

January 23, 2008

Mr. Masahiko Kaneda, General Manager  
APWR Promoting Department  
Mitsubishi Heavy Industries, Ltd.  
16-5 Konan 2-Chome, Minato-Ku  
Tokyo, 108-8215, Japan

SUBJECT: NUCLEAR REGULATORY COMMISSION AUDIT REPORT FOR THE  
MITSUBISHI HEAVY INDUSTRY LTD. US-ADVANCED PRESSURIZED  
WATER REACTOR DESIGN CERTIFICATION APPLICATION REVIEW

Dear Mr. Kaneda:

On November 26-30, 2007, U.S. Nuclear Regulatory Commission (NRC) staff conducted an audit of the Mitsubishi Heavy Industries, Ltd. (MHI) US-Advanced Pressurized Water Reactor (US-APWR) design certification (DC) application at the National Conference Center facility in Lansdowne, Virginia. The enclosed audit report presents the details of that activity.

The NRC auditors reviewed the implementation of selected portions of the quality assurance programs applied by MHI and its contractors to the development of the US-APWR DC application. Additionally, the NRC auditors assessed the completeness and accuracy of the US-APWR application using the guidance in Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants," dated June 2007. The NRC audit team did not identify any issues with the quality assurance activities associated with the US-APWR DC application development. However, the NRC audit team did identify several issues associated with the completeness of the draft US-APWR DC application that should be addressed by MHI prior to finalizing the US-APWR DC application. These issues are described in the enclosed audit report as audit response requests (ARRs). Your responses to these ARRAs, as part of US-APWR DC application, are under review. At the time of the audit, the Final Safety Analysis Report for the US-APWR DC application was in a draft form but still on course for your scheduled submittal date.

In accordance with §2.390, "Public Inspections, Exemptions, Requests for Withholding," of 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter, and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Document Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,  
/RA/

Jeffrey A. Ciocco, Senior Project Manager  
US-APWR Projects Branch  
Division of New Reactor Licensing  
Office of New Reactors

Docket Nos.: PROJ0751

Encls: Audit Report

cc: See next page

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MITSUBISHI HEAVY INDUSTRY LTD. US-ADVANCED PRESSURIZED  
WATER REACTOR DESIGN CERTIFICATION APPLICATION REVIEW

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**U.S. NUCLEAR REGULATORY COMMISSION  
OFFICE OF NEW REACTORS**

Audit Report No: PROJ0751-2007-001

Organization: Mitsubishi Heavy Industries, Ltd. (MHI)

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Nuclear Industry: MHI provides comprehensive services including basic planning, design, manufacture, construction, and post operational services for nuclear power plants worldwide.

Audit Dates: November 26 through 30, 2007

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Division of Construction Inspection & Operational Programs  
Office of New Reactors

## 1.0 AUDIT SUMMARY

The purpose of this audit was to verify that quality assurance activities were adequately established, documented, and implemented to support the development of the design certification (DC) application for the Mitsubishi Heavy Industry, Ltd (MHI) US-Advanced Pressurized Water Reactor (US-APWR). An additional purpose of the audit was to assess the completeness and accuracy of the US-APWR DC application using the guidance in Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants," June 2007.

The audit was conducted at the National Conference Center facility in Lansdowne, Virginia. The audit bases were:

- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations* (Appendix B),
- Part 21, "Reporting of Defects and Noncompliance," to Part 50 of Title 10 of the *Code of Federal Regulations* (Part 21) and,
- Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)."
- 10 CFR 50.9, "Completeness and Accuracy of Information."

During this audit, the NRC audit team identified several issues associated with the completeness of the draft US-APWR DC application that should be addressed by MHI prior to the finalizing the US-APWR DC application. These issues are described in section 3.10 of this audit report as audit response requests (ARRs). At the time of the audit, the Final Safety Analysis Report (FSAR) for the MHI US-APWR DC application was in draft form. The audit team reviewed approximately 8,000 pages of the draft US-APWR DC application.

## 2.0 STATUS OF PREVIOUS AUDITS

There were no previous NRC audits in support of the MHI US-APWR DC application.

## 3.0 AUDIT OBSERVATIONS AND OTHER COMMENTS

### 3.1 QUALITY ASSURANCE PROGRAMS

#### a. Audit Scope

The NRC audit team reviewed the quality assurance (QA) program requirements and the implementation process for MHI US-APWR DC activities. Specifically, the NRC audit team reviewed the quality assurance program manuals that govern the implementation of quality activities performed for US-APWR DC activities by MHI and its contractors.

b. Observations

The NRC audit team reviewed MHI's and contractors' policies governing quality assurance programs to assure those policies provided an adequate description of the implementation requirements consistent with the applicable requirements of Appendix B.

(i) MHI US-APWR Quality Assurance Program Description

Revision 1 of the MHI PQD-HD-19005, "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR" topical report was under review by the NRC at the time of the audit. PDQ-HD-19005 describes the QAP for the design certification of the US-APWR that is contained in Revision 0 of the MHI PQF-HD-18041, "US-APWR Quality Assurance Manual for the Nuclear Energy Systems Engineering Center (N-Center)," dated December 7, 2006. PQF-HD-18041 defines the QA requirements and methodologies that are used to control, perform, document and assess quality-related activities associated with the US-ARWR design certification project.

(ii) Takasago R&D Center Quality Assurance Program

Revision 7 of the Takasago R&D Center QMS91-N01, "QA Manual for Nuclear R&D QA Program Description (QAPD)," dated November 9, 2007, establishes the quality program to assure that sections within Takasago which design/analyze and/or test nuclear products ordered by the internal customers of MHI comply with the quality requirements of Appendix B to 10 CFR 50, NQA-1-1994, and the requirements of MHI Nuclear Energy Systems Division.

(iii) Obayashi Corporation Quality Assurance Program

Revision 2 of the Obayashi Corporation US-01, "US-APWR Structural Design Quality Assurance Program," dated October 31, 2007, establishes the quality program governing the development of the structural design of the US-APWR. Specifically, the US-01 covers the activities affecting quality of the safety-related structures and buildings of the US-APWR.

(iv) Engineering Development Co., Ltd Quality Assurance Program

Revision 5 of the Engineering Development Co. Ltd. (EDC) EDC SOP-409, "US-APWR Quality Assurance Program (QAPD: Quality Assurance Program Description)," dated November 2007 establishes the quality program for design services. Specifically, EDC SOP-409 covers the activities affecting quality of the reactor core design.

c. Conclusions

The NRC audit team concluded that QA program requirements for quality activities implemented to support the MHI US-APWR DC application were consistent with the requirements of Appendix B. The NRC audit team also concluded that the applicant's and/or its sub-suppliers' QA program requirements were appropriately translated into implementing procedures to support development of the US-APWR DC application. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the US-APWR DC application.

## 3.2 DESIGN CONTROL

### a. Audit Scope

The NRC audit team reviewed the implementation of the MHI design control processes for the US-APWR DC application. Specifically, the NRC audit team reviewed the policies and procedures governing the implementation of the MHI design control process and reviewed selected draft completed portions of the FSAR, which were in various stages of review by MHI.

### b. Observations

The NRC audit team reviewed the MHI policies and procedures governing the design process to assure those guidelines provided an adequate description of the process and its implementation consistent with the requirements of Criterion III, "Design Control," of Appendix B.

#### b.1 Design Control Policy and Procedures

Design Control Procedure, PQF-HD-18041-020, Revision 3, dated November 14, 2007, provides requirements relating to quality assurance in the planning of design procedures, the selection of design inputs, design outputs, design studies and analysis, preparation of design documents, responsibilities for the preparation of design plan, design verification, approval, and revision and control of calculations.

Design Control Document Procedure, UAP-HF-07124, Revision 2, dated November 12, 2007, describes the process for the development of design control document (DCD) structure, and compliance to the requirements, and it describes the chain of command for the assignment of Chapters. It details out the compliance requirements of the contents, approval process, reporting process, reporting structure and applicable checklist, such as completeness adequacy checklist, design change effect evaluation, influence of design changes, and consistency check sheet.

Design Interface Control Procedure, PQF-HD-18041-021, Revision 2, dated September 18, 2007, provides the process and responsibilities to clarify the interface among the departments involved in the nuclear design activities of the US-APWR project.

Design Verification Procedure, PQF-HD-022, Revision 2, dated September 18, 2007, outlines the methods and responsibilities for design verification so that design requirements are appropriately reflected in the design documents and the design is adequately accomplished.

Design Change Control Procedure, PQF-HD-18041-023, Revision 2, dated September 18, 2007, provides the method and responsibilities for evaluation of the effect of design changes and the transmission of information about design changes.

Re-Evaluation Procedure of Past Acquired Design Results, PQF-HD-18041-026, Revision 2, dated September 18, 2007, describes the process for evaluating the acceptability of previous design verification data or results when applied to the US-APWR project.

Computer Software Control Procedure, PQF-HD-18041-024, Revision 2, dated September 18, 2007, provides guidelines for performing computer software validation and verification prior to installation. The procedure follows the guidelines of NQA-1 provisions.



b.2 Implementation of Design Controls

The NRC audit team reviewed a sample of the MHI technical documents and calculations for conformance with the above QA design control and design verification procedures, including selected packages associated with the draft COLA/FSAR sections that were in the process of being reviewed by MHI. These reviewed documents and packages included:

- Section 3.9.5, "Reactor Pressure Vessel Internals."
- Section 3.9.5.1.2, "Lower Reactor Internal Assembly."
- Design Output for Upper Thimble Assembly Structure Design Report - UAP-HTT-0050 Revision 2. The calculations were used as input in the Section 3 of the FSAR.
- Design Output of Neutron Reflector Thermal Analysis Calculations - UAP-HTT-0073R1 Revision 1 dated 11/26/07- The design output calculations were performed using ABAQUS Version 6.2.3 program. The calculation was used as input in the Section 3 of the FSAR.
- Neutron Reflector Fluid Thermal Coupling Preliminary Analysis of the ABAQUS Version 6.2.3, Verification and Validation - KCS-20012304 Revision 0.
- US-APWR DCD Tier 2 Chapter 3.9.5 Reactor Internals - UAP-HTT-0143 Revision 1 dated 11/23/07 – provides a summary of revision for DCD Tier 2 Section 3.9.4 Reactor Internals that are included in the DCD Draft B. The document includes the Completeness and Adequacy checklist (UAP-HTT-0143R) for Section 3.9.5.
- EDC US-APWR Seismic/LOCA Analysis Interim Report – 07-YSC-110 Revision 0 dated 11/20/07. This interim report submitted by EDC to MHI is the process of being reviewed.
- EDC US-APWR Computer Validation and Verification of ANSYS Mechanical Version 11.0 Revision 0, dated 11/16/07.
- Topical Report for the Advanced Accumulator - MUAP-07001-P (R1), the topical report includes MHI re-evaluation and verification of the ACC Test program performed by Takasgo. The ACC Test program has been confirmed reliable and accurate for use in the US-APWR with the testing program compliant with 10 CFR 50 Appendix B and ASME NQA-1 1994 requirements.
- Design Output for Interface Configuration between Active Core and Control Rod - UAP-HTT-0091 Revision 1, dated 10/17/07. The design output includes the calculation for estimation of the effect of temperature change and growth by radiation, calculation for estimation of interface between active core and absorption, estimation at HOT 0% power, estimation at HOT 100% power.

c. Conclusions:

The NRC audit team concluded that the design control process requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's and its sub-supplier's procedures

to support the MHI US-APWR DC development program. The NRC audit team also concluded, that MHI prepared the technical documents and calculations in accordance with the implementing procedures. The NRC audit team did not identify any issue requiring additional action by the applicant prior to completion of the US-APWR DC application.

### **3.3 DOCUMENT CONTROL**

#### **a. Audit Scope**

The NRC audit team reviewed the implementation of MHI document control processes for the development of the US-APWR DC application. Specifically, the NRC audit team reviewed policies and procedures governing the MHI document control process to verify the overall extent and effectiveness of the program. The NRC audit team verified that quality-related documents were developed, reviewed, approved, issued, used, and revised under an established program.

#### **b. Observations**

The NRC audit team reviewed the MHI policies and procedures governing the document control processes to assure those guidelines provided an adequate description of the process and its implementation consistent with the requirements of Criterion VI, "Document Control," of Appendix B.

##### **b.1 Policies and Procedures for Document Control**

PQD-HD-19005 references Document Control Procedure, PQF-HD-18041-010, which describes, in part, the methods for the preparation, review, approval, issue, distribution, revision, receipt, filing, and disposition of important documents for quality assurance activities.

##### **b.2 Implementation of Document Control Programs**

The NRC audit team reviewed the design packages described in Section 3.2 of this audit report and the following MHI documents to determine if the documents had been prepared and issued in accordance with NQA-1 and ANSI N18.7 requirements:

- PQF-HD-18041-010, Document Control Procedure, Rev 2 Dated September 18, 2007
- PQF-HD-18041-011, Quality Manual Control Procedure, Rev 1 Dated September 18, 2007
- PQF-HD-18041-012, Control Procedure for Instructions, Procedures, and Drawings, Rev. 0 Dated September 18, 2007
- PQF-HD-18041-013, Translation Control, Rev 0 Dated September 18, 2007
- PQF-HD-18041-021, Design Interface Control Procedure, Rev 2 Dated September 18, 2007

The NRC audit team identified that PQF-HD-18041-010 did not describe a process for requesting minor changes be made to procedures when such changes were identified by personnel implementing them. MHI demonstrated that they have an independent process in place that captures minor change requests to documents, however, this process is not described in the procedures. As a result, MHI revised PQF-HD-18041-011, during the NRC audit, to include the process for requesting minor changes. The audit team reviewed the revised procedure and found it acceptable.

c. Conclusions

The NRC audit team concluded that the document control process requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the US-APWR DC development program. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the US-APWR DC application.

**3.4 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES**

a. Audit Scope

The NRC audit team reviewed the implementation of the MHI process of controlling purchased material, equipment, and services for the US-APWR DC application development program. Specifically, the NRC audit team reviewed the policies and procedures governing the process to verify the quality of suppliers providing engineering services for US-APWR DC application development activities.

b. Observations

The NRC audit team reviewed the MHI policies and procedures governing the control of design engineering services and activities for the MHI US-APWR DC to assure that those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B.

b.1 Policies and Procedures for Control of Purchased Material, Equipment, and Services

The NRC audit team reviewed MHI PQD- HD-19005, Revision 1, "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR", dated October 15, 2007. QAP Section 7, Control of Purchased Material, Equipment, and Services, describes the process for the procurement of items and services to assure conformance with specified requirements. These controls include, as appropriate, source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items and services. This QAP establishes and implements measures to assess the quality of purchased items and services, whether purchased directly through contractors at intervals and to a depth consistent with the item's or services importance to safety, complexity, quantity and the frequency of procurement. This QAP also includes the applicable NQA-1-1994 commitments to Basic requirement 7 and Supplemental Requirement 7S-1, and exceptions. This QAP is implemented by PQF-HD-18041, Revision 0, the MHI Nuclear Energy Systems Engineering Center (N-Center) "US-APWR Quality Assurance Manual," (QAM) dated September 7, 2007.

The NRC audit team reviewed QAM procedure PQF-HD-18402-080, Revision 2, "Audit Procedure," dated September 18, 2007. The purpose of this procedure is to provide guidance for the implementation of the audit process for both internal and procurement (supplier audits). This includes the requirements for preparing the audit plan for new and renewal audits,

conducting these audits, the qualification of auditors, and for the utilization of external audit organizations. The NRC audit team also reviewed QAM 080 Appendix 6, the supplier audit implementation procedure flowchart to become familiar with the entire supplier qualification process.

b.2 Review of Supplier Audits for US-APWR

The NRC audit team reviewed the US-APWR Approved Vendor List dated November 20, 2007, and selected four of the current eight approved suppliers for review. This included the following suppliers who are or will be providing safety related engineering services: (1) MHI Takasago Research and Development Center (2 audits); (2) Obayashi Corporation (2 audits); (3) Engineering Development Company Ltd (EDC); and (4) Washington Group International (WGI).

The NRC audit team reviewed the following documents supporting the supplier qualification process for each supplier: the new supplier evaluation sheet, audit notification, audit plan detail, Report on Supplier Quality Assurance, audit check sheet, audit findings sheet, supplier corrective actions for the identified audit findings, and the final Certificate of Approved Vendor for US-APWR .

During the review of the audit reports and the accompanying audit checklists the NRC audit team identified that neither the audit reports nor checklists included documented objective evidence to demonstrate implementation for the audited areas. The audits did not verify effective implementation, but only that a QA program was in place. MHI stated to the NRC audit team that they had very recently (November 6, 2007) issued PQG1-HD-19040, "US-APWR Supplier Monitoring Plan," to document a supplier monitoring plan for MHI Takasago, EDC, and Obayashi, including QA program implementation audits in approximately 6 months. This is particularly important for Takasago since their QA program was significantly revised after the first two audits performed by MHI for the US-APWR project identified numerous audit findings requiring corrective action by Takasago.

Also during the audit documentation review, the NRC audit team identified that the audit check sheet PQF-HD-19001 did not include all relevant areas to be reviewed. Specifically, Control of instructions, procedures, and drawings, and controls for computer software were not covered by the audit check sheet. MHI developed audit check sheet PQF-HD-19008, during the audit, to address these omissions. The NRC reviewed the revised "US-APWR Project Supplier QA Program/Audit Checklist," PQG1-HD-19042, revision 0 to the NRC audit team. This checklist replaces all of the previously utilized check sheets described above and US-APWR presents a comprehensive and complete audit checklist. Also, MHI presented "draft" revision 1 of "Auditor Training Document," PQG1-HD-19026, which now includes specific training to the audit team leaders requiring documentation of objective evidence of the audited material in both the audit report and the audit checklist. These revisions were made to address the NRC observation concerning the lack of documented, objective evidence for the areas audited.

c. Conclusions

The NRC audit team concluded that the requirements for the control of purchased material, equipment and services have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the MHI US-APWR DC application development program. Supplier audits conducted by the applicant were satisfactory and the resolution of identified deficiencies and corrective actions were adequately documented, tracked, and resolved in a timely manner.

The NRC audit team identified certain issues requiring additional action by the applicant as described above. However, these issues were subsequently addressed prior to the completion of the audit. Therefore, the NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the US-APWR DC application.

### **3.5 NONCONFORMANCE CONTROL AND CORRECTIVE ACTION PROCESS**

#### **a. Audit Scope**

The NRC audit team reviewed the nonconformance control and corrective action processes associated with the preparation of the MHI US-APWR DC application. Specifically, the NRC audit team reviewed the policies and controlling procedures associated with the project, and reviewed the status of a number of nonconformance reports and corrective actions, which were predominantly identified through internal audits and surveillances performed in support of the US-APWR DC application development.

#### **b. Observations**

The NRC audit team reviewed the MHI policies and procedures governing the nonconformance control and corrective action processes to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion XV, "Nonconforming, Materials, Parts or Components" and Criterion XVI, "Corrective Action," of Appendix B.

##### **b.1 Policies and Procedures for Nonconformance Control and Preventive Action of Recurrence**

The NRC audit team reviewed Section 15 of PQD- HD-19005. Section 15, "Nonconformance Control and Preventive Action of Recurrence," describes the procedures used to control items, including services, which do not conform to specified requirements to prevent inadvertent installation or use. Controls are described which govern identification, documentation, evaluation, segregation when practical, disposition of nonconforming items, notification to affected organizations and the implementation of a reporting program which conforms to the requirements of 10 CFR Part 52 and 10 CFR Part 21, as applicable.

MHI US-APWR Quality Assurance Manual procedure, PQF-HD-18041-060, "Nonconformance Control and Preventive Action of Recurrence," Revision 2, dated September 18, 2007, establishes the process for identifying, documenting, evaluating, segregating when practical, disposition of nonconforming items, and for notifying affected organizations.

Nonconformance Report Sheets, (NCRs) are used by MHI to provide a summary of the nonconformance (event, date of occurrence, etc.), a description of the corrective action and scheduled date of reflection in design documents, the category of the report (report to the governmental authority or client or within Mitsubishi), and nonconformance information control code (category of impact extent, phenomenon code). Additionally, the procedure establishes the means for the identification of and resolution to near misses, customer identified issues, and areas for improvement. This procedure details the process of identifying and documenting apparent conditions of nonconformance that fall under the scope of the MHI Quality Assurance group of Nuclear Energy Systems Quality & Safety Management Department (NESQD).

b.2 Policies and Procedures for Corrective Actions

The NRC audit team reviewed the MHI policies and procedures governing the corrective action process to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion XVI, "Corrective Action" of Appendix B.

MHI US-APWR Quality Assurance Manual procedure, PQF-HD-18041-061, "Corrective Action," Revision 2, dated September 18, 2007, and PQF-HD-18041-062, "Reporting Procedure of Defects and Nonconformance to NRC," Revision 1, dated September 18, 2007, establishes the process for reporting, tracking, and correcting conditions adverse to quality and those events/conditions as directed by management. Additionally, the procedure establishes the process for determining root cause, extent of condition, and preventing recurrence. This procedure details the process of identifying and documenting apparent conditions adverse to quality that fall under the scope of the MHI NESQD, investigating and correcting those adverse conditions, and closing corrective and preventive action requests/reports upon completion of corrective actions.

The NRC audit team reviewed Section 16 of PQD- HD-19005. Section 16, "Corrective Action," describes procedures to identify, control, document, classify and correct conditions adverse to quality. The procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards, and the implementation of a program to identify, evaluate, and report defects and non-compliances in accordance with 10 CFR Part 52 and 10 CFR Part 21.

b.3 Implementation of the Nonconformance Control and Corrective Actions Processes

Corrective and Preventive Action Request/Reports, (CARs) and the Corrective Action Report logbook are used by MHI NESQD to identify an issue, determine the root cause, identify corrective/preventative actions taken, resolve apparent conditions adverse to quality, determine the extent of condition and track required actions through completion. PQF-HD-18041-061 describes the general requirements for implementation of the corrective action process, including: (1) identification of the potential condition adverse to quality; (2) screening assignment to determine the extent of condition; (3) initial 10 CFR Part 21 screening; (4) documented recommended actions to preclude recurrence; (5) impact on related internal or external work activities or processes; and (6) identification when further deviation determinations are required as part of the Part 21 evaluation process. The corrective and preventative action reports are retained as a quality record.

The NRC audit team reviewed a selected sample of MHI CARs that demonstrated the entire corrective action process for US-APWR work. The audit team determined these CARs were adequately addressed, the reports were found to adequately document the issues, evaluations were adequately documented, corrective actions were determined to appropriately address the identified conditions, and closure and verification were adequately documented. As of the date of the status reports, all corrective action reports had been closed or were in the process of closure verification by MHI.

However, the NRC audit team did identify three issues regarding implementation of the nonconformance and corrective action processes requiring additional action by the applicant. The first issue identified by the audit team was the apparent lack of guidance on the use of the Nonconformance Report logbook within the text of PQF-HD-18041-060 and the need to include

a copy of the NCR logbook in the appendix section in the procedure. The audit team also identified that guidance on the use of the Corrective Action Report logbook was not described within the text of PQF-HD-18041-061 and a copy of the logbook was not included in the appendix of section 061 of the manual. Finally, the audit team identified that the explanation of the 10 CFR Part 21 determination procedure in the PQF-HD-18041-060 was inconsistent with similar explanations in other sections of the manual. MHI agreed with the audit team's observations and provided a revised "draft" version of PQF-HD-18041-060 and PQF-HD-18041-061 that documented the revisions that would resolve the identified issues. The NRC audit team reviewed the proposed changes and found the revisions to be adequate.

c. Conclusions

The NRC audit team concluded that the requirements for the nonconformance control and corrective action processes have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the MHI US-APWR DC application development program.

### **3.6 QUALITY ASSURANCE RECORDS**

a. Audit Scope

The NRC audit team reviewed QA program record controls to verify that the QA program provides for the preparation of sufficient records to furnish documentary evidence of activities affecting quality. Specifically, the NRC audit team verified that the QA program provides for the administration, identification, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records. Also, the audit team verified that the procedures and policies were developed to adequately implement the requirements for record retention.

b. Observations

The NRC audit team reviewed the HMI policies and procedures governing quality assurance records to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion XVII, "Quality Assurance Records," of Appendix B.

b.1 Policies and Procedures for Quality Assurance Records

MHI's US-APWR QAM contains Procedure PQF-HD-18041-070, "Quality Assurance Record Control Procedure," Revision 2 dated September 18, 2007, which follows the guidance in NRC Standard Review Plan (SRP) 17.5, paragraph II.Q, Records. Procedure PQF-HD-18041-070 contained the requirements for preparation, traceability, handling, storing, preservation, safekeeping, and a storage facility for quality records. Appendix 1 of the procedure designates the retention periods for QA records. The procedure gives each manager of a department/section the responsibility to prepare the necessary quality records. Procedure PQF-HD-18041-070 states that each department has its own procedure which must meet the requirements of PQF-HD-18041-070. The procedure describes that each record of quality shall contain the dates of preparation, review, and approval, and the signatures of those personnel who prepared, reviewed, and approved the record.

b.2 Review of Quality Assurance Records

The NRC audit team reviewed the implementation of the MHI quality record control program and found that all MHI QA records are retained in two copies of microfilm. The microfilm copies are stored in separate facilities which are access and environmentally controlled. The original records are returned to the record owner. The audit team reviewed pictures of one of the storage facilities to review the layout of the storage room.

All design documents go to storage immediately after approval and issuance. QA records which are designated as nonpermanent, such as audit reports and training and qualification records, are stored in a temporary storage container which meets NQA-1 requirements for up to a year before being transferred to final record storage as allowed by procedure PQF-HD-18041-070.

The audit team reviewed a sample of quality records including: (1) training and qualification records and (2) a design package, and determined that the records were adequately prepared, maintained, reviewed, approved, and stored in an easily auditable fashion.

c. Conclusions

The NRC audit team concluded that the QA record control requirements have been appropriately translated into implementing procedures. For those activities reviewed by the NRC audit team, requirements were implemented as required by the applicant's procedures to support the MHI US-APWR application. The NRC audit team did not identify any issues requiring additional action by the applicant prior to completion of the US-APWR application.

**3.7 AUDITS**

a. Audit Scope

The NRC audit team reviewed a representative sample of internal audits conducted by MHI to determine the effectiveness of the audit process and timely completion of audits. Audit findings reported by the audits were reviewed for any adverse significance they may have on the results of the US-APWR DC application. Corrective actions to resolve deficiencies identified by the findings and observations were reviewed for reasonableness and timely resolution.

b. Observations

The NRC audit team reviewed the MHI policies and procedures governing the audit process to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion XVIII, "Audits," of Appendix B.

b.1 Policies and Procedures for Audit Control

MHI QAPD Section 18, "Audits." The QAPD provides for the top level requirements for audits. The QAPD provides for the performance of annual internal audits and the reporting of the results to the responsible section manager.

MHI procedure PQF-HD-18041-080, "US-APWR Quality Assurance Manual Audit Procedure," Revision 2, describes the methods to be used in conducting QA audits for quality activities for the US-APWR project. Section 7 and 8 provide description of the internal and MHI's supplier audit processes, respectively, for assuring implementation of quality activities consistent with



the QA plan for the US-APWR project. The procedure provides requirements for the preparation and conduct of internal audits once each calendar year, and every three years for supplier audits. The procedure also provides a process for the evaluation of the quality acceptability of a supplier, and requirements to include new suppliers on the approved supplier list.

During the review of PQF-HD-18041-080, the auditors observed that the procedure did not reference or include as an attachment, the checklists used during the conduct of audits. In addition, the procedure did not provide a description of how the checklist must be completed and when each of the different supplier checklists should be used. The NRC audit team discussed this with MHI QA staff, and MHI agreed to revise the procedure to include this information in the procedure. During the course of the audit, MHI had started to revise the procedure to address the issue by including the reference to each checklist. The NRC audit team reviewed the proposed changes and found them to be acceptable.

MHI procedure PQF-HD-18041-028, "US-APWR Quality Assurance Manual Design Review Audit Procedure," Revision 2, describes the methods to conduct design review audits for design activities for US-APWR activities. The purpose of this audit is to verify that the individual design output (document) preparation activities meet the QA program. The procedure provides requirements for the conduct of design review audits once a month to each department and section on every completed document.

#### b.2 Internal and Design Review Audit Activities

The NRC audit team selected a representative sample of the internal and design review audits associated with the activities performed during the preparation of the US-APWR Design Certification application.

The NRC audit team reviewed internal audits performed to the following sections to verify each section's compliance with the quality assurance manual:

- Instrument and Control Engineering Section, dated November 5, 2007.
- Radiation Safety Engineering Section, dated October 26, 2007.
- Thermal Hydraulics and Core Internal Engineering Section, dated October 19, 2007.
- Water Reactor System Engineering, dated October 25, 2007.
- Electrical Engineering Section, dated October 23, 2007.
- Nuclear Energy System Quality and Safety Management Section, dated November 9, 2007.

The audit team noted that the checklist used to perform the internal audit was very extensive and included areas that were not applicable for the US-APWR project. The NRC Audit team found that one did not verify the same areas in the checklist as the other audits. MHI QA staff explained that the lead auditor had a different interpretation of what was required for that area in the checklist. MHI agreed that the procedure did not describe the applicability and requirement of each area of the checklist. During the course of the audit, MHI QA staff had revised the procedure to include this guidance on the use of the checklist for both internal and external audits, in addition to requiring the lead auditor to add justification when determination is made that an area is not applicable to the audit. The NRC audit team reviewed the revision to the procedures prior to the end of the audit, and found the proposed changes to be acceptable.

The NRC audit team noted that the internal and design review audits reviewed identified a number of issues that were administrative in nature, and did not materially affect the quality of the US-APWR DC application. The NRC audit team also reviewed the corrective action files for these findings and found the resolution had been performed in a timely manner in accordance with project requirements.

c. Conclusions

Except for the two examples identified above, the NRC audit team concluded that the audit process requirements have been appropriately translated into implementing procedures, and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the MHI US-APWR DC application development program. In response to the examples identified by the audit team, MHI addressed each issue prior to the end of the audit in a revision to the affected procedure. The NRC audit team reviewed the revisions and found them to be acceptable. The NRC audit team, therefore, did not identify any issues in this area requiring additional action by the applicant prior to completion of the US-APWR DC application.

### **3.8 TRAINING AND QUALIFICATION**

a. Audit Scope

The NRC audit team reviewed the MHI QA program to verify that it provided for the indoctrination and training of personnel performing activities affecting quality to assure that proficiency was achieved and maintained. Specifically, the NRC audit team verified that MHI adequately implemented and maintained personnel training and qualification processes.

b. Observations

The NRC audit team reviewed the MHI manuals and standards governing training and qualification to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion II, "Quality Assurance Program," of Appendix B.

b.1 Policies and Procedures for Training and Qualification

MHI QAM contains the documents which details the QA training for MHI employees including specific requirements for the training and qualification of managers, auditors, and design personnel. Procedure PQF-HD-18041-003, "Indoctrination and Training Control Procedure," Revision 2, dated September 18, 2007, provides the training requirements for MHI personnel to be engaged in the US-APWR project and follows the guidance in NRC SRP 17.5, paragraph II. S and T. Training and Qualification. Procedure PQF-HD-18041-003 states that it is the responsibility of the manager to draw up and implement the indoctrination and training plan for personnel. Procedure PQF-HD-18041-002, "Qualification Procedure for the Management of US-APWR Activities," Revision 4, dated November 14, 2007, provides the training requirements for managers involved in the US-APWR project. Procedure PQF-HD-18041-027, "Design Personnel Qualification Procedure," Revision 1, dated September 18, 2007, provides the requirements for training and qualification of personnel who prepare, review, and authorize design packages for the US-APWR project. MHI NESQD Standard 5HD9-052, "Auditor Qualification Procedure," and Standard 5HD9-051, "Qualification and Certification Procedure of Lead Auditor," contain the requirements for the training and qualification of QA auditors and lead auditors for the US-APWR project.

MHI QAM states that training and qualification records are to be maintained for 10 years. The record retention requirement is also stated in Appendix A to Procedure PQF-HD-18402-070, "Quality Assurance Records Control Procedure," Revision 2.

The NRC audit team reviewed MHI's contractor's EDC, Osayashi Corporation, and Takasago Research and Development (R&D) Center training and qualification programs. EDC's US-APWR Quality Assurance Program, Revision 5, dated November 2007, contains the requirements for the training and qualification of personnel. Osayashi Corporation's Quality Assurance Program, dated October 2007, requires that training shall be given in accordance with training and indoctrination procedures. Takasago R&D Center's QAM requires certification of test personnel, auditors, and lead auditors.

#### b.2 Review of Training Activities and Records

It is the responsibility of each section manager to prepare and implement an indoctrination and training plan each year. The training plan includes training on new revisions of procedures relevant to the section's activities. The QA department reviews the adequacy of the indoctrination and training plan and ensures that new procedure revisions relevant to the sections are in the plan. The NRC audit team reviewed an indoctrination and training plan and noted that a new revision of a procedure was listed as a training item.

The NRC audit team sampled 11 training records for design personnel participating in the US-APWR project. All "Design Engineer Performance Qualification" records were complete, approved by the required management, and maintained as quality records. In addition, the NRC audit team reviewed the training records for an auditor and two lead auditors. In all cases, the training records were complete with documentation of qualifications, previous audits completed, examination grade, and manager approval signature.

The NRC audit team sampled a design package and verified that the reviewer and preparer of the package were qualified to perform the function. In both cases, the personnel were trained in accordance with Procedure PQF-HD-18041-027 and records were complete and maintained.

#### c. Conclusions

The NRC audit team concluded that the training process requirements reviewed were implemented appropriately by the applicant. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the US-APWR application.

### **3.9 10 CFR PART 21 IMPLEMENTATION**

#### a. Audit Scope

The NRC audit team reviewed the process for implementing 10 CFR Part 21 requirements for reporting defects and noncompliance. These reviews were performed to verify that requirements for quality-related activities, consistent with 10 CFR Part 21, were being adequately implemented.

b. Observations

b.1 Policies and Procedures for Part 21 Controls

The NRC audit team reviewed implementing procedures and policy guidelines governing the MHI 10 CFR Part 21 program. The NRC audit team verified that the MHI process adequately outlined the requirements for identification, evaluation, and reporting of significant conditions adverse to quality.

MHI Procedure PQF-HD-18041-062, "US-APWR Quality Assurance Manual Reporting Procedure of Defects and Nonconformance to NRC," Revision 1, establishes procedures and responsibilities to ensure compliance with and timely execution of 10 CFR Part 21 requirements. Section 5 of the procedure assigns responsibility to a Safety Review Board for the evaluation of deviations and failure to comply identified in Nonconformance Reports or Corrective Action Reports. The procedure contains guidance for the notification to the NRC of evaluated deviations and failures to comply that could create a substantial safety hazard.

The NRC audit team noted that the procedure was only applicable to Chapters 1 through 3 of the draft DC application for safety-related activities described within those chapters. In addition, the NRC audit team noted that Figure 1, "Action Program for Reporting to the NRC" (included in the procedure to show a time-line of actions required by the regulations) was not consistent with the time requirements specified in 10 CFR Part 21. The NRC audit team discussed these issues with the MHI QA staff, and as a result, the MHI QA staff initiated a revision to the procedure to address these concerns. Specifically, the procedure revisions included: (1) expanding the applicability of the procedure to all safety-related activities; (2) removed the time-line figure from the procedure; and (3) specifying the action time requirements consistent with the regulation within the body of the procedure. The NRC audit team reviewed the revisions to the procedure prior to the end of the audit, and found the proposed changes to be acceptable.

b.2 10 CFR Part 21 Program Implementation

Nonconformances and corrective actions are processed through the MHI corrective action and nonconformance programs as discussed in Section 3.5 of this report. The NRC audit team reviewed a sample of CARs and NCRs to determine whether MHI personnel had considered the evaluation of deviations for potential reportability of defects and failures to comply. After discussions with MHI personnel, the NRC audit team found that MHI had determined that none of the deficiencies identified during the US-APWR Design Certification application development had reached the threshold of a "substantial safety hazard."

c. Conclusions

The NRC audit team concluded that the 10 CFR Part 21 requirements have been appropriately translated into an implementing procedure, and for the sample activities reviewed, implemented as required to support the US-APWR COLA development process. However, as described above, the NRC audit team did identify several issues associated with the 10 CFR Part 21 procedure that were addressed by MHI prior to completion of the NRC audit. Therefore, no issues requiring additional action by the applicant prior to completion of the US-APWR DC application were identified.

### 3.10 CONSISTENCY WITH REGULATORY GUIDE 1.206, "COMBINED LICENSE APPLICATIONS FOR NUCLEAR POWER PLANTS," JUNE 2007

#### a. Audit Scope

The NRC audit team assessed the completeness and accuracy of the MHI US-APWR DC application. Based on RG 1.206 guidance, each section of the draft US-APWR DC FSAR and Tier 1 information was compared to the guidance in Regulatory Guide 1.206 and the requirements of 10 CFR 52.47. A gap in information was defined as information not present in the FSAR, Tier 1.

#### b. Observations

The intent of the NRC assessment was to provide the potential applicant, MHI, and the staff with insights into the completeness and accuracy of the US-APWR DC application consistent with 10 CFR 50.9 requirements. MHI plans to submit the application on or before December 31, 2007. As a result of the NRC audit, the NRC identified a number of gaps in information in the US-APWR DC FSAR. These gaps are identified as ARRs and are discussed in detail below. The following table presents the results of this assessment:

<b>US-APWR Pre-Application Audit – NRC Comments on Draft Design Control Document</b>		
<b>Chapter</b>	<b>Section</b>	<b>Issue</b>
Tier 1	-	Contrary to 10 CFR 52.47 which requires the DCD to describe an essentially complete design; the access building, turbine building, and auxiliary building were not included within the DCD scope.
Tier 1	2.2	Tier 1, Section 2.2 and Tier 2, Section 1.8 are inconsistent with regard to the Auxiliary Building, Turbine Building and Access Building being within the scope of the DCD. ITAACs are not provided for these buildings although these building are described in Tier 2 as being in scope.
Tier 1	-	MHI should clearly identify design areas in which it is using DAC. Tier 1 is currently unclear in this respect.
Tier 1	2.2	Tier 1 and Tier 2 information is inconsistent. Specifically, Figure 2.2-14 and Table 2.2.-2 in Tier 1 could not be found in Tier 2.
Tier 1	2.2	Figure 2.2-1 in Tier 1 is inconsistent with Table 3.7.1-3 in Section 3.7.1 of Tier 2 with respect to building dimensions. Because these dimensions have significant impact on load calculations, the application should provide specific dimensions.
3	3.7	Sections 3.7 and 3.8 of the DCD do not include a set of structural drawings or floor plans, or key dimensions for structural analysis.
3	3.7.2.1 to 3.7.2.5	Sections 3.7.2.1 to 3.7.2.5 of the DCD do not provide the final seismic in-structural response spectra for components or structures.
3	3.8	Section 3.2 classifies the East and West PS/B as Category 1 structures but does not provide detailed descriptions of building structures, methods, loadings or figures. Although

<b>US-APWR Pre-Application Audit – NRC Comments on Draft Design Control Document</b>		
<b>Chapter</b>	<b>Section</b>	<b>Issue</b>
		the DCD states that MHI would provide a design analysis by May 2008, or make it a COL item, the NRC indicated that this information should be included in the DCD itself.
3	3.12.5.10	Section 3.12.5.10 of the DCD does not include a program description for thermal stratification to ensure the continued integrity of piping systems, as required by SRP 3.1.2.
5	5.2.1.2	In Section 5.2.1.2 there is no table listing the components for which a code case has been applied.
5	5.2.3.1	Section 5.2.3.1 of the DCD does not identify the material specifications for weld filler material (specification for the material is missing from tables in this section).
5	5.2.3.1	The Table in Section 5.2.3.1 of the DCD does not identify material grade for Alloy 690 material.
5	5.2.3.3.2	Section 5.2.3.3.2 of the DCD does not provide the details of the minimum preheat temperature or maximum interpass temperature.
5	5.4.1.1	Section 5.4.1.1 contains a statement of compliance of the reactor coolant pump flywheel with RG 1.14 but no details are provided to demonstrate compliance.
5	5.4.7.2.2.1	Section 5.4.7.2.2.1 does not provide pump characteristic curves, power requirements, or NPSH limits for the RHR pumps, as required by RG 1.206.
6	6.2.1.1	Section 6.2.1.1 should identify locations in the containment where water may be trapped and not returned to the containment sump and discuss how the retained water may affect the head of the recirculation pumps.
6	6.2.2.3	Section 6.2.2.3 of the DCD should describe the extent to which the containment accident pressure is credited in calculating the NPSH and the uncertainties in this calculation. The discussion in Section 6.2.2.3 does not include a discussion of the uncertainties.
7	--	The MHI Topical Report on I&C Safety Design commits to providing information as part of future licensing submittals. MHI should identify this information either in the DCD, in the ITAACs or as a COL item.
9	9.3.2.1	Section 9.3.2.1 of the DCD should provide the design basis for the post accident sampling system in accordance with 10 CFR 50.34(f)(2)(viii) and 50.34(f)(2)(xvii).
9	9.3.3.	Section 9.3.3 of the DCD does not contain the general design criteria, as required by RG 1.206, for the floor drain system.
11	11.2.1.2, 11.2.1.3, 11.2.2.1	Sections 11.2.1.2, 11.2.1.3, and 11.2.2.1 provide no analysis to demonstrate compliance with SRP Section 11.2 and BTP 11.6.
11	11.2.1.5	Section 11.2.1.5 applies a wrong interpretation of an NEI topical report. The topical report provides a bounding envelope for ALARA cost-benefit analysis, but MHI provides no analysis to show that it falls within the envelope.

<b>US-APWR Pre-Application Audit – NRC Comments on Draft Design Control Document</b>		
<b>Chapter</b>	<b>Section</b>	<b>Issue</b>
11	11.2.2	Section 11.2.2 references Figures 11.2-2A to 11.2-2H, which are not included in the DCD.
11	11.2.3	Section 11.2.3 provides no analysis to demonstrate compliance with the dose criteria in Section 2.A of Appendix I to 10 CFR Part 50.
11	11.3	Figure 11.3-1C and Figure 11.3-2 are referenced but are not included in the DCD.
11	11.3.1.2	Section 11.3.1.2 does not provide design criteria for cross contamination of radioactive material between systems.
11	11.3.1.2	Section 11.3.1.2 does not have an analysis specified by RG 1.140 for the design of filtration exhaust systems.
11	11.3.1.4	Section 11.3.1.4 refers to Table 11.3-4, which describes the assessment of a component failure of the gas waste management system. However, the DCD does not provide any model assumptions and there is no demonstration that failure of the gas surge tank is more limiting than failure of the charcoal bed. The section provided no comparison to criteria in BTP 11.5 referenced in SRP Section 11.3.
11	11.3.3	Section 11.3.3 references Table 11.3-3 which is not included in the DCD.
11	11.3.3	Section 11.3.3 does not demonstrate compliance with Section 2B or 2C of Appendix I to 10 CFR Part 50. No dose results, no calculations for noble gases, and no dose criteria are provided.
11	11.4	Figure 11.4-5 is missing from the DCD.
11	11.4.4	Section 11.4.4 does not describe the design features or the operational characteristics for the evaporator or drum dryer shown in Figure 11.4-3.
11	11.5.1.2	Section 11.5.1.2 does not include the applicable references for the design criteria, specifically, 50.34(f)(2), NUREG 0718, NUREG 0737, BTP 7-10, and RG 1.33.
12	12.2.1.1.3 to 12.2.1.1.10	Sections 12.2.1.1.3 through 12.2.1.1.10 do not provide parameters for the sources, density, or self shielding for the locations discussed in these sections.
12	12.3	Section 12.3 refers to Figure 12.3-2. This figure should be scaled, or a separate table should be provided, to show wall, floor and ceiling thicknesses which are necessary to confirm radiation shielding.
12	12.3.4.2.1	Section 12.3.4.2.1 of the DCD does not provide the sensitivity of the airborne radiation monitors. The DCD should indicate that the radiation monitors are capable of detecting 10 DAC hours for particulate and iodine for any compartment where radiation may exist.
14	14.2	Section 14.2 does not describe the general prerequisites or specific objectives for each phase of the initial preoperational test program as specified by RG 1.206.
14	14.2	Section 14.2 has many Bin 2 or Bin 3 issues which in their aggregate raise a larger concern. The overall concern is that

<b>US-APWR Pre-Application Audit – NRC Comments on Draft Design Control Document</b>		
<b>Chapter</b>	<b>Section</b>	<b>Issue</b>
		the test abstracts do not systematically address key test parameters, e.g., redundancy, loss of offsite power, etc.
19	-	In Chapter 19, the fire and flooding analysis does not include significant accident sequences and leading contributors for risk. This information should be included.
19	19.2.6	Section 19.2.6 of the DCD should include a discussion of improvements in core heat removal and containment heat removal systems reliability that are significant and practicable as required by the TMI requirements. Substantively, this is the same issue as the Severe Accident Mitigation Design Alternative (SAMDA) issue identified below.
Environmental Report	-	The Environmental Report (related to SAMDA) required by 52.47 and 51.55 that should be a part of the DCD has not been provided.

c. Conclusions

The NRC audit team concluded that the FSAR chapters and Tier 1 of the MHI US-APWR DC application are consistent with the format and content prescribed in RG 1.206, with the exceptions noted above. These exceptions are identified as ARRs and need to be addressed to demonstrate adherence to RG 1.206 and compliance with 10 CFR 52.47. These ARRs are to be addressed by MHI before or as part of the US-APWR DC application submittal.

**4.0 ENTRANCE AND EXIT MEETINGS**

In the entrance meeting on November 26, 2007, the NRC audit team discussed the scope of the audit, outlined the areas to be reviewed, and established interfaces with MHI's staff management and contractors involved in the US-APWR DC application development. In the exit meeting on November 30, 2007, the NRC audit team discussed the audit activities conducted during the audit with representatives of MHI's management staff.

**5.0 PARTIAL LIST OF PERSONS CONTACTED**

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