions

a) Westinghouse to submit a safety case to support the GDA Design Reference and then to control, maintain and develop the GDA submission documentation, including the SSER, the MSL 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.

b) Westinghouse is required to make and implement arrangements to control, maintain and develop the GDA safety submission documentation. This must include the SSER, MSL and design reference documents. As part of this action, Westinghouse shall deliver final consolidated versions of these documents as the key references to any DAC/SODA we may issue at the end of GDA. This should involve the incorporation of all relevant amendments into the impacted documentation associated with design changes, including the Design Reference UKP-GW-GL-060, MSL and the PCSR. This should include any other additionally agreed design changes associated with other GDA Issue Resolution Plans. Westinghouse arrangements shall ensure no modification to the design or safety case, which may affect safety, is made except in accordance with agreed arrangements and will provide for the classification of modifications according to their safety significance.

c) Westinghouse to implement the outstanding GDA agreed design changes, by incorporating the change details into all impacted DR, the MSL documentation including the PCSR, ER. The scope of this work should include those design changes already agreed for inclusion in GDA Step 4 but not incorporated and any additional design changes arising as part of other GDA Issue resolution plans or arising during the GDA close out stage.

14 The GDA Issue will require an associated Resolution Plan to be proposed by Westinghouse and will require satisfactory resolution before Environment Agency would issue a full Statement of Design Acceptability, and ONR would agree to the commencement of nuclear island safety related construction of an AP1000 reactor in the UK.

15 Our findings on the wider environmental impacts and waste management arrangements for the AP1000 reactor may be found in our Decision Document (Environment Agency, 2011).

2 Introduction

16 We originally published this report in June 2010 to support our GDA consultation on the AP1000 design. On 28 June 2010, our consultation began on our preliminary conclusions following our detailed assessment of this submission. This consultation closed on 18 October 2010. We received additional information from Westinghouse after June 2010 and we undertook additional assessment and inspections in regard to our reservation on QA in our consultation. We also take into account matters arising from ONR's Step 4 activities including planned inspections.

17 This report is an update of our original report covering assessment undertaken between June 2010 and the end of March 2011 when Westinghouse published an update of their submission. Where any paragraph has been added or substantially revised it is in a blue font.

18 We set out in our Process and Information Document (P&ID, (Environment Agency, 2007)) the requirements for a Requesting Party (RP) to provide a description of the management system for the development of the design and production of the submission for GDA. This information should include identification of management responsibilities for both development of the design and the submission. The management arrangements should include those for

a) Maintaining records of design and construction, and;

b) Control and documentation of modifications to the submitted design.

19 Our P&ID also requires a description of the requesting party's expectations of the operating utility's management system to cover the reactor's operations throughout its lifecycle.

20 We published our Radioactive Substances Regulation Environmental Principles (Environment Agency, 2010b) and principles MLDP1-5 on management and leadership for the environment refer to this topic. We consider that management systems and the leadership shown by senior management have key roles in ensuring that business and other users use radioactive substances in a way that fully protects people and the environment. We expect an operator to manage its business and provide that leadership to ensure that the business minimises its impact on people and the environment from the use of radioactive substances.

21 This assessment aims to establish the adequacy of Westinghouse's management arrangements, and to identify demonstrable evidence that these arrangements are effectively implemented by Westinghouse, both to control changes to the AP1000 design, and for the production of submission documents for GDA.

22 This assessment comprises a review of Westinghouse' submission on management arrangements, together with inspections to assess the implementation of Westinghouse arrangements to control the production of submission documents for GDA, and the development of the design, including design changes. Our assessment is performed on a sampling basis, and a significant part of our assessment has focused on the findings of the Joint Regulators Inspection carried out in 2009.

23 During the Environment Agency's detailed assessment stage, we have kept Westinghouse's management arrangements under review. The Joint Regulators, ONR and the Environment Agency, have worked closely to review the adequacy of Westinghouse's management arrangements in GDA. Our assessment of management arrangements has involved review of Westinghouse's GDA submissions and arrangements for quality management, in particular the overarching project quality plan and supporting procedures.

24 We assessed information contained in the Environment Report and supporting GDA submission documents. We raised two Regulatory Observations (ROs) on Westinghouse. In addition, we added further actions to an existing Regulatory Observation on Quality Assurance:

a) RO-AP1000-33 Quality Assurance Issues for the Environment Report, and supporting documents

b) RO-AP1000-35 Application of Westinghouse QMS to UK GDA

c) An earlier RO, RO-AP1000-17 UK GDA Quality Assurance Processes was raised by HSE in October 2008. Two additional Regulatory Observation Actions were added by the Joint Regulators in May 2009 requiring Westinghouse to update, revise and implement the Project Quality Plan, and the supporting procedures in line with formal comment provided by the Regulators in May 2009.

25 Following our consultation, further regulatory observations were raised relevant to GDA Submissions and Design Reference Point, RO-AP1000-88 and RO-AP1000-103. These regulatory observations are discussed later in the section on ongoing work since our consultation.

26 We raised 43 Technical Queries (TQs) on Westinghouse during our assessment. Two raised jointly with ONR, and four raised directly by ONR were relevant to this report:

a) TQ-AP1000-330 Expectations of Operating Utility Management System (Joint Regulators)

b) TQ-AP1000-393 PCSR Update

c) TQ-AP1000-404 PCSR and Environment Report update Procedures (Joint Regulators)

d) TQ-AP1000-626 QMS Level 2 Level 3 Procedures

e) TQ-AP1000-737 Trending Analysis and Management Review

f) TQ-AP1000-1120 DCPs requested for inclusion in GDA

27 Westinghouse responded to all the ROs and TQs. Westinghouse reviewed and updated the ER in December 2009 in response to RO-AP1000-33, and subsequently an updated Environment Report was provided in April 2010 to include all the relevant information provided by the ROs and TQs.

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

29 In March 2011, Westinghouse provided an updated ER, Plant Lifecycle Safety Report (LCSR) and design reference point (DRP).

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

a) Our assessment of any further information provided by Westinghouse since the consultation date.

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

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

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

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

31 We have published the consultation responses submitted in regard to our preliminary conclusions for the AP1000 design on our website (see: https://consult.environment-agency.gov.uk/portal/ho/nuclear/gda).

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

3 Assessment

3.1 Assessment methodology

33 The basis of our assessment was to:

a) review appropriate sections of the ER and its supporting documents including the project quality plan and supporting procedures for UK GDA;

b) carry out inspections jointly with ONR to assess the implementation of Westinghouse's management systems

c) hold technical meetings with Westinghouse to clarify our understanding of the information presented and explain any concerns we had with that information;

d) raise Regulatory Observations and Technical Queries where we believed information provided by Westinghouse was insufficient;

e) consider consultation responses and comments from our stakeholder seminar relevant to this topic;

f) decide on any GDA Issues;

g) identify assessment findings to carry forward from GDA.

3.2 Assessment objectives

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

a) Are adequate management systems and arrangements in place to control design changes, and to control the production of submission documents for GDA?

b) Are management arrangements being effectively implemented, including the application of the full rigours of the Westinghouse QMS to the UK GDA project?

c) Has Westinghouse adequately specified its expectation for any operating utility's management system

d) Has Westinghouse provided information on how it expects to transfer knowledge and provide continuing support to any operating utility

35 We have examined Westinghouse's GDA submissions, and jointly with ONR we have carried out inspections to assess their management systems, processes and documentation. We carried out a Joint Regulators Inspection of Westinghouse at their headquarters in Pittsburgh from 31 March to 3 April 2009. The purpose of the inspection was to examine in more detail areas such as design change control and submission configuration control, and to clarify progress on implementation of recommendations made during the initial Joint Regulators inspection visit carried out in November 2007. This initial inspection was part of our preliminary assessment of the AP1000 design, and was reported in our Public Statement in March 2008 (Environment Agency, 2008) .

3.3 Westinghouse documentation

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

Document reference	Title	Version number
UKP-GW-GL 790	UK AP1000 Environment Report Chapter 1 Section 1.4 Management System	04
UKP-GW-GL-710	UK Compliance Document for AP1000 Design: Section E Westinghouse Quality Management System (dated 2002, revision 5)	01
APP-GW-GLR-040	Plant Operations, Surveillance, and Maintenance Procedures	01
UKP-GW-GL-793	Pre-Construction Safety Report, Chapter 7 Life cycle engineering and safety	0
UKP-GW-GL-737	Plant Life Cycle Safety Report	02
UKP-GW-GAH-001	Project Quality Plan for the UK Generic Design Assessment	3
EPS-GW-GL-700	European Design Control Document	1
UN REG WEC 000179	WEC response to regulatory expectations for UK AP1000 GDA	March 2010
UKP-GW-GL-060	Design Reference Point	5

3.4 Detailed Assessment of Westinghouse Management System

37 We examined Westinghouse's management system in some detail during our preliminary assessment and we carried out a Joint Regulators Inspection at Westinghouse's head office in Pittsburgh, USA in November 2007. We concluded that Westinghouse's management system was suitable for controlling the content and accuracy of the information Westinghouse has provided to us for GDA (Environment Agency, 2008). There were, however, some matters that we felt could be improved and we made the following recommendations:

a) Recommendation 1: Westinghouse should consider developing a quality plan and programme for the UK GDA process with clearly defined responsibilities.

b) Recommendation 2: Westinghouse should consider producing a history of the development of the AP Series design, showing the design options considered and the reasons for those adopted. This will support justification of BAT and ALARP principles.

c) Recommendation 3: Westinghouse should develop awareness and understanding for chapter leads of the UK regulatory process, with emphasis on applying ALARP and BAT principles.

d) Recommendation 4: Westinghouse should formalise its current arrangements for capturing operational experience feedback and other sources of feedback.

e) Recommendation 5: Westinghouse should produce its waste and decommissioning strategy for submission to JPO before the start of Step 3.

38 Westinghouse documented the Joint Regulator's November 2007 inspection findings as issue reports in its Corrective Action Process, CAPs using its Quality Management System, QMS. Westinghouse responded formally to our recommendations on 1 April 2008 with a commitment to implement these recommendations and to provide us with

an update on progress. Westinghouse's progress in relation to implementation of the recommendations is summarised below:

a) Recommendation 1: a formal project quality assurance plan has been produced for the UK project.

b) Recommendation 2: Westinghouse produced a formal history documenting the development of the AP1000 design.

c) Recommendation 3: Westinghouse produced a training module for staff working on the UK project and implemented training for the staff. However, an internal audit carried out by Westinghouse in August 2009 identified the need for training to be implemented on the UK Project Quality Plan for new staff working on the project. Training has subsequently been carried out for staff working on the UK GDA Project, see later.

d) Recommendation 4: Westinghouse created and implemented a formal learning organisation to capture and communicate learning from operating experience.

e) Recommendation 5: Westinghouse provided further information on waste strategy and decommissioning in its submission documents. Waste Strategy and decommissioning is addressed in our public consultation document for the AP1000 design.

39 Our conclusion is that Westinghouse responded to the Joint Regulators recommendations and worked positively to take on board some of our recommendations for improvement. For example, the creation of an organisational learning section in Westinghouse, emphasising and encouraging the use of organisational learning.

40 Our assessment of management arrangements has involved review of Westinghouse's GDA submissions and arrangements for quality management, in particular the overarching project quality plan and supporting procedures.

41 Westinghouse Quality Management System (QMS) dated October 2002 describes Westinghouse's commitments to the quality assurance requirements of recognised international standards and is externally audited . The Quality Plan developed for UK GDA sets out the detail of how Westinghouse's QMS is applied to the UK project with reference to specific procedures. The project quality plan is supported by procedures that have been developed for the UK GDA project. The plan and procedures were reviewed by the Regulators following our inspection in March-April 2009, and formal comments were provided in May 2009 in the form of two additional regulatory observation actions to Regulatory Observation RO-AP1000-17.

a) The effectiveness of the Quality Plan is part of the scope of RO-AP1000-17 and therefore an additional action A3 was raised under the existing Regulatory Observation RO-AP1000-17 for Westinghouse to update, revise and implement the provisions of the Quality Plan to address the comments and observations made by the UK Regulators in a letter dated 27 May 2009. A revised quality plan was received by the Joint Regulators on 5 March 2010, and a further revision was issued in draft on 19 April 2010. A further action A4 was raised under the existing Regulatory Observation RO-AP1000-17 for Westinghouse to update, revise and implement the provisions of the Quality Procedures UKP-GW-GAP-011-16 inclusive to address the comments and observations made by the UK Regulators in a letter dated 29 May 2009. Westinghouse provided these updated procedures to the Joint Regulators in June 2010, following issue of a TQ by HSE, TQ-AP1000-626 QMS Level 2 Level 3 Procedures.

42 One respondent (GDA124[2]) to our consultation queried ' *what standard is each management system based on….Have the management systems been third party assessed by a recognised accreditation body?*'. Information is provided in the project quality plan (Revision 3, April 2010) to indicate that Westinghouse management systems applied to the AP1000 project comply with international standards, for example ISO 9001 Quality Management Systems. The Westinghouse Quality Management System is certified to ISO 9001:2008 by LRQA. There are external audits carried out, including assessments by recognised accreditation bodies.

43 Ingleby Barwick Town Council (GDA 39) commented in response to our consultation ' *I am doubtful as to whether the same health and safety and environmental concerns will be addressed in the USA and China as it is in Great Britain. We must therefore err on the side of caution and ensure that all aspects of their management systems are ideal for Great Britain*'.

44 Westinghouse management systems have been assessed in line with UK regulatory requirements by ONR and Environment Agency who share regulatory responsibility for QA issues. The joint Regulators assessments and inspections of Westinghouse's management systems have been underway since late 2007. Westinghouse established a UK project office with management systems in place in support of the UK GDA project, including UK specific procedures, and work instructions, as detailed later.

45 Our Process and Information Document requires the Requesting Party's management system to identify management responsibilities for development of the design and the submission documents. The Westinghouse QMS sets out management responsibilities at a high level. A GDA specific Quality Plan was developed and first issued in March 2008 with further revisions issued in 2010. This is the head document that cites Westinghouse QMS procedures to be applied to the UK Project and is supported by a number of related GDA procedures, that are designed to formalise the interface between the Joint Programme Office (JPO) and Westinghouse.

46 The Quality Plan for UK GDA sets out how Westinghouse's QMS is applied to the UK project. The plan references the established Westinghouse QMS procedures for design and document control. It is supported by a number of procedures that have been developed for the UK GDA Project. The procedures developed specifically for GDA identify the management responsibilities, for example in respect to transmission of documents to the Regulators. The quality plan and the supporting procedures were revised by Westinghouse in 2010.

47 Our Process and Information Document also requires details of the management arrangements for maintaining records of design and construction, and for control and documentation of modifications to the submitted design. Westinghouse's arrangements for design control are set out in the QMS and include design verification and control of design changes. This is an area that has been reviewed in detail during the Joint Regulators Inspections in 2007 and 2009, and again by HSE in its Inspections in 2010 see later.

48 Westinghouse's QMS sets out requirements for document and data control including document approval and issue, and arrangements for maintaining and reviewing quality records. Arrangements for auditing are set out including internal audits and self assessments. Westinghouse also implement a Design Reliability Assurance

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2 We list the names of all the organisations that responded to the consultation in Annex 7 of the Decision Document (Environment Agency, 2011a). We have not given names of individuals or members of the public. The list gives a GDA number to each response (for example, GDA76 is for the Health & Safety Executive), so that the documents can be searched to allow all respondents to see where their responses have been considered. Where we quote consultation responses in this document, we have not corrected spelling or grammar.

Programme (D-RAP) for AP1000. The AP1000 D-RAP is implemented as an integral part of the AP1000 design process to provide confidence that reliability is designed into the plant, and that important reliability assumptions made as part of the AP1000 probabilistic risk assessment, PRA remain valid throughout the life of the plant (AP1000 European Design Control Document, DCD Revision 1, see table in 3.2).

49 The UK AP1000 Environment Report (see table in 3.2) provides summary information on Westinghouse's management system in Section 1.4.

50 There are nominated contacts in Westinghouse responsible for production and control of UK GDA documents, including a specific contact for the Environment Report, and a document controller for UK GDA documents, who is based in the UK project organisation.

51 A significant part of our assessment activity has involved inspection to review the application of Westinghouse's arrangements to the UK GDA project, and to identify evidence of effective implementation of Westinghouse's management arrangements to GDA, including Westinghouse's GDA Quality Plan and supporting procedures.

52 The purpose of the inspections was to assess Westinghouse systems, processes and documentation, including specific discussions on areas where we required further information and clarity for the UK AP1000 Project. The inspections were carried out jointly with ONR.

53 A Joint Regulators inspection of Westinghouse's management arrangements was arranged for March 2009. The inspection was carried out to assess whether Westinghouse was applying its Quality Management Systems to the UK GDA process, namely to establish that Westinghouse has implemented and continue to review arrangements that adequately control their GDA related activities. The purpose of the inspection was also to inform the UK Nuclear Regulators' assessment of Westinghouse's submission, and to follow up progress on implementation of the recommendations from our initial inspection in November 2007.

54 The inspection focused on control of modifications to the AP1000 design, configuration control for GDA submission documents and arrangements for transmission of submission documents to the regulators, internal, external and third party certification audits, learning from experience, and procurement arrangements.

55 In particular, during the inspection, we re-examined the arrangements for:

a) Control of Modifications to the Design

b) Arrangements for Transmission of Submission Documents to the Regulators

c) Learning from Experience

d) Effectiveness of Auditing Arrangements-Internal, External and Third Party Audits

e) Procurement

56 One aspect of particular interest to ONR is in relation to procurement of "long lead items". These are items that need to be procured some time in advance of construction of new nuclear powers stations such as reactor pressure vessels. Our discussions covered arrangements for inclusion of operators in the design and manufacturing activities, including inspection, for long lead items. Procurement of long lead items was subsequently agreed to be out of scope for GDA.

57 The scope and details of the inspection were agreed in discussions held with Westinghouse in advance of the inspection. We also agreed that recommendations made by the Regulators during the inspection would be set out in the form of Regulatory Observations, and their progress tracked by the Regulators to satisfactory completion.

58 The inspection was attended by a member of the US Nuclear Regulatory Commission, US NRC who acted as an observer, at the invitation of the UK Joint Regulators.

Representatives of potential UK operators EON, Iberdrola and RWE were also present during the inspection at the invitation of Westinghouse. The findings of the inspection were discussed with Westinghouse at the close of each day, and at the closing session of the inspection.

59 A copy of the Joint Regulators Inspection findings was issued to Westinghouse in June 2009. The Joint Regulators Inspection report was published on the Joint Regulators website in 2009 (Joint Regulators, 2009).

60 The Joint Regulators findings from the inspection in March-April 2009 were that Westinghouse continues to operate a quality programme to meet international standards for quality management. A Project Quality Plan for the UK GDA project was provided to the Regulators in March 2009 during the inspection. This provides a top level quality management document for the UK AP1000 project which heads a number of project specific procedures. For example, Receipt and Processing of Technical Queries from the UK Regulators. The project quality plan cites those procedures within Westinghouse's Quality Management System that are to be applied to the UK GDA project.

61 Since the previous inspection in November 2007, which found that Westinghouse has a strong focus on learning and development in the organisation, there have been a number of quality initiatives set up across Westinghouse such as the arrangements for self assessment in Nuclear Power Plants (NPP). These initiatives support the concepts of a learning organisation and continuous improvement and as such are seen as positive by the Joint Regulator's inspection team. However, as a result of the way of working established in Westinghouse whereby its formal arrangements are only applied to a project once a firm customer contract agreement is in place, the UK AP1000 project has not benefited from these initiatives (at the time of the March-April 2009 Joint Regulators inspection).

62 The Joint Regulators confirmed that the configuration control/change management processes within Westinghouse are well established and there is evidence that these documented arrangements are implemented. There is an obvious strong ownership of the process which provides additional levels of assurance to the more formal means of independent review and the use of a properly constituted change committee.

63 There is evident strong leadership and ownership of the design configuration and change processes, however, there remains a significant workload to clear the backlog of unincorporated Design Change Proposals (DCPs). These are design changes that have been formally approved and subject to due process by Westinghouse. They require changes to be incorporated into design documentation and can be as simple as changes to a number in a document. They can remain unincorporated into design documentation for up to 6 months or up to 6 changes to the DCP, or when included on the design schedule. Westinghouse has recognised the challenge and has plans in place to address this situation. Subsequently Westinghouse has updated the Joint Regulators on progress with incorporation of DCPs, for example in their detailed response dated 11 March 2010.

64 Westinghouse continues to operate a matrix management structure. The AP1000 project organisation is established under the NPP Business Unit of the organisation. There has been a significant pan-Westinghouse initiative to achieve integration of processes and procedures with both the Nuclear Services and Nuclear Fuel Business Units which both provide resource and technical expertise to the AP1000 programme.

65 The following recommendations were made by the Joint Regulators and discussed with Westinghouse during the 2009 inspection:

a) Recommendation 1: Westinghouse should consider the application of the self-assessment process to the UK GDA project.

b) Recommendation 2: Westinghouse should consider covering all aspects of the UK GDA project in the internal audit programme.

c) Recommendation 3: Westinghouse should consider the application of the organisational learning initiative to the UK GDA project

d) Recommendation 4: Westinghouse should consider carrying out a review of effectiveness of the self assessment programme as part of the 2009 internal audit programme and to include directly the UK GDA project.

e) Recommendation 5: Westinghouse should inform the Joint UK Regulators of progress with the closeout of unincorporated DCPs by the end of November 2009.

f) Recommendation 6: Westinghouse should consider the installation and use of a data centre dedicated to the UK GDA project.

g) Recommendation 7: Westinghouse should consider the amendment of its DCP procedure as related to the UK GDA project to ensure that both the Westinghouse and UK categorisations are fully taken into account.

66 The Joint Regulators conclusion from the 2009 Inspection was that

a) Westinghouse continues to operate a well developed set of quality arrangements which include sub-tier procedures which are periodically reviewed and audited.

b) A GDA specific Quality Plan was developed, supported by a number of related GDA procedures, that are designed to formalise the interface between the Joint Programme Office (JPO) and Westinghouse.

c) The Inspection Team considers that the Joint Regulators' confidence in the arrangements for the remainder of GDA could be improved by the application of all the elements of the Westinghouse quality programme to the UK GDA project.

d) It is acknowledged that Westinghouse has experienced and knowledgeable staff and a commitment to retain adequate technical resources. Westinghouse have established a number of targeted initiatives such that organisational learning and continuous improvement have been addressed. However, the full benefit of these initiatives has not been realised for the UK GDA project as the level of application to the project appears to be minimal. This leads to some doubt regarding the effective application of Westinghouse processes to the UK GDA project.

e) There is evident strong leadership and ownership of the design configuration and change processes, however, there remains a significant workload to clear the backlog of unincorporated Design Change Proposals (DCPs). Westinghouse has recognised this challenge and has plans in place to address this situation. The joint regulators require to be updated on progress with regard to the closeout of unincorporated DCPs.

f) Westinghouse operates well established arrangements for the selection and surveillance and suppliers as part of its procurement activities.

67 The Regulators note that Westinghouse has strong management systems in place at its US Head Office and we have been presented with evidence that these systems are being implemented effectively across US operations. The extent to which the arrangements are applied by Westinghouse to the UK GDA project appears to be limited, on the basis of our inspections and in GDA to date. Westinghouse have not always responded in a timely manner on these matters.

68 Westinghouse discussed details of its progress in regard to implementation of the 2009 inspection recommendations in a letter dated 31 August 2009 and at a progress update meeting with the Joint Regulators in September 2009:

a) Recommendation 1 Self Assessment to be applied to UK GDA: Westinghouse has planned two self assessments on the UK GDA Project with a projected completion of 30 September 2009. A further update was provided by a Westinghouse response dated 11 March 2010. Two further self assessments were carried out in September 2010, and reports were provided to the joint Regulators in March 2011; these are discussed later.

b) Recommendation 2 Internal Audit: Westinghouse conducted an internal audit in August 2009 which included the UK GDA project as part of an audit of AP1000 international projects (internal audit WEC-09-34). There were 5 issues identified during the audit that are directly relevant to UK GDA project and these have been documented as issues in CAPs. These issues included one suggested improvement. A further internal audit was carried out in October 2010, and a report was provided to the joint Regulators in March 2011; this is discussed later.

c) Recommendation 3 Organisational learning: Westinghouse have included the UK GDA project in their system for organisational learning.

d) Recommendation 4 Effectiveness Review: Self Assessments: Westinghouse carried out a review of the self assessment process and identified 4 issues including two suggested improvements in the CAP.

e) Recommendation 5 Unincorporated DCPs: Westinghouse have been working to progress unincorporated DCPs and an update on progress will be provided by 30 November 2009. Updates were provided in a response dated 11 March 2010.

f) Recommendation 6 UK Data Centre: Westinghouse have established an e-room to host documents which can be accessed by the UK Regulators.

g) Recommendation 7 UK Safety Categories: Westinghouse have amended their DCP procedure to take into account the 4 UK safety categories.

69 Westinghouse's response letter of 31 August 2009 provided information on progress made in regard to specific inspection recommendations as detailed above where progress is summarised against each recommendation. Westinghouse' response was also to demonstrate by providing evidence that Westinghouse's quality procedures are being applied to the UK GDA project. Westinghouse provided a further update in a letter of 26 October 2009. In their October letter, Westinghouse provide an attachment detailing how Westinghouse quality procedures apply to the UK GDA project.

70 The letter from Westinghouse of 26 October 2009 stated that Westinghouse had conducted an internal audit of the UK GDA Project Quality Plan against the requirements of its corporate QMS. Westinghouse did not provide the audit report but did provide a summary that the results of the audit found a general compliance with Westinghouse QMS requirements and identified 6 trend findings that need remedial action or that were recorded for trending purposes. These were

a) Document issues with International Licensing

b) No work instruction for a complicated UK regulator process

c) Technical Queries from UK regulator not being archived in the Electronic Document Management System (EDMS) as correspondence

d) UK level 3 procedures need to be updated for recent changes

e) No training needs assessment for International Licensing

f) No training to UK GDA Project Quality Planning

71 The internal audit also identified a strength; the development of detailed level 3 work instructions to address the GDA UK Regulator interface.

72 At that time, Westinghouse were developing and implementing a QA system for Westinghouse UK to support GDA activities.

73 Progress has been made by Westinghouse in developing a UK based organisation for AP1000 with supporting management systems specific to the UK. Westinghouse began to apply the rigours of its QMS to the UK GDA Project with an internal audit of nuclear power plants projects including the UK GDA project in August 2009, with self assessments also planned, and the incorporation of organisational learning. An update on these activities was provided by Westinghouse letter of 11 March 2010. This response contained several hundred pages of detailed response and was

received too late to be considered in our public consultation document and the first version of this assessment report that were published in June 2010. The response from Westinghouse is considered later in this report.

74 We continued to work closely with ONR and Westinghouse during the remainder of GDA on these matters, and we reviewed this detailed information and considered it in our decision document. This information is considered later herein.

3.5 Regulatory Observations

75 We issued Regulatory Observations following our inspection, carried out between 31 March and 3 April 2009, on areas where we required Westinghouse to undertake to carry out specific work. A new Regulatory Observation, RO-AP1000-35, Application of Westinghouse QMS to UK GDA, was issued in June 2009 requiring Westinghouse to demonstrate that the full rigour of its Quality Management System (QMS) is being applied to the UK GDA Project. For example, the application of Westinghouse's established learning from experience, internal audit, self assessment and document verification processes and procedures to the UK GDA project.

76 The background to the RO-AP1000-35 indicated that the Joint Regulators had commented on the GDA specific Quality Plan and Procedures and that our comments had identified a number of aspects requiring attention. The Inspection also found that the level of application of the Westinghouse QMS appeared to be minimal to the UK Project and hence the full benefit of these processes and procedures has not been realised for the UK GDA project. This led to doubt regarding the effective application of appropriate quality processes to the UK GDA project and problems were seen with submissions to date in 2008-9 (RO-AP1000-17 refers, see later).

77 By issuing RO-AP1000-35, the UK Regulators required Westinghouse to demonstrate that they were applying the full rigour of its QMS to the UK GDA process, including the implementation of adequate procedures needed to meet its specific requirements. The two supporting Regulatory Observation Actions to RO-AP1000-35 required Westinghouse to provide a programme for the application of the full suite of Westinghouse QMS procedures to the UK GDA process, and to identify those aspects of the QMS that do not apply or do not apply without modification (A1) and for Westinghouse to demonstrate the effective application of its QMS to the UK GDA process (A2).

78 Westinghouse provided a response to RO-AP1000-35 on 31 August 2009 (as referred to previously) and the response was discussed at a meeting between Westinghouse and the Regulators on 10 September 2009. Their response provided information on the application of Westinghouse quality procedures to the UK GDA project. As an example of the application of Westinghouse's QMS, Westinghouse carried out an internal audit of AP1000 International Projects in 2009 which included the UK GDA project, as discussed earlier. Two self assessments of the UK GDA project were planned and completed in 2009. Westinghouse also confirmed it had made significant progress in efforts to address the close out of unincorporated DCPs.

79 Westinghouse provided information to the Joint Regulators on an internal audit of AP1000 projects carried out in August 2009. The audit scope was International Projects including UK and China, and NPP Engineering Contracts.

80 The audit findings in relation to UK GDA were reviewed by the Regulators. The findings included that the UK GDA procedures (also referred to as level III work instructions) were recommended for re-issue following update and corrections. For example, to refer to the more recent Westinghouse Policy and Procedures issued in 2009. The Regulators awaited the revised procedures as at April 2010 when this report was first prepared for issue with our consultation. The procedures were revised by Westinghouse in 2010, see later.

81 The findings also identified the need for a work instruction to be prepared for responding to the UK Regulators regulatory observation process, similar to the procedure that has been developed by Westinghouse for dealing with Technical Queries from the UK Regulators. This new procedure was prepared and provided to the Regulators at the end of March 2010. A number of CAPs issue reports were prepared from the audit. For example to ensure that technical queries and their responses arising in the UK GDA project are maintained as long term records in Westinghouse's electronic data management system, EDMS. Another CAPs issue identified a resolution that staff working on the UK GDA project should be trained in regard to the requirements of the UK Project Quality Assurance Plan. This is a formal requirement of the Westinghouse quality system where a project quality plan has been prepared.

82 A further update response to RO-AP1000-35 was provided by Westinghouse letter of 26 October 2009. This included an attachment specifically to advise on how the Westinghouse QMS applies to UK GDA and also provided summary details of an audit of the UK GDA Project Quality Plan for compliance with Westinghouse QMS, as detailed earlier. A further update response was provided by Westinghouse letter dated 11 March 2010. This was a 444 page response too detailed for review and consideration in the timescale for production of the June 2010 version of this report. This information is discussed later in this document.

83 A meeting was held between the Joint Regulators and Westinghouse in regard to QA matters on 1 April 2010. It was agreed that a commitment letter outlining the work programme for Westinghouse to close out any remaining QMS matters during GDA would be provided mid April from Westinghouse. Westinghouse submitted a letter to the Regulators on 14 April 2010 in regard to their quality assurance (QA) improvement plan including specific commitments. We reviewed this information and continued with the planned meeting programme on QA matters with Westinghouse. A further internal audit of the UK GDA was completed in 2010.

84 Following our inspection the Joint Regulators issued comments on Westinghouse's Quality Plan and Procedures for UK GDA. These were issued as Regulatory Observation Actions A3 and A4 under existing Regulatory Observation RO-AP1000-17 UK GDA Quality Assurance Processes. Action A3 required Westinghouse to update, revise and implement the provisions of the Project QA plan to address the comments of the UK Regulators provided in a letter dated 27 May 2009. Action A4 required Westinghouse to update, revise and implement the provisions of the Quality Procedures developed for UK GDA to address the comments of the UK Regulators in a letter dated 29 May 2009.

85 A Regulatory Observation RO-AP1000-17 had been issued previously in late 2008 concerning Westinghouse's application of quality management arrangements specifically to GDA submission documents. The regulatory observation indicated that there may be a deficiency in the quality assurance arrangements being applied to document production and review for the UK GDA process. This would undermine the quality of the submissions, and could reduce the regulators confidence in the safety claims, arguments and evidence being provided during GDA. A number of comments and recommendations were made by the Regulators in regard to the submission documents received to date during GDA, as regards to quality management matters. These were formalised in Regulatory Observation RO-AP1000-17 UK GDA Quality Assurance Processes issued in October 2008. The action associated with RO-AP1000-17 required Westinghouse to demonstrate to the regulators that its quality plan for the UK AP1000 process is effective and to agree other actions designed to ensure that documents submitted as part of the GDA process are fit for purpose.

86 Westinghouse responded to RO-AP1000-17 with proposed actions in a letter in December 2008. The Joint Regulators responded to this letter from Westinghouse since the focus of the response from Westinghouse appeared to concentrate on the

Interface Protocol between the Joint Regulators and Westinghouse, rather than the main matter of quality issues with documents provided as submissions for GDA.

87 Regulatory observation, RO-AP1000-17, required Westinghouse to demonstrate to the Regulators the effectiveness of Westinghouse's quality procedures. A number of documents issued by Westinghouse to the Regulators did not include changes which had been previously discussed and agreed between the Regulators and Westinghouse, or contained a variety of minor errors, as documented in RO-AP1000-17. For example, omission of agreed changes reflecting the Environment Agency's role in GDA, and poor cross-referencing between documents that contain related information. Also, a document appeared to have been modified without re-issue. One particular omission which has since been addressed related to recognition of the Joint Regulatory Process for GDA, and in particular recognition of the Environment Agency's specific requirements. The omission of agreed changes indicated to the Regulators that there may be a deficiency in the quality assurance arrangements being applied by Westinghouse to document production and review for the UK GDA process.

88 Westinghouse provided a further update response on 9 September 2009, prior to a meeting between the Joint Regulators and Westinghouse on 10 September 2009. This response was specifically in regard to action A3 requiring an update, revision and implementation of the Quality Plan. Following that meeting there were no further progress meetings on QA matters until 2010. This coincided with Westinghouse establishing its UK team for QA with the appointment of UK staff with specific responsibilities to deliver for QA matters. Progress has been made by Westinghouse in developing a UK based organisation for AP1000 and there have been regular meetings between the regulators and Westinghouse to discuss QA.

89 A further Regulatory Observation, RO-AP1000-33 was issued in June 2009 in regard to quality issues for the Environment Report submission. This noted the requirement for a coherent environment report submission with clear linkages. There was a lack of clarity in the presentation of information such that the public may find it difficult to locate and understand the cross links between the Environment Report and supporting documents, and other GDA submissions including the PCSR and European DCD. The QA issues included inconsistencies in data across the document sections, areas of incomplete text, and missing information. The Regulators asked Westinghouse to develop clear cross linkages between the PCSR, the Environment Submission and the UK Quality Plan as ONR and Environment Agency share joint expectations on management arrangements. We asked Westinghouse to carry out a comprehensive review, and to update and reissue the Environment Report and its supporting documentation ensuring that the full rigour of Westinghouse quality assurance procedures have been applied.

90 Westinghouse responded to RO-AP1000-33 with details of how they would address the Regulator's comments in a revision to the Environment Report. The response included a draft copy of a proposed revision to the management system section (1.4) of the Environment Report, and a programme of work. Westinghouse confirmed the new Environment Report would be reviewed for consistency with supporting and other related documents such as the European DCD. Further to ensure that document revision numbers are appropriate and consistent. The new Environment Report, revision 2 was issued in December 2009 in line with the Westinghouse programme. The Regulators undertook a review of the new report and wrote to Westinghouse in March 2010 to close out RO-AP1000-33 since the matters raised by the Regulators were addressed satisfactorily in the new report revision.

91 TQ-AP1000-404 was issued by the Joint Regulators in late 2009 asking Westinghouse to state which procedures were used in preparing the update to the PCSR and Environment Report due at the end of 2009. In particular, Westinghouse were required to identify those procedures that ensure the accuracy, consistency of data, configuration control and verification of the documents, and to describe the extent to

which the procedures had been applied. Westinghouse responded to confirm that both the PCSR and Environment Report are classed as documents and subject to the requirements of Westinghouse Level II Policies and Procedures, including the procedure for document control. This procedure addresses accuracy and consistency of data, including verification, and also configuration control requirements. There is also a specific level III procedure "preparation of UK licensing documentation-regulatory submissions" for GDA submissions to the UK regulators. Westinghouse confirmed that the PCSR and Environment Report submissions were subject to the full implementation of these requirements, and that this is demonstrated by the document approvals listed on the relevant document cover sheets.

92 TQ-AP1000-393 was issued by ONR to require Westinghouse to confirm its intention to reference the project quality plan as part of the PCSR update, and to confirm the application of Westinghouse QA procedures dealing with document control and verification during the PCSR updating process. Westinghouse responded in January 2010 to confirm that the project quality plan and other applicable Westinghouse document control procedures had been used in the preparation of the revised PCSR, Environment Report and associated documents. The processes adhered to include document configuration control, verification, accuracy and consistency.

93 Westinghouse has responded to those Regulatory Observations which address the wider application of its Quality Management systems, and has made progress as detailed herein in regard to the application of its QMS to the UK GDA project. It has established a UK team with staff responsible for management of QA matters for UK GDA, and a regular programme of progress meetings between these staff and the Regulators is underway. However, some QA matters remained ongoing at the time that our consultation, and the June 2010 version of this assessment report, were published. Meetings were held between the Regulators in early March and on 1 April 2010 to discuss QA matters. The meeting in April specifically discussed the response provided by Westinghouse on 11 March 2010 to address the Regulatory Observations. This response was very detailed and comprised a large set of documentation. It was agreed that a commitment letter outlining the work programme for Westinghouse to close out any remaining QMS matters during GDA would be provided mid April from Westinghouse. Westinghouse submitted a letter to the Regulators on 14 April 2010 in regard to their quality assurance (QA) improvement plan including specific commitments. We reviewed this information and continued with the planned meeting programme on QA matters with Westinghouse.

94 At the time of our consultation, when this report was first published in June 2010, Westinghouse had yet to fully demonstrate the effective implementation of its UK project plan and procedures, in particular, given that the UK GDA Project Quality Plan for GDA and the supporting procedures that underpin the work undertaken by Westinghouse for the UK GDA project were being revised and were due to be provided to the Regulators by the end of April 2010. Westinghouse needed to demonstrate to the Regulators that the plan and procedures are being effectively implemented for the UK GDA work.

95 Thus, some of these Regulatory Observations remained outstanding, with the detailed Westinghouse response provided too late for detailed review and consideration in our consultation document, and with Westinghouse work ongoing to resolve and close out the observations during the Environment Agency's detailed assessment stage of GDA, and ONR's Step 4.

96 We stated our conclusion, at the time of our consultation, when this supporting assessment report was first published in June 2010, that whilst some progress had been made, the revised Quality Procedures had yet to be provided for the UK project, and a further update to the Quality Plan was provided in draft in April 2010 following the update received in March 2010. Westinghouse committed at the meeting on 1 April to close out remaining matters to the satisfaction of the Regulators with an agreed work plan, and subsequently provided a letter on 14 April 2010 detailing their

proposed quality assurance improvement plan. The matters were to be examined during a planned inspection by ONR in their Step 4. Given our reservation on QA at this time, the inspection was carried out by the joint Regulators so that we could assess this matter and inform our decision for GDA.

3.6 Ongoing work since our consultation proposals were published

97 During its Step 4 review, ONR intended to examine the application of the full breadth and depth of the Westinghouse QMS applicable to the UK GDA project. ONR proposed to carry out one or more targeted inspections to establish Westinghouse's consistent and comprehensive application of adequate quality assurance arrangements.

98 The Environment Agency continued to work closely with ONR and Westinghouse on the outstanding QA matters. Working jointly with ONR, we carried out two further inspections of Westinghouse's management arrangements at Westinghouse's UK Project Office in July and December 2010, following the publication of our consultation document.

99 As a result of the outstanding QA matters, we reviewed new information from Westinghouse, and we participated in regular progress meetings with ONR and Westinghouse to discuss its QA Improvement Plan. More details are presented below.

100 HSE carried out an inspection of Westinghouse's QA arrangements for procurement of GDA services in July 2010. The scope was procurement arrangements for delivering the design presented in the GDA submission including the PCSR.

101 ONR carried out further planned inspections in Step 4. The inspection findings are discussed in the following sections where relevant to our decision, and are discussed in ONR's Step 4 report on QA. (ONR, 2011)

3.6.1 Westinghouse's Quality Assurance Improvement Plan

102 Westinghouse submitted a letter to the Regulators on 14 April 2010 in regard to its quality assurance improvement plan for the UK GDA Project including specific commitments. We considered the 'WEC response to regulatory expectations for UK AP1000 GDA' dated 11 March 2010 response in detail (see table in 3.2), and the revised quality plan and procedures for GDA, and the Quality Assurance Improvement Plan from Westinghouse. These are discussed further below.

103 Meetings to discuss QA progress took place monthly between Westinghouse and the Regulators from February 2010 to January 2011. Items for discussion included Westinghouse's QA Improvement Plan which was submitted in April 2010, TQ and RO responses, third party audits, joint Regulators Inspections, design change and Design Reference Point (DRP). Some additional meetings were held on specific topics such as DRP.

104 In addition to the Regulator inspections and progress meetings, convergence meetings on QA were held between the Regulators and Westinghouse in September and October 2010 to confirm the status of QA matters.

3.6.2 Westinghouse's Quality Management System for the UK GDA Project

105 At the time of our consultation, two regulatory observations remained open, RO-AP1000-17 and RO-AP1000-35. These required the UK GDA Project Quality Plan and Procedures to be revised, and for Westinghouse to demonstrate the application of the full rigour of its QMS to the UK GDA project.

106 Westinghouse provided a detailed response to the Regulators 'WEC response to regulatory expectations for UK AP1000 GDA' dated 11 March 2010. This response

provided further details of how the Westinghouse QMS is applied to the UK GDA project. There was an increase in Westinghouse resources allocated to the UK GDA project from 2010, and a review and realignment of responsibilities was completed that gave more day to day control to the UK GDA Project. The UK GDA Project Quality Plan and Procedures were under revision to reflect these developments. A revision 2 version of the UK GDA Project Quality Plan was issued to the Regulators in March 2010, with a further update made to revision 3 at the end of April 2010 to reflect the recent resource increase and change in responsibilities.

107 The response from Westinghouse included information on the Westinghouse AP1000 UK organisation and responsibilities. It included details of the revision status of the existing level III procedures, a number of which still required to be updated as at March 2010 when Westinghouse's response was submitted, to reflect the comments provided by the Regulators in May 2009. It also included details of planned new procedures for UK GDA.

108 Westinghouse's response included internal assessment reports carried out for US projects. Internal Assessment Report WEC-09-35 of Nuclear Power Plants (NPP) AP1000 Projects US conducted May-June 2009 was considered relevant to GDA since it found 'The QMS is not being effectively implemented in the AP1000 Projects US Organisation, specifically in the areas of document and data control, resource management (training), contract review, design control and procurement'. Additionally, Westinghouse noted that Internal Assessment WEC-09-38 of the ASME Code Quality Programme Implementation in the NPP/AP1000 organisation carried out in March 2009 found similar problem areas to those reported in WEC-09-35. It was recommended that, 'based on these emerging trends' NPP review these issues' in order to determine an action plan that will remedy these problem areas in NPP'. We assessed these matters in our inspection in July 2010, in particular to focus on how learning from such issues and events is addressed by Westinghouse.

109 Westinghouse's response included a series of documents and attachments as supporting evidence to actions taken on the inspection recommendations that resulted in RO-AP1000-35 and additional actions to RO-AP1000-17 being issued. Information was included in regard to the two self-assessments relating to the UK project that were planned for 2009. The US licensing team performed a self assessment in September 2009 on the receipt and processing of technical queries (TQs) from the UK Regulator; the Westinghouse process is described in a level III procedure UKP-GW-GAP-012. The report was included with the response, and concluded that a total of three CAPs were opened as a result of the assessment, and recommended that a training refresher be provided to the personnel involved with this process. A second self assessment was carried out by the UK licensing team in December 2009 'Supplier Oversight (Design) for ND activities'. The report was not available with the response but a corrective action had been issued as the report was overdue. Two further self-assessments were planned for 2010 for the UK licensing team.

110 Westinghouse provided details of the two self assessments carried out in 2010 to the joint Regulators in March 2011. The self assessments were carried out to assess compliance with the specific procedures on handling of regulatory observations, and handling and archiving of TQs, and with the Westinghouse QMS. There were six suggestions for improvement identified from the self assessment on handling of regulatory observations. These included for example some amendments to the procedure on receipt and processing of regulatory observations. Similarly, there were three suggestions for improvement from the self assessment on handling and archiving of TQs, including modification of the procedure on receipt and processing on TQs.

111 A schedule of corrective actions and internal findings relative to the UK GDA project was included in Westinghouse's 11 March 2010 response with actions assigned to individuals and dates. These actions included revision of the level III procedures to address RO-AP1000-17.

112 Details of a Westinghouse learning event were included in their response for OEQ-09-11 dated 9 July 2009. It summarised 'We have received some negative feedback from the lead UK regulatory QA assessor- We have now received a documented listing of the actions from the NII (joint Regulators) Inspection held April of this year….The lead UK regulatory QA assessor was under the impression that his suggestions would be given a priority. He had hoped he would be able to write a Step 3 (public status report published November 2009) report that documented what actions we had taken. He now understands we have not acted on any of his suggestions to date and he has expressed disappointment in our performance.'

113 We made clear and formalised our expectations for Westinghouse in regard to QA following our joint Regulators inspection in April 2009. The joint Regulators inspection report was shared with Westinghouse in draft following our inspection, before it was formally published. We issued a new regulatory observation, RO-AP1000-35 to Westinghouse in June 2009, and additional actions to RO-AP1000-17 were issued in May 2009, to follow up our inspection findings.

114 Westinghouse's response to TQ-AP1000-737 "Trending Analysis and Management Review" provided in August 2010 included information on how they responded to CAPs. One of the issue reports showed that the issues raised by our 2009 joint Regulators Inspection, which led to issue of RO-AP1000-17 and RO-AP1000-35, generated corrective actions reports that were not addressed and lay dormant for a period of time due to lack of resources and support.

115 As noted earlier, we began a series of monthly progress meetings between the Regulators and Westinghouse to discuss progress in the implementation of their QA improvement plan. There was an increase in Westinghouse resources allocated to the UK GDA project from the start of 2010.

116 A readiness review was conducted in May 2010 at the UK GDA project office of Westinghouse by Westinghouse US head office based professional QA staff. The review concluded that 'overall, the Westinghouse QMS is being effectively implemented in the UK GDA office'.

117 The joint Regulators carried out a further inspection in July 2010 at the Westinghouse UK GDA project office to assess Westinghouse arrangements for quality assurance and the implementation of their quality management system to deliver GDA. The scope of the inspection included the interface between USA and UK offices, considering how information is managed and controlled between the two sites, training and qualification of staff, development of safety and environment submissions, event raising and learning from experience, and knowledge transfer including interface with the utilities. Representatives from Vattenfall, RWE and EoN, members of the Multi-Party Agreement (MPA) utility group with Westinghouse, attended as observers.

118 The inspection found the Quality Plan and the level III procedures for the UK GDA project had been revised. There was evidence that staff had been trained and were aware of their role and responsibilities in GDA. Regular US-UK interface meetings occur with invites to utilities and suppliers as appropriate. The utilities are involved in review of safety and environment submissions.

119 There were a number of opportunities for improvement identified in the joint Regulators inspection, although no recommendations were made. For example, there is a reliance on a small number of key personnel to provide the required breadth of knowledge and experience for the UK project, that is in terms of UK licensing and operation and US design and licensing staff.

120 Our findings were supported by a successful third party audit conducted by Lloyds Register in June/July 2010, which tested the adequacy of Westinghouse's QMS arrangements in respect to the GDA project. No significant issues or non-conformances were raised.

121 On the basis of our July 2010 Inspection findings, and evidence provided by

Westinghouse in implementing their QA improvement plan, the Joint Regulators agreed to close out RO-AP1000-17 and RO-AP1000-35. These required the Project Quality Plan and Procedures to be revised, and for Westinghouse to demonstrate the application of the full rigour of its QMS to the UK GDA project. The Regulators wrote to Westinghouse in July 2010 to close out the regulatory observations, and providing further comment on the Project Quality Plan and Procedures; these comments were not of significant severity to prevent the close out of the regulatory observations. Westinghouse provided an update on progress in updating the level III procedures in regard to comments made by the Regulators with details of how our comments would be addressed in a letter in October 2010.

122 Thus our reservation on QA matters as detailed in our consultation is considered closed.

123 A GDA project internal audit was completed by Westinghouse in October 2010. Westinghouse provided a copy of the audit report in March 2011 to the joint Regulators. The scope of the audit was to assess the implementation of Westinghouse QMS requirements to the UK GDA project. Six CAPs were raised, five were fix/trend and of one was of medium significance; inappropriate and ineffective closure of CAPs issues for UK GDA related items.

124 The Westinghouse internal audit team concluded that Westinghouse UK GDA team is effectively implementing the requirements of the QMS, although some QMS requirements were not being implemented in full compliance with the requirements identified. The audit found that management of corrective actions from previous audits is ineffective. These issues were identified to be processed in the CAPs system.

125 Westinghouse confirmed in April 2011 that actions have been taken in response to these CAPs. For example in response to the medium significance CAPs including ;

a) CAPs training provided to UK GDA office staff

b) Access to the CAPs system set up to allow action owners to access the system and enter close out details

c) Use of CAPs system tools to highlight and follow up actions.

126 ONR concluded in their Step 4 report (ONR, 2011) that the QMS for the GDA project, and its application, has developed considerably during Step 4, and the revised project quality plan provides clarity and guidance on the QA arrangements supporting the project. ONR also noted that in some cases the processes were under development while the project is being delivered. HSE's report noted, that during their assessment they found that a couple of activities were not sufficiently documented in the GDA QMS, prior to the task or activity commencing. No significant issues were identified. However, it is important that a project is governed by adequate QMS arrangements and that these are clearly defined prior to commencing a project, therefore ONR raised an assessment finding, to ensure that the licensee has adequate QMS arrangements for the licensing / permissioning phase of the project.

127 We discuss our requirements for management arrangements for the future operator, including transfer of knowledge between Westinghouse and the future operator, later in this report.

3.6.3 Management of Design Changes during GDA and changes to the Design Reference Point (DRP)

128 One of the questions raised at our GDA Stakeholder Seminar in regard to management systems was '*Once the design is approved to what extent is the design frozen?*' Westinghouse is required to submit a design reference point (DRP) as the basis for GDA; effectively the design is frozen at the time of the DRP. All GDA submissions made to the Regulators should be based solely on that defined design. Supporting procedures are in place for DRP and changes to the DRP can only be

made by submission to the joint Regulators Assessment Review Group (ARG).

129 Cumbria County Council (GDA166) commented on our consultation in regard to the UK EPR design querying how the joint Regulators plan to manage changes to the design in GDA, specifically design improvements arising from construction of new reactors in France and Finland. This comment is considered applicable for the AP1000 since AP1000 reactors are under construction currently in China.

130 There is a process for changes in design, resulting from design improvements or regulatory requirements, to be taken into account during GDA ; this is described in more detail below.

131 The Regulators wrote to Westinghouse in June 2010 to confirm our expectations for scope of GDA submissions with reference to the DRP, and providing comments on the DRP. The letter outlined HSE's 6 step change control process, for the consideration of design changes for inclusion in Step 4 of GDA. Westinghouse are required to notify the Regulators of the proposed design change, and the rationale for the design change, and to provide confirmation of the design change categorisation and impact assessment.

132 The proposed changes are considered by the joint Assessment Review Group (ARG) The Regulators then provide formal agreement (or not) in writing to Westinghouse in regard to inclusion of the change proposal in GDA.

133 RO-AP1000-88 GDA Submission was issued in July 2010 which required Westinghouse to review the DRP and related regulator comments. Action A3 required Westinghouse to review and reconcile the DRP with the current HSE assessment activity. Action A4 required the submission of the Master Submission List in accordance with the GDA Interface Protocol. RO-AP1000-88 GDA Submission Actions A3 and A4 were closed by HSE in November 2010.

134 Once a design change has been decided, the proposal for the change is submitted via the Design Change Proposal (DCP) process documented by a Westinghouse procedure. In November 2010, Westinghouse responded to TQ-AP1000-1120 DCPs requested for inclusion in GDA, to provide information requested by HSE including impact assessment of design change proposals (DCPs) to address engineering, safety and environmental analysis. Detailed descriptions of the DCPs listed in Step 4 for RO-AP1000-88 action A2 were included. Of relevance to the Environment Agency was the DCP for "Increase in Exhaust Vent Stack Height to meet UK Regulations".

135 Westinghouse provided details of their design change control process for GDA to the Regulators, recognising that correct categorisation of design changes is important to UK licensing and for initiating changes to the DRP. Westinghouse carried out a review, as described in their response to RO-AP1000-88 action A5 "Westinghouse Integration of UK Safety Categorisation and GDA Change Control Process", which identified that UK safety categories were not always selected correctly. In order to correct the deficiencies in the change control process, several corrective actions (CAPs) were initiated by Westinghouse. Of most significance to the Environment Agency was to 'include environmental impact in the categorisation of design changes'.

136 Westinghouse wrote to the Regulators in January 2011 and then in February 2011, with an update of design changes, providing further information on DCPs that Westinghouse wish to be considered for inclusion in GDA. These include for example design improvements in filtration in regard to meeting the regulators requirements for nuclear ventilation.

137 ONR note in their Step 4 report (ONR, 2011) that a CAPs issue is being progressed by Westinghouse on the inconsistent application of UK GDA safety categories in the DCP process. Westinghouse provided an update on progress by letter dated 1st April 2011. The letter explained that the CAPs issue was classified as medium significance and therefore an Apparent Cause Analysis was completed. It is noted in the letter that several of the actions which would address DCPs specific for a UK customer are on

hold pending a commercial decision in the UK. It is the ONR's expectation that the action associated with the application of the UK safety categorisation is resolved within GDA and will be followed up as part of the Cross Cutting GDA Issue GI-AP1000-CC-02.

138 During the site specific phase, further design changes may be proposed for the AP1000 design as a result of learning from experience on AP1000 construction projects. ONR raised an assessment finding in their step 4 report for the future licensee to manage and control design changes as a result of learning from experience during construction. We would expect the future operator to have appropriate arrangements in place to control and manage such design changes at the site specific stage.

3.6.4 Design Reference Point

139 The AP1000 design reference for UK GDA is described in 'Design Reference Point' UKP-GW-GL-060. The Design Reference Point (DRP) must describe the generic reactor design for which Westinghouse are seeking a UK design acceptance confirmation (DAC), and statement of design acceptability (SODA) from the Regulators.

140 For GDA, Westinghouse needs to ensure the DRP, the safety, security and environment reports (SSER) and supporting documentation as captured in the master submission list (MSL) are valid, consistent and applicable to the UK. The Regulators wrote to Westinghouse in December 2010 in regard to consolidation of the DRP, PCSR and ER. For the regulators to be able to complete a meaningful GDA, we require clear and consistent links to be established between DRP, the PCSR and ER and supporting documentation, including the information we have assessed.

141 Our draft interim statement of design acceptability (SODA), and the findings and preliminary conclusions that we consulted on for the AP1000 in 2010, were based on the design described in the Reference Design Point (subsequently referred to as DRP) of 23 December 2009. Westinghouse updated their Design Reference Point (DRP) in 2010. Revision 1 to the DRP is for a design freeze of 16 September 2010. Further revisions were made in 2011, with the most recent version being revision 5.

142 We asked Westinghouse to consider the impact of the change in DRP in a regulatory observation RO-AP1000-103 GDA Submission with actions A1-A4 issued on 1 November 2010. This detailed our expectations for Westinghouse to ensure the alignment of the DRP and the GDA submissions. Action A4 required Westinghouse to describe the process for controlling the DRP and how they would keep the GDA submission documentation aligned, particularly where assessment reports are based on potential changes which have not been incorporated into GDA.

143 The Regulators wrote to Westinghouse in November 2010 in regard to DRP and design change control to confirm the Regulators acceptance that the DRP for GDA is revision 1 based on design freeze of 16 September 2010; we had already identified through RO-AP1000-103 that further work was required to ensure consistency between the documents referenced in DRP and the corresponding tracking sheet. We confirmed our expectation that the DRP be revised to address RO-AP1000-103, and our view of the process for reviewing UK categorisation for design changes that could affect the DRP, but that the DRP would still be retained as 16th September 2010. Environment Agency confirmed our requirements for Westinghouse to review the impact of changes from revision 0 to revision 1 of the DRP for their environmental impact.

144 Westinghouse confirmed details of the GDA driven changes to be included in the DRP in November 2010, and requested that the design changes be presented to the ARG as required by the HSE six step design change process. Westinghouse submitted its internal procedure on changes to the DRP for GDA to the Regulators in December

2010. This included GDA change evaluations for design changes to the European AP1000 plant.

145 Westinghouse produced a response to Regulatory Observation RO-AP1000-103 actions A1-A4 in December 2010, noting 'there remains some misalignment between the PCSR and the DRP… the PCSR and DRP will be aligned in March 2011 in the consolidated safety submission'. Their response to actions A1-A4 was updated and resubmitted in January 2011. In addition, they provided with their response, revision 2 of the DRP as approved for use to support actions A3 and A4. Action A4 was closed by the Regulators in February 2011.

146 RO-AP1000-103 Action A5 issued in November 2010 asked Westinghouse to identify and review the impact of changes in DRP from revision 0, on which our public consultation on our findings for the AP1000 was based, to revision 1, on the environment including environment submissions made in GDA. In December 2010, the Regulators issued further actions A6, A7, and A8. These required Westinghouse to reconcile the Master Submission List (MSL) for GDA, the PCSR, and ER with the DRP. We required identification and assessment of environmental impacts to be carried out by Westinghouse for design changes proposed and resulting amendment to the DRP for the AP1000.

147 Westinghouse's response to Action A5 was provided in January 2011. Westinghouse provided information on the production of revision 4 of the ER, including review processes. They identified DCPs included in GDA that were approved during ONR's Step 4 and that might impact the ER. Westinghouse included a justification why the DCP might impact on ER. For example, their response identified the reactor system or building change and what its impact might be; they have commissioned an impact analysis to evaluate the planned increase in exhaust vent stack height.

148 A revision 2 DRP was issued to the Regulators in January 2011 to support the submission and response to RO-AP1000 action A4. The revised DRP included an independently verified list of DCPs to be included within GDA.

149 Westinghouse provided their internal procedure 'Design Reference Point Change for GDA' UKP-GW-GAP-026 revision 0 in December 2010 outlining their process for amending the DRP for UK GDA. This was provided in response to RO-AP1000-103 action A4 and RO-AP1000-88 action A5. This instruction incorporates the Regulators' 6 stage process, freezing the design reference for the purposes of the GDA project and has resulted in a number of safety significant design changes being presented for formal agreement for inclusion into GDA . Once agreed by the Regulators, Westinghouse's intention is to include these design changes into the Design Reference document. ONR wrote to Westinghouse in January 2011 seeking clarification on a number of comments raised following their assessment of the procedure.

150 A further update of the design reference to revision 2 was made since the impact of design changes to the referenced documents was unclear, and discrepancies were identified. DRP revision 2 included the outstanding unincorporated design changes that impact the design reference documents. RO-AP1000-103 Action A9 was issued in February 2011 requiring Westinghouse to assess the impact of these design changes to the safety submission, and associated supporting references to provide assurance that the design changes have been considered and where appropriate assessed. This will be followed up under the GDA Issue, GI-AP1000-CC-02 .

151 ONR identified in its Step 4 report (ONR, 2011) that design changes to the design reference have been made during Step 4 without consideration of the impact to the safety submission, and without notification and agreement with the regulators. Further assessment by Westinghouse has been requested under RO-AP1000-103; the response is expected at the end of GDA. The timing of this additional information makes it difficult to assess within ONR's Step 4 and for the Environment Agency's decision, so this will be followed up within the GDA Issue GI-AP1000-CC-02.

152 The Master Submission List, MSL is a key deliverable of the GDA project. There is no Westinghouse QMS procedure governing this activity, the MSL has been developed using the information from the PCSR, ER and DRP developments. However in response to RO-AP1000-103 actions, the MSL has been fully reviewed against the transmittal log, DRP and PCSR, and errors identified have been corrected. Further alignment was required between the DRP, PCSR and ER, and therefore the MSL was subject to further change prior to submission at the end of March 2011. Westinghouse commissioned an independent sample check of the MSL that provided confidence in the accuracy and completeness of the submitted MSL.

153 ONR noted in their Step 4 report that the Design Reference was not frozen in December 2009 for GDA, and has been reset as 16 September 2010 and has not been used as the key reference in the development of the PCSR chapters to support the December 2010 submission. The alignment of the PCSR submitted in March 2011 with other GDA deliverables will be resolved as part of the GDA issue, GI-AP1000-CC-02.

3.6.5 Inspections carried out following our Consultation on Design Change and Configuration Control and Product Acceptance for GDA support contracts

154 ONR carried out an inspection of Westinghouse's QA arrangements associated with design detail development and change control for UK GDA activities in August 2010 in the US. Several positive findings were recorded in the conclusions of the inspection. The inspection identified a number of improvement opportunities, and recommendations were made for Westinghouse to align the UK safety categorisation to the design change proposal, DCP class, that the DCP process considers fully UK impact, and that once these recommendations were completed, that Westinghouse should seek endorsement from ONR on design modifications that they propose to include into GDA (see previous section).

155 A further inspection by HSE took place in November 2010 on design configuration control. The inspection focused on the Radiological Controlled Area Ventilation (VAS) system within the fuel pond area, sampling the design review, design engineering and change control processes that ensure configuration control from the design engineering into the final safety and environment submissions for GDA.

156 The November 2010 Inspection concluded that Westinghouse recognise that there are shortfalls with the application of their design change proposal (DCP) process for the UK GDA project; these shortfalls are being monitored through RO-AP1000-103 and associated actions. For example, the PCSR and Environment Report (ER) were not identified as impacted documents in the design change proposal, and it is unclear how design changes from the DRP are incorporated into the UK GDA project. The design reviews carried out to date have been limited in scope to the standard plant design and therefore do not consider UK specific changes. No formal recommendations were raised by HSE.

157 At this inspection, it was discussed that Westinghouse were developing an approach to conduct a number of design reviews considering the UK specific changes. HSE issued TQ-AP1000-1179 requesting further information in regard to design review strategy for the UK. Westinghouse responded in December 2010 with details of their proposals for UK specific design reviews, based on experience gained in other design reviews.

158 Westinghouse provided documents in support of this approach such as the procedure for revising AP1000 DCP affected documents.

159 A further inspection was carried out by the joint Regulators in December 2010 in regard to assessment of supplier product acceptance. Environment Agency were seeking assurance from this Inspection on Westinghouse's process to demonstrate intelligent customer capability in regard to selection, review, acceptance and approval

of supplier services for Environment submissions in GDA.

160 Westinghouse demonstrated a professional and rigorous approach to selection of contractors using defined criteria for development of the PCSR; reference to Westinghouse systems and evidence was provided, in response to RO-AP1000-89 GDA Procurement. However, we did not receive the same level of assurance for the selection of contractors used for the environment report. This may be explained in part by the fact that the selection was made early in GDA when RP familiarity with UK GDA environment requirements was limited. However, it is understood that subsequent to the initial contract selection, Westinghouse carried out a full audit of the contractor supplying environmental services, and the audit had no findings.

161 Recommendations were made from the inspection to ensure consistency between ER and PCSR, plus DRP and MSL, resulting in the issue of RO-AP1000-103 actions A6, A7, and A8.

162 RO-AP1000-103 action A6 required Westinghouse to review the documents contained in their Master Submission List (MSL) and provide evidence that the suite of documents are suitable for Generic Design assessment of the UK AP1000 at the reference point of 16 September 2010 as described in the Revision 1 DRP.

163 RO-AP1000-103 action A7 required Westinghouse to review the PCSR and supporting references to ensure it aligns with the documents contained in the Westinghouse reconciled Master Submission List (MSL), the PCER and the 16th September 2010 Design Reference Point (DRP) and any GDA accepted DCPs.

164 RO-AP1000-103 action A8 required Westinghouse to review the Environment Report and supporting references to ensure it aligns with the PCSR; and the 16th September 2010 Design Reference Point (DRP), and any GDA accepted DCPs, and the documents contained in the Westinghouse reconciled Master Submission List.

165 Westinghouse provided their response to RO-AP1000-103 actions 5-8 in January 2011. These issue actions are discussed in the previous section; the alignment of the DRP, PCSR and ER will be resolved as part of the GDA issue, GI-AP1000-CC-02. RO-AP1000-103 actions A1, A2, A3, A5, A6, A7, and A8 were closed by the Regulators in May 2011; A4 was closed previously.

166 The recommendations from the joint Regulators December 2010 inspection included that evidence be provided to demonstrate the application of the rigour of Westinghouse review processes to the ER, in line with the approach applied to the PCSR. Westinghouse provided a letter response in January 2011 in regard to the ER production process. This response was considered satisfactory.

3.7 Conclusions - Design Change in GDA and DRP

167 The inspections carried out in November and December 2010 confirmed that there were still several issues related to the content and definition of the design reference, and design change control. A milestone was achieved with the agreement that the DRP i.e. the date at which the AP1000 design was frozen for GDA was declared at 16 September 2010.

168 Design changes to the design reference have been made during Step 4 without consideration of the impact to the safety submission and during Step 4 without formal notification and agreement with the regulators. Further assessment by Westinghouse was requested by the Regulators via RO-AP1000-103 which was closed in May 2011. These matters are being followed up within the GDA Issue GI-AP1000-CC-02 to provide confidence that the Design Reference and Safety submission incorporates the design changes agreed for inclusion into GDA.

169 ONR also identified that at the end of GDA Step 4, a large number of DCPs impacting the design reference documentation (i.e. System Specification Documents, Design Specifications and Codes and Standards) will remain unincorporated. For UK specific

modification requirements, approved changes will not be implemented and incorporated into the design documentation until a Utility contract is signed. Therefore, whilst Westinghouse is committed to these design changes they have not been implemented and the current design reference documentation does not directly support the safety submission. These will also be resolved via the GDA issue GI-AP1000-CC-02.

170 There will be a number of design changes which will remain incomplete at the end of GDA and will need to be transferred into the site-specific Licensing phase. ONR have an assessment finding for the future licensee to implement adequate QA arrangements to capture, and track the implementation of unincorporated approved design changes transferred from UK GDA project. It will also be a requirement of the Environment Agency that future operators demonstrate that adequate management arrangements are in place for identifying, transferring, tracking and implementing the unincorporated approved design changes for AP1000, see also section 3.7.

171 As discussed earlier, the design reviews conducted so far have been limited to the AP1000 standard plant and have not considered the UK specific design changes or regulatory requirements. ONR has included an assessment finding in their Step 4 report (ONR, 2011) that the licensee shall provide design reviews for systems, equipment and civil structures which have been impacted by a UK or European specific design change, following the completion of the strategy incorporating a graded approach, to ensure that the design change has been well executed and has not resulted in an adverse effect to safety.

172 ONR include in their Step 4 report a number of assessment findings for the future licensee to address in the areas of records management, training and competency, in particular in regard to design development.

173 ONR concluded in their Step 4 report that the QMS for the GDA project, and its application, had developed considerably during Step 4, and the revised project quality plan provides clarity and guidance on the QA arrangements supporting the project. It was also noted that in some cases the processes were under development whilst the project was being delivered.

174 In conclusion, the Environment Agency is satisfied that Westinghouse's management arrangements for the AP1000 in GDA are adequate, on the basis of assessment work documented in our consultation and the ongoing work reviewed herein. In particular, the further inspections carried out by the Regulators, and the further work carried out by Westinghouse to implement their QA improvement plan.

175 We conclude that Westinghouse has an appropriate management system in place to:

a) control the content and accuracy of the information provided for GDA;

b) maintain records of design and construction;

c) control and document modifications to the design.

176 However, some of the findings and observations identified within this assessment report, for example concerning design changes and DRP are of particular significance and will require resolution before Environment Agency would grant a permit, and ONR would agree to the commencement of nuclear safety related construction of an AP1000 reactor in the UK. These are identified in this report as a GDA Issue and this will require an associated Resolution Plan to be proposed by Westinghouse.

177 Our conclusions remain unchanged since our consultation. However, they are subject to a GDA Issue which will need to be satisfactorily resolved. This reflects that Westinghouse will need to control changes to GDA submission documents, resulting from the management of design changes, until the issue of final design acceptance confirmation/statement of design acceptability from the Regulators.

178 It is our expectation that Westinghouse will control, maintain and develop the GDA submission documentation and design reference and deliver final consolidated

versions of these documents as the key references to any SODA we may issue, and DAC that ONR may issue at the end of GDA.

179 Westinghouse shall ensure that these key deliverables are subject to appropriate review and that the review comments are included, as appropriate, in the final consolidated submission.

180 This is the basis for our GDA Issue, GI-AP1000-CC-02, joint with ONR.

181 The GDA issue, GI-AP1000-CC-02, has three actions

a) Westinghouse to submit a safety case to support the GDA Design Reference and then to control, maintain and develop the GDA submission documentation, including the SSER, the MSL 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.

b) Westinghouse is required to make and implement arrangements to control, maintain and develop the GDA safety submission documentation. This must include the SSER, MSL and design reference documents. As part of this action, Westinghouse shall deliver final consolidated versions of these documents as the key references to any DAC/SODA we may issue at the end of GDA. This should involve the incorporation of all relevant amendments into the impacted documentation associated with design changes, including the Design Reference UKP-GW-GL-060, MSL and the PCSR. This should include any other additionally agreed design changes associated with other GDA Issue Resolution Plans. Westinghouse arrangements shall ensure no modification to the design or safety case, which may affect safety, is made except in accordance with agreed arrangements and will provide for the classification of modifications according to their safety significance.

c) Westinghouse to implement the outstanding GDA agreed design changes, by incorporating the change details into all impacted DR, the MSL documentation including the PCSR, ER. The scope of this work should include those design changes already agreed for inclusion in GDA Step 4 but not incorporated and any additional design changes arising as part of other GDA Issue resolution plans or arising during the GDA close out stage.

3.8 Expectations for the Operator's Management System

182 Before a site-specific application for an AP1000 can be made, the potential operator will need to begin establishing its management system, including organisational structure and resources, and there will need to be considerable knowledge transfer about the design. We thus require a requesting party to address, in its GDA submission, the implications of the design for the potential operator's management system, and how it intends to facilitate the required knowledge transfer and provide ongoing support to the potential operator.

183 Issues concerning the transfer of knowledge about the design between the vendor and the future operator were examined by the Regulators in GDA and are discussed below. Respondents to our consultation also raised the issue of knowledge transfer as discussed in our decision document. We assessed evidence provided by Westinghouse against our expectations for the operators management systems.

184 Westinghouse's submission addresses these matters in:

a) Pre-Construction Safety Report PCSR

b) Plant Life Cycle Safety Report

c) UK AP1000 Environment Report Section 1.4 Management System, section 1.4.2.1 Intelligent Customer

d) Plant Operations, Surveillance, and Maintenance Procedures

185 The Operator is required to establish a Design Authority with arrangements in place to ensure that sufficient information and knowledge about the design is transferred from Westinghouse as the Design Organisation to the Operator so that it can act as an effective Design Authority.

186 Westinghouse provide information on knowledge transfer in Chapter 7 Lifecycle Engineering and Safety of the PCSR (December 2010). They say 'Westinghouse will support the licensee to ensure that the knowledge of the aspects of the design, construction, commissioning, and future operability of the plant is transmitted in an effective and appropriate manner and provide visible assurance that this has been achieved.'

187 Westinghouse provided information ' *Westinghouse will ensure that design and operational knowledge is transferred to the licensee of the operating organisation in order to permit it to perform as an intelligent customer. This knowledge transfer include the provision of design information and comprehensive training and education programmes such that the licensee can establish a credible design authority*. Westinghouse recognise the process of transfer of the design authority role to the operating organisation and note it will be given high importance by Westinghouse. Westinghouse also recognise the importance of training and development during the design phase for licensee personnel in regard to AP1000.

188 Westinghouse submitted a draft scope for the Life Cycle Safety Report to the Joint Regulators in August 2009. The report described the arrangements for the overall AP1000 GDA project and the requirements and provisions for different phases from design through to decommissioning. The Joint Regulators provided comment in September 2009, and a review meeting took place between the Regulators and Westinghouse in December 2009.

189 Westinghouse continued to develop the Plant Life Cycle Safety Report, LCSR and submitted a new revision (2) in March 2011. The Utility Partners provided comment to the revised LCSR. We reviewed this report and considered it when preparing our decision document. The report includes a safety and quality philosophy, and incorporates issues such as knowledge transfer in developing an 'intelligent operator' (we use the term to describe the capability of an operator to have a clear understanding and knowledge of the reactor design being supplied), The LCSR also includes details of organisational arrangements for moving to an operational regime with information on procedures, training and records.

190 Westinghouse provided a copy of the plant operations, surveillance and maintenance procedures for the AP1000. This document includes listings of emergency operating procedures, normal operating procedures and abnormal operating procedures that will be required for operation of AP1000. Westinghouse developed writers guidelines for procedure development, working with plant operators and incorporating learning from experience.

191 Reference 1.1 of Table 1 of the Environment Agency's process and information document for GDA requires Westinghouse to set out its expectations of the Operator's Management System to cover the reactor's operations throughout its lifecycle. The Regulators asked Westinghouse to provide further information in TQ-AP1000-330, specifically, to address in its GDA submission, the implications of the AP1000 design for the potential Operator's management system. In particular, how Westinghouse intends to facilitate the required knowledge transfer in regard to the AP1000 design and the arrangements to provide ongoing support to the potential Operator. Westinghouse developed its proposals in liaison with its Utility Partners for GDA.

192 Westinghouse has agreed with its potential utility customers that the submissions made to the Regulators during GDA will describe the management of the process to cover vendor expectations of the Operator's management arrangements, and interactions between the vendor and operator, prior to any site licence application being made.

193 Westinghouse has an established design procedure that includes a thorough design review process. The process is described in the Life Cycle Safety Report. Robust design change procedures are in place to assess and control the effect of design changes on safety and these aspects have been discussed with the Joint Regulators during the 2007 and 2009 inspections.

194 Westinghouse in responding to TQ-AP1000-330 sets out its expectations for a potential operators management system where safety and environment may be impacted. It describes in overview those aspects of the management arrangements where information transfer, education or continued support will be necessary to ensure safe and environmentally sound operations. The arrangements for knowledge transfer and competence retention are set out. Westinghouse state that knowledge transfer will be systematically carried out starting from the arrangements in place during GDA. This includes the involvement of the Utility partners who play an active role in review and input to the environment and safety submissions. The Utility partners have formed the AP1000 GDA Submission Steering Committee (AGSSC) to input, review and comment on GDA submissions for AP1000. In this respect, the process of knowledge transfer in regard to the design is occurring. Further information on knowledge and information transfer to the Operator for the AP1000 design is provided in the March 2011 update to the LCSR (revision 2).

195 Westinghouse have updated their Environment Report (ER) to address TQ-AP1000-330, and have provided information in ER section 1.4 on Westinghouse support to knowledge transfer and development of intelligent operator.

196 There will be a number of design changes which will remain unincorporated at the end of GDA and will need to be transferred into the site-specific and Licensing phase. In their Step 4 Report (ONR, 2011), ONR have an assessment finding for the future licensee to implement adequate QA arrangements to capture, and track the implementation of unincorporated approved design changes transferred from UK GDA project. It will also be a requirement of the Environment Agency that future operators demonstrate that adequate management arrangements are in place for identifying, transferring, tracking and implementing the unincorporated approved design changes for AP1000.

197 ONR have included assessment findings for the future licensee to address, for example in the area of records management, training and competency etc. We will consider such issues in any permit application we receive at phase 2 site-specific.

198 One of the 'other issues' (OI[3]) included in Chapter 8 of our consultation document was that detailed arrangements for the handover between Westinghouse and future operators shall be provided at site-specific permitting, in particular with respect to matters that relate to the use of BAT to minimise radioactive discharges (AP1000 OI02).

199 For example, Chapter 12 of our decision document provides more information on tritium production in aqueous discharges. Westinghouse claims that plant operation can significantly affect the amount of tritium produced and that the AP1000 design that optimises plant availability contributes to minimising tritium production. Management techniques such as operator training which optimise operations are relevant to reducing the production of tritium. Optimising plant availability to minimise plant shutdowns and tritium production will be a matter for future Operators of the AP1000. We will continue to seek assurances that the hand over between Westinghouse and future Operators will address this matter. On the basis of the above information, with the arrangements for transfer of knowledge considered satisfactory for GDA, we consider that this other issue AP1000 OI02 is closed out. These arrangements will be assessed in more detail at site-specific permitting.

[3] Now referred to as Assessment Findings (AFs).

200 We conclude that Westinghouse has adequately specified:

a) its expectations for any operating utility's management system;

b) how it expects to transfer knowledge and provide continuing support to any operating utility

4 Public comments

201 We received no relevant public comments on management systems before 1 April 2010. Comments made in response to our public consultation in regard to management systems for the AP1000 design were considered in our decision document, and herein where relevant to our assessment

202 Questions were also raised and published from our 6 July GDA 2010 stakeholder seminar and are considered in our decision document, and herein where relevant to our assessment.
http://www.hse.gov.uk/newreactors/seminar-060710.pdf

5 Conclusion

203 At the time our consultation was published in June 2010, there remained outstanding matters for Westinghouse to resolve and close out during GDA in agreement with the Regulators. Westinghouse submitted a letter to the JPO on 14 April 2010 in regard to its quality assurance (QA) improvement plan including specific commitments. We reviewed this information and continued with the planned meeting programme on QA issues with Westinghouse in 2010 and 2011. ONR examined the application of the full breadth and depth of the Westinghouse QMS applicable to the UK GDA project during its Step 4. ONR carried out further targeted inspections to establish the consistent and comprehensive application of adequate quality assurance arrangements by Westinghouse.

204 Following the publication of our consultation, the Environment Agency carried out, jointly with ONR, two further inspections of Westinghouse management arrangements including matters relating to our consultation reservation on Westinghouse QA. We continued to work closely with ONR in regard to the satisfactory resolution of the outstanding Westinghouse QA matters during GDA and our decision document was informed by this. We closed out the associated Regulatory Observations RO-AP1000-17 and RO-AP1000-35 in July 2010 on the basis of our inspections findings.

205 Thus, the following reservation was resolved:

a) Westinghouse has still to demonstrate to the UK Regulators the application of the full rigours of its Quality Management System (QMS) to the UK GDA project.

206 ONR concluded in its Step 4 report that the QMS for the GDA project, and its application, had developed considerably during Step 4, and the revised project quality plan provides clarity and guidance on the QA arrangements supporting the project. ONR also noted that in some cases the processes were under development whilst the project was being delivered.

207 On the basis of our assessment, including review of submissions, inspection activities and discussions with Westinghouse, we concluded that Westinghouse has an appropriate management system in place to:

a) Control the content and accuracy of information provided for GDA

b) Maintain records of design and construction

c) Control and document modifications to the design;

208 Westinghouse have given consideration to transfer of knowledge about the design to the future operating organisation, and have provided supporting information. We are satisfied that Westinghouse have arrangements in place to facilitate the knowledge transfer and to fully support the plant owner/operator at all phases of the nuclear new build project, through the provision of training programmes and data and document and technical information transfer.

209 We conclude that Westinghouse has adequately specified:

a) its expectations for any operating utility's management system;

b) how it expects to transfer knowledge and provide continuing support to any operating utility.

210 Our conclusions remain unchanged since our consultation. However, they are subject to a GDA Issue, joint with ONR which reflects that Westinghouse will need to control changes to GDA submission documents, resulting from the management of design changes, until the issue of final design acceptance confirmation/statement of design acceptability from the Regulators.

211 The GDA issue, GI-AP1000-CC-02, has three actions

a) Westinghouse to submit a safety case to support the GDA Design Reference and then to control, maintain and develop the GDA submission documentation,

including the SSER, the MSL 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.

b) Westinghouse is required to make and implement arrangements to control, maintain and develop the GDA safety submission documentation. This must include the SSER, MSL and design reference documents. As part of this action, Westinghouse shall deliver final consolidated versions of these documents as the key references to any DAC/SODA we may issue at the end of GDA. This should involve the incorporation of all relevant amendments into the impacted documentation associated with design changes, including the Design Reference UKP-GW-GL-060, MSL and the PCSR. This should include any other additionally agreed design changes associated with other GDA Issue Resolution Plans. Westinghouse arrangements shall ensure no modification to the design or safety case, which may affect safety, is made except in accordance with agreed arrangements and will provide for the classification of modifications according to their safety significance.

c) Westinghouse to implement the outstanding GDA agreed design changes, by incorporating the change details into all impacted DR, the MSL documentation including the PCSR, ER. The scope of this work should include those design changes already agreed for inclusion in GDA Step 4 but not incorporated and any additional design changes arising as part of other GDA Issue resolution plans or arising during the GDA close out stage.

212 The GDA Issue will require an associated Resolution Plan to be proposed by Westinghouse and will require satisfactory resolution before Environment Agency would issue a full Statement of Design Acceptability, and ONR would consent to the commencement of nuclear island safety related construction of an AP1000 reactor in the UK.

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Abbreviations

ALARP	As Low As Reasonably Practicable
BAT	Best available techniques
CAP	Corrective Action Process
DAC	Design Acceptance Confirmation
DCD	Design Control Document
DCP	Design Change Proposal
DRAP	Design Reliability Assurance Programme
EDMS	Electronic Document Management System
EPR 10	Environmental Permitting (England and Wales) Regulations 2010
EPRI	Electrical Power Research Institute – an independent USA organisation
ER	Environment Report
GDA	Generic Design Assessment
HSE	Health and Safety Executive
IAEA	International Atomic Energy Agency
INSA	Independent Nuclear Safety Assessment
INSAG	International Nuclear Safety Advisory Group
JPO	Joint Programme Office
LCSR	Life Cycle Safety Report
NPP	Nuclear Power Plant
MSL	Master Submission List
ONR	Office for Nuclear Regulation, an Agency of the HSE (formerly HSE's Nuclear Directorate)
P&ID	Process and Information Document
PCSR	Pre-Construction Safety Report
PWR	Pressurised Water Reactor
QA	Quality Assurance
QMS	Quality Management System
QP	Quality Plan
REPs	Radioactive substances environmental principles
RGN	Regulatory Guidance Note
RGS	Regulatory Guidance Series
RO	Regulatory Observation
SoDA	Statement of Design Acceptability
TQ	Technical Query
US NRC	United States Nuclear Regulatory Commission
WEC	Westinghouse Electric Company LLC

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