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TOKYO, JAPAN

March 2, 2011

Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Mr. Jeffrey A. Ciocco

Docket No. 52-021
MHI Ref: UAP-HF-11056

Subject: Reply to Notice of Violation No. 05200021/2010-201

Reference: 1) "NRC INSPECTION REPORT NO. 05200021/2010-201 AND NOTICE OF VIOLATION" dated February 2, 2011

With this letter, Mitsubishi Heavy Industries, Ltd. ("MHI") transmits to the U.S. Nuclear Regulatory Commission ("NRC") the responses to Notice of Violation No. 05200021/201-01, -02 and -03 (Reference 1).

Please contact Dr. C. Keith Paulson, Senior Technical Manager, Mitsubishi Nuclear Energy Systems, Inc. if the NRC has questions concerning any aspect of the submittals. His contact information is below.

Sincerely,

Y. Ogata

Yoshiki Ogata,
General Manager- APWR Promoting Department
Mitsubishi Heavy Industries, LTD.

Enclosures:

1. Response to Notice of Violation No. 05200021/2010-201-01
2. Response to Notice of Violation No. 05200021/2010-201-02
3. Response to Notice of Violation No. 05200021/2010-201-03

CC: J. A. Ciocco
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Enclosure 1

UAP-HF-11056
Docket No. 52-021

Response to Notice of Violation No. 05200021/2010-201-01

March 2011

Response to Notice of Violation
(NRC Identification No. 05200021/2010-201-01)

1. Contents of Violation

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.

2. Reason for the Violation

MHI found some checklists that did not sufficiently describe satisfactory/unsatisfactory conditions or evaluation result of effective implementation, though they included titles and document numbers of evidences. Particularly, when the implementation was satisfactory, the auditors did not describe the evaluation result. In addition, MHI found some checklists where N/A (not applicable) was used without explaining the reason.
MHI's Quality Assurance Manual states, in part, that "objective evidence shall be examined to the depth necessary to determine if the selected elements are being implemented effectively." However, MHI did not provide sufficient guidance and failed to collect adequate objective evidence necessary to confirm the conclusions documented in several supplier external audits and internal audits.

3. Corrective Steps That Have Been Taken and Results Achieved

MHI has instructed the audit leaders of upcoming internal audits and supplier audits to examine objective evidence to the depth necessary and include the following in the audit checklists:

- Reason when N/A (not applicable) is used.
- Evaluation result of the implementation and supporting objective evidences. When the implementation is satisfactory, the satisfactory condition should be clearly described, so that the third persons can understand later.

MHI issued a CAR (UAP-CAR-HEQ-10098, CAR-10-023) to address the violation cited above and initiated corrective actions.

4. Corrective Steps That Will Be Taken to Avoid Further Violations

An auditor guideline will be prepared to instruct lead auditors and auditors to examine objective evidence to the depth necessary and include the following in the checklists:

- Reason when N/A (not applicable) is used.
- Evaluation result of the implementation and supporting objective evidences. When the implementation is satisfactory, the satisfactory condition should be clearly described, so that the third persons can understand later.

MHI will indoctrinate lead auditors and auditors on the audit guideline.

5. Date When Full Compliance Will be Achieved

Full compliance will be achieved by April 30, 2011

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Enclosure 2

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Docket No. 52-021

Response to Notice of Violation No. 05200021/2010-201-02

March 2011

Response to Notice of Violation
(NRC Identification No. 05200021/2010-201-02)

1. Contents of Violation

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.

2. Reason for the Violation

MHI examined all delayed 12 nonconformance reports (NCRs). There were no NCRs issued by MHI Kobe Shipyard. They were issued by MHI Nuclear Energy Systems Headquarters (NESH) and MHI Nuclear Energy Systems Engineering center (N-Center) and related to the design documents of DCD. For these NCRs, we immediately implemented evaluation of the condition; however, we failed to issue NCRs promptly due to the following reasons:

(1) Since it took time to evaluate the condition, NCRs were delayed to be issued.
(2 of 12 delayed NCRs)

(2) Since a nonconformance was evaluated to have no impact on other activities, the NCR issuance was delayed because it was incorrectly assumed that documentation of the condition could wait until its disposition or the next DCD revision.
(5 of 12 delayed NCRs)

(3) When a computer program error was identified, it was disposed in accordance with the computer software control procedure, and it was not clear whether an NCR should be issued or not. As the result, the NCR was issued later.
(2 of 12 delayed NCRs)

(4) A nonconformance was identified at a supplier and disposed in accordance with the supplier's QA program, but MHI failed to issue an NCR of MHI promptly.
(1 of 12 delayed NCRs)

(5) When NESH and N-Center QA program was established, NESH and N-Center QA Manuals required that the cause and draft dispositions of a nonconformance be included in an NCR at the issuance of the NCR, which resulted in delays in issuing some NCRs. After that, NESH and N-Center QA Manuals were revised not to require the cause and dispositions at the issuance of NCRs.
(2 of 12 delayed NCRs)

3. Corrective Steps That Have Been Taken and Results Achieved

MHI issued a CAR (UAP-CAR-HEQ-10097) to address the violation cited above, and initiated corrective actions.

4. Corrective Steps That Will Be Taken to Avoid Further Violations

MHI will train all personnel to clarify MHI expectations regarding the documentation of nonconforming conditions and the need to issue NCRs promptly in accordance with Procedure (PQF-HD-19019-E040, "Control of Nonconformance," and 5HE9-092-060E, "Control Procedure of Nonconformance,"). Training material will be uploaded on the MHI portal site to summarize important points, including the need for prompt NCR issuance.

We will revise NESH and N-Center QA Manuals to specify the issuance rule of NCRs for computer program errors.

5. Date When Full Compliance Will be Achieved

Full compliance will be achieved by April 30, 2011.

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Enclosure 3

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Docket No. 52-021

Response to Notice of Violation No. 05200021/2010-201-03

March 2011

Response to Notice of Violation
(NRC Identification No. 05200021/2010-201-03)

1. Contents of Violation

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.

2. Reason for the Violation

The MHI Kobe-Shipyard (MHI-Kobe) QA Manual adequately describes the Kobe process for identifying, classifying, documenting, and correcting conditions adverse to quality and significant conditions adverse to quality. The time-course and systematic trend analyses on the causes of the nonconformance have been implemented at MHI-Kobe.

MHI Nuclear Energy Systems Headquarters (NESH) QA Manual Procedure PQF-HD-19019-041 and MHI Nuclear Energy Systems Engineering Center (N-Center) QA Manual Procedure 5HE9-092-061 describe the process to identify "significant nonconformances" as conditions adverse to quality and to implement proper corrective actions to prevent recurrence. However, both procedures do not provide sufficient guidance to classify significant conditions adverse to quality, and MHI failed to implement measures to assure that the cause of significant conditions adverse to quality was

determined and corrective action taken to preclude repetition.

NESH and N-Center QA Manual Procedures describe the time-course and systematic trend analyses on the causes of the nonconformance. However, both procedures do not specify the detail implementing procedure, including the analysis method and frequency. As the result, MHI failed to implement measures to perform the time-course and systematic trend analyses.

3. Corrective Steps That Have Been Taken and Results Achieved

MHI issued a CAR (UAP-CAR-HEQ-10096) to address the violation cited above and initiated corrective actions.

4. Corrective Steps That Will Be Taken to Avoid Further Violations

MHI will revise NESH and N-Center QA Manual Procedures to provide sufficient guidance to classify significant conditions adverse to quality and to implement measures to assure that the cause of significant conditions adverse to quality was determined and corrective action taken to preclude repetition.

MHI will revise NESH and N-Center QA Manual Procedures to specify the implementing procedure (frequency, timing, evaluation viewpoints, analysis method, etc.) of trend analyses, and will perform the trend analyses in accordance with the revised procedures.

5. Date When Full Compliance Will be Achieved

Full compliance will be achieved by June 30, 2011