

February 2, 2011

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

SUBJECT: NRC INSPECTION REPORT NO. 05200021/2010-201 AND NOTICE OF VIOLATION

Dear Mr. Ogata:

On December 6–10, 2010, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Mitsubishi Heavy Industries, Ltd. (MHI) office in Kobe, Japan. The purpose of the inspection was to assess MHI's compliance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." The enclosed report presents the results of the inspection. This inspection report does not constitute NRC endorsement of your overall quality assurance or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC determined that three violations of NRC requirements occurred. The enclosed Notice of Violation (Notice) cites the violations, and the subject inspection report describes in detail the circumstances surrounding the violations. The violations are being cited in the Notice because the NRC inspection identified examples where MHI failed to adequately implement aspects of its Corrective Action, Control of Nonconformances, and Audit Programs in accordance with Appendix B to 10 CFR Part 50.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or Safeguards Information, so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from

public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide, in detail, the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,
/RA/

Juan Peralta, Chief
Quality and Vendor Branch 1
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No.: 05200021

Enclosures: 1. Notice of Violation
2. Inspection Report No. 05200021/2010-201 and Attachments

public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide, in detail, the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,
/RA/

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(Revised 06/23/2010)

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NOTICE OF VIOLATION

Mitsubishi Heavy Industries, Ltd.
Wadasaki-cho-1-1-1, Hyogo-ku
Kobe 652-8285 Japan

Docket Number 05200021
Inspection Report Number 2010-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Mitsubishi Heavy Industries, Ltd. (MHI) office in Kobe, Japan, on December 6–10, 2010, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50 states, in part, that “Measures shall be established to assure that purchased material, equipment and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.”

Criterion XVIII, “Audits,” of Appendix B to 10 CFR Part 50 states, in part, that “a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited.”

MHI procedure 5HE9-092-080E, “Audit Procedure,” Section 8.2(2), dated October 13, 2010, states, in part, that “the audit team leader shall direct and assume the leadership of the audit team, and confirm the implementation of the QA activities based on the evidences relating to the check sheets. The title, document number (revision number) and the evaluation result regarding the document confirmed according to each check item shall be recorded in the check sheet.”

MHI’s Quality Assurance Program Description QAPM (US-APWR Project Addenda), Section 4(4)(b)iii, dated November 30, 2010, states, in part, that “sufficient objective evidence is available to support conclusions of the audit.”

MHI’s Quality Assurance Manual (QAM), Section 4.4.2(3), dated November 18, 2010, states, in part, that “objective evidence shall be examined to the depth necessary to determine if the selected elements are being implemented effectively. The examined objective evidence shall be recorded by the auditing personnel on the checklist.”

MHI's QAM, Section 19.3.6 states, in part, that "objective evidence shall be evaluated against the requirements of the QA program by the assigned audit team leader."

Contrary to the above, as of December 11, 2010, MHI failed to collect adequate objective evidence necessary to confirm the conclusions documented in several supplier external audits and internal audits conducted by MHI.

This issue is identified as Violation 05200021/2010-201-01.

- B. Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states that "Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures."

MHI Quality Assurance Program Description (QAPD), Section 15, "Nonconforming Materials, Parts, or Components," states, in part, that MHI has established measures and governing procedures to control items, including services, that do not conform to specified requirements to prevent inadvertent installation or use.

MHI Procedure PQF-HD-19019-E040, "Control of Nonconformance," Revision 2, dated March 30, 2010, states, in part, that any personnel who have discovered a nonconformance shall promptly prepare a nonconformance report.

MHI Procedure 5HE9-092-060E, "Control Procedure of Nonconformance," Revision 0, dated August 30, 2010, states, in part, that when the responsible department/section receives notification of a nonconformance (or finds the nonconformance), the responsible department/section shall start the disposition of the nonconformance.

Contrary to the above, MHI nonconformance reports issued to document nonconformances related to the U.S. Advanced Pressurized-Water Reactor (US-APWR) design certification application were not issued promptly as prescribed in MHI procedures. Specifically, 12 of the 45 nonconformance reports were initiated 1 month to 2 years after the discovery date of the nonconformance.

This issue is identified as Violation 05200021/2010-201-02.

- C. Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and

nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.”

Criterion V, “Instructions, Procedures, and Drawings,” of Appendix B to 10 CFR Part 50 states, in part, that “activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.”

MHI QAPD, Section 16, “Corrective Action,” states, in part, that MHI has established measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of significant conditions adverse to quality, the cause is determined and actions to preclude recurrence are taken.

MHI Procedure 5HE9-092-061E, “US-APWR Quality Assurance Manual - Corrective Action Procedure,” Revision 0, dated August 30, 2010, states, in part, that MHI shall promptly identify the significant conditions that fail to comply with the quality requirements and take any corrective action as soon as possible. Additionally, 5HE9-092-061E states, in part, that MHI shall conduct the time-course and systematic trend analyses on the causes of the nonconformance described in the finding and observation items of the nonconformance reports, corrective action reports, internal audit reports, and external audits/customer audits.

MHI Procedure PQF-HD-19019-E041, “US-APWR Quality Assurance Manual, Corrective Action,” Revision 2, dated March 30, 2010, states, in part, that MHI shall promptly identify significant conditions adverse to quality and take corrective action as soon as possible. Additionally, PQF-HD-19019-E041 states, in part, that MHI will review nonconformance reports, corrective action reports, internal audit reports, and external audits/customer audits in which conditions adverse to quality are identified and documented to understand the condition and classification of trends.

Contrary to the above, MHI failed to implement measures to (1) assure that the cause of significant conditions adverse to quality was determined and corrective action taken to preclude repetition, and (2) perform time-course and systematic trend analyses. In addition, MHI Procedures 5HE9-092-061E and PQF-HD-19019-E041 did not provide sufficient guidance to classify conditions adverse to quality and significant conditions adverse to quality.

This issue is identified as Violation 05200021/2010-201-03.

These are Severity Level IV violations (Section 6.5.d).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," MHI is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality and Vendor Branch 1, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, the NRC will consider extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or Safeguards Information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this the 2th day of February.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND OPERATIONAL PROGRAMS
QUALITY ASSURANCE IMPLEMENTATION INSPECTION REPORT

Docket No.: 05200021

Report No.: 05200021/2010-201

Applicant: Mitsubishi Heavy Industries, Ltd.
Wadasaki-cho-1-1-1, Hyogo-ku
Kobe 652-8285 Japan

Applicant Contact: Mr. Yoshiki Ogata, General Manager
Mitsubishi Heavy Industries, Ltd.
APWR Promoting Department
16-5, Konan 2-Chome, Minato-Ku
Tokyo, 108-8215 Japan
yoshiki_ogata@mhi.co.jp

Background: Mitsubishi Heavy Industries, Ltd., submitted an application for standard design certification for the U.S. Advanced Pressurized-Water Reactor (US-APWR) on December 31, 2007.

Inspection Dates: December 6–10, 2010

Inspectors: Greg Galletti NRO/DCIP/CQVA Lead Inspector
Juan Peralta NRO/DCIP/CQVA
Kerri Kavanagh NRO/DCIP/CQVA
Yamir Diaz-Castillo NRO/DCIP/CQVA
George Khouri RII/DCI/CIB3

Approved by: Juan Peralta, Chief
Quality and Vendor Branch 1
Division of Construction Inspection
& Operational Programs
Office of New Reactors

EXECUTIVE SUMMARY

Mitsubishi Heavy Industries, Ltd.
05200021/2010-201

The U.S. Nuclear Regulatory Commission (NRC) inspection focused on quality assurance (QA) policies and procedures implemented to support the design certification (DC) application for the U.S. Advanced Pressurized-Water Reactor (US-APWR), as described in NRC Inspection Manual Chapter 2508, "Construction Inspection Program: Design Certification." The purpose of this inspection was to verify that Mitsubishi Heavy Industries, Ltd. (MHI) had implemented an adequate QA program that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The inspection also verified that MHI had implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets NRC regulatory requirements.

During this inspection, the NRC inspection team implemented Inspection Procedure 35017, "Quality Assurance Implementation Inspection," dated July 29, 2008, and Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Noncompliance," dated October 3, 2007. In addition, the NRC inspection team reviewed aspects of the MHI QA program which included activities conducted by the MHI Nuclear Energy Systems Headquarters (NESH), Nuclear Energy Systems Engineering Center (N-Center), and the Kobe Shipyard & Machinery Works (Kobe).

With the exception of the violation described below, the NRC inspection team concluded that the portions of the MHI QA program and the MHI Part 21 program reviewed by the NRC inspection team comply with the applicable requirements of Appendix B to 10 CFR 50 and 10 CFR Part 21, respectively.

10 CFR Part 21

The NRC inspection team concluded that the implementation of the MHI 10 CFR Part 21 program is consistent with the regulatory requirements of 10 CFR Part 21. Based on its review, the NRC inspection team also determined that MHI is effectively implementing its policies and associated procedures to support the DC application for the US-APWR. No findings of significance were identified.

Design Control

The NRC inspection team concluded that the implementation of the MHI design control process is consistent with the regulatory requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that MHI is effectively implementing its policies and procedures to support the DC application for the US-APWR. No findings of significance were identified.

Procurement Document Control

The NRC inspection team concluded that the implementation of the MHI procurement document control process is consistent with the regulatory requirements of Criterion IV, "Procurement

Document Control,” of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that MHI is effectively implementing its policies and procedures to support the DC application for the US-APWR. No findings of significance were identified.

Control of Purchased Material, Equipment, and Services

The NRC inspection team identified one violation associated with MHI’s failure to implement the requirements of Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50. An example of Violation 05200021/2010-201-01 identifies MHI’s failure to collect adequate objective evidence necessary to confirm the conclusions documented in supplier external audits conducted by MHI.

Nonconforming Materials, Parts, or Components

The NRC inspection team identified one violation associated with MHI’s failure to implement the requirements of Criterion XV, “Nonconforming Materials, Parts, or Components,” of Appendix B to 10 CFR Part 50. Violation 05200021/2010-201-02 identifies MHI’s failure to promptly issue nonconformance reports consistent with MHI procedures.

Corrective Action

The NRC inspection team identified one violation associated with MHI’s failure to implement the requirements of Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50. An example of Violation 05200021/2010-201-03 identifies MHI’s failure to implement measures to (1) assure that the cause of significant conditions adverse to quality was determined and corrective action taken to preclude repetition, and (2) perform time-course and systematic trend analyses. In addition, MHI Procedures 5HE9-092-061E and PQF-HD-19019-E041 did not provide sufficient guidance to classify conditions adverse to quality and significant conditions adverse to quality.

Audits

The NRC inspection team identified one violation associated with MHI’s failure to implement the requirements of Criterion XVIII, “Audits,” of Appendix B to 10 CFR Part 50. An example of Violation 05200021/2010-201-01 identifies MHI’s failure to collect adequate objective evidence necessary to confirm the conclusions documented in internal audits conducted by MHI.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed the implementation of the Mitsubishi Heavy Industries, Ltd. (MHI) program under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliances," in support of the design certification (DC) for the U.S. Advanced Pressurized-Water Reactor (US-APWR). Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of the MHI 10 CFR Part 21 process to verify compliance with the requirements of 10 CFR Part 21. The NRC inspection team also discussed this process with members of MHI management and technical staff.

The NRC inspection team reviewed the following documents for this inspection area:

- PQF-HD-19029-E042, "US-APWR Quality Assurance Manual, Reporting Procedure of Defects and Nonconformance to NRC," Revision 3, dated March 30, 2010
- 5HE9-092-062E, "US-APWR Quality Assurance Manual, Reporting Procedure of Defects and Nonconformance to NRC," Revision 0, dated August 30, 2010
- UES-69-020008, "ASME Code Job, Identification and Reporting of Condition Adverse to Safety, Reporting of Defects and Noncompliance (10 CFR Part 21)," Revision 12, dated September 9, 2009
- PQD-HD-19005, "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR," Revision 3, dated October 1, 2009
- UAP-CFR-HEQ-10001, "Problem with Seismic Analysis Software," dated September 3, 2010

b. Observation and Findings

b.1 10 CFR Part 21 Procedure

Procedures PQF-HD-19029-E042, 5HE9-092-062E, and UES-69-020008, for NESH, N-Center, and Kobe, respectively, outline the process used at MHI for the reporting of defects and nonconformances discovered by the vendor or reported to the vendor by its suppliers or customers. The procedure provides for the review of such deviations by the safety review team that completes the evaluation based on the preliminary evaluation result submitted by the responsible section manager. Within 60 days of discovery, the safety review team is responsible for determining if the identified deviation is reportable to the NRC. This determination is documented as described in a form provided in Appendix 8 to UES-69-020008, along with the supporting documentation to substantiate the decision. The safety review team is also responsible for (1) notifying the customer or affected licensees within 5 days of determining that the responsible section cannot perform the review, (2) providing an interim report within 60 days, if necessary, (3) informing the deputy general manager within 5 working days if

notification of the NRC is required, (4) notifying the NRC Operation Center via phone within 2 days if a defect or failure to comply exists, and (5) notifying the section manager to prepare a written report within 30 days.

The NRC inspection team verified that MHI procedural guidance was adequate to initiate the 10 CFR Part 21 process when a nonconformance report (NCR) or corrective action report (CAR) was written that could have an impact on the US-APWR DC application.

b.2 10 CFR Part 21 Implementation

The NRC inspection team determined that UES-69-020008 contains adequate procedural guidance to initiate the 10 CFR Part 21 process when an NCR or CAR is written and that the MHI staff is knowledgeable about the conditions that would warrant a 10 CFR Part 21 evaluation. The NRC inspection team reviewed the only Part 21 evaluation that MHI has performed in support of the US-APWR DC application. UAP-CFR-HEQ-10001 documents the evaluation of errors generated by the ACS SASSI NQA Version 2.2.1, "Software for Application to Deep Soft Soil Deposits," for soil layers above 80. Sargent and Lundy had previously notified the NRC about the software errors in their 10 CFR Part 21 report, Event Number 45343, dated September 11, 2009. MHI determined that analyses performed using ACS SASSI Version 2.2.1 did not exceed the maximum number of soil layers described in the Part 21 report. Additionally, analyses in support of the US-APWR design control document (DCD) have been performed by using ACS SASSI Version 2.3, which has been modified based on the Part 21 report of ACS SASSI Version 2.2.1. The NRC inspection team noted that MHI has not made any Part 21 notifications related to the US-APWR DC application.

c. Conclusions

The NRC inspection team concluded that the implementation of the MHI 10 CFR Part 21 program is consistent with the regulatory requirements of 10 CFR Part 21. Based on its review, the NRC inspection team also determined that MHI is effectively implementing its policies and associated procedures to support the DC application for the US-APWR. No findings of significance were identified.

2. Design Control

a. Scope

The NRC inspection team reviewed MHI's policies and procedures that govern design control activities to verify compliance with the requirements of Criterion III, "Design Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50. In addition, the NRC inspection team interviewed MHI personnel and reviewed source documentation to verify implementation of the design control program.

Specifically, the NRC inspection team reviewed the following MHI policies and procedures:

- B91U-N0001, Section 1, "Order Entry and Design Control," Revision 28, dated November 9, 2007
- Nuclear Energy Systems Engineering Center (N-Center) 5HE9-001E, "Quality Assurance in General," Revision 13, dated December 28, 2010

- N-Center 5HE9-092E, "US-APWR Quality Assurance Manual" (QAM), Revision 1, dated October 28, 2010
- N-Center QAM 5HE9-092-002, "Qualification Procedure for the Management of US-APWR Activities," Revision 0
- N-Center 5HE9-092-020E, "US-APWR Quality Assurance Manual: Design Control Procedure," Revision 1
- N-Center 5H9-092-021E, "US-APWR Quality Assurance Manual: Design Interface Control Procedure," Revision 1
- N-Center 5HE9-092-022E, "US-APWR Quality Assurance Manual: Design Verification Procedure," Revision 0
- N-Center 5HE9-092-023E, "US-APWR Quality Assurance Manual: Design Change Control Procedure," Revision 1
- N-Center 5HE9-092-027E, "Design Personnel Qualification Procedure," Revision 0, dated October 13, 2010
- N-Center 5HE9-092-050E, "Procurement Control Procedure," Revision 0
- N-Center 5HE9-092-051E, "Procedure for Procurement Planning Sheet," Revision 0
- N-Center 5HE9-092-052E, "Supplier Quality Assurance Program Requirements for Design and Test Activities," Revision 0
- N-Center, 4DS-UAP-20060058, "US-APWR Structural and Seismic Design Job Assignment," Revision 7, dated July 14, 2007
- PQD-HD-19005, "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR," Revision 3, dated October 1, 2009
- Section Standard, BKB60-N01E, "Procedure for Controlling of the Design Activities," Revision 12, dated June 4, 2010
- Water Reactor System Engineering Section Standard, 5H16-120, "US-APWR Design Control Procedure," Revision 4, dated November 15, 2010
- Water Reactor System Engineering Section Standard, 5H16-101, "US-APWR Quality Assurance Manual Department Operation," Revision 5, dated November 15, 2010
- Water Reactor System Engineering Section Department Standard, 5H16-122, "US-APWR Design Verification Procedure," Revision 4, dated November 15, 2010

b. Observations and Findings

b.1 Design Control Policy and Procedures

The NRC inspection team reviewed the MHI policies and procedures that govern design control to verify conformance with Criterion III of Appendix B to 10 CFR Part 50. The NRC inspection team verified that MHI's program had provisions to control design inputs, processes, output changes, interfaces, records, organizational interfaces, and storage. The NRC inspection team verified that provisions existed to ensure that design documents specify and include appropriate quality standards and requirements and the identification, documentation, and control of changes or deviations from specified design requirements and quality standards.

The NRC inspection team also verified that the quality assurance (QA) program provided for design verification and that design verification is completed before design outputs are used by other organizations for design work. The NRC inspection team verified that the QA program provided for additional design verification when changes are made to previously verified and approved designs. This included evaluating the effects of changes on the overall design and on any design analyses or bases.

For the US-APWR project, 5HE9-092E (the QAM) has been prepared to perform QA activities by the N-Center. Section 7.3, "Design Control," describes the process to be followed and includes design planning, design inputs, design outputs, design verification, design change, and design validation. Specific design control is accomplished through the implementation of QA procedures within the N-Center QAM related to design control, design interface control, design verification, design change control, reevaluation procedure for past acquired design results, and design personnel qualification.

N-Center 5HE9-092-020E defines the control processes to ensure proper implementation of the design phase activities. These include requirements for QA related to planning of design procedures, the selection of design inputs, the design studies and analyses, and preparation of the design documents.

Water Reactor System Engineering Section Standard 5H16-120 provides additional detailed requirements for the conduct of design activities for the US-APWR by the Nuclear Plant Engineering Department (HI). The procedures address the areas specified in N-Center Procedure 5HE9-092-020E and provide additional detailed information regarding design process controls, design change control, design verification, preparation and distribution of design documents, and control of design interfaces.

Water Reactor System Engineering Section Standard 5H16-101 provides additional detailed requirements for the conduct of all quality activities for the US-APWR by the HI. With respect to design control, the document includes requirements for design interface control, design verification, design change, past design data reevaluation, and design engineer qualification. For each area, the standard specifically describes the scope of activity, relevant department or N-Center procedures to be implemented for the conduct of such activities, and responsibility for ensuring adequate implementation of the activity.

The MHI design change process is controlled in accordance with N-Center 5HE9-092-023E. It describes requirements associated with preparation of design document change requests, design change effects evaluations, results of the effects evaluation, confirmation of the proposed design changes by affected organizations, and implementation of the design change.

The MHI design verification process is controlled in accordance with N-Center 5HE9-092-022E. The purpose of the procedure is to specify the design verification process to verify that the design requirements are appropriately reflected in the design documents. The procedure requires the independence of the verifier from the originator or the design initiator and describes the methods that are to be used to perform the verification (e.g., design review, alternate calculation verification tests).

Additionally, Water Reactor System Engineering Section Department Standard 5H16-122 defines the HI control of the design verification process to ensure the adequacy of design requirements. The procedure covers roles and responsibilities of design personnel, implementing procedures, and verification methods and provides a design verification checklist for each type of verification method.

The MHI Design Personnel Qualification Control Program is controlled by N-Center QAM 5HE9-092-002, which provides the requirements for qualifying managers within the line organizations responsible for the US-APWR technical activities. The procedure details specific education and experience in engineering, as well as in QA, and provides for a formal qualification record and acceptance criteria for each.

Additionally, N-Center 5HE9-092-027E establishes the requirements for competency evaluations and qualifications, including indoctrination and training, associated with the qualification of engineers responsible for design and analysis of the US-APWR. The procedure provides standardized records for individual competency evaluation and the technical improvement program (i.e., qualification requirements).

b.2 Implementation of Design Controls

The NRC inspection team reviewed the implementation of the MHI design control process, including design documentation and reports associated with the plant seismic reanalysis and several calculations, piping and instrumentation diagrams, and design change requests for the US-APWR Standard Design advanced accumulator (advanced Accumulator). The inspectors also reviewed a representative sample of MHI contractors' design activities associated with the DC of the US-APWR to verify that design control was appropriately implemented and that applicable design inputs were correctly translated into design output documents.

In addition, the NRC inspection team interviewed MHI personnel and sampled personnel qualification records to verify that personnel associated with the design activities were adequately qualified to perform design activities. Specifically, the NRC inspection team reviewed the following technical documents and calculations:

- USAP-KBS-01-2033, "Owner Acceptance Review NO-F000M01—Design Document Check Sheet," dated March 30, 2010
- 4DS-UAP-20060058, "Job Assignment," Revision 7
- BK60-N06E, Department Standard, "ASME Code Job Procedure for Preparation of Design Reports," Revision 1

- BKB60-N01E, Section Standard, "Procedure for Controlling of the Design Activities," Revision 12
- BK90-N01E, Department Standard, "ASME Code Job Procedure for Control of Design Quality Assurance Records," Revision 1
- BUG99-01(9), "Retention Procedure of Quality Assurance Record"
- BKB20-N01E, "Procedure for Qualification of Designing Engineers"
- N0-F000L01, "US-APWR Standard Design Accumulator Design Specification," Revision 1, dated January 6, 2010
- KBS-20090440, "US-APWR Accumulator Design Input Summary," Revision 2, dated July 7, 2010
- KBS-20081025, "US-APWR Accumulator Design Plan," dated June 16, 2010
- NO-F000M01, "US-APWR Standard Design Accumulator Stress Report," Revision 0
- KBS-20090124, "US-APWR Standard Design Specification for Accumulator Design Analysis," Revision 5, dated October 30, 2009
- KBS-UAP-20100018, "Check Evidence for Accumulator Seismic Analysis (Accumulator Stress Report)," Revision 0, dated January 18, 2010
- Water Reactor System Engineering Section Standard, 5H16-120, "US-APWR Design Control Procedure," Revision 4, dated November 15, 2010
- Water Reactor System Engineering Section Standard, 5H16-101, "US-APWR Quality Assurance Manual Department Operation," Revision 5, November 15, 2010
- 4DS-UAP-2010064, "Seismic Condition 1 Building Seismic Design Plan," Revision 0, dated October 29, 2010
- 5H16-122, "Water Reactor System Engineering Section Department Standard," US-APWR Design Verification Procedure, Revision 4
- 5HIK6-016, "Seismic Design Bases of the US-APWR Standard Design (4DS-UAP-201000027, R1) Soil-Structure Interaction Analyses and Results for the US-APWR Standard Plant", Revision 1
- 4DR-NA3-2010002, "In-Structure Response Spectra of Reactor Building for North Anna Unit 3 (4DS-NA3-20100006, rev 1 for Review)," Revision 0
- "US-APWR Standard Design Pressurizer Design Specification," Revision 3
- "US-APWR Pressurizer Design Plan," Revision 5

- “US-APWR Pressurizer Design Input Summary,” Revision 0
- Design Report No. MG-1209207, “Check Sheet for the Pressurizer Design Report,” dated January 26, 2010
- MG-1209207, “Stress Analysis for the Surge Nozzle of the US-APWR Pressurizer,” Revision 2
- USAP-KBS-10-2065, “Pressurizer Specification N0-F500L01(3) Design Verification Check Sheet,” dated April 14, 2010
- 4BS-UAP-070242, Final Design Document, “US-APWR ISS System,” Revision 0
- L3-01AA505, “Nuclear Plant Component Standard Specification for Design Analysis,” Revision 3

The responsible design organization for the advanced accumulator was Kobe and the N-Center was responsible for the seismic reanalysis. The engineering work associated with both activities was multidisciplinary and involved the services of several subcontractors. The NRC inspection team reviewed all aspects of design control associated with these activities.

Specifically, the inspectors verified the following:

- The design control program establishes adequate provisions to control design inputs, processes, output changes, interfaces, records, and organizational interfaces.
- The applicable design inputs are correctly translated into design output documents.
- Provisions exist to ensure that design documents specify and include appropriate quality standards and requirements.
- Provisions exist to ensure the identification, documentation, and control of changes from specified design requirements.
- The QA program provides for documented indoctrination and training of personnel performing the design activities.
- The QA role in design and analysis activities is adequately defined. Specifically, the inspectors verified that individuals who are knowledgeable and qualified in QA review design the documents to ensure that they contain the necessary QA requirements.
- The QA program provides for design verification. Verification methods include design reviews, alternative calculations, and qualification testing.
- Design verification has been completed before design outputs are used by other organizations for design work and before they are used to support other activities, such as procurement or manufacturing.

The QA program provides for additional design verification when changes are made to previously verified and approved designs. This includes evaluating the effects of changes on the overall design and on any design analyses or bases.

The NRC inspection team did not identify any significant issues associated with the control of design activities by the applicant.

b.3 Design Interface and Configuration Control

The NRC inspection team reviewed MHI policies and procedures that describe the process governing design interface and configuration control of the US-APWR DCD to verify compliance with applicable requirements of Appendix B to 10 CFR Part 50. The NRC inspection team selected a limited sample of design change and licensing process products to evaluate compliance with program requirements and adequate implementation of those requirements by MHI personnel. Specific products reviewed include the following:

- N-Center 5H9-092-021E, "US-APWR Quality Assurance Manual: Design Interface Control Procedure," Revision 1
- UAP-HF-08054, "US-APWR Standard Design: Design Change Control Procedure of Design Documents for US-APWR DCD," Revision 3
- NO-AA00001, "US-APWR Standard Design: US-APWR Standard Design Plan," Revision 2
- UAP-HF-08055, "DCD Revision," Revision 0
- UAP-HTT-F113, "US-APWR FA Grid Span Length Change," dated April 18, 2008
- RAI 562-4427, "Subject: Short-Term Atmospheric Dispersion Estimates for Accident Releases," Revision 2

The NRC inspection team reviewed NO-AA00001, which defines and establishes the MHI organizational interfaces for conducting all design work in support of DC of the US-APWR. UAP-HF-08054 governs the design change process for US-APWR design and licensing-related activities conducted at the N-Center, Kobe, and the APWR Promoting Department (licensing). Under this process, design department and section managers are responsible for controlling design interfaces across organizational boundaries in accordance with 5H9-092-021E, as well as for executing all design phases related to the US-APWR in accordance with 5H9-092-020E. The process outlined in 5H9-092-020E includes design verification activities to be conducted in accordance with 5H9-092-022E. Once a given design activity is finalized (i.e., a design plan has been generated), any subsequent changes are governed by 5H9-092-023E.

To verify effective implementation by MHI personnel of the process outlined above, the NRC inspection team selected for review a design change package (UAP-HTT-F113) and requested that MHI personnel describe the internal processes in place to maintain the integrity of the US-APWR DCD as a result of changes implemented to resolve NRC requests for additional information (RAIs).

UAP-HTT-F113

MHI implemented this design change to incorporate operating experience lessons learned into the fuel design of the US-APWR. Through its review of the design change package as well as through its interviews of affected MHI personnel, including licensing, the NRC inspection team verified that the technical section leading the design change effort effectively implemented the process described in 5H9-092-023E (design change control). Specifically, the lead technical section effectively interfaced with other technical organizations affected by the proposed design change to request their evaluation. Once the affected technical sections documented their evaluation, the lead technical section sought approval by the licensing department in accordance with UAP-HF-08054. After licensing granted its approval, the design change was incorporated into the US-APWR DCD through the process outlined in UAP-HF-08055.

RAI 562-4427

The NRC inspection team asked to see an example of an RAI that resulted in a change to the US-APWR DCD. MHI provided RAI 562-4427 as an example that effectively describes the process implemented by licensing personnel in accordance with requirements in UAP-HF-08054.

This RAI requested that MHI justify the use of certain key site parameters related to the atmospheric dispersion factor in the US-APWR DCD Tier 2, Section 2.3.4. MHI opted to revise the US-APWR to resolve this RAI. MHI licensing personnel provided the NRC inspection team with an update of the status of the planned changes to the US-APWR DCD as a result of this RAI. Based on this update and interviews with MHI licensing personnel, the NRC inspection team verified that the process used for this DCD change adhered to requirements in UAP-HF-08054.

The NRC inspection team did not identify any significant issues in these areas.

b.4 US-APWR Standard Design Advanced Accumulator Testing

The NRC inspection team reviewed MHI policies and procedures and design products associated with the half-scale advanced accumulator testing that was performed by the Takasago Research and Development Center (Takasago), a subsidiary of MHI.

Specifically, the NRC inspection team reviewed the following test documentation:

- 4BG-UAP-070020, "Advanced Accumulator ½ Scale Model Test Plan, Design Verification Check Sheet (Experimental Verification)"
- 4BS-UAP-070242, "US-APWR ISS System Package"
- IAW PQF-HD-18041-026, "Evaluation Sheet of Past Design Qualification Data Performed," Revision 1
- PQD-HD-19004, "US-APWR Quality Assurance Manual Re-evaluation Procedure of Past Acquired Design Results," Revision 0
- WS S50761, "Plan of ½ Scale Advanced ACC Model Test," dated April 20, 1996

Testing was performed by Takasago in 1995 in accordance with QA standard Japanese Energy Agency Guideline (JEAG)-4101-1993, which was the Japanese national standard at the time.

Following this test campaign, MHI performed a comparison between JEAG-4101 and the NRC's QA requirements and industry standards including Appendix B to 10 CFR Part 50, NRC Standard Review Plan (SRP 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants"), and American Association of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities," to identify any significant differences between JEAG-4101 and these regulatory requirements and related guidance. This evaluation was documented in PQD-HD-19004. As part of this evaluation, MHI assessed the differences between these various documents to determine the potential impact on the MHI QAM.

The NRC inspection team reviewed the comparison matrix associated with Criterion XI, "Test Control," and Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50 and determined that MHI had performed a comprehensive evaluation of the subject documents and identified those items that could have an impact on the QA program used for the testing by Takasago.

The NRC inspection team confirmed that MHI had adequately performed an evaluation of each item identified as having differences, provided objective evidence to support the conclusion described in the evaluation results, and reviewed portions of the supporting design documents generated for the initial tests and subsequently to support the use of past acquired data. The NRC inspection team did not find any significant issues of concern.

In addition, the NRC inspection team reviewed the controls associated with measuring and test equipment applied to the advanced accumulator testing, which included a review of the test plan developed by Takasago. The test plan included a description of each type of measurement device used (i.e., level indicators, thermocouples, and pressure transmitters), unique serial numbers for each device, the location of individual measurement equipment within the test configuration, and calibration data for thermocouples and pressure transmitters.

The NRC inspection team reviewed the calibration data for the test equipment and confirmed that the equipment was calibrated in accordance with the applicable national standards and calibration results were recorded, reviewed, and verified by test personnel. For each sensor, the calibration information captured included sensor identification number, calibration constant, output range, and data acquisition channel number. The sensor position within the test assembly was recorded, and the range of equipment use was within the test conditions.

The NRC inspection team noted that applicable test items including items tested, date of test, identification of test equipment and test recorder, type of observations, results and rationale for acceptability of test results, test personnel information, summary of test results, and ambient temperature conditions. The NRC inspection team did not identify any significant issues in this area.

c. Conclusion

The NRC inspection team concluded that the implementation of the MHI design control process is consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50.

Based on its review, the NRC inspection team determined that MHI is effectively implementing its policies and procedures to support the DC application for the US-APWR. No findings of significance were identified.

3. Procurement Document Control

a. Inspection Scope

The NRC inspectors reviewed MHI's QA policies and implementing procedures that govern the control of procurement documents to verify compliance with the requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by MHI:

- "MHI Quality Assurance Program (QAP) Description for Design Certification of the US-APWR," Section 4, "Procurement Document Control," Revision 3, dated October 1, 2009
- B91U-N0001, "MHI Quality Assurance Manual (QAM)," Section 4, "Procurement Control," Revision 37, dated November 18, 2010
- "Quality Assurance Program Manual (QAPM) (US-APWR Project Addenda)," Section 4, "Procurement Control," Revision 6, dated November 30, 2010
- 5HE9-092-050E, "Procurement Control Procedure," Revision 0, dated October 13, 2010

In addition, the NRC inspectors reviewed a sample of purchase orders (POs) to verify proper implementation of MHI's procurement document control program:

- POs HIS-09T-013 and HIS-09T-014 to MHI Takasago Research and Development Center for "CFD Analysis of Advanced Accumulator for NRC," dated June 21, 2009, and July 7, 2007, respectively
- POs HIS-10T-002 and HIS-10T-006 to MHI Takasago Research and Development Center for "CFD Analysis of Advanced Accumulator for RAI," dated April 1, 2010, and July 21, 2010, respectively
- PO HKS-09-0004 to MHI Takasago Research and Development Center for "US-APWR Sump Debris Chemical Effects Evaluation," dated January 7, 2009
- PO 850B8E9D-L91038-00 to MHI Nuclear Engineering Co., Ltd., for "Pressurizer Seismic and Accident Analysis," dated March 14, 2010
- PO MNP-0729 to URS for "US-APWR Soil-Structure Interaction Seismic Analysis for Reactor Building Complex and Power Source Building," Revision 2, dated September 3, 2010
- PO MNP-0730 to URS for "US-APWR Basic Design for Reactor Building, Prestressed Concrete Containment Vessel, & Containment Internal Structures on a Common Mat, and Power Source Building," Revision 3, dated August 5, 2010

- PO F1483 to Nuclear Development Corporation for “US-APWR Requirement Specification for Sump Strainer Downstream Evaluation (Grid Blockage),” dated November 28, 2008
- PO F1501R1 to Nuclear Development Corporation for “US-APWR Requirement Specification for Fuel Assembly Horizontal Vibration Test (Atmospheric),” Revision 1, dated May 11, 2009
- PO MNP-0195 to Performance Contracting, Inc., for “Design and Evaluation of Sump Strainer,” Revision 1, dated September 17, 2010
- PO MNP-0004 to Structural Integrity Associates, Inc. (SI) for “Evaluation of Pressurizer Surge Line Temperature Stratification Profile,” Revision 0, dated January 19, 2009
- PO MNP-0580 to SI for “US-APWR Reactor Coolant Pump Flywheel Probabilistic Fracture Mechanics Analysis,” Revision 0, dated December 8, 2008
- PO 011581 to Seiry Engineering Co., Ltd., for “Pressurizer Design Analysis,” Revision 1, December 1, 2010
- PO 8289647-ZF-K00568 to Ryosen Engineers Co., Ltd., for “US-APWR Two-Way Liner Plate Analysis for PCCV Liner System,” Revision 1, March 16, 2010
- PO 011081 to Ryoyu System Engineering, Inc., for “Reactor Vessel Fracture Evaluation,” Revision 1, dated February 1, 2010
- PO 850B8EE-ZF-N00205 to MHI Tagasako Research and Development Center for “US-APWR RCP Stress Analysis Report,” Revision 2, dated March 24, 2010
- PO MNP-270 to URS for “Development of Design Specifications for ASME Section III Class 3 Pumps of Spent Fuel Pit Cooling System, Refueling Water Storage System, Chilled Water System, and Essential Service Water System,” Revision 1, dated July 9, 2010

b. Observations and Findings

b.1 Policies and Procedures

Section 4 of MHI’s QAP description (QAPD) establishes the measures and governing procedures to ensure that purchased items and services are subject to the appropriate technical, quality, regulatory, and administrative requirements. All procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21) are invoked for procurement of items and services. This QAPD is applicable to the activities related to the procurement of design services for the US-APWR project in the N-Center.

Section 4 of B91U-N0001 establishes the control procedure for the procurement process to ensure that the requirements for items and services are clearly identified in the procurement documents generated at Kobe. In addition, MHI developed a US-APWR Project Addenda QAM,

which was created to supplement the requirements of Kobe's QAM for work on design activities related to the US-APWR DC project.

5HE9-092-050E supplements the requirements of MHI's QAPD by providing specific guidance for the preparation, review, and approval of procurement documents and revisions to them. The NRC inspectors determined that the documents that control the procurement process provide sufficient guidance to ensure that the necessary technical, quality, regulatory, and administrative requirements are imposed on vendors supplying to MHI.

b.2 Implementation of Procurement Document Controls

The NRC inspectors reviewed a sample of POs to determine whether the requirements identified in the procedures were imposed on applicable purchasing documents. The NRC inspectors found that the POs adequately documented the procurement requirements as established by the governing policies and procedures. Documentation included task definitions and responsibilities; imposition of appropriate quality, technical, and regulatory requirements; and identification of applicable codes and standards. In addition, the NRC inspectors also found that the POs adequately defined contract deliverables, disposition of nonconformances, access rights, and extension of contractual requirements to subcontractors.

In addition the NRC inspection team confirmed that all of the POs reviewed, included clauses invoking the provisions of 10 CFR Part 21 and requiring the vendor to conduct the work under its QA program related to Appendix B to 10 CFR Part 50. The NRC inspectors did not identify any issues in this area.

c. Conclusions

The NRC inspectors concluded that MHI's program requirements for the control of procurement documents for the US-APWR DC project were consistent with the regulatory requirements of Criterion IV of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspectors also concluded that MHI's QAPD and associated procedures for the control of procurement documents were being effectively implemented. No findings of significance were identified.

4. Control of Purchased Material, Equipment, and Services

a. Inspection Scope

The NRC inspectors reviewed MHI's QA policies and implementing procedures that govern the control of purchased material, equipment, and services to verify compliance with the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by MHI:

- "MHI QAP Description for Design Certification of the US-APWR," Section 7, "Control of Purchase Equipment, Material and Services," Revision 3, dated October 1, 2009
- B91U-N0001, "MHI Quality Assurance Manual (QAM)," Section 4, "Procurement Control," Revision 37, dated November 18, 2010

- “Quality Assurance Program Manual (US-APWR Project Addenda),” Section 4, “Procurement Control,” Revision 6, dated November 30, 2010
- 5HE9-092-050E, “Procurement Control Procedure,” Revision 0, dated October 13, 2010
- 5HE9-092-052E, “Supplier Quality Assurance Program Requirements for Design and Test Activities,” Revision 1, dated November 30, 2010
- 5HE9-092-080E, “Audit Procedure,” Revision 0, dated October 13, 2010
- 2ZBS-KAIGAI-100002, “Nuclear Energy Systems Engineering Center Supplier QA Audit Plan for Export Jobs Fiscal Year 2010,” Revision 2, dated December 3, 2010
- BU91-54, “Procedure for Annual Evaluation of Vendors,” Revision 1, dated July 12, 2010
- UEQ-20100261, “Periodic Vendor Survey/Audit Plan,” Revision 2, dated October 12, 2010

b. Observations and Findings

b.1 Policies and Procedures for Vendor Qualification

Section 7 of MHI’s QAPD establishes the measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The NRC inspection team noted that MHI’s control of procurement of items and services consisted of source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audits, and examination of items and services. Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored.
- Qualified suppliers are audited on a triennial basis supplemented by annual evaluations.
- Source verification, receipt inspection, certificates of conformance, and document reviews are performed.

Section 4 of B91U-N0001, as well as the US-APWR Project Addenda QAM, establish the control procedures to confirm that the items and services received meet the requirements as specified in the procurement documents.

5HE9-092-050E supplements the requirements of MHI’s QAPD by providing specific guidance on the evaluation of suppliers and the verification that items and services procured conform to the specified requirements.

5HE9-092-052E specifies the general quality requirements that MHI imposes on all of its suppliers. This document is attached to all procurement documents to ensure the consistency of the quality requirements described in procurement specifications.

2ZBS-KAIGAI-100002 and BU91-54 define the requirements for the annual evaluation of suppliers for N-Center and Kobe, respectively.

b.2 Maintenance of the Approved Vendors List

Section 3 of MHI's QAPD and Section 4.3.7.2 of B91U-N0001 define the controls for the maintenance, distribution, and update of the approved vendors list (AVL) for N-Center and the qualified vendors list (QVL) for Kobe, respectively. Both procedures state that the QA department has the responsibility for preparing, approving, and distributing the AVL and QVL and any revisions to these lists. Before issuing a QAM revision, approved suppliers are required to send a copy to MHI for review and approval, after which MHI updates both the AVL and QVL with the latest revision number and date, as applicable. The NRC inspectors verified that both the AVL and QVL were being kept up to date and that any revisions to the lists were being implemented following the applicable procedures.

b.3 External Audits

5HE9-092-080E establishes the requirements and methods for implementation of the program for performing vendor surveys and audits, including the actions to be taken to correct findings identified during surveys and audits.

The NRC inspectors reviewed a sample of external audits and annual vendor evaluations to verify MHI's implementation of its audits program. The NRC inspectors verified that audit plans identifying the audit scope, focus, and applicable checklist criteria had been prepared and approved before the initiation of the audit activity. In addition, the NRC inspectors verified that external audits were performed by qualified lead auditors and auditors. During the review of the checklists, the NRC inspectors observed that for several of the external audits, the checklists did not contain adequate objective evidence necessary to confirm the conclusions documented in supplier external audits conducted by MHI. For example, for some areas of a supplier's QA program criteria being audited, the objective evidence included in the checklist was a reference to a procedure with no indication of what the auditor reviewed in order to verify the vendor's effective implementation of that procedure. This issue has been identified as an example of Violation 05200021/2010-201-01.

For audits and surveys resulting in findings, the NRC inspectors verified that the supplier had established a plan for corrective action and that MHI had reviewed and approved the corrective action and verified its satisfactory completion and proper documentation.

b.4 Source and Receiving Inspections

Sections 5.9.1.2 and 5.9.1.3 of MHI's QAPD describe the requirements for performing source and receiving inspections, respectively. Source inspections are performed at intervals consistent with the importance and complexity of the item or services. As of December 11, 2010, MHI had not performed any source inspections for work related to the US-APWR DC. Receiving inspections are performed using a checklist to verify that the items or services received satisfy all the procurement requirements.

Sections 4.3.10.1 and 4.3.10.2 of B91U-N0001 describe the requirements for performing source and receiving inspections, respectively. Source inspections are performed at the vendor as required by the purchase specification and shall be performed by qualified QA or quality control personnel. Receipt inspections are also performed using a checklist and are performed by qualified quality control personnel.

The NRC inspectors reviewed the receipt inspection performed on the following:

- “Stress Analysis for Surge Nozzle of US-APWR Pressurizer,” Revision 2, dated September 28, 2009
- “Stress Analysis for Main Piping of US-APWR RCL Piping,” Revision 1, dated December 14, 2009
- “US-APWR Reactor Vessel Stress Analysis for Radial Support,” Revision 1, dated January 1, 2010

The NRC inspectors verified that the inspection checklists were adequately completed and that there was enough objective evidence provided to verify that the purchased items conformed to the purchase specifications.

c. Conclusions

The NRC inspection team identified one violation associated with MHI’s failure to implement the requirements of Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50. An example of Violation 05200021/2010-201-01 identifies MHI’s failure to collect adequate objective evidence necessary to confirm the conclusions documented in supplier external audits conducted by MHI.

5. Nonconforming Materials, Parts, or Components

a. Inspection Scope

The NRC inspection team reviewed the implementation of the MHI control of nonconformances in support of the DC for the US-APWR. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of the MHI control of nonconformance to verify compliance with Criterion XV, “Nonconforming Materials, Parts, or Components,” of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team discussed the control of nonconformances with members of the MHI management and technical staff.

The NRC inspection team reviewed the following documents for this inspection area:

- PQD-HD-19005
- PQF-HD-19019-E040, “Control of Nonconformance,” Revision 2, dated March 30, 2010
- 5HE9-092-060E, “Control Procedure of Nonconformance,” Revision 0, dated August 30, 2010
- B91U-N0001, Section 16, “Control of Nonconforming Items and Activities,” Revision 27, dated November 18, 2010
- BU91-051(8), “Guideline for Implementation on NCR/CAR,” Revision 8, dated September 9, 2010
- UES-20080024, “Quality Assurance Program Manual (US-APWR Project Addenda),” Revision 6, dated November 30, 2010

- Nonconformance Reports: UAP-NCR-HD-20002, UAP-NCR-HD-20004, UAP-NCR-HD-20005, UAP-NCR-HD-20008, UAP-NCR-HD-20009, UAP-NCR-HD-21002, UAP-NCR-HD-21003, UAP-NCR-HD-21005, UAP-NCR-HD-21006, UAP-NCR-HD-21009, UAP-NCR-HD-21010, UAP-NCR-HD-21011, UAP-NCR-HEQ-10001, UAP-NCR-HEQ-10006, UAP-NCR-HEQ-10007, UAP-NCR-HEQ-10015, and UAP-NCR-HEQ-10024

b. Observations and Findings

b.1 Policies and Procedures for the Control of Nonconformances

MHI QAPD, Section 15, "Nonconforming Materials, Parts, or Components," describes the measures and governing procedures that MHI has established to control items, including services, that do not conform to specified requirements to prevent inadvertent installation or use.

NESH Procedure PQF-HD-19019-E040 describes the NESH process for the control of nonconformances. Specifically, this procedure requires that any personnel who have discovered a nonconformance shall promptly prepare a nonconformance report (NCR).

N-Center Procedure 5HE9-092-060E describes the N-Center process for the control of nonconformances. Specifically, this procedure requires that, when the responsible department or section receives notification of a nonconformance (or finds the nonconformance), the responsible department or section shall start the disposition of the nonconformance.

b.2 Review of Nonconformance Reports

The NRC inspection team reviewed the MHI QAPD procedures and NCR log associated with the US-APWR DC application. The NRC inspection team reviewed 17 of the 45 NCRs issued between 2008 and 2010. NESH and N-Center groups of MHI generated all of the NCRs. The NRC inspection observed that there was a delay between the date of discovery of the nonconformance and the issue date of the NCR in 7 of the 17 NCRs reviewed. The NRC inspection team discussed the NCRs with the MHI representatives in an effort to understand the reason for the delay. In all seven cases, MHI was able to demonstrate that MHI implemented review and analysis of the nonconformance and, in some cases, implemented corrective actions associated with the nonconformance. However, the actual documenting of the nonconformance in an NCR was completed at a later date. The NRC inspection team verified the discovery date and the NCR issuance date on all NCRs related to the US-APWR. Of the 45 NCRs related to the US-APWR, 12 NCRs had a delay between the discovery date and the NCR issuance date ranging from 1 month to 2 years. Based on the above, the NRC inspection team concluded that MHI failed to meet Criterion XV of Appendix B to 10 CFR Part 50 in that MHI failed to promptly issue NCRs for nonconformances related to the US-APWR DC application consistent with MHI procedures. This is identified as Violation 05200021/2010-201-02.

The NRC inspection team noted that MHI issued a CAR, UAP-CAR-HEQ-10097, on December 9, 2010, to address the violation cited above.

c. Conclusions

The NRC inspection team identified one violation associated with MHI's failure to implement the requirements of Criterion XV of Appendix B to 10 CFR Part 50. Violation 05200021/2010-201-02 identifies that MHI nonconformance reports issued to document nonconformances related to the U.S. Advanced Pressurized-Water Reactor (US-APWR) design certification application were not issued promptly as prescribed in MHI procedures. Specifically, 12 of the 45 nonconformance reports were initiated 1 month to 2 years after the discovery date of the nonconformance.

6. Corrective Action Program

a. Inspection Scope

The NRC inspection team reviewed the implementation of the MHI corrective action program in support of the DC for the US-APWR. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of the MHI corrective action process to verify compliance with Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team discussed the corrective action program with members of MHI management and technical staff.

The NRC inspection team reviewed the following documents for this inspection area:

- PQD-HD-19005
- PQF-HD-19019-E041, "US-APWR Quality Assurance Manual, Corrective Action," Revision 2, dated March 30, 2010
- 5HE9-092-061E, "US-APWR Quality Assurance Manual, Corrective Action Procedure," Revision 0, dated August 30, 2010
- B91U-N0001, Section 18, "Corrective Action, Preventive Action and Lessons Learned," Revision 21, dated November 18, 2010
- BU91-051(8), "Guideline for Implementation on NCR/CAR," Revision 8, dated September 9, 2010
- UES-20080024, "Quality Assurance Program Manual (US-APWR Project Addenda)," Revision 6, dated November 30, 2010
- Corrective Action Reports: UAP-CAR-HD20006, UAP-CAR-HD-20010, UAP-CAR-HD-20013, UAP-CAR-HD-20014, UAP-CAR-HD-20015, UAP-CAR-HD-20017, UAP-CAR-HD-21007, UAP-CAR-HD-21011, UAP-CAR-HD-21017, UAP-CAR-HD-21018, UAP-CAR-HD-21022, UAP-CAR-HD-21029, UAP-CAR-HEQ-10005, UAP-CAR-HEQ-10006, UAP-CAR-HEQ-10042, UAP-CAR-HEQ-10055, UAP-CAR-HEQ-10066, UAP-CAR-HEQ-10091, CAR-08-005, UAP-CAR-HD-21021, and UAP-CAR-HEQ-10004

b. Observations and Findings

b.1 Policies and Procedures

Section 16 of the MHI QAPD describes the process for promptly identifying, controlling, documenting, classifying, and correcting conditions adverse to quality. The QAPD requires that reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of significant conditions adverse to quality, the QAPD requires that the cause be determined and actions to preclude recurrence be taken.

NESH Procedure PQF-HD-19019-E041 describes the NESH process to identify the cause of significant nonconformances in the US-APWR and to implement proper corrective actions to prevent recurrence. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of significant conditions adverse to quality, the cause is determined and actions to preclude recurrence are taken.

N-Center Procedure 5HE9-092-061E describes the N-Center process to identify the causes of nonconformances in the activities associated with the US-APWR project and implement proper corrective actions to prevent recurrence. Additionally, this procedure states, in part, that MHI shall conduct the time-course and systematic trend analyses on the causes of the nonconformance described in the finding and observation items of the NCRs, CARs, internal audit reports, and external and customer audits.

Kobe Procedure B91U-N0001 describes the Kobe process for identifying, classifying, documenting, and correcting conditions adverse to quality and significant conditions adverse to quality associated with activities conducted at Kobe.

b.2 Implementation of Corrective Action Program

The NRC inspection team reviewed the MHI QAPD, procedures, and CAR log associated with the US-APWR DC application. The NRC inspection team reviewed 21 of the 86 CARs issued between 2008 and 2010. All but one of the CARs was generated from the NESH and N-Center groups of MHI. The NRC inspection discussed the CARs with the MHI representatives to establish whether the 86 were conditions adverse to quality or significant conditions adverse to quality since the documentation was not clear. MHI stated that all of the CARs concern significant conditions adverse to quality. However, neither the NESH nor N-Center CAR procedure established criteria for classifying the significance of the condition. Based on the significant classification of the CARs, the NRC inspection team questioned the root cause analyses performed on the 86 CARs. While all of the CARs had a statement about the cause of the condition, the level of the causal analyses did not appear to be commensurate with the significance of the condition. The NRC inspection team concluded that MHI Procedures 5HE9-092-061E and PQF-HD-19019-E041 failed to meet Criterion XVI of Appendix B to 10 CFR Part 50 in that the procedures failed to provide sufficient guidance to classify conditions adverse to quality and significant conditions adverse to quality. This is identified as one example of Violation 05200021/2010-201-03.

The NRC inspection team evaluated the time-course and systematic trend analysis performed on the CARs as required by the NESH and N-Center procedures. The trend analysis minimally identified the areas where the conditions adverse to quality were being identified. The NRC

inspection team concluded that the time-course and systematic trend analysis was not performed as required by the NESH and N-Center procedures. This is identified as another example of Violation 05200021/2010-201-03.

The NRC inspection team noted that MHI issued a CAR, UAP-CAR-HEQ-10096, on December 9, 2010, to address the violation cited above.

c. Conclusions

The NRC inspection team identified one violation associated with MHI's failure to implement the requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Violation 05200021/2010-201-03 identifies MHI's failure to implement measures to (1) assure that the cause of significant conditions adverse to quality was determined and corrective action taken to preclude repetition, and (2) perform time-course and systematic trend analyses. In addition, MHI Procedures 5HE9-092-061E and PQF-HD-19019-E041 did not provide sufficient guidance to classify conditions adverse to quality and significant conditions adverse to quality.

7. Audits

a. Inspection Scope

The NRC inspectors reviewed MHI's QA policies and implementing procedures that govern the audit process to verify compliance with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by MHI:

- "MHI QAP Description for Design Certification of the US-APWR," Section 18, "Audits," Revision 3, dated October 1, 2009
- B91U-N0001, "MHI Quality Assurance Manual (QAM)," Section 19, "Internal Audit," Revision 21, dated November 18, 2010
- "Quality Assurance Program Manual (US-APWR Project Addenda)," Section 19, "Internal Audit," Revision 6, dated November 30, 2010
- 5HE9-092-080E, "Audit Procedure," Revision 0, dated October 13, 2010
- 5HE9-081E, "Qualification Procedure for Lead Auditor and Auditor," Revision 0, dated November 4, 2010
- BU91-04, "Qualification and Certification Procedure of Lead Auditor," Revision 7, dated November 12, 2004
- BUE91-03, "Auditor Qualification Procedure," Revision 4, dated June 6, 1995
- 2ZBS-GE-100003, "Nuclear Energy Systems Engineering Center 2010 Internal QA Audit Plan," Revision 1, dated August 31, 2010
- UES-20100121, "2010 Periodic Internal Audit Program," Revision 4, dated October 1, 2010

b. Observations and Findings

b.1 Auditor Training and Qualification

5HE9-081E, BU91-04, and BUE91-03 establish the requirements for the qualification and certification of lead auditor and auditors. The NRC inspectors reviewed a sample of lead auditor and auditor qualifications and confirmed that auditing personnel had completed all required training and maintained qualification and certification in accordance with MHI's policies and procedures.

b.2 Internal Audits

5HE9-092-080E establishes the requirements and methods for implementation of the program for performing N-Center internal audits, including the actions to be taken to correct findings identified.

B91U-N0001 describes the process and requirements for performing Kobe internal audits.

During the review of a sample of internal audits, the NRC inspectors observed that formost of the internal audits, MHI failed to collect adequate objective evidence necessary to confirm the conclusions documented in internal audits conducted by MHI. This issue has been identified as an example of Violation 05200021/2010-201-01.

The NRC inspectors verified that audit plans identifying the audit scope, focus, and applicable checklist criteria had been prepared and approved before the initiation of the audit activity. In addition, the NRC inspectors verified that internal audits were performed by qualified lead auditors and auditors and that, for any findings identified, MHI had established a corrective action plan and it had reviewed and approved the corrective action and verified its satisfactory completion and proper documentation.

c. Conclusions

The NRC inspection team identified one violation associated with MHI's failure to implement the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. An example of Violation 05200021/2010-201-01 identifies MHI's failure to collect adequate objective evidence necessary to confirm the conclusions documented in internal audits conducted by MHI.

8. Entrance and Exit Meeting Summary

On December 6, 2010, the NRC presented the inspection scope during an entrance meeting with MHI staff. On December 10, 2010, the NRC presented the inspection results during an exit meeting with Makoto Kanda, General Manager, US-APWR NESH, and other MHI personnel. The entrance and exit meeting attendees are listed in the attachment to this report.

ATTACHMENT 1

1. ENTRANCE/EXIT MEETING ATTENDEES

<u>Name</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>Exit</u>
G. S. Galletti	NRC/NRO	X	X
K. A. Kavanagh	NRC/NRO	X	X
Y. Diaz-Castillo	NRC/NRO	X	X
J. D. Peralta	NRC/NRO	X	X
G. Khouri	NRC/RII	X	X
N. Miyakoshi	MHI	X	X
Y. Komano	MHI	X	X
M. Kanda	MHI	X	X
K. Hirakawa	MHI	X	X
I. Otake	MHI	X	X
K. Imamura	MHI	X	X
N. Shimizu	MHI	X	X
T. Hasegawa	MHI	X	X
Y. Ogata	MHI	X	X
A. Kumaki	MHI	X	X
T. Oketani	MHI	X	X
S. Matsumi	MHI	X	X
S. Yamada	MHI	X	X
O. Watanabe	MHI	X	X
S. Morita	MHI	X	X
Y. Kosugi	MHI	X	X
K. Mori	MHI	X	X
E. Saji	MHI	X	X
K. Ajiki	MHI	X	X
M. Nakano	MHI	X	X
H. Taniguchi	MHI	X	X
S. Yonemoto	MHI	X	X
C. Kurimura	MHI	X	X
S. Umezawa	MHI	X	X
M. Otake	MHI	X	X
H. Takahashi	MHI	X	X
M. Yamagishi	MHI	X	X
H. Yamada	MHI	X	X
H. Nishino	MHI	X	X
R. Umehara	MHI	X	X
T. Nakahara	MHI	X	X

K. Inoue	MHI	X	X
K. Kurahayashi	MHI	X	X
Y. Kataoka	MHI	X	X
T. Kitani	MHI	X	X
M. Yokoyama	MHI	X	X
Y. Nagata	MHI	X	X
F. Kono	MHI	X	X
H. Mimaki	MHI	X	X
J. Matsumoto	MHI	X	X
T. Okamoto	MHI	X	X
M. Mukai	MHI	X	X
K. Hamada	MHI	X	X
Y. Kitayama	MHI	X	X
Y. Ueda	MHI	X	X
M. Suzuki	MHI	X	X
K. Aizawa	MHI	X	X
K. Kano	MHI	X	X
M. Vann Mitchell	MNES	X	X
J. Tapia	MNES	X	X
R. Sprengel	MNES	X	X
M. Onozuka	MNES	X	X
S. Jin	Simul International, Inc.	X	X
Y. Tokumaru	Simul International, Inc.		X
C. Sakuta	Simul International, Inc.	X	
J. Namba	Interpretation and Translation Services	X	X
C. Okado	Interpretation and Translation Services	X	X
M. Tabiraki	Interpretation and Translation Services	X	X

2. PERSONS CONTACTED

S. Suzuki—Deputy General Manager, MHI
Y. Komano—General Manager, NESH, MHI
E. Kadokami—Deputy General Manager, NESH, MHI
N. Miyakoshi—General Manager, QA NESH, MHI
M. Kanda—General Manager, NESQA, MHI
J. Matsumoto—General Manager, QA Department, MHI
M. Muramoto—Acting Manager, Export Marketing Section, MHI
S. Matsumi—Group Manager, Engineering QA Group, MHI
K. Imamura—Acting General Manager, NESQA, MHI
K. Hamada—Engineering Manager, Component Design Section, MHI
I. Otaki—Manager, QA Department HD/NESH, MHI

T. Nakano—Acting Manager, HTT Section, MHI
 Y. Ueda—Component Design Section, MHI
 H. Fuyama—Engineering Manager, Structural & Seismic Engineering, MHI
 T. Kitani—Manager, Structural & Seismic Engineering, MHI
 N. Murakami—Senior Engineer, HTT Section, MHI
 S. Yonemoto—Senior Engineer, HTT Section, MHI
 J. Ogawa—Senior Engineer, HTT Section, MHI
 S. Suzuki—Engineer, HKC Section, MHI
 R. Narutomi—Engineer, HKS Section, MHI
 M. Nishiura—Engineer, HKS Section, MHI
 H. Kuramoto—Senior Engineer, HKS Section, MHI
 Y. Nagata—Section Manager, AHRB Section, MHI
 N. Shimizu—Manager, NESQA, MHI
 Y. Kosugi—QA Engineer, EQAG, MHI
 K. Aizawa—Engineering Manager, NPQAS, MHI
 H. Nishino—Section Manager, RSES, MHI
 R. Sprengel—Licensing Engineer, MNES
 J. Tapia—Licensing Manager, MNES

3. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 35017, “Quality Assurance Implementation Inspection”

IP 36100, “Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance”

4. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
05200021/2010-201-01	Opened	NOV	Criterion VII, XVIII
05200021/2010-201-02	Opened	NOV	Criterion XV
05200021/2010-201-03	Opened	NOV	Criterion V, XVI