

**Generic Design Assessment – New Civil Reactor Build**  
**Step 4 Management of Safety and Quality Assurance Assessment of the**  
**Westinghouse AP1000<sup>®</sup> Reactor**

Assessment Report: ONR-GDA-AR-11-013  
Revision 0  
11 November 2011

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First published December 2011

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## PREFACE

The Office for Nuclear Regulation (ONR) was created on 1st April 2011 as an Agency of the Health and Safety Executive (HSE). It was formed from HSE's Nuclear Directorate (ND) and has the same role. Any references in this document to the Nuclear Directorate (ND) or the Nuclear Installations Inspectorate (NII) should be taken as references to ONR.

The assessments supporting this report, undertaken as part of our Generic Design Assessment (GDA) process, and the submissions made by Westinghouse relating to the AP1000<sup>®</sup> reactor design, were established prior to the events at Fukushima, Japan. Therefore, this report makes no reference to Fukushima in any of its findings or conclusions. However, ONR has raised a GDA Issue which requires Westinghouse to demonstrate how they will be taking account of the lessons learnt from the events at Fukushima, including those lessons and recommendations that are identified in the ONR Chief Inspector's interim and final reports. The details of this GDA Issue can be found on the Joint Regulators' new build website [www.hse.gov.uk/newreactors](http://www.hse.gov.uk/newreactors) and in ONR's Step 4 Cross-cutting Topics Assessment of the AP1000<sup>®</sup> reactor.

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## EXECUTIVE SUMMARY

This report presents the findings of the Management of Safety and Quality Assurance (MSQA) assessment of the AP1000 reactor undertaken as part of Step 4 of the Health and Safety Executive's Generic Design Assessment (GDA). The assessment has been carried out on the Pre-construction Safety Report, its supporting documentation and the processes applied by Westinghouse to maintain and develop the GDA submission during Step 4.

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

The scope of the Step 4 assessment was to review Westinghouse's processes to maintain and develop the GDA submission and the safety aspects of the AP1000 reactor in greater detail. This was achieved by examining and inspecting the evidence, supporting arguments and claims made in the safety documentation, building on the assessments and inspections already carried out for Steps 2 and 3, and to make a judgement on the adequacy of the MSQA control arrangements and information contained within the Pre-construction Safety Report and supporting documentation.

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

My GDA Step 4 assessment was based on the findings from the Step 3 assessment, my assessment of the 2009 Pre-construction Safety Report, the European Design Control Document and Westinghouse's responses to Technical Queries and Regulatory Observations contained in the Master Submission List and inspecting the evidence supporting the design development. The 2009 Pre-construction Safety Report was found to have significant shortfalls in terms of content and quality. Recognising the shortfalls with the 2009 Pre-construction Safety Report, Westinghouse submitted a replacement draft Pre-construction Safety Report in December 2010, which extensively restructured and enhanced the 2009 Pre-construction Safety Report in order to address Nuclear Directorate's concerns. Westinghouse then submitted an approved Pre-construction Safety Report in March 2011 but this was too late for a meaningful assessment during Step 4. Notwithstanding the GDA Issue raised within my assessment, I have no fundamental reasons to believe that Westinghouse cannot produce an adequate Pre-construction Safety Report to support their GDA application, based on the information I have reviewed. I will need to assess the revised Pre-construction Safety Report, which Westinghouse must provide as part of a Cross-cutting GDA Issue.

My assessment has focused on:

- Management System, including records management.
- Training and Competency of personnel.
- Audit and Assessment, including non-conformance reporting
- Quality Assurance arrangements for the control of design detail development.
- Quality Assurance arrangements for the control of software use in design development
- Quality Assurance arrangements for the control of design changes.

- Quality Assurance arrangements supporting the procurement of Generic Design Assessment services.
- Configuration control of GDA submission documentation (Safety Case, Design Reference and Master Submission List).

A number of items have been agreed with Westinghouse as being outside the scope of the GDA process and hence have not been included in my assessment, such as Quality Assurance arrangements for all manufacturing activities. This will be addressed during the site specific phase.

From my assessment, I have concluded that:

- The Management System for the GDA project, and its application, has developed considerably during Step 4, in some cases the processes have been under development while the project is being delivered.
- Robust monitoring and assessment processes have been applied to the project; this has included adequate arrangements for non-conformance management.
- Adequate training arrangements are in place and the UK office has developed systems to overcome the challenges of working with the different IT systems within the company. That said, the assessment of competency is weak, little evidence was provided on how employees were deemed competent for their post. Training is performed, however, the standard criteria to which the individual is assessed against to determine competency was unclear. The assessment is solely based upon line management judgement.
- Although the Pre-construction Safety Report was submitted in December 2009 the Design Reference was not frozen at that time for the purposes of the project. Therefore a number of design changes have been made during Step 4 which the Nuclear Directorate were not formally notified of and the basis of assessment that the assessors were working on has been changing. As a result the Design Reference does not align with the Pre-construction Safety Report submitted in December 2010 and the Pre-construction Environment Report.
- There are a large number of Design Change Proposals which are unincorporated within the engineering documentation. Therefore the design changes are not fully implemented and the supporting design and safety case documentation will be subject to further change after March 2011.
- The Quality Assurance arrangements supporting the development of the design appear adequate, for example design verification, software control, design review, and design change. However the application of some of these processes to the UK project has been limited, for instance the design reviews conducted to date have not included UK requirements and the design change process has not fully considered the impact to the UK safety submission.

In some areas there has been a lack of detailed information as this will not be provided until the site specific phase and this has limited the extent of my assessment. As a result the Nuclear Directorate will need additional information to underpin my conclusions and these are identified as Assessment Findings to be carried forward as normal regulatory business. These are listed in Annex 1; an example is given below:

***AF-AP1000-QA-01: The Licensee shall confirm that Design Reviews have been conducted for Systems, Equipment and Civil structures to support the UK AP1000 design. The Design Reviews should consider the impact of UK or European specific design changes and confirm that the design changes have been well executed and have not resulted in an adverse effect to safety.***

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

- Long lead items and SSC procurement specifications.

One observation identified within this report is of particular significance and will require resolution before The Health and Safety Executive's Nuclear Directorate would agree to the commencement of nuclear safety related construction of an AP1000 reactor in the UK. It is identified in this report as a GDA Issue. However, due to the fact that this will affect many topic areas, this GDA issue will be reported in and progressed under the Cross-cutting topic area. GDA Issue **GI-AP1000-CC-02** is as follows:

***GI-AP1000-CC-02: 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 Environmental Report (SSER), the Master Submission List (MSL) and Design Reference document and deliver final consolidated versions of these as the key references to any Design Acceptance Confirmation (DAC) / Statement of Design Acceptance (SODA) the Regulators may issue at the end of GDA.***

Overall, based on the sample undertaken in accordance with the Nuclear Directorate's procedures, I am broadly satisfied that the processes applied by Westinghouse to maintain and develop the GDA submission during Step 4 and the MSQA claims, arguments and evidence laid down within the Pre-construction Safety Report and supporting documentation submitted as part of the GDA process are adequate for the generic AP1000 reactor design. The AP1000 reactor is therefore suitable for construction in the UK, subject to: satisfactory progression and resolution of the GDA Issue which is to be addressed during the forward programme for this reactor; and assessment of additional information that becomes available as the GDA Design Reference is supplemented with additional details on a site-by-site basis.

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## LIST OF ABBREVIATIONS

ALARP	As Low As Reasonably Practicable
ASN	Autorite de sûreté nucléaire
BMS	(Nuclear Directorate) Business Management System
CAP	Corrective Action Process
CCB	Change Control Board
COMIT	Construct, Operate, Maintain, Inspect and Test
DAC	Design Acceptance Confirmation
DCD	US Design Control Document
DCP	Design Change Proposal
DECC	Department of Energy and Climate Change
DfT	Department for Transport
DRP	Design Reference Point
EDCD	AP1000 European Design Control Document
EDMS	Enterprise Document Management System
ER	Environment Report
FDR	Final Design Review
GDA	Generic Design Assessment
HSE	Health and Safety Executive
HVAC	Heating Ventilation and Air Conditioning System
IAEA	International Atomic Energy Agency
ISO	International Standards Organisation
JPO	Joint Programme Office
LCSR	AP1000 Lifecycle Safety Report
MDEP	Multinational Design Evaluation Programme
MPA	Multi-Party Agreement (involving Utilities partnering with Westinghouse for AP1000)
MS	Management System
MSL	Master Submission List
MSQA	Management of Safety and Quality Assurance
NCB	Non Classified Building
ND	The (HSE) Nuclear Directorate
NDA	Nuclear Decommissioning Authority
NPP	Nuclear Power Plant

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**LIST OF ABBREVIATIONS**

NUPIC	Nuclear Procurement Issues Committee
OCNS	Office for Civil Nuclear Security
OJEU	Official Journal of the European Union
ONR	Office for Nuclear Regulation
PCCS	Passive Containment Cooling System
PCER	Pre-construction Environment Report
PCS	Containment Cooling System
PCSR	Pre-construction Safety Report
PID	Project Initiation Document
PQP	Project Quality Plan
PR	Purchase Requisition
PRA	Probabilistic Risk Analysis
PSA	Probabilistic Safety Assessment
PSR	Preliminary Safety Report
QA	Quality Assurance
QMS	Quality Management System
QP	Quality Plan
RCA	Root Cause Analysis
RGP	Relevant Good Practice
RI	Regulatory Issue
RIA	Regulatory Issue Action
RO	Regulatory Observation
ROA	Regulatory Observation Action
SAP	Safety Assessment Principles
SFAIRP	So Far As Is Reasonably Practicable
SFI	Suggestions for Improvements
SODA	Statement of Design Acceptance
SPF	Smart Plant Foundation
SQEP	Suitably Qualified and Experienced Person
SSC	Systems, Structures and Components
SSD	System Specification Document
SSER	Safety, Security and Environmental Report
TAG	(Nuclear Directorate) Technical Assessment Guide
TL	Technical Lead



**LIST OF ABBREVIATIONS**

TQ	Technical Query
TSC	Technical Support Contractor
UNITS	Unified Issue Tracking System
US NRC	Nuclear Regulatory Commission (United States of America)
WEC	Westinghouse Electric Company LLC
WENRA	The Western European Nuclear Regulators' Association

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- Annex 2: GDA Issues - Management of Safety and Quality – AP1000 (to be confirmed as Resolved in Final DAC)

## 1 INTRODUCTION

- 1 This report presents the findings of the Step 4 Management of Safety and Quality Assurance (MSQA) assessment of the AP1000 reactor under the Health and Safety Executive's (HSE) Generic Design Assessment (GDA) process. The assessment has been carried out on the PCSR (Ref. 11) and supporting documentation and the MSQA processes applied by Westinghouse to develop, deliver and maintain the GDA submission during Step 4. Assessment was undertaken of the PCSR and the supporting evidentiary information derived from the Master Submission List (Ref. 57). The approach taken was to assess the principle submission, i.e. the PCSR, and then undertake assessment of the relevant documentation sourced from the Master Submission List on a sampling basis in accordance with the requirements of ND Business Management System (BMS) procedure AST/001 (Ref. 2). The Safety Assessment Principles (SAP) (Ref. 4) have been used as the basis for this assessment. Ultimately, the goal of assessment is to reach an independent and informed judgment on the adequacy of a nuclear safety case.
- 2 During the assessment a number of Technical Queries (TQ) and Regulatory Observations (RO) were issued and the responses made by Westinghouse assessed. Where relevant, detailed design information from specific projects for this reactor type has been assessed to build confidence and assist in forming a view as to whether the design intent proposed within the GDA process can be realised.
- 3 A small number of items have been identified by Westinghouse as being outside the scope of the GDA process and hence have not been included in this assessment (Ref. 14). Whilst this went some of the way to clarify out of scope there is one additional item with respect to this technical topic area. Documentation listed in the Master Submission List as Level 4 has been submitted to HSE-ND for information purposes only and will be excluded from the submission listing for any interim Design Acceptance Confirmation (iDAC) / Design Acceptance Certificate (DAC) we may issue. Level 4 documentation will include site specific detailed design information or supplier information.

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

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

### 2.1 Assessment Plan

5 The MSQA assessment plan for Step 4 (Ref. 21), followed on from the Step 3 assessment report findings. It addresses the findings from Step 3 and it planned to assess the AP1000 project deliverables and the supporting Quality Assurance (QA) arrangements applied by Westinghouse.

### 2.2 Standards and Criteria

6 The main standards and criteria used are ND's Safety Assessment Principles (SAP) (Ref. 4) which take cognisance of IAEA guidance, including the International Atomic Energy Agency (IAEA) Safety Standard GS-R-3, the Management System for Facilities and Activities Safety Requirements (Ref. 15) and ISO 9001:2008 Quality Management Systems (Ref. 39) in particular:

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

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

- T/INS/017 – LC 17 Quality Assurance (Ref. 26)
- T/AST/027 – Training and Assuring personnel Competence (Ref. 27)
- T/AST/057 – Design Safety Assurance (Ref. 28)
- T/AST/077 – Procurement of Nuclear safety related items or services (Ref. 29)

### 2.3 Assessment Scope

8 The objective of the Step 4 assessment was to review the safety aspects of the AP1000 reactor design by examining the claims, arguments and evidence made in the Westinghouse safety documentation, building on the assessment already carried out for

Steps 2 and 3 and make a judgement on the adequacy of the MSQA arrangements supporting the delivery of the consolidated PCSR and supporting documentation.

9 For MSQA “evidence” is broadly interpreted as being the demonstrable application of the policies and procedures, and confirmation that the final outputs of the project meet the UK Regulator’s requirements as defined in the GDA guidance.

10 The overall basis for the MSQA assessment in GDA Step 4 were:

- Management System, including records management.
- Training and Competency of personnel.
- Audit and Assessment, including non-conformance reporting.
- QA arrangements for the control of design detail development.
- QA arrangements for the control of software use in design development
- QA arrangements for the control of design changes.
- QA arrangements supporting the procurement of GDA services.
- Configuration control of GDA Submission Documentation.

11 It was intended that the conclusion of my assessment in GDA Step 4 would include:

- Verification that all questions and queries that I raised have been resolved and are suitably dealt with in the GDA Safety Submission documentation.
- Where there has been a lack of detailed information which has limited the assessment, further information has been requested through a number of Assessment Findings to underpin the conclusions.
- If full resolution of Regulatory queries has not been achieved during Step 4, a GDA Issue would be raised detailing the remaining action(s) to be taken. These GDA Issues would require Westinghouse to submit a Resolution Plan detailing the approach to be taken to resolve the issue prior to nuclear island safety-related construction.

### 2.3.1 Findings from GDA Step 3

12 The conclusions and recommendations of the Step 3 assessment as detailed in the Step 3 Assessment Report AR09/022-P (Ref. 6) were as follows:

- Westinghouse continues to operate a well developed set of quality arrangements which include sub-tier procedures which are periodically reviewed and audited. A GDA specific Project Quality Plan (PQP) was developed and first issued in March 2008 and a revision issued in March 2009. This is supported by a number of related GDA procedures, also issued in March 2009, that are designed to formalise the interface between the Joint Programme Office (JPO) and Westinghouse. The PQP and procedures have been reviewed by the Regulators and comments were provided formally by letter (WEC70080R (Ref. 40) and WEC70081R (Ref. 59). This work is progressing.
- It was acknowledged that Westinghouse has experienced and knowledgeable staff and a commitment to retain adequate technical resources. Through a number of targeted initiatives, organisational learning and continuous improvement have been addressed. However, the full benefit of these initiatives had not been realised for the

UK GDA AP1000 project, at the time of the Joint Regulators' inspection, as the level of application to the project appears to be minimal. This leads to some doubt regarding the commitment to apply Westinghouse processes to the GDA project.

- There is 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 (DCP). Westinghouse had recognised the challenge and had plans in place to address this situation.
- Westinghouse operates well established arrangements for the selection and surveillance of suppliers as part of its procurement activities. Particular attention is given to the controls applied through the procurement stages for safety related items and services.
- Westinghouse has not always responded in a timely manner to questions, Technical Queries and Regulatory Observations posed by the Regulators, however, this is being addressed and should improve during Step 4. Of particular significance is the need for Westinghouse to address RO-AP1000-035 fully and demonstrate the application of applicable elements of the Westinghouse Management System (MS) to the GDA process. A comprehensive audit has been undertaken by Westinghouse on the applicability of the Westinghouse MS to the UK AP1000 GDA project and a number of corrective actions have been identified. On that basis ND sees no reason why the UK AP1000 GDA project should not proceed to Step 4 of the GDA process on Quality Assurance grounds providing there is a clear and sustained commitment to the application of the full rigours of the Westinghouse MS to the UK AP1000 GDA project. This is of particular relevance to the update and control of the PCSR. The application and adequacy of Westinghouse's proposals will be closely monitored during Step 4 and this will include further Joint Regulators' inspections.

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

13 For the most part the MSQA areas, or topics, assessed in Step 4 are broadly the same as those in Step 3, but the level of detail has been more focused on establishing the evidence demonstrating application of the MS to the UK GDA project. In addition, the Quality Assurance (QA) arrangements supporting design development and configuration control of the GDA submission documentation were assessed.

### **2.3.3 Use of Technical Support Contractors**

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

### **2.3.4 Cross-cutting Topics**

15 MSQA is cross-cutting in nature; therefore information has been shared and integrated within all the technical areas' assessments as and when appropriate, for example the QA arrangements applied to the Heating Ventilation and Air Conditioning (HVAC) system within the Mechanical Engineering assessment was examined and information was shared with the Mechanical Engineering Assessor.

16 The following 'cross-cutting' sub-topics have been identified as being particularly relevant in the MSQA topic area:

- Design Change.

- Safety Function Categorisation and Systems, Structures and Components Classification, as it feeds into the graded approach adopted for procurement and design change assessment.

17 For these instances advice has been shared with the topic leads for these areas and the work reported in the cross-cutting topic report (Ref. 44).

### 2.3.5 Out of Scope Items

18 The following items have been agreed with Westinghouse as being outside the scope of GDA.

- QA arrangements for early procurement of long lead items, to be addressed during the site specific phase.
- Post GDA Westinghouse Project organisation and processes to be applied during Licensing / Permissioning project execution, as project site specific arrangements may need to be developed.
- Documentation listed in the Master Submission List (MSL) as Level 4, as this information was submitted to HSE-ND for information purposes only, for example site specific or supplier design information. Level 4 information is included in our assessment but excluded from the submission listing for any interim Design Acceptance Confirmation (iDAC) / Design Acceptance Certificate (DAC) we may issue.



**3 REQUESTING PARTY'S SAFETY CASE**

- 19 The MSQA arrangements are covered within the Introduction, Section 1.5, of the PCSR submitted at the end of Step 3, UKP-GW-GL-732 Rev 2 (Ref. 11). The section states that Westinghouse's MS meets the requirements set out in ISO9001, 10 CFR 50, ASME NQA-1 and IAEA 50C-QA. It also makes reference to the Project Quality Plan (PQP) for the UK GDA.
- 20 UKP-GW-GL-732 Rev 2 (Ref. 11) states that the central document for the delivery of evidence is the WEC EPS-GW-GL-700, AP1000 European Design Control Document (EDCD) (Ref. 41), supported by related detailed technical documentation and the AP1000 Plant Life Cycle Safety Report (LCSR). The LCSR describes the management arrangements and philosophies of safety and quality that will be applied throughout the lifecycle of UK application of the AP1000; these are documented within the Westinghouse MS. Therefore the QA arrangements are described at a high level; the details of what will be applied to the project are documented in the Project Quality Plan (PQP).
- 21 The revised PQP, Rev 2, submitted in January 2010 was inadequate because it did not fully address all of the comments raised within the Joint Regulators' letter WEC70080R (Ref. 40). It had insufficient information on the project organisation and the design assurance arrangements to be applied to the project. In addition, it was noted a number of working level procedures for the project were yet to be implemented. PQP Rev 3 (Ref. 18) was submitted during Step 4 and has incorporated the Joint Regulators comments.
- 22 During Step 4 the PCSR has been extensively rewritten and was submitted in December 2010 for comment, UKP-GW-GL-793 Rev A (Ref. 12). This version comprises of six volumes, the QA arrangements are described in Volume 1, Chapter 3 – Management of Safety.
- 23 Volume 1, Chapter 3 - Management of Safety explains the Westinghouse MS arrangements, referencing the Project Quality Plan Rev 3 (Ref. 18) and summarising the arrangements for the following aspects of the project:
- Generic Design Assessment
  - Interfaces with Utilities
  - Security
  - Management of Safety through the plant life cycle
  - Role profiles

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

### 4.1 Management System (Including Records Management)

24 Building on the Step 3 assessment, I have based the Step 4 assessment on sampling the application of Westinghouse's MS to the UK GDA project. My main focus has been on the adequacy and implementation of the revised Project Quality Plan and supporting GDA procedures, in accordance with the requirements of IAEA Safety Standard GS-R-3 (Ref. 15) and ISO9001:2008.

25 During Step 3 the UK Regulators provided detailed feedback to Westinghouse and requested further work to be conducted in regard to the effectiveness of the UK GDA MS and its implementation. This resulted in the issue of RO-AP1000-017 and RO-AP1000-035 (Ref. 9). During Step 4, Westinghouse has acted upon the Regulators' feedback and in response to the Regulatory Observations, established an improvement plan to address the gaps within the current UK GDA procedural arrangements and submitted the revised Project Quality Plan (Ref. 18). The improvement plan included the commitment to conduct an internal assessment of the adequacy of the Project MS and to schedule a third party audit once all the MS arrangements for the project have been sufficiently implemented.

26 The third party audit was performed by Lloyds Register against the requirements of ISO9001:2008, and resulted in no significant findings (Ref. 19). Following the feedback from the third party audit I arranged a Joint Regulators' Inspection in July 2010. The objectives of the inspection were:

- To examine the suitability of the Westinghouse MS arrangements to deliver the UK GDA.
- Obtain evidence to support the consideration of RO-AP1000-017 and RO-AP1000-035 close out (Ref. 9).

#### 4.1.1 Assessment

27 The UK GDA project is delivered using the Westinghouse MS, which comprises of three levels; Level I documents are management system company wide processes, Level II documents are Westinghouse company wide policies and procedures, and Level III documents are working level procedures and working instructions.

28 The PQP, UKP-GW-GAH-001 Rev3 (Ref. 18) lists the applicable Westinghouse Level II procedures and lists the Level III procedures created specifically for the UK GDA project. It is noted that the PQP has been further updated to reflect the Project MS developments.

29 The Joint Regulators' inspection in July 2010 (Ref. 20) concluded that the revised Level III procedures and PQP were in the main found to be suitable and sufficient to deliver the project. There was evidence that employees had been trained and were aware of their role and responsibilities. However, at the time of the inspection in July 2010, there were a number of procedures yet to be issued and implemented, such as the Role Proficiency Graphs procedures. That said I found the evidence sufficient to support the close out of RO-AP1000-017 and RO-AP1000-035 (Ref. 9). The implementation status of these procedures has been monitored through the Improvement Plan at regular Technical topic meetings.

- 30 The e-Room is the system used by Westinghouse for temporary storing and transmitting of correspondence and supporting documentation to and from the Regulator. The e-Room has a number of databases and access is restricted for each; this allows Westinghouse to collate information and review it, prior to issuing to the Regulator's Joint Programme Office (JPO). Both Utility companies and Serco have limited access to a number of folders within the database, to allow access to information relevant to their needs (Serco has been contracted to develop the 2009 PCSR in line with regulatory expectations on behalf of Westinghouse).
- 31 During the Joint Regulators' inspection in July 2010, a TQ and RO were sampled to assess the application of the process for capturing, tracking and responding to Regulatory queries. The evidence presented was adequate and the process used for the sample examined followed the Level III requirements. The sample included email correspondence, completed TQ / RO pro forma and supporting information or letters stored within the e-Room folders or rows as PDF files. Any attached supporting documentation is loaded into the e-Room for transmission to the JPO, for these examples this was tested and found to be correct.
- 32 Westinghouse has continued to develop the MS for the project; this has been triggered by regulatory requirements such as the 6 step design change control process and to meet the needs of the project. In a couple of cases the arrangements have not been fully documented and formally issued prior to commencing the task or activity described, for example Working Instruction to Assess the Suitability of Contractor "Key Personnel" issued December 2010, Master Submission List content and Response to Regulatory Issues (RI). No significant issues have been identified as a result of the MS operating in a stage of development, however it is important for an organisation to clearly identify the MS arrangements required to deliver the project as soon as reasonably possible to ensure consistency of approach and product quality.
- 33 In order to manage the interfaces and information, Westinghouse has established a meeting framework involving both UK and US personnel, and, if necessary, invitations are extended to include Utility groups (such as Horizon UK Ltd) and Suppliers, such as Serco. Examples of such meetings are:
- bi-weekly technical meetings
  - weekly teleconference between UK and US
  - monthly executive project board meeting
  - deep dive reviews for complex technical issues
- 34 At the weekly teleconference and monthly project board meetings performance measures are presented and discussed in order to ascertain project risks and resource issues. If through these meetings a project issue or risk is identified within a particular technical area, then a deep dive review is actioned. Examples of where a deep dives have been conducted are in Control and Instrumentation, and in the Mechanical Engineering topic areas. This meeting framework has provided focus and support, strengthening interfaces with the different parts of the business, including Suppliers and Utility companies.
- 35 Records management for the project is governed by the Westinghouse Level II procedure, WEC 17.1 (Ref. 54). Record types are defined within two Record Management Directories. The Directories specify for each record type the applicable regulatory requirements, storage format, retention period, and destruction method. Westinghouse utilise an Enterprise Document Management System (EDMS) for long term storage of business and quality records. Westinghouse also maintains business

and quality records in hard copy and microfilm format at a long term storage facility. The records management process is a component of the Westinghouse Quality Assurance Programme, and as such is regularly subjected to internal assessment and 3<sup>rd</sup> party audits by the industry Nuclear Procurement Issues Committee (NUPIC) an international collaboration between Utilities. Since 2005 it is reported by Westinghouse that no major findings have been raised as a result of these audits and assessments.

36 During Step 4 inspections, I have tested a number of times the records management process and found it to be sufficient. However there has been one report of a missing calculation note within the Fault Studies technical area. This non-conformance was raised as a corrective action and investigated by Westinghouse.

#### 4.1.2 Findings

37 From my assessment of the management system arrangements the following strengths were identified:

- The PQP and the Level III procedures for the UK GDA project have been revised and implemented to meet the requirements of the project and address regulatory comments.
- Clear programme controls and monitoring arrangements have been established, which include a number of Westinghouse US-UK interface internal meetings, and invites to key stakeholder groups such as Utilities and Suppliers.
- Record management arrangements are suitable and sufficient and retrieval of records during inspections has been successful.

38 From my assessment of the management system arrangements the following observations were identified:

- An adequate PQP was not submitted for assessment until April 2010.
- There has been one instance in the Fault Studies technical area, where a calculation note supporting the GDA safety submission has been lost and retrieval could not be achieved. Westinghouse has raised a Corrective Action Process (CAP) to investigate and resolve.
- During the assessment a number of activities being performed were not documented sufficiently within the Westinghouse MS. No significant issues have been identified as a result of the MS operating in a stage of development; however it is important that the MS arrangements are established prior to commencing a project. An assessment finding, AF-AP1000-QA-06 has been raised to ensure the site specific project MS is clearly defined prior to embarking on the Licensing / Permissioning phase.

***AF-AP1000-QA-06: The Licensee shall implement adequate MS arrangements to transition the UK GDA project output into the site specific phase. The MS arrangements must be adequate to meet the requirement of the project during Licensing and subsequent Permissioning activities.***

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

- Long lead items and SSC procurement specifications.

## 4.2 Training and Competency

39 The RP's training and competence arrangements were sampled during three MSQA inspections (Refs. 20, 23 and 42). I used sections of the Technical Assessment Guide (TAG) for Training and Assuring Personnel Competence T/AST/027 Issue 3 (Ref. 27) in my assessment. The TAG is principally intended to provide guidance on SAP EHF.8, which states that a systematic approach should be taken to the identification and delivery of personnel competence. It also assists in the application of other Safety Assessment Principles including MS.2 which set out expectations for training processes and arrangements for assuring competence, it is this area of the TAG which has been used in this assessment.

40 Westinghouse has descriptions of generic job roles for engineers; these are then customised for a specific post, e.g. Engineer, Senior Engineer and Principle Engineer. These three levels are used as a starting point for developing more specific roles and responsibilities, for which employees are recruited against. I have requested on a number of occasions for Westinghouse to demonstrate why an individual is competent to fulfil their role and undertake the task being inspected. I have also assessed Westinghouse's arrangements for training and developing employees, the details of which are discussed below.

### 4.2.1 Assessment

41 New recruits progress through an induction process which includes the provision of two welcome packs, including the high level training requirements (Law, MS Level II procedures and the Corrective Action Process), company information and where to locate the training information.

42 The completion of the training programme is the responsibility of the employee with direction from their Line Manager. Training is available in a number of delivery methods, such as self study (i.e. read and confirm), classroom and quizzes. Each delivery method for the training is allocated a unique training course number which is recorded in SAP once the training course has been completed.

43 Due to the geographical locations and organisational growth there are two IT systems for managing personnel training and qualification within Westinghouse (SAP in the US and Peoplesoft in the UK). As the UK Project offices have both US and UK Westinghouse employees along with a mix of external secondees e.g. from Utility companies, managing and assessing staff training and qualification has proven difficult. To address this, Westinghouse UK offices have set up performance agreements and training profiles which will feed into Role Proficiency Graphs/Passports, this is documented within the UK GDA Project Level III working level procedure.

44 Training and competency is managed through regular performance reviews, the performance reviews include;

- Personal objectives (these are filtered down from senior management),
- Development objectives,
- Key competencies, such as Driving for Results, Delivering customer success etc.
- Line management commentary on performance, mid-term and final review.

45 For example, if a new engineer joins the team the Line Manager will note their current experience and technical knowledge, and start to complete a performance review. Their objectives will start with learning a particular system or equipment design and then once this has been achieved they will be expected to broaden their knowledge of the team

activities. All work performed by the new team member is verified, and the Line Manager will obtain feedback from the verifiers, such as the Senior Engineer on their performance.

46 With respect to the UK GDA Project, it was noted that a number of objectives relating to the project were allocated to some of the design team members interviewed during the MSQA inspections (Refs. 23 and 42) and training had been provided through pre-job briefs. Objectives such as:

- provide quality response to UK Regulatory RI/RO/TQ's by the required time; and
- participate and support UK GDA Technical meetings.

47 During the interactions with the technical leads it is apparent that both UK and US personnel are aware of the requirements defined in the Project Quality Plan (UKP-GW-GAH-001) and the UKP Level III procedures. Westinghouse's arrangements for training meet the basic requirements of the Technical Assessment Guide for Training and Assuring Personnel Competence T/AST/027 Issue 3 (Ref. 27).

48 For the assurance of personnel competency the Westinghouse MS places the responsibility on the Line Manager, there are no role specifications set at a company level other than the job vacancy notices, which specify technical and professional qualification requirements for interview selection. Although there are adequate training arrangements and performance agreements it is difficult to see how Line Management makes a suitable and consistent judgement on employee competency. It was noted in the Balance of Plant Engineering group, the Line Manager has developed in addition to the MS arrangements a role matrix, which assigns a Lead Engineer, a Cognisant Engineer and a Support Engineer, a sample of performance agreements in this group were examined and found to be satisfactory. However, this approach is not standard across the organisation, so assessment of competency will be followed up as an Assessment Finding **AF-AP1000-QA-04** (Annex 1).

***AF-AP1000-QA-04:** The Licensee shall implement adequate arrangements to demonstrate their Intelligent Customer capability for Design development activities. These arrangements shall include assessment of supplier competency for design development activities.*

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

- Long lead items and SSC procurement specifications.

49 It was noted in the Joint Regulators' Inspection in July 2010 (Ref. 20) that there is reliance on a small number of key employees who have the understanding of the UK Regulatory expectations and UK licensing arrangements, and knowledge on US licensing and design change. This does result in a level of vulnerability for the project; however the project meeting structures and metrics enable information and knowledge to be shared mitigating the risk.

#### 4.2.2 Findings

50 From my assessment of the training and competency arrangements the following strengths were identified:



- Structured induction and generic training programmes are in place for new recruits. Training and assessment can be delivered using a number of methods, i.e. Read and Confirm, Online training with quizzes and Classroom training.
- Clear role and responsibilities are defined both within the MS and training profiles examined.
- Training records have been made available upon request and additional processes have been developed for the UK GDA project to resolve difficulties with current IT access constraints.

51 From my assessment of the training and competency arrangements the following observations were identified:

- Assessment of competency is reliant on the judgement of Line Management as there are no standard criteria for the specific roles within the Westinghouse organisation. This does not fully address the requirements of T/AST/027 (Ref. 27). However, considering that there is evidence of criteria being set within individual departments, and the recruitment and selection process used includes clear technical and professional qualifications, this is not considered to be a significant problem for GDA for these reasons it is deemed proportionate to follow this up as an Assessment Finding **AF-AP1000-QA-04** (Annex 1).

**AF-AP1000-QA-04:** *The Licensee shall implement adequate arrangements to demonstrate their Intelligent Customer capability for Design development activities. These arrangements shall include assessment of supplier competency for design development activities.*

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

- Long lead items and SSC procurement specifications.

#### 4.3 Audit and Assessment (Including Non-Conformance Reporting)

52 I have sampled the application and delivery of Westinghouse's Quality Assurance Programme to the UK GDA project, sampling reports from both Internal Audits and Self Assessments conducted on the GDA project.

53 In the assessment I have examined the learning from the Management Review activities and sampled examples of non conformance reporting and corrective action. I have assessed the evidence presented by Westinghouse against IAEA Safety Standard GS-R-3 (Ref. 15) and Technical Assessment Guide LC17 Quality Assurance T/INS/017 (Ref. 26).

##### 4.3.1 Assessment

54 Westinghouse has annual Internal Audit and Self Assessment programmes in place, the UK GDA project has been included in these programmes. During Step 4, Westinghouse has performed Internal Audits on the Project MS arrangements, and Project Management, and has conducted a Self Assessment on the management of TQs and ROs. In addition to the Internal Audit and assessment activities Westinghouse arranged for a Third Party assessment to be performed focused on the adequacy of the Project

Level III MS arrangements. This was conducted to gain confidence in the application of the MS to the Project, including the adequacy of local arrangements.

- 55 Issues raised from these audits and assessments are assigned a significance level which determines the level of investigation required. All issues are recorded in the Corrective Action Process (CAP) database as corrective actions. From the Self Assessment conducted on the UK GDA Project during Step 4, a number of Suggestions for Improvements (SFIs) were raised, associated with clarity of language used and inconsistency between the procedures for TQs and ROs respectively. No non-conformances were identified; the SFIs were actioned using the CAP system.
- 56 Westinghouse perform a management review every year, and the last three years were submitted for assessment during Step 4. From the information received it is clear that Nuclear Power Plants (NPP), which includes the GDA project, have struggled over the last couple of years to meet internal targets associated with Root Cause Analysis (RCA) completion rates, Commitment close-out to time and the number of Repeat events. Following implementation of a number of Customer 1st Projects, CAP Issue Reports and management intervention the performance has improved.
- 57 The FY09 Management Review for NPP was conducted in June 2010, the trending analysis highlighted the majority of learning events raised from Internal and External Audits are associated with Design Control, Document Control and Resource Management. The majority of these are due to inadequacies in specifications, Level III procedures and/or training. As expected a number of actions have been raised to address these Management Review findings, the progress against these CAPs was examined in August 2010 (Ref. 23).
- 58 The commitments were due for completion at the end of Sept 2010, at the time of the inspection in August 2010 close-out evidence was being collated and progress being made. For example, a Customer 1st Project had been launched. The root cause of the findings has been identified and counter measures and metrics to drive the improvement have been designed ready for implementation, demonstrating strong commitment to action close-out.
- 59 Westinghouse has established processes for audit and assessment, programmes are being adhered to and resulting findings are actioned and tracked to completion. This is aligned to principles within IAEA Safety Standard GS-R-3 (Ref. 15) and TAG T/INS/017 LC 17 Quality Assurance (Ref. 26).

#### 4.3.2 Findings

- 60 From my assessment of the audit and assessment arrangements the following strengths were identified:
- Annual audit and assessment programmes are produced every year and performance against the schedule is monitored. These programmes have included the UK GDA Project.
  - Learning from audit, assessment and non-conformance reporting is used within the Management Review process, and action is taken to address any weaknesses identified during the reviews.
  - Issues from audit and assessment activities are graded based upon significance and there is evidence of actions being assigned, recorded and tracked to completion.



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61 Based upon the sample assessed, no significant concerns were identified associated with Westinghouse's audit and assessment processes.

#### 4.4 Control of Design Detail Development

62 I have assessed the arrangements for controlling the development of the design detail and sampled their application to the GDA project. The Design Safety Assurance TAG, T/AST/057 (Ref. 28) looks at how safety is integrated into the design production process, and has been partially used for assessing the detailed design development phase.

##### 4.4.1 Assessment

63 The design codes and standards applied to the AP1000 are documented within APP-GW-G1X-001 Rev 5 (Ref. 30). The codes and standards specified in this document align to the Design Certification Document (DCD) submitted to US NRC in 2002. Changes to the document are subject to the design change proposal process. It is Westinghouse's expectation that all Design Engineers know what standards and codes they need to work to.

64 This current version of the design codes and standards (Ref. 30) does not fully cover the codes and standards recognised within the UK. The suitability of the US codes and standards has been addressed on a case by case basis within each of the technical topic areas where it applies. For Electrical Systems a gap analysis between the US codes and standards and the European / UK requirements has been completed and recorded in UKP-GW-GL-059 (Ref. 35), revision 1 of the document was presented during the August 2010 inspection. This gap analysis within Electrical System triggered a Design Change Proposal (DCP) and the affected documents have been identified, however, they will not be amended to reflect the approved DCP until a Utility contract is signed.

65 The three main Westinghouse Level II procedures governing the design development are:

- WEC 3.1.1 - Design Planning and Project Development (Ref. 47),
- WEC 3.3.1 - Design Reviews (Ref. 48), and
- NSNP 3.4.1 - Change Control for the AP1000 Program (Ref. 45).

66 Design development is assessed through Design Reviews. The Design Review is regarded by Westinghouse as a critical stage of the design process, its purpose is to minimise risk to both the company and customer and is integral to the design verification process. Design Reviews are conducted on either the equipment or the system. Once the need for a Design Review has been identified by the Cognizant Manager, a chair is appointed followed by scope definition, schedule and creation of a multi-disciplined team.

67 The Design Reviews involve three stages, Preliminary, Intermediate and Final. As the AP1000 was developed from the AP600 detailed design, it was concluded that no benefit would be achieved from conducting a preliminary review on systems already reviewed during the AP600 design so all open items from the AP600 design reviews are being collated and closed through the AP1000 intermediate reviews. The intermediate review is generally done when the layout and schematic drawings with supporting calculations are at a stage where improvements can be made. The key output is the compliance matrix which addresses the compliance to the DCD sections and US regulatory requirements. Design Reviews look neither at the UK specific design changes nor the UK regulatory requirements; and they are constrained to the AP1000 standard plant.

- 68 The following Design Review examples have been sampled during the MSQA Inspection in August 2010 (Ref. 23); the Intermediate Design Review (IDR-09-23) and Final Design Review (FDR-09-23) for the Steam Generation System. The Cognizant Manager responsible for the design development and review explained the process followed and the results achieved. The Design Review Team included technical members, some of which were independent to the design development.
- 69 The Intermediate Design Review record package for the Passive Containment Cooling System (PCCS), APP-PCS-GGR-200 Rev A (Ref. 36) was examined. The generation of this type of review pack is not required by the Westinghouse MS and therefore is not common practice across the organisation. However, it is seen as good practice by this department. The completed IDR package examined included the following:
- review team members;
  - safety related functions reviewed;
  - non-safety related functions reviewed;
  - system diagrams;
  - DCP lists applicable;
  - FMEA results;
  - equipment lists and descriptions; and
  - open items / open 'chits'.
- 70 Three months prior to the scheduled Final Design Review (FDR) meeting, readiness reviews were conducted to ensure the design development was progressing to programme. In preparation for the FDR meeting the System Specification Document (SSD) (APP-SGS-M3-001 Rev 3) was updated for final review and sent out to the review team along with details on DCPs, open items and the US DCD compliance matrix.
- 71 The status of 'chits' is monitored with the aid of a metric by the Cognizant Manager, this metric illustrates the number of 'chits' opened, closed, or requiring DCP against each scheduled FDR. Chits can only be closed by the Cognizant Manager and the FDR Chair.
- 72 Westinghouse has introduced a Construct Operate Maintain Inspect and Test (COMIT) project, however the process involved is outside the current MS and is yet to be documented and approved. The COMIT review involves a multidiscipline team focusing on a particular area or room and considering the likely tasks personnel will have to undertake. The reviews namely concentrate on Operate, Maintain, Inspect and Test rather than construction matters. Decommissioning, safety assumptions or risk reduction (ALARP) are not part of the reviews currently. The review process is still developing and could be extended to cover these topics. Any findings from the reviews are recorded as Open action items on the Smart Plant Foundation database for the relevant Cognizant Manager to consider.
- 73 In order to assess the QA arrangements governing the design development process, the Heating Ventilation and Air Conditioning (HVAC) system within the fuel pond area was taken as an example. For this system a Lead Design Engineer, a Cognizant Engineer and a Support Engineer have been assigned. For the HVAC system, the Cognizant Engineer has the responsibility for the system design and the Lead Engineer has the responsibility for liaising with the external supplier, Shaw Charlotte, and developing the design. The assignment of Lead, Cognizant and Support Engineers is unique to the Balance of Plant Engineer group, where the HVAC is designed.

- 74 For the HVAC system, Westinghouse has produced the System Specification Document (SSD) Sections 1 and 2, which identifies the system requirements and design criteria. The development of the design and supporting documentation is contracted to Shaw Charlotte through a Purchase Order supported by an Interface Agreement. The Purchase Order with Shaw Charlotte is generated by a Purchase Requisition (PR), for example PR1000208748 requires Shaw Charlotte to provide HVAC engineering services to support the development of the Design Finalisation Plan. A deliverable identified on the PR was a 3 month work plan, which was witnessed during the inspection. This work plan listed the tasks associated with completing the design development and issue of the SSD and Piping & Instrumentation Drawings (P&IDs). It was noted that Shaw Charlotte are only contracted to provide engineering services to the standard US plant design, therefore will not be used to develop the UK project specific requirements, this is performed by the Westinghouse Design team.
- 75 The Interface Agreement, APP-GW-M8-045 Rev 0 (Ref. 37) quoted in the Purchase Order, details the level of sanctioning Westinghouse will perform on supplier produced documentation. For example, for SSDs, Design Criteria documents and P&IDs, Westinghouse will Review and Concur, for other document types Westinghouse, depending on design hierarchy will, either Review and Comment or Sign for Acceptance. For the Shaw Charlotte contract the documents need to be produced using the Westinghouse templates and be subjected to the same preparation and verification processes. With respect to the SSD version available in November 2010, Shaw Charlotte had signed the prepared by and verified by boxes. When it was submitted to Westinghouse, the Lead Design Engineer reviewed and concurred, signing a second verification box confirming the technical accuracy on behalf of Westinghouse. It was noted that, if certain design criteria need to be included in the SSD, Westinghouse will suggest to Shaw Charlotte suitable wording to be included in the document, this is generally conducted through email correspondence.
- 76 If a design change is required, Shaw Charlotte has access to the Westinghouse DCP process and Smart Plant Foundation (SPF) database, therefore Shaw Charlotte is able to raise DCPs if required within the Westinghouse system. If Shaw Charlotte raises a DCP, Westinghouse will identify a proxy to review and sign, as Westinghouse retains the Design Authority role for the AP1000.
- 77 The HVAC system has a number of system interfaces, these interfaces are identified in the SSD Appendix A. The functional requirements of these system interfaces are recorded within the Smart Plant Foundation database as either dependent systems (inputs) or supporting systems (outputs). The Design Engineers are responsible for maintaining the data within these fields and using the information when developing the system design within their area of responsibility.
- 78 When design changes are approved the Lead Design Engineer will work with a Designer to model the changes within the 3D Modelling tool in order to generate the layout drawings following the change. Any calculations will be draft at this stage requiring verification later in the Design Review process.
- 79 The current SSD is at Revision D it is expected to be updated to Revision 0 and placed under configuration control shortly, however the current revision is based upon the AP1000 standard plant and does not include UK specific requirements. Westinghouse stated that a UK version incorporating the UK specific design change requirements will not be generated until a Utility contract is signed, so Revision 0 will exclude the UK approved design changes agreed within the GDA project. To ensure that the Safety Submission, PCSR Chapter 23 aligns with UK requirements and expectations the

Chapter will need to be written to include the SSD and any approved UK specific design changes relevant to this system. The Lead Engineer for the HVAC system is currently reviewing the PCSR Chapter for technical accuracy and alignment and is responsible for informing the Environment Technical Lead of any changes which may have impact on the Environment Report (ER).

- 80 Design verification is described in Westinghouse Level II procedure, NSNP 3.3.3 - Design Verification by Independent Reviewer or Alternative Calculations (Ref. 38). A verifier is assigned by the Line Manager; the verifier must be competent, understand the scope and applicability of the work and is independent from the work performed. The verification can be either an independent review or an alternative calculation method; the method is identified by the Cognizant Manager, generally identified at the time of assigning a Design Engineer and Verifier. The intention of the verification is to ensure that the design calculation or analysis is correct.
- 81 If calculations are done using Microsoft Excel, the equations used are listed and the inputs are recorded. A PDF file of the raw data and the Excel Spreadsheet calculation is produced and attached to the Calculation Note to support the verification step. The Verifier will check that the equation in Excel and the inputs used are correct, in some cases either an alternative calculation method or hand calculation is used to confirm the working out. The steps within this process meet the principles set out in T/AST/057 (Ref. 28).
- 82 The 3D model for the HVAC system within the Auxiliary Building was presented, the tool used is WEMMEX, a proprietary system. The purpose of the modelling tool is to check layouts and generate the 2D layout drawings. This can not be done automatically by the model as it is not under configuration control, so the Modeller will transfer the data from the model into the 2D drawing annotating the changes using 'bubbles'. The Verifier must then compare the 2D drawing against the previous version to ensure the required changes have been identified and incorporated into the drawing correctly and that no other uncontrolled changes have been introduced prior to document approval, this is a labour intensive exercise. Revised layout drawing APP-VAS-M0-550 was presented as an example; the drawing was amended and up issued from Rev 0 to Rev 1. APP-VAS-M0-550 Rev 1 amendment history had quoted the incorporation of DCP APP-GW-GEE-355, 760 and 1267.
- 83 The scope of the Design Reviews conducted so far has been limited to the AP1000 standard plant requirements and has not included any UK specific design changes. Westinghouse believe that the verification and Design Change Proposal approval processes ensure that the change has been engineered correctly, however they have submitted a Design Review strategy for the UK specific design changes to AP1000 systems which involves a graded approach. The systems have been grouped into the following categories which are listed together with Westinghouse's expectation on the level of design review to be conducted is stated:
- AP1000 Universal Design – no UK or European only design change proposed so no further design review to be conducted
  - Design Enhancement for European Design – a full or partial review will not be necessary as the DCP process would provide adequate scrutiny; the systems will be assessed on a case by case basis.
  - Specific Design for 50Hz Applications – a design review will be required; however each system will be assessed to ascertain whether a partial or full review would be suitable.
-

- Site Specific Design – a full design review will be conducted.

84 A detailed schedule for this design review work will be developed once contractual arrangements are in place with a potential customer. This design review strategy is for the AP1000 systems. It is not clear what arrangements for design reviews will be applied to UK specific design changes associated with structures and components.

#### 4.4.2 Findings

85 From my assessment of the control arrangements for design detail development the following strengths were identified:

- The Design Reviews are conducted in three stages, Preliminary, Intermediate, and Final, these are conducted by multidiscipline teams and chaired by an independent.
- The Steam Generation System package sampled during the inspection demonstrated good use of briefing packs and collation of relevant data.
- The COMIT reviews have been introduced and the process is developing, this is regarded as a useful tool to assess maintainability and operational ease.
- The design verification process is documented within Westinghouse MS and the arrangements meet the principles in T/AST/057 (Ref. 28), such as allocation of an independent verifier, use of alternative calculation methods.

86 From my assessment of the control arrangements for design detail development the following observations were identified:

- The COMIT reviews are still in infancy stage, are not documented within the MS and do not cover sufficiently such topics as, safety case assumptions, ALARP and Human Factors. However the COMIT project does not claim to perform these topic reviews and so this has been raised as a missed opportunity within the Human Factors topic report (Ref. 43).
- The 3D model is not configuration controlled and is used for the production of 2D layout drawings, this places responsibility on the document checker and verifier to stop any transcription errors and is a labour intensive exercise.
- Design Reviews conducted so far have been limited to AP1000 standard plant and have not considered the UK specific design changes or regulatory requirements. A Design Review strategy for the UK has been developed for the AP1000 systems, however a detailed schedule is yet to be developed and the UK design review strategy for AP1000 equipment and civil structures is not fully understood. This will be followed up by Assessment Finding **AF-AP1000-QA-01** (Annex 1).

**AF-AP1000-QA-01:** *The Licensee shall confirm that Design Reviews have been conducted for Systems, Equipment and Civil structures to support the UK AP1000 design. The Design Reviews should consider the impact of UK or European specific design changes and confirm that the design changes have been well executed and have not resulted in an adverse effect to safety.*

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

- Long lead items and SSC procurement specifications.



#### 4.5 Software Control Supporting Design Development

87 My assessment has focused on the arrangements for the control of software use in design development, sampling the arrangements for validation of software codes, access and user controls in accordance with ISO9001:2008 requirements (Ref. 39) and IAEA Safety Standard GS-R-3 (Ref. 15).

##### 4.5.1 Assessment

88 Each software code and program has a Responsible Manager allocated, who ensures that the software code or program is working properly, the software is configuration controlled, user access is maintained and reported errors are assessed / resolved.

89 Once a software need is identified through Product and Project planning the decision to acquire or develop in-house is made. For both sources of software, validation is performed prior to configuration control and release; this is performed within a testing configuration control system. Validation in Westinghouse is defined as a set of tests performed to check the performance of the software. Verification is checking that the validation was done correctly against procedure. These arrangements demonstrated adequate controlled issue of software.

90 For externally supplied safety related software, if the Supplier is on the Qualified Supplier's List, the Supplier will issue a set of validation test cases along with the software. Westinghouse will re-run these validations tests and check against the Suppliers' results. For software not procured from a Qualified Supplier the procedures and validation tests need to be developed in-line with Westinghouse arrangements.

91 The Responsible Managers hold a user list for each item of software they are responsible for; if someone needs to gain access the Line Manager must submit a request to the Responsible Manager. It is the responsibility of the Line Manager, not the Responsible Manager, to ensure the User is trained and competent to use the code.

92 All engineering with respect to software is restricted to designated computers. The Engineer will check the computer system state prior to use. Users are encouraged to record the software configuration used, the computer used and the date conducted on the design records. The design verification activity confirms the software, system and task have been completed correctly. The competence of the individuals performing the Authoring and Verification is confirmed by the Line Manager's approval signature.

93 An example of externally supplied software was presented during a MSQA inspection (Ref. 23); Westinghouse had purchased software for Pipe Stress analysis from DST Switzerland. The software was developed and validated by the Supplier. Upon receipt the Responsible Engineer validated the software using the Supplier's test cases and recorded the results in a Calculation Note. The Calculation Note was only applicable on PepS Ver. 3.0 and PIPESTRESS Ver. 3.6.2. After checking that the results obtained were the same as the supplied set of test results the software was transferred to configuration control and released to the users via a Release Letter (LTR-SST-10-26 Authorising release of PIPESTRESS 3.6.2).

94 An example of a software error investigation was sampled during the inspection (Ref. 23), HOTSPOT Version 6.1 Cladding Heat-up Rate and Burst. The error was associated with the temperature calculation and recorded in Unified Issue Tracking System (UNITS) as a Cat. A error. A CAP was raised to investigate, this identified no work-around required and no impact. Upgrading to version 7.0T3 and 7.0T9 was identified as the resolution. There were 4 commitments raised under the CAP, commitment 1 was to perform an apparent cause analysis and commitment 4 was to complete and document the validation

of the resolution. Commitment 4 was sampled and referenced a release letter (LTR-LIS-08-656), releasing Version 7.0 for use. The validation was recorded in a Calculation Note (Sept 2008 – Software Validations Package for HOTSPOT Version 7.0). The summary of the results and conclusions stated there were no exceptions to the program's Safety Evaluation Report limitations and that the test configured version can be released for production use.

95 This Calculation Note referenced another Calculation Note which was generated to amend the software specification. Within Section 6 of this document, amendments to user documentation were identified. The relevant information was communicated to all Users of HOTSPOT via the Release Letter LTR-LIS-08-630.

96 This example demonstrated the value of the UNITS tool for tracking error reporting and showed evidence of good linkage through the use of document referencing between the error record and any corrective action taken.

97 Training of Users on the software is managed by Line Management; a new User will be given training on the relevant Level II and III procedures, and the User Manual. Classroom training will also be performed and the new User will be tasked with performing a set of test calculations which are verified by an Experienced User. Evidence of the classroom training and completion of the test calculations could not be provided during the inspection. Competency assessment of the User is the responsibility of the Line Manager and is done based upon judgement; refer to Section 4.2 Training and Competency.

#### 4.5.2 Findings

98 From my assessment of the software control arrangements supporting design development the following strengths were identified:

- Software code development and control processes are adequately managed through the infrastructure of Responsible Engineers, identified users and designated computers.
- Error reporting is recorded, tracked and resolved and cross referencing between calculation notes and corrective actions was used to good effect.

99 From my assessment of the software control arrangements supporting design development the following observation was identified:

- Competence of the user is based upon Line Manager judgement; refer to **AF-AP1000-QA-04**.

**AF-AP1000-QA-04:** *The Licensee shall implement adequate arrangements to demonstrate their Intelligent Customer capability for Design development activities. These arrangements shall include assessment of supplier competency for design development activities.*

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

- Long lead items and SSC procurement specifications.

## 4.6 Control of Design Changes

100 My assessment sampled the QA arrangements for controlling the identification, impact assessment and implementation of design changes against T/AST/057 Design Safety Assurance (Ref. 28). I have sampled a number of design changes during this assessment in order to test the application and adherence of the Westinghouse MS arrangements for change control. The management arrangements and tracking of individual design changes within the scope of GDA is covered by the Cross Cutting topic report (Ref. 44).

### 4.6.1 Assessment

101 The Design Reference was submitted to the Regulators in May 2010 defining the Design Reference Point at 23 December 2009. For the purposes of the project the design reference was not frozen, therefore a number of design changes have been made during Step 4 which ND have been unaware of. We wrote to Westinghouse in letter WEC70190R dated 18 June 2010 (Ref. 49), explaining our expectations for the Design Reference and change control. This letter explained the arrangements for inclusion of design changes in the GDA submission post the design freeze. It introduced the Regulator's 6 step process for agreeing design changes that could be brought into the scope of GDA, and it raised concerns about the Design Reference point document dated 23 December 2009.

102 The MSQA inspection on the control of design development and change control in August 2010 (Ref. 23) highlighted that changes to the design were being made by Westinghouse but were not formally submitted to the Regulators. This resulted in a Regulatory Observation Action, RO-AP1000-088.A5 (Ref. 9), being raised.

103 Following on from further discussions, Westinghouse responded in letter WEC000385 dated 8 October 2010 (Ref. 50) acknowledging that design changes had been made without formal notification to the Regulators. This letter (Ref. 50), noted that the Design Reference had been revised and frozen on 16 September 2010, therefore a number of historic design changes had been made to the Design Reference and would need to be progressed through the 6 step process. However, a number of the safety significant design changes had been triggered by the Step 4 assessment therefore the relevant assessors were aware of the changes.

104 Westinghouse proposed a way forward seeking Regulatory agreement for inclusion of design changes that originated prior to the 16 September into GDA based upon the safety significance of the design change modification. The Design Reference document was revised to accommodate this Regulatory agreement process (Ref. 34). This is discussed further in the Cross Cutting topic report (Ref. 44).

105 In addition, Westinghouse has developed a project instruction, UKP-GW-GAP-026 Rev 0 (Ref. 51), on controlling the Design Reference point for GDA after the 16 September 2010. This instruction incorporates the Regulators' 6 step 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 on inclusion into GDA (Ref. 50). Once agreed by the Regulators, Westinghouse's intention is to include these design changes into Table 5 of the Design Reference document (Ref. 34).

106 Management of design changes within Westinghouse is an established process; this process was examined during the MSQA inspections in Pittsburgh (Ref. 23 & 42). Design change optioneering is performed within the technical teams, the discussion and justification of the optioneering is not formally recorded. Once a design change option



has been decided the proposal is routed through the Design Change Proposal (DCP) process documented by the Westinghouse Level II procedure NSNP 3.4.1 (Ref. 45).

- 107 There are three sources which can trigger a design change within Westinghouse: Designers, Utilities and / or Regulators. In the current design finalisation stage, a design change is only initiated if a design safety feature could be improved or if a design feature could be improved from an operation perspective; this reduces unnecessary cost and impact to the design documentation. When a DCP is initiated it is first classified by the initiator, and dependant on the class will either be discussed at the Change Control Board (CCB) or discussed with the Responsible Manager. DCPs are classified 1, 2 or 3 (Class 1 being the highest), in accordance with the procedural requirements. The criteria are largely associated with the impact to the US DCD commitment and the potential cost to the company; it does not consider the safety consequence of an inadequately conceived or executed modification, which would be the normal expectation for the UK.
- 108 To meet the UK regulatory expectations, Westinghouse started applying a UK safety categorisation to the DCP process in July 2009 limited to three categories; although this was later extended to four categories. This is documented in the Design Change Proposal Initiation form and is termed as UK Safety Categorisation for Modification. This UK safety category is allocated to the DCP in isolation to the DCP Class; there is no correlation between the UK Safety Categorisation for Modification and the DCP Class.
- 109 The DCP Class links to the level of scrutiny performed by the CCB and the scope of impact assessment performed. For Class 1 and 2 changes, an impact assessment is conducted and once all impact assessment sheets have been completed and comments incorporated, the DCP package is verified, approved and archived. The approval step authorises the change to be implemented. It is the expectation that the DCP change details will be incorporated into the design documentation within 6 months of CCB approval, or when a total of six DCPs are impacting the document, or in accordance with the design schedule. That said an update provided in response to Technical Query TQ-AP1000-627 (Ref. 8) showed that in May 2010, more than 800 DCPs which were approved more than 6 months ago remained un-incorporated in at least one of the documents impacted by each change. A proportion of these are safety significant and a list of all the DCPs impacting GDA is provided within the Design Reference (Ref. 65). Un-incorporated DCPs applicable to the UK AP1000 GDA Project will be followed up under the Cross-cutting GDA Issue, **GI-AP1000-CC-02** (Ref. 44).
- 110 In the case of UK specific design changes it is understood by ND that no implementation of the design change will be performed until a Utility contract is signed i.e. any documents impacted by a UK GDA specific design change will not be amended to incorporate the design change details. That said, the implementation of any Westinghouse approved changes to the standard AP1000 generic fleet including UK i.e. prefixed by APP, will be progressed by Westinghouse.
- 111 A number of DCPs were sampled during a MSQA inspection (Ref. 23) these are listed below. The review focused on the scope of the change, who was involved, the class and UK category and finally the details of the safety and licensing impact assessment performed by Westinghouse.
- APP-GW-GEE-316 – Change to mainstream piping (Initiated January 2008, Class 1, no UK Cat allocated). Safety assessment identified that re-analysis is required.
  - EPS-GW-GEE-006 – KSB Wet Winding Reactor Coolant Pumps (Initiated December 2009, Class 1, UK Cat 2). No impact on PRA. Safety assessment identified no

significant impact however reanalysis will have to be performed. Licensing assessment identified EDCD, EPS-GW-GL-700.

- APP-GW-GEE-1119 – Shield Building (Initiated November 2010, Class 1, UK Cat 2). No impact on PRA. Safety assessment identified impact associated with radiation fields outside building however Westinghouse states the current analysis is based on more conservative position. Licensing assessment identified EDCD.
- APP-GW-GEE-1942 – Height of Stack ventilation (Initiated August 2010, Class 1, UK Cat 2). Developing further from the DCP raised for the China project (DCP916). No impact assessment has been completed at the time of the inspection.
- EPS-GW-GEE-009 – Battery ventilation (initiated June 2010, Class 1, currently at UK Cat 3 but initiator recommending UK Cat 4). DCP only in draft therefore no impact assessment sent out at the time of the inspection.
- EPS-GW-GEE-1 – Normal Residual Heat Removal System (UK Cat 4). There is no impact to nuclear safety and is regarded as non-safety related in accordance with US definitions. Due to the nature of the change and claims made in response to Regulatory Observations RO-AP1000-047, RO-AP1000-052 and RO-AP1000-054, (Ref. 9) ND would expect a higher categorisation.
- APP-GW-GEE-2085 – HEPA Filtration. Limited interaction with the Probabilistic Risk Analysis (PRA), this is because the HVAC system is not regarded by Westinghouse as a safety related system according to the US definitions. So for the purposes of the change, to understand the potential release, radiation dose calculations were performed but did not form part of the US PRA analysis.

112 In summary, the DCPs reviewed did not address the impact to the UK GDA project, i.e. they did not fully consider UK affected documents such as the PCSR and ER, but they were limited to the EDCD (Ref. 41). Changes to the AP1000 fleet are being progressed by Westinghouse but were not formally notified to HSE-ND at time of approval for consideration into GDA. It was not visible to the Regulator's assessment team in August 2010 what changes have been engineered since the Design freeze in December 2009 and what changes are yet to be engineered. In addition, the full rigour of the CCB is only applied to Class 1 changes, which does not take into account the UK safety categorisation. These concerns were discussed with Westinghouse and a CAP was raised to address the findings.

113 This CAP also included the inconsistent and incorrect application of the UK Safety Categorisation for Modification to the Design Change Proposals. The CAP has a number of commitments, looking at increasing the involvement of UK Licensing impact assessment, performing training and education on the UK safety categories, and ensuring that the PCSR is flagged as an impacted document for UK impacted changes.

114 An update on the progress made against these commitments at the end of March was provided under the cover of letter WEC000541 dated 1 April 2011 (Ref. 53). The letter explained that the CAP 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 ND's expectation that the action associated with the application of the UK safety categorisation will be resolved within GDA prior to any DAC we may wish to issue. This will be followed up as part of the Cross-cutting GDA Issue **GI-AP1000-CC-02** (Ref. 44).

- 115 In response to the CAP commitments, a summary of the changes made to the Westinghouse Level II Procedure NSNP 3.4.1 Change Control for the AP1000 Program are as follows:
- Smart Plant Foundation has been modified in November 2010 to include the UK Safety Categorisation as a separate field in the database to increase visibility of the UK category and allow ease of searching and reporting on design change status.
  - A new section in the procedure has been added to allow the initial creation of a site specific or unit specific design document as a result of a DCP requiring a deviation from the standard plant.
  - It was the intention that the Technical Leads for the PCSR will become the document owners for their relevant area and chapter. Therefore if a UK applicable design change has the potential to impact the PCSR Chapter, the relevant UK document / chapter will be clearly identified in the impact assessment and the Technical Lead will have responsibility to review the impacted document. However the UK PCSR does not have the same legal standing as the US Design Certification and, at this point Westinghouse does not have a UK customer therefore the decision has been taken not to specify the UK documents, such as the PCSR and Design Reference, but to only use the general European one, the European DCD (Ref. 41).
- 116 It is recognised that during site specific design development or construction, the number of design changes may increase as a result of operating experience. The QA arrangements to manage this flow of information will need to be considered to ensure that the design documentation reflects as-built plant. This has been raised as an assessment finding, **AF-AP1000-QA-05** (Annex 1).

**AF-AP1000-QA-05:** *The Licensee shall make and implement adequate QA arrangements for managing and controlling design changes triggered by learning from experience activities during construction, including suitable records management arrangements to ensure the plant design documentation reflects as built status.*

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

- First structural concrete.

#### 4.6.2 Findings

- 117 From my assessment of design change control the following strength was identified:
- Smart Plant Foundation provides a useful tool for recording and tracking the design changes. The database also allows visibility of design documentation impacted by the change.
- 118 From my assessment of design change control the following observations were identified:
- Changes to the Design Reference have been made during Step 4 without consideration of the impact on the safety submission and without formal notification and agreement with the Regulators. Further work by Westinghouse has been requested by ND under the cover of RO-AP1000-103 (Ref. 9) to provide confidence that the Design Reference and Safety submission does incorporate the design changes agreed for inclusion into GDA. The response is expected at the end of GDA,

so the timing of this additional information makes it difficult to assess within Step 4, and so this will be followed up within GDA Issue **GI-AP1000-CC-02** (Ref. 44).

- A large number of DCPs will remain unincorporated into the impacted Design Reference documentation (i.e. System Specification Documents, Design Specifications and Codes and Standards) at the end of GDA Step 4. For UK specific modification requirements, approved changes will not be implemented and incorporated into the design documentation until a Utility contract is signed. This will also be followed up as an action within GDA Issue, **GI-AP1000-CC-02** (Ref. 44). In addition to this, an assessment finding, **AF-AP1000-QA-07** (Annex 1), will be raised to ensure that the Licensee approves and progresses incomplete design changes in line with ND's expectations.

**AF-AP1000-QA-07:** *The Licensee shall introduce adequate QA arrangements to capture, track and implement unincorporated approved design changes transferred from UK GDA project.*

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

- Long lead items and SSC procurement specifications.
- DCPs are being graded against a UK safety category, however inconsistency of application has been identified and a CAP has been raised. The progress made against this CAP was submitted to ND (Ref. 53). The results from the review of UK Safety Categorisation for Modifications are still outstanding. Also, the DCP process will trigger the EDCD to be impact assessed, not the UK PCSR and ER, due to the legal standing of the documents and this needs to be corrected. The application of the UK safety category will be followed up under the GDA Issue, **GI-AP1000-CC-02** (Ref. 44).

## 4.7 Procurement Arrangements

119 I have assessed the arrangements for the procurement of services supporting the GDA project. I have sampled supplier selection, contract specification, performance monitoring and non-conformance arrangements against the requirements set out in TAG Procurement of Nuclear Safety Related Items or Services T/AST/077 (Ref. 29) and SAP MS.2.

### 4.7.1 Assessment

120 For GDA, the MSQA assessment has focused on the arrangements developed and used by Westinghouse to procure services specific to the delivery of the UK AP1000 GDA safety submission. The QA arrangements supporting procurement of manufactured goods including long lead items has been identified as out of scope so will be followed up under Assessment Finding **AF-AP1000-QA-03** (Annex 1).

**AF-AP100-QA-03:** *The Licensee shall make and implement adequate QA arrangements for the procurement of manufactured items including long lead items. These arrangements shall include a suitable and sufficient quality graded approach with is commensurate with safety significance of the goods or items being procured. The arrangements must be based upon the principles that the responsibility for*

*supply chain quality is retained with the Licensee. Therefore the Licensee will be required to have appropriate oversight of all supply chain activities to ensure quality of supply.*

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

- Long lead items and SSC procurement specifications.

- 121 Westinghouse use a graded approach commensurate with safety significance; namely safety related and non safety related. Arrangements are aligned to US requirements NUREG 0800 and NQA-1 and implemented through the company's Level II procedure WEC 7.5. The key principles of this Level II procedure were applied. However, due to the differences in UK and US procurement contracts and the legal requirements in the US, Westinghouse adapted the established company procurement arrangements for the purposes of the UK GDA service contracts. The adapted arrangements were not documented within the MS, as Westinghouse intend to adhere to the Level II procedure, WEC 7.5, for future UK procurement requirements.
- 122 The services contracts procured within the UK to support the GDA project were Serco and Rolls Royce (PCSR production), and CRA and Kingsley (HF/PSA input support). The contract to produce the UK GDA PCSR is exclusively professional services and consultancy, it is simply focused on translation of US safety submission documentation into the UK safety case format and collation of evidence to build the safety case, therefore was considered by Westinghouse to be non-safety related. The supplier selection process used for the PCSR contract included six steps, these were:
- Vendor identification to select a short list
  - Pre-contract vendor assessment plan
  - Vendor meetings and discussion
  - Receipt and assessment of vendor information
  - Numeric summary of the information and ranking
  - Management summary and recommendations
- 123 The assessment of vendor information was based on four criteria; technical, corporate, commercial and other - location and personnel availability, the majority of the weighting is allocated to technical. Application of their vendor assessment process clearly identified Serco as the contract winner.
- 124 The contract to produce the UK GDA PCSR was graded as non-safety related therefore would not be subject to a supplier audit as per the requirements of WEC 7.5. That said, Westinghouse has performed a supplier audit looking at Serco's internal PCSR chapter review and verification processes.
- 125 It is noted that Westinghouse had a previous contract with Rolls Royce to produce a safety submission at the end of Step 3. This contract was closed at the end of Step 3. A lessons learned review was conducted, however, Westinghouse was reluctant to share this report with ND due to proprietary and commercially sensitive statements it contained.
- 126 The initial assessment of the QA arrangements supporting the procurement of the UK GDA PCSR service contract identified weaknesses within the specification arrangements and documented MS. To address these weaknesses and clarify the position with the
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graded approach applied to such service contracts, Regulatory Observation RO-AP1000-089 and associated actions was raised. In response to these actions, Westinghouse provided further evidence on the specification requirements and development of the project MS arrangements under the cover of letter WEC00442N dated 7 December 2010 (Ref. 46).

- 127 A Framework Agreement was set up with Serco to develop the safety case, the overall deliverable for Serco is defined in Schedule 1 of this framework agreement. It is defined as, delivering a fully completed and quality assured integrated safety case in the form of a PCSR and all supporting safety case documentation. The conditions relevant to the Serco deliverables, competency requirements and communications are detailed in Schedule 2 of the framework agreement.
- 128 Schedule 1 of the Framework Agreement also specifies the requirements for Suitably Qualified and Experienced Personnel (SQEP) to manage the projects and the tasks defined within the work scopes. As per the agreement, Serco submitted CVs of proposed Key Personnel for each technical topic area. Westinghouse reviewed this information against the guidance documented within the working instruction UK-GDA-WI-203 Rev 0 - Assessing the suitability of Contractor 'Key Personnel' and agreed to a final list (Ref. 46). The list of Key Personnel is recorded under the contract and therefore any changes to this list must be agreed by Westinghouse, examples of how changes have been managed was presented and found to be satisfactory.
- 129 The PCSR contract is to be delivered by Serco in three phases:
- Phase 1 – Gap analysis.
  - Phase 2 – Safety case development.
  - Phase 3 – Delivering of PCSR Chapters incorporating TQs / ROs.
- 130 Phase 1 was regarded as the basic scope of supply and specified the initial work scope for Serco. This work scope both initiated the contract programme management functions and established the working relationships between Westinghouse technical leads and Serco Key Personnel. Through familiarisation and assessment of the AP1000 design, and reviewing the regulatory expectations, the Serco Key Personnel were able to identify technical gaps and weaknesses within the existing safety case. This information informed the specific task analysis and clarified deliverables to be achieved in Phase 2 of the contract.
- 131 In collaboration, Westinghouse and Serco developed a PCSR document structure / template to aid the production of the PCSR Chapters. This was completed early in Phase 2 and allowed further detailed development of the PCSR content. This development exercise was lead by Serco and cascaded throughout the contract once agreed and authorised by Westinghouse.
- 132 Since the initial launch of the PCSR contract under the Framework Agreement, Serco have been recognised as a Westinghouse design partner for selected services as detailed in the contract under Addendum No.1. Westinghouse obtained confidence to enter into a design partner agreement on the basis of Serco's demonstrated expertise in a number of technical areas, and ability to interrogate Westinghouse design information and incorporate it into the PCSR. The addendum restricts the scope to certain technical areas and report types; an example of where this arrangement has been exercised is the Internal Hazards Topic Report UKP-GW-GLR-001 Rev 2 (Ref. 58).
- 133 The response to close out RO-AP1000-089 (Ref. 9) demonstrated a professional and rigorous approach to selection of contractors with defined criteria, and clarified the

specification arrangements defining the key deliverables of the contract. The improvements made to the arrangements were sufficient to close out RO-AP1000-089 actions A2 and A3.

- 134 The management of the Serco contract is split between a Superintending Officer whose responsibilities include contract amendment and task order authorisation, and an Intelligent Customer representative who is responsible for the coordination of the technical development of the PCSR.
- 135 The contract was launched by a meeting, attended by Westinghouse and Serco Management. This launch meeting discussed both contract and deliverable expectations and potential risks such as communications and individual personalities. The Serco Key Personnel attended an AP1000 design familiarisation session and were introduced to their Westinghouse Technical correspondent. To manage and strengthen communication between Technical leads, a Serco member was relocated to the US.
- 136 As already mentioned the contract is to be delivered in three phases, this was discussed further with the Serco Structural Integrity Technical Lead. The Serco Technical Lead (TL) identified the need for Component Safety Case topic reports to support and feed into the Structural Integrity PCSR Chapter. During Phase 1 gap analysis, the Serco TL explained that time was spent reviewing the existing GDA Step 3 PCSR against HSE-ND's Safety Assessment Principles, attending a ½ day familiarisation training event and liaising with the Westinghouse Technical contact. An output from Phase 1 was an agreed safety classification methodology for high integrity and standards class 1 components. This was applied and it identified the set of component safety case topic reports required to support the PCSR chapter, for example reactor vessel, steam generator.
- 137 The Serco TL submitted a Task Initiator document along with a Task Order Estimate to Westinghouse for authorisation. These documents defined the process of developing the component safety case topic reports and the schedule and resource required to complete the Structural Integrity PCSR Chapter. The Task Initiator also identified the list of documents and information to be provided by Westinghouse to support the development of the topic reports and chapters. Serco are reliant on Westinghouse for provision of this information through the eRoom system.
- 138 The Serco TL confirmed he was aware of Design Reference Point of 16 September 2010, however, did not refer to the previous design freeze in December 2009 and has not used this in the development of his chapter. A review performed by Westinghouse Licensing team and Serco Programme office has confirmed there were a number of discrepancies with document revisions and it is Westinghouse's intention to resolve these at the final PCSR submission at the end of Step 4.
- 139 Serco explained once the contract was let they produced an overarching Quality Plan (QP) to deliver the contract requirements, which requires each Chapter to have its own QP to define the scope and quality controls to be applied. The Structural Integrity Chapter has gone through a Serco review and verification process as per the Quality Plan prior to submission to Westinghouse.
- 140 Following the verification of each chapter by Serco, they provided a list of any issues or gaps remaining to Westinghouse as part of the contract deliverables. These issues and gaps may be due to open regulatory observations or might be due to unanswered questions or reference documents which are yet to be issued. These issues and gaps are for Westinghouse to resolve during the next stage of development and will be addressed prior to final submission of the PCSR to the Regulators. The list for the draft Structural Integrity chapter produced by Serco was provided as an example.
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- 141 To support the standard AP1000 fleet design development work, Westinghouse utilise a supply chain. Westinghouse operates a qualified supplier list; the companies listed are assessed through audit and surveillance, against a defined scope of service. The status of a number of companies listed on this qualified supplier list were requested and examined during Step 4, in order to assess the adequacy and application of Westinghouse's MS arrangements for supplier assessment against the requirements of T/AST/077 (Ref. 29). The sample included Korea Power, Shaw, KSB and TECNATOM. The supplier audits had been completed to time and re-evaluation had been conducted where necessary, it was also noted that the details of the qualification such as expiry date, scope of qualification and details of any specific contract requirements or constraints were also recorded in the qualified supplier list. This level of detail, and documented evidence of evaluation, demonstrate sufficient control and focus on managing the qualified supplier list and meet the expectation of the relevant Technical Assessment Guide.
- 142 Shaw is regarded by Westinghouse as a design partner and as such is managed under an interface agreement as well as the qualified supplier process. To examine the application of Westinghouse MS arrangements for managing suppliers the contract agreement with Shaw was examined further during this assessment. Shaw is registered at a number of locations, two of which are Shaw Stoughton (supporting the China Project as part of the Utility contract) and Shaw Charlotte (providing design development in support of the AP1000 fleet).
- 143 The standard AP1000 fleet design development is performed by Shaw Charlotte, this work is governed by the WEC-Shaw-Toshiba Interface Agreement (APP-GW-M8-045). SAP is used as the procurement software and for this contract a framework agreement has been set-up (4500229857) and Purchase Orders are raised to place an order or manage variations to the contract. The adequacy of the contracted arrangements, purchase orders and product conformity process were not assessed.
- 144 The contract with Shaw Charlotte quotes APP-GW-GEP-001 Rev 6, this document stipulates which Westinghouse procedures Shaw; SHALL follow, SHOULD follow, and which ones are DISCRETIONARY.
- 145 For example, Shaw are allowed to follow their own design review process, however during the Design Reviews conducted by Shaw, Westinghouse identified a number of weaknesses. The Shaw process did not provide sufficient focus and detail on nuclear safety aspects. Westinghouse discussed this finding with Shaw and subsequently raised it at the Engineering Management Committee where an action (EML-D37) was taken to work with Shaw on improving their Design Review process. The Westinghouse Engineering Management Committee meeting minutes for November 2010, dated 5 November 2010 showed that this action was closed on the 10 March 2010. Supplier Quality Assurance team were not automatically informed but will consult prior to the Supplier Evaluation process with the Engineering department using the Suppliers to gather information on performance.

#### 4.7.2 Findings

- 146 From my assessment of the QA arrangements supporting procurement, the following strengths were identified:
- Westinghouse followed a 6 step process to evaluate and select a suitable supplier for the PCSR production contract. The evaluation process adopted looked at Technical,



Corporate, Commercial and Other, with Technical assessment having the highest weighting.

- The competency of Serco's key personnel put forward for the contract was assessed by Westinghouse against a set of criteria. The list of key personnel has been controlled throughout the project.
- The production of the individual PCSR chapters and the consolidation of these chapters into a safety submission have been integrated into the GDA project schedule.
- Westinghouse arranged for technical leads to be identified and organised the re-location of a Serco employee to the US offices, to maximise interaction and improve communication during the development of the PCSR chapters.
- Westinghouse maintains a qualified supplier list, these companies are assessed against a specified scope of work aligned to the contract arrangements, and once qualified are subjected to periodic surveillance and contract conditions.

147 From my assessment of the QA arrangements supporting procurement, the following observations were identified:

- Serco was not made aware of the Design Reference document during contract launch and it was not included in the familiarisation training, subsequently they have not used this reference point in the development of the draft PCSR chapters. This is discussed further in Section 4.8.1.1 Design Reference and will be followed up by GDA Issue, **GI-AP1000-CC-02**, requesting Westinghouse to align the PCSR to the Design Reference and submit a final consolidated safety submission.
- The QA arrangements supporting procurement of manufactured goods, including long lead items, has been identified as out of scope. This will be followed up during the site specific phase under Assessment Finding **AF-AP1000-QA-03** (Annex 1).

**AF-AP100-QA-03:** *The Licensee shall make and implement adequate QA arrangements for the procurement of manufactured items including long lead items. These arrangements shall include a suitable and sufficient quality graded approach with is commensurate with safety significance of the goods or items being procured. The arrangements must be based upon the principles that the responsibility for supply chain quality is retained with the Licensee. Therefore the Licensee will be required to have appropriate oversight of all supply chain activities to ensure quality of supply.*

This assessment finding should be addressed as part of the following procurements and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

#### 4.8 Configuration Control of GDA Submission Documentation

148 I have assessed Westinghouse's arrangements for controlling the GDA submission documentation, sampling the control and tracking of information, and safety submission development, against the requirements in T/INS/017 (Ref. 26) and international standards (Ref. 15 and Ref. 39).

#### 4.8.1 Assessment

##### 4.8.1.1 Design Reference

- 149 In May 2010 Westinghouse submitted the Design Reference defining the Design Reference Point (DRP) dated 23<sup>rd</sup> December 2009, UKP-GW-GL-060 Rev 0 (Ref. 31). This version was developed in accordance with the Design Principles referenced in the Regulator's letter WEC70116R dated 21 October 2009 (Ref. 55) and following numerous discussions during Step 3. Following assessment of the DRP, it was concluded that the hierarchy of design documentation was unclear and was not consistent with the corresponding submission tracking sheet.
- 150 At the same time it was identified that Westinghouse was no longer meeting the requirements of the Interface Protocol (Ref. 16), in that they were no longer providing regular Submission Tracking Sheets, and they had not yet created a Master Submission List. The shortfalls were communicated to Westinghouse in letter WEC70190R (Ref. 49) requesting action to be taken. Within this letter, ND also stated their expectations with regard to controlling the Design Reference. The letter provided details of a 6 step process developed by the Regulators to control changes to the GDA Design Reference. Westinghouse was requested to consider this process and incorporate it within their design change arrangements for GDA.
- 151 It was considered by both Westinghouse and the Regulators that the DRP, UKP-GW-GL-060 Rev 0, included lower level design documents, and that maintenance of the document would require significant resource. Therefore ND provided additional guidance to help Westinghouse simplify the DRP. To address this action, Regulatory Observation RO-AP1000-88 and associated actions (Ref. 9) were raised. Using the guidance within the Regulatory Observation Action, Westinghouse reviewed the Design Reference document against the submission tracking sheet and regulatory feedback and submitted a revised version of Revision 1 – Design Reference dated 16 September 2010 (Ref. 32). The tracking sheets were reinstated and a Master Submission List was submitted.
- 152 The submitted Design Reference Rev 1 (Ref. 32) with design freeze reference date 16 September 2010 was shared with other ND assessors to ascertain the accuracy of the content and gain confidence in the design freeze. A number of the assessors did not recognise the references in the Design Reference document and believed they were already assessing a later version of the documents. This suggested that the design base had changed without formal notification to the Regulators. This situation was confirmed during a Joint Regulators' inspection (Ref. 20) when a number of Licensing Engineers and Technical Area Experts interviewed could not explain the role of the Design Reference in relation to the UK GDA process and therefore were inconsistent in their approach when using the DRP to respond to Regulatory Technical Queries (TQ) and Observations (RO). For example one of the Licensing Engineers explained how they ensured the TQ / RO response aligns to the DRP, whereas another responded with the latest design document revision.
- 153 This resulted in the generation of Regulatory Observation RO-AP1000-103 (Ref. 9), which requested Westinghouse to provide a Design Reference document which reflects the current assessment being conducted by ND, and provide details of any design changes made during GDA Steps 3 and 4, in order to understand the current impact to the regulatory assessment. In response to RO-AP1000-103, the Design Reference was reviewed and resubmitted in December 2010, UKP-GW-GL-060 Rev 1A (Ref. 33). Design Reference Rev 1A Table 4 listed the Approved Category 1 and 2 Design Changes accepted or excluded from GDA. To confirm the position with respect to Design Reference design changes, Westinghouse formally submitted a list of design changes to

the Regulators requesting agreement for inclusion into GDA via the 6 step process under the cover of letters WEC000433 (Ref. 63) and WEC00470 (Ref. 64).

- 154 However, the impact of design changes on the referenced documents was still unclear and a number of discrepancies were identified, and this resulted in a further update to the Design Reference Rev 2 (Ref. 34). Revision 2 included Tables 4a, 4b and 5 identifying the unincorporated design changes that have an impact on the Design Reference documents. ND has requested Westinghouse to assess the impact of these design changes on the safety submission as an action under RO-AP1000-103 (Ref. 9), to provide assurance that the design changes have been considered in the safety submission and assessed where appropriate. This will be followed up under the GDA Issue within the Cross-cutting topic report, **GI-AP1000-CC-02** (Ref. 44).

#### 4.8.1.2 Safety Case Development

- 155 The PCSR submitted at the end of Step 3, UKP-GW-GL-732 (Ref. 11) had significant shortfalls, recognising these shortfalls Westinghouse have extensively restructured and enhanced the case to address ND's concerns.
- 156 The initial development of the revised PCSR Chapters was contracted to Serco, through a Framework Agreement, (refer to Section 4.7 for details on the QA arrangements supporting procurement). The Chapters were developed using the Step 3 2009 PCSR, regulatory feedback (ROs / TQs), Safety Assessment Principles and additional Westinghouse design information. To support this work Westinghouse identified Technical Leads for each technical area, who would act as the point of contact for the relevant Serco technical correspondent (Key Personnel). The PCSR Chapters were submitted to Westinghouse for acceptance after successful internal verification by Serco.
- 157 Westinghouse has completed a two step review and approval process on the consolidated PCSR. The first step is to review each Chapter; this was conducted by Westinghouse and involved an initial review to confirm the Chapter meets the basic acceptability criteria followed by a detailed technical review performed by nominated Technical Leads within Westinghouse. This Chapter review process is documented in working instruction UK-GDA-WI-201 Rev 0 (Ref. 24) and involves a number of GO / NO GO stages to allow prompt assessment and response if the Chapter is unacceptable. The Chapter review process does request comments from both the Regulators and Utility companies. Comment sheets were produced and provided as evidence during an MSQA meeting to demonstrate feedback was received from Vattenfall, EoN and ND and that the comments were considered.
- 158 The second step is a final review and verification of the Consolidated Report and is documented in a Westinghouse Level III procedure UKP-GW-GAP-027 Rev 0 (Ref. 25). The key step within this process is the involvement of a Red Book Review Team. The Red Book Review team is a technical team responsible for the review of the PCSR in its entirety, looking at readability, consistency and technical accuracy. All the reviews have been completed for the PCSR submitted March 2011.
- 159 The Chapter review and Consolidated Report final review and verification processes have suitable countermeasures to ensure consistency and technical accuracy of the product. However, it was noted in December 2010 by ND that the two processes do not require consideration of the Design Reference and the existing Environment Report (ER), therefore alignment between these documents can not be guaranteed. This was raised with Westinghouse as a concern, and additional actions were raised on RO-AP1000-103,

for Westinghouse to investigate and ensure alignment of the PCSR and ER with the Design Reference and the Regulator's assessment.

160 In response to RO-AP1000-103 Actions Westinghouse has performed an independent review, identifying any misalignment of references within the Design Reference, Master Submission List (MSL), PCSR and ER. The first step was to compare the transmittal log with the information on the tracking sheet and MSL to confirm alignment; any discrepancies found were rectified to align with the transmittal log. The next step was to compare the MSL with the references quoted in the DRP, PCSR and ER, any discrepancies found this time have been investigated further to ascertain which reference supports the Design Reference and the Regulators assessment. This step included the involvement of the Westinghouse Technical Leads. This exercise has been completed and the discrepancies resolved within the March 2011 submission. An overview of this review was examined in a MSQA meeting in April 2011. The Regulators have requested this review to be written up into a report and submitted to ND for consideration and to support close out of RO-AP1000-103 Action 7.

161 Westinghouse has generated a PCSR Road Map to track where Regulatory queries such as RIs, ROs, TQs and Design Changes have been incorporated into the PCSR Chapters, the adequacy of the tool was sampled during a MSQA meeting in April 2011. A number of ROs (RO-AP1000-36, RO-AP1000-74, RO-AP1000-75 and RO-AP1000-83) were sampled and the information against the RO response and DCP details were tracked through to the relevant PCSR Chapter with the aid of the PCSR Road Map. The PCSR submitted in March 2011 is considered as a new PCSR, as it has been extensively rewritten the Chapters will require assessment by ND to ascertain whether the commitments made and information assessed during Step 4 in response to Regulatory queries have been suitably consolidated into the March 2011 PCSR.

#### 4.8.1.3 Master Submission List

162 In September 2010 Westinghouse was requested by RO-AP1000-088 A4 to generate a Master Submission List, to meet the requirements of the Interface Protocol (Ref. 16). A diagram to illustrate the content of the MSL was attached to the Regulatory Observation Action providing further guidance. Westinghouse responded to RO-AP1000-088 A4 in October and submitted a MSL which aligned to the tracking sheet #51. The MSL was assessed and provided a good base, however further development was required. For example the version did not include enough details on the submission route of the documentation and did not include the PCSR and ER Chapters. RO-AP1000-088.A4 was closed and notification was sent by letter WEC70271R (Ref. 60) dated 29 November 2010. The letter also requested further improvements to be made prior to submission in December 2010 to support the draft PCSR.

163 The MSL is a key deliverable of the GDA project, therefore the QA arrangements supporting the generation and development of the document required assessment. There is no Westinghouse MS procedure on the content and development of the MSL, the control and approval process is governed by WEC 6.1. The MSL has been developed using the information from the PCSR, ER and DRP developments. In response to RO-AP1000-103 Actions, the MSL has been 100% reviewed against the transmittal log, DRP and PCSR, and errors identified have been rectified. Further alignment needed to be achieved between the DRP, PCSR and ER, therefore the MSL was subject to further change prior to submitting the documentation in March 2011. With that in mind Westinghouse performed an independent verification of the MSL prior to final submission.

164 This independent verification of the MSL was completed prior to the final submission at the end of March 2011. The details of which were submitted under the cover of letter WEC000578 dated 20 May 2011 (Ref. 56). The independent verification activity to review the accuracy and completeness of the list comprised of two reviews.

- Sample verification of MSL entries against the document transmittal log.
- Check that all entries within the SSER are recorded correctly in the MSL.

165 Both reviews identified a number of findings ranging from typographical errors, to omitted revisions of documents. The findings were corrected by the MSL originator and the resolution details were provided to the MSL reviewer for confirmation prior to final approval of the document. This verification performed by Westinghouse has provided confidence in the accuracy and completeness of the submitted MSL (Ref. 57).

#### 4.8.2 Findings

166 From my assessment of the configuration control of the GDA submission documentation the following strengths were identified:

- Westinghouse has established strong interfaces with the Utilities in the Multi-Party Agreement (MPA) and is encouraging Utility groups to be involved in the review of the SSERs and the developing Chapters of the PCSR.
- The Chapter review and the Consolidated Report final review and verification processes have suitable arrangements to ensure consistency and technical accuracy of the GDA product.
- The independent verification activity conducted on the MSL has provided confidence in the accuracy and completeness of the document submitted in March 2011.

167 From my assessment of the configuration control of the GDA submission documentation the following observation was identified:

- The Design Reference was not frozen in December 2009, and was subsequently set at 16 September 2010. For the PCSR Rev A submission, neither of these DRPs were used in the development of the PCSR Chapters and have not been considered during the Chapter review and the Consolidation Report final verification processes conducted in December 2010. Actions associated with RO-AP1000-103 have been raised to address this shortfall and ensure alignment of the safety submission documentation. The final consolidated PCSR and supporting submission documentation have been submitted at the end of March 2011, therefore the alignment has not yet been assessed and will be followed-up under the Cross Cutting GDA Issue **GI-AP1000-CC-02** (Ref. 44).

#### 4.9 Overseas Regulatory Interface

168 HSE's Strategy for working with Overseas Regulators is set out in (Ref. 61) and (Ref. 62). In accordance with this strategy, HSE collaborates with Overseas Regulators, both bilaterally and multinationally.



#### **4.9.1 Bilateral Collaboration**

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

- the US Nuclear Regulatory Commission (US NRC)
- the French L'Autorité de sûreté nucléaire (ASN)
- the Finnish STUK

#### **4.9.2 Multilateral Collaboration**

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

171 In the MSQA assessment the information from the US NRC website has been useful with respect to vendor inspections conducted by US NRC and a number of ND inspections have been witnessed by a US NRC representative.

#### **4.10 Interface with Other Regulators**

172 The principal interface with other UK Regulators is with the Environment Agency with whom we have a close working relationship and a shared Joint Programme Office (JPO) for GDA. MSQA has been an area of interest to the Environment Agency so regular interactions and invitations to inspections and meetings have been extended and information shared. Joint Inspections were conducted during Step 4 in July and December 2010 (Ref. 20 and Ref. 52).

#### **4.11 Other Health and Safety Legislation**

173 Not applicable.

## 5 CONCLUSIONS

174 This report presents the findings of the Step 4 Management of Safety and Quality Assurance (MSQA) assessment of the Westinghouse AP1000 reactor.

175 To conclude, I am broadly satisfied with the claims, arguments and evidence laid down within the PCSR (Ref. 11) and supporting documentation for the MSQA included in the Master Submission List (Ref. 57). I consider that from a MSQA view point, the Westinghouse AP1000 design is suitable for construction in the UK. However, this conclusion is subject to satisfactory progression and resolution of the Cross-cutting GDA Issue GI-UKEPR-CC-02 (Ref. 44) to be addressed during the forward programme for this reactor and assessment of additional information that becomes available as the GDA Design Reference is supplemented with additional details on a site-by-site basis.

### 5.1 Key Findings from the Step 4 Assessment

176 At the start of Step 4, the Management System arrangements for controlling and delivering the GDA project were inadequate, two ROAs raised in Step 3 required action. During Step 4 Westinghouse has addressed these actions satisfactorily, and the PQP (Ref. 18) provides clarity and guidance on the QA arrangements supporting the project. That said it is noted that in a number of cases the activity being performed is either not adequately documented in the GDA MS or the procedure is formally issued after the activity has been performed, this suggests the MS for GDA is still developing at this late stage. It is important that a project is governed by adequate MS arrangements and that these are clearly defined prior to commencing a project. An assessment finding, **AF-AP1000-QA-06** (Annex 1) has therefore been raised to ensure that the Licensee has adequate MS arrangements for the site specific phase of the project.

**AF-AP1000-QA-06:** *The Licensee shall implement adequate MS arrangements to transition the UK GDA project output into the site specific phase. The MS arrangements must be adequate to meet the requirement of the project during Licensing and subsequent Permissioning activities.*

This assessment finding should be addressed as part of the following procurements and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

177 The QA arrangements supporting Records Management are suitable and sufficient. There has been a non-conformance associated with record retrieval within another technical assessment area, which Westinghouse has investigated. The transfer of records from GDA to site specific projects will be achieved through customer contracts, however post GDA the Licensee will need to demonstrate adequate capture of the relevant GDA submission documentation to support Licensing activities, refer to **AF-AP1000-QA-02** (Annex 1).

**AF-AP1000-QA-02:** *The Licensee shall implement adequate arrangements for the capture of GDA submission documentation into their records management system, in order to support the further development of the PCSR.*

This assessment finding should be addressed as part of the following procurements and construction generic milestone for assessment findings:

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- Long lead items and SSC procurement specifications.

178 Structured induction and generic training programmes are in place for new recruits. Training records have been made available upon request and additional processes have been developed for the UK GDA project to resolve difficulties with current IT access constraints. The training arrangements are adequate, however the assessment of competency is weak as it is left to the Line Manager's judgement and not supported by defined standard criteria for the key roles within the organisation. Standard criteria is set for recruitment purposes against Engineering posts within the organisation however, limited evidence was presented on the assessment of competency for a particular task. This will be followed up under Assessment Finding **AF-AP1000-QA-04** (Annex 1).

**AF-AP1000-QA-04:** *The Licensee shall implement adequate arrangements to demonstrate their Intelligent Customer capability for Design development activities. These arrangements shall include assessment of supplier competency for design development activities.*

This assessment finding should be addressed as part of the following procurements and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

179 Westinghouse has established monitoring and assessment processes and these are being applied to the GDA project. For example, a number of self assessment and internal audits have been performed on the GDA activities the key focus being the management of ROs and TQs. In addition, Westinghouse operates a robust CAP system to capture and track any non-conformances and corrective actions raised, which again has been used to good effect in the GDA project.

180 The Design Reference for GDA was not frozen until September 2010 and the Design Reference document was not used as the key reference in the development of the PCSR Chapters to support the December 2010 submission. Since December 2009 a number of design changes have been raised, in some cases the updated design documentation has been used to answer ROs and TQs, however the list of design changes for inclusion in GDA was not formally submitted to the Regulators for consideration until November 2010 under the cover of letter WEC000433 (Ref. 63). As a result design development, the DRP, PCSR and ER were not aligned when PCSR Rev A was submitted in December 2010, signifying that configuration control between the GDA deliverables has been insufficient during Step 4. In response to RO-AP1000-103 Actions Westinghouse has conducted a number of reviews to rectify the alignment between the DRP, PCSR and ER prior to submission in March 2011. The March 2011 PCSR and the alignment between all submission documents has not been assessed; a GDA Issue has been raised within the Cross-cutting topic report (Ref. 44) to follow this up, **GI-AP1000-CC-02**.

181 At the end of GDA Step 4, a large number of DCPs impacted the Design Reference documentation (i.e. System Specification Documents, Design Specifications and Codes and Standards) and 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 even though 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. A GDA Issue within the Cross Cutting topic report (Ref. 44) has been raised to ensure completion (**GI-AP1000-CC-02**). However 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 phase, the requirements on the Licensee are captured in Assessment Finding **AF-AP1000-QA-07** (Annex 1).

**AF-AP1000-QA-07:** *The Licensee shall introduce adequate QA arrangements to capture, track and implement unincorporated approved design changes transferred from UK GDA project.*

This assessment finding should be addressed as part of the following procurements and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

182 It should also be noted that Westinghouse raised a CAP relating to the inconsistency in application of the UK safety category to DCPs. Progress has been made against the corrective actions raised, however the application of the revised arrangements to GDA has not been tested. The assessment of the corrective action taken will be followed up by the GDA Issue **GI-AP1000-CC-02** (Ref. 44).

183 It is recognised that during site specific design development or construction the number of design changes may increase as a result of operating experience during construction. The QA arrangements to manage this flow of information will need to be considered to ensure that the design documentation reflects as built, this has been raised as Assessment Finding, **AF-AP1000-QA-05** (Annex 1).

**AF-AP1000-QA-05:** *The Licensee shall make and implement adequate QA arrangements for managing and controlling design changes triggered by learning from experience activities during construction, including suitable records management arrangements to ensure the plant design documentation reflects as built status.*

This assessment finding should be addressed as part of the following procurements and construction generic milestone for assessment findings:

- First structural concrete.

184 The Design Review process is used to finalise the design at each stage of development; the arrangements applied are robust and introduce a level of challenge into the development process. However 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. A graded approach to the Design Review strategy for the UK has been developed for the AP1000 systems, however a detailed schedule is yet to be developed since there is no Utility customer at this time. The UK design review strategy for AP1000 equipment and civil structures is not fully understood at this time by ND. This will be followed up by the Assessment Finding **AF-AP1000-QA-01** (Annex 1).

**AF-AP1000-QA-01:** *The Licensee shall confirm that Design Reviews have been conducted for Systems, Equipment and Civil structures to support the UK AP1000 design. The Design Reviews should consider the impact of UK or European specific design changes and confirm that the design changes have been well executed and have not resulted in an adverse effect to safety.*

This assessment finding should be addressed as part of the following procurements and construction generic milestone for assessment findings:

- Long lead items and SSC procurement specifications.

- 185 The design verification process and the software code development and control processes are documented within Westinghouse MS and the arrangements meet the principles in T/AST/057 and ISO9001:2008. The application of these arrangements has been sampled and found to be satisfactory.
- 186 The 3D model is not configuration controlled and is used for the production of 2D layout drawings, this places responsibility on the document checker and verifier to stop any transcription errors and is a labour intensive exercise. However during the MSQA inspection (Ref. 42) no errors were identified.
- 187 The QA arrangements supporting procurement of GDA services was assessed and the arrangements for supplier selection, performance monitoring and non-conformance arrangements was found to be adequate. Weakness were identified in contract specification, these weakness were addressed satisfactorily during Step 4 with little adverse effect to the project. The QA arrangements supporting procurement of manufactured goods including long lead items has been identified as out of scope so will be followed up under Assessment Finding **AF-AP1000-QA-03** (Annex 1).

**AF-AP100-QA-03:** *The Licensee shall make and implement adequate QA arrangements for the procurement of manufactured items including long lead items. These arrangements shall include a suitable and sufficient quality graded approach with is commensurate with safety significance of the goods or items being procured. The arrangements must be based upon the principles that the responsibility for supply chain quality is retained with the Licensee. Therefore the Licensee will be required to have appropriate oversight of all supply chain activities to ensure quality of supply.*

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

- Long lead items and SSC procurement specifications.

### 5.1.1 Assessment Findings

- 188 I conclude that the Assessment Findings listed in Annex 1 should be programmed to be addressed by the Licensee during the forward programme of this reactor as normal regulatory business.

### 5.1.2 GDA Issues

- 189 I conclude that the GDA Issue listed in Annex 2 of the Cross-cutting report (Ref. 44) must be satisfactorily addressed before Consent will be granted for the commencement of nuclear island safety related construction.

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- 63 *GDA-driven changes to be included in the Design Reference Point. Letter to ND from AP1000 Project Front Office. WEC000433. 18 November 2010. TRIM Ref. 2011/575788.*
- 64 *Design Changes for ND/EA GDA Change Process. Letter to ND from AP1000 Project Front Office. WEC000470. 11 January 2011. TRIM Ref. 2011/26491.*
- 65 *AP1000 Design Reference Point for UK GDA. UKP-GW-GL-060 Revision 3. Westinghouse Electric Company LLC. 31 March 2011. TRIM Ref. 2011/194626.*

Table 1

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

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

## Annex 1

## Assessment Findings to Be Addressed During the Forward Programme as Normal Regulatory Business

## Management of Safety and Quality Assurance – AP1000

Finding No.	Assessment Finding	MILESTONE (by which this item should be addressed)
AF-AP1000-QA-01	The Licensee shall confirm that Design Reviews have been conducted for Systems, Equipment and Civil structures to support the UK AP1000 design. The Design Reviews should consider the impact of UK or European specific design changes and confirm that the design changes have been well executed and have not resulted in an adverse effect to safety.	Long lead items and SSC procurement specifications
AF-AP1000-QA-02	The Licensee shall implement adequate arrangements for the capture of GDA submission documentation into their records management system, in order to support the further development of the PCSR.	Long lead items and SSC procurement specifications
AF-AP1000-QA-03	The Licensee shall make and implement adequate QA arrangements for the procurement of manufactured items including long lead items. These arrangements shall include a suitable and sufficient quality graded approach with is commensurate with safety significance of the goods or items being procured. The arrangements must be based upon the principles that the responsibility for supply chain quality is retained with the Licensee. Therefore the Licensee will be required to have appropriate oversight of all supply chain activities to ensure quality of supply.	Long lead items and SSC procurement specifications
AF-AP1000-QA-04	The Licensee shall implement adequate arrangements to demonstrate their Intelligent Customer capability for Design development activities. These arrangements shall include assessment of supplier competency for design development activities.	Long lead items and SSC procurement specifications

## Annex 1

## Assessment Findings to Be Addressed During the Forward Programme as Normal Regulatory Business

## Management of Safety and Quality Assurance – AP1000

Finding No.	Assessment Finding	MILESTONE (by which this item should be addressed)
AF-AP1000-QA-05	The Licensee shall make and implement adequate QA arrangements for managing and controlling design changes triggered by learning from experience activities during construction, including suitable records management arrangements to ensure the plant design documentation reflects as built status.	First structural concrete
AF-AP1000-QA-06	The Licensee shall implement adequate MS arrangements to transition the UK GDA project output into the site specific phase. The MS arrangements must be adequate to meet the requirement of the project during licensing and subsequent permissioning activities.	Long lead items and SSC procurement specifications
AF-AP1000-QA-07	The Licensee shall introduce adequate QA arrangements to capture, track and implement unincorporated approved design changes transferred from UK GDA project.	Long lead items and SSC procurement specifications

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

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

**Annex 2**

**GDA Issues - Management of Safety and Quality Assurance – AP1000**

There are no GDA Issues for this topic area.