

**Generic design assessment  
AP1000 nuclear power plant design by  
Westinghouse Electric Company LLC**

**Assessment report  
Management systems**



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## Generic design assessment

### AP1000 nuclear power plant design by Westinghouse Electric Company LLC

#### Assessment report - Management Systems

<b>Protective status</b>	This document contains no sensitive nuclear information or commercially confidential information.
<b>Process and Information Document<sup>1</sup></b>	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
<b>Radioactive Substances Regulation Environmental Principles<sup>2</sup></b>	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
<b>Report author</b>	Dr Colette Grundy

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

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

2. 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 .....	5
2	Introduction.....	7
	2.1 Assessment methodology .....	8
	2.2 Assessment objectives .....	8
	2.3 Westinghouse documentation .....	9
3	Detailed Assessment of Westinghouse Management Systems .....	10
	3.1 Regulatory Observations .....	16
	3.2 Expectations for the Operator's Management System .....	20
4	Public comments .....	22
5	Conclusion.....	23
	References .....	24
	Abbreviations.....	25

## 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.
- 2 The Joint Regulators for GDA, the HSE 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 HSE 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.
- 5 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;

- 6 However, there remain outstanding matters for Westinghouse to resolve and close out during GDA in agreement with the Regulators. Westinghouse recently 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 will review this information and continue with the planned meeting programme on QA matters with Westinghouse. Thus, the following reservation needs to be 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.
- 7 HSE intends to examine the application of the full breadth and depth of the Westinghouse QMS applicable to the UK GDA project during its Step 4. HSE proposes to carry out one or more targeted inspections to establish the consistent and comprehensive application of adequate quality assurance arrangements by Westinghouse. We will continue to work closely with HSE in regard to the satisfactory resolution of the outstanding Westinghouse QA matters during GDA and our decision document will be informed by this.
- 8 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.
- 9 Our findings on the wider environmental impacts and waste management arrangements for the AP1000 reactor may be found in our Consultation Document (Environment Agency, 2010a).

## 2 Introduction

- 10 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.
- 11 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.
- 12 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.
- 13 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.
- 14 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.
- 15 During the Environment Agency's detailed assessment stage, we have kept Westinghouse's management arrangements under review. The Joint Regulators, HSE 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.
- 16 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.
- 17 We raised 42 Technical Queries (TQs) on Westinghouse during our assessment. Two raised jointly with HSE, and one raised directly by HSE were relevant to this report:

- a) TQ-AP1000-330 Expectations of Operating Utility Management System (Joint Regulators)
  - b) TQ-AP1000-393 PCSR Update (HSE only)
  - c) TQ-AP1000-404 PCSR and Environment Report update Procedures (Joint Regulators).
- 18 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.

## 2.1 Assessment methodology

- 19 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 HSE 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) decide on any exclusions to carry forward from GDA.

## 2.2 Assessment objectives

- 20 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
- 21 We have examined Westinghouse's GDA submissions, and jointly with HSE 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) .

## 2.3 Westinghouse documentation

22 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	03
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-732	Pre-Construction Safety Report, Chapter 9 Safety Management Throughout the Plant Lifecycle	02
UKP-GW-GL-737	Plant Life Cycle Safety Report	01
UKP-GW-GAH-001	Project Quality Plan for the UK Generic Design Assessment	2
EPS-GW-GL-700	European Design Control Document	1

### 3 Detailed Assessment of Westinghouse Management Systems

23 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.

24 Westinghouse documented the Joint Regulator's November 2007 inspection findings as issue reports in its Corrective Action Programme, 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. Review comments were provided by the Joint Regulators in May 2009. 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 have confirmed these procedures are due for issue to the Joint Regulators by the end of April 2010.
- 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 staff working on the project.
- 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.

- 25 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.
- 26 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.
- 27 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. The plan was revised and provided to the Regulators in March 2010 and a further revision provided in draft on 19 April 2010. The revisions to the procedures remain outstanding. However the dates for completion are provided in a letter from Westinghouse dated 11 March 2010, and it is understood all revisions are due to be completed by the end of April 2010.
- 28 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 and a revision issued in March 2009. 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, issued to the Regulators in March 2009 (currently under revision), that are designed to formalise the interface between the Joint Programme Office (JPO) and Westinghouse.
- 29 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 has recently been revised by Westinghouse, and the supporting procedures are currently under revision and due for completion by end of April 2010.
- 30 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, see later.
- 31 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 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, see table in 2.3).

- 32 The UK AP1000 Environment Report (see table in 2.3) provides summary information on Westinghouse's management system in Section 1.4.
- 33 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 organisation.
- 34 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.
- 35 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 HSE.
- 36 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.
- 37 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.
- 38 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
- 39 One aspect of particular interest to HSE is in relation to procurement of "long lead items". These are items that need to be procured some time in advance of construction of new nuclear powers stations such as reactor pressure vessels. Our discussions covered arrangements for inclusion of operators in the design and manufacturing activities, including inspection, for long lead items.
- 40 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.
- 41 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.
- 42 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).

- 43 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.
- 44 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 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).
- 45 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.
- 46 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. 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, most recently in a letter dated 11 March 2010.
- 47 Westinghouse continues to operate a matrix management structure. The AP1000 project organisation is established under the Nuclear Power Plants (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.
- 48 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.
- 49 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 assessment on the UK GDA Project with a projected completion of 30 September 2009. A further update was provided by a Westinghouse letter dated 11 March 2010.
  - 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 the CAP. These issues included one suggested improvement.
  - 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 most recently in a letter 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.
- 50 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.
- 51 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
- 52 The internal audit also identified a strength; the development of detailed level 3 work instructions to address the GDA UK Regulator interface.
- 53 Westinghouse are currently developing and implementing a QA system for Westinghouse UK to support GDA activities.
- 54 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.
- 55 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. Progress is being 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 contained several hundred pages of detailed response and was received too late to be considered in our public consultation document and this supporting assessment report. We will continue to work closely with HSE and Westinghouse during the remainder of GDA on these matters, and we will review this detailed information and consider it in our decision document.

### 3.1 Regulatory Observations

- 56 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.
- 57 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 appears 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 leads to doubt regarding the effective application of appropriate quality processes to the UK GDA project and problems have been seen with submissions to date (RO-AP1000-17 refers, see later).
- 58 By issuing RO-AP1000-35, the UK Regulators require Westinghouse to demonstrate that they are 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).
- 59 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 due for completion in September 2009. Westinghouse also confirmed it had made significant progress in efforts to address the close out of unincorporated DCPs.
- 60 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.
- 61 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 await the revised procedures as at April 2010 when this report was prepared, and we understand from Westinghouse these will be completely revised by end April 2010.
- 62 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 CAP 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 CAP 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.
- 63 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 this report. The Regulators will review this information and this will include a review to assess how the audit findings have been addressed. The findings of our review will be used to inform our decision document.
- 64 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 will review this information and continue with the planned meeting programme on QA matters with Westinghouse. A further internal audit of the UK GDA is scheduled for 2010.
- 65 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.
- 66 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.
- 67 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.
- 68 The existing 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.
- 69 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 is being 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.
- 70 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 HSE ND 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.
- 71 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.
- 72 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.
- 73 TQ-AP1000-393 was issued by HSE 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.
- 74 Westinghouse has responded to those Regulatory Observations which address the wider application of its Quality Management systems, and has made some 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 remain ongoing and have not been closed out. 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 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 will review this information and continue with the planned meeting programme on QA matters with Westinghouse.
- 75 Westinghouse have 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 are currently being revised and are to be provided to the Regulators by the end of April 2010. Westinghouse will need to demonstrate to the Regulators that the plan and procedures are being effectively implemented for the UK GDA work.
- 76 Thus, some of these Regulatory Observations remain outstanding, with the detailed Westinghouse response provided too late for detailed review and consideration in our public 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 HSE's Step 4.
- 77 HSE intend to examine the application of the full breadth and depth of Westinghouse QMS applicable to the UK GDA project during their Step 4. HSE propose to carry out one of more targeted inspections to establish the consistent and comprehensive application of adequate quality assurance arrangements by Westinghouse. We will continue to work closely with HSE in regard to this issue and our work and decision document will be informed by this.
- 78 In conclusion, whilst some progress has been made, the revised Quality Procedures have 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. This is too late for detailed consideration in this document. 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 detailing their proposed quality assurance improvement plan. The matters will be examined during a planned inspection by HSE in their Step 4 and we will continue to liaise closely with HSE to address this and this work will inform our decision document.

### 3.2 Expectations for the Operator's Management System

79 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.

80 Westinghouse's submission addresses these matters in:

- a) Pre-Construction Safety Report PCSR, Chapter 9
- 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

81 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.

82 PCSR Chapter 9, Safety Management throughout the Plant Lifecycle notes "*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. They also recognise the importance of training and development during the design phase for licensee personnel in regard to AP1000.

83 Westinghouse submitted a draft scope for the Life Cycle Safety Report to the Joint Regulators in August 2009. The report is to describe 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.

84 Westinghouse is continuing to develop the Plant Life Cycle Safety Report, LCSR and submitted a new revision in March 2010, following a meeting with the Regulators in December 2009. The report describes the arrangements for the overall AP1000 GDA project and the requirements and provisions for different phases from design through to decommissioning. It will include a safety and quality philosophy, and incorporate issues such as 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), It will also include organisational arrangements for moving to an operational regime with information on procedures, training and records.

85 A new revision to the LCSR report was provided to the Regulators in March 2010, too late for consideration in this report. The Utility Partners provided comment to the revised LCSR. We will review this report and consider it when preparing our decision document.

86 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.

- 87 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.
- 88 Westinghouse have agreed with their 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.
- 89 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.
- 90 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 2010 update to the LCSR.
- 91 Westinghouse have updated their Environment Report to address TQ-AP1000-330, and have provided information in section 1.4 on Westinghouse support to knowledge transfer and development of intelligent operator.

## **4 Public comments**

92 We received no relevant public comments on management systems before 1 April 2010. Any comments received after that time will be addressed in our final decision to be published in June 2011.

## 5 Conclusion

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;

93 However, there remain outstanding matters for Westinghouse to resolve and close out during GDA in agreement with the Regulators. Westinghouse recently submitted a letter to the JPO on 14 April 2010 in regard to its quality assurance (QA) improvement plan including specific commitments. We will review this information and continue with the planned meeting programme on QA issues with Westinghouse. Thus, the following reservation needs to be 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.

94 HSE intends to examine the application of the full breadth and depth of the Westinghouse QMS applicable to the UK GDA project during its Step 4. HSE proposes to carry out one or more targeted inspections to establish the consistent and comprehensive application of adequate quality assurance arrangements by Westinghouse. We will continue to work closely with HSE and our work will be informed by this.

95 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.

96 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.

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## Abbreviations

ALARP	As Low As Reasonably Practicable
BAT	Best available techniques
CAP	Corrective Action Programme
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
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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