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October 5, 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-11339

Subject: Reply to Notice of Violation No. 05200021/2011-202

Reference: 1) "NRC INSPECTION REPORT NO. 05200021/2011-202 AND NOTICE OF VIOLATION" dated September 1, 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. 05200021/2011-202 (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. MHI Action Plan to Notice of Violation (NOV) for Core Inlet Blockage (CIB) Test at Takasago Research and Development Center (Takasago)

CC: J. A. Ciocco
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Docket No. 52-021
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Enclosure 1

UAP-HF-11339
Docket No. 52-021

MHI Action Plan to Notice of Violation (NOV) for Core Inlet Blockage (CIB) Test at Takasago Research and Development Center (Takasago)

October, 2011

MHI Action Plan to Notice of Violation (NOV) for Core Inlet Blockage (CIB) Test at Takasago Research and Development Center (Takasago)

NOV-A (NRC Identification No. 05200021/2011-202-01)

1. Content of NOV

Title 10 of the *Code of Federal Regulations* (10 CFR), Section 21.21, "Notification of Failure To Comply or Existence of a Defect and Its Evaluation," paragraph 21.21(a), requires, in part, that each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable.

Contrary to the above, as of July 25, 2011, MHI Takasago's implementing procedure TA QMS91-N05, "Report Procedure for Defects and Nonconformities for Nuclear R&D," Revision 2, dated September 10, 2007, had not adopted an appropriate procedure for evaluating deviations and failures to comply. Specifically, TA QMS91-N05 did not contain adequate guidance for evaluating deviations and failures to comply as required by 10 CFR 21.21(a)(1).

2. Reason for violation

MHI Takasago verified that the following items were not stated in TA QMS91-N05, "Report Procedure for Defects and Nonconformities for Nuclear R&D."

- A procedure for evaluating whether deviations or failures to comply could lead to a substantial safety hazard.
- Definitions of Key Terms such as deviation, failures to comply, substantial safety hazards, etc.

The cause was that MHI Takasago did not adequately understand the requirements of 10 CFR 21.

3. Corrective steps that have been taken and results achieved, and Corrective steps that will be taken to avoid further violation

MHI Takasago revised TA QMS91-N05, "Report Procedure for Defects and Nonconformities for Nuclear R&D," and the following are described in the revised procedure.

- 10 CFR 21 Evaluation Procedure
- Definitions of Key Terms

MHI Takasago performed indoctrination and training of related employees on this issue.

MHI Kobe will verify completion of corrective actions described above.

(This is not significant condition adverse to quality and there was no impact on any testing results.)

4. Date when full compliance will be achieved

Corrective actions have been completed by MHI Takasago.

The results will be reviewed by MHI Kobe by the end of October, 2011.

NOV-B (NRC Identification No. 05200021/2011-202-02)

1. Content of NOV

Criterion II, "Quality Assurance Program," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that, a program must be established "to provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant shall regularly review the status and adequacy of the quality assurance program."

MHI Takasago's Quality Assurance Manual (QAM) TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual," Revision 12, dated June 30, 2011, Section 2.2, "Skill Evaluation and Certification of Personnel," Step 2 states, in part, that "Testers shall be certified after passing the test by applying Center Standard TA QMS91-N02 'Nuclear Energy R&D Tester Certification Procedure.' The certifier shall prepare the Nuclear Energy R&D Individual Tester Certification Record, and the head of the relevant unit shall retain that record together with the test answer sheet for record."

MHI Report TA QMS91-N02, "Nuclear Energy R&D Tester Certification Procedure," Steps 4.7.2, 4.7.3 and 4.8 further states that MHI shall document results of visual acuity evaluations, perform and document periodic reevaluation of testers, and document written test results on the Nuclear Energy R&D Individual Tester Certification Record. Contrary to the above, as of July 25, 2011, MHI failed to establish measures to ensure the implementation of applicable requirements associated with test personnel training and qualification activities. Specifically, MHI failed to adequately document the results of the following:

- visual acuity examinations of test personnel on Nuclear Energy R&D Individual Tester Certification Records
- periodic reevaluations of test personnel on Nuclear Energy R&D Individual Tester Certification Records
- written examinations of test personnel on Nuclear Energy R&D Individual Tester Certification Records.

2. Reason for violation

MHI Takasago verified that there were no distinction between annual evaluation results and triennial re-evaluation results in the Certification Records of Subject Test Personnel.

The cause was that the assigned person did not accurately understand the distinction between 2 evaluation results.

3. Corrective steps that have been taken and results achieved, and Corrective steps that will be taken to avoid further violation

MHI Takasago corrected Certification Records of all Test Personnel as follows:

Evaluation results were added to the Certifications in which annual evaluation results and triennial re-evaluation results were not stated.

Furthermore, Certificate of Test Personnel, "QMS91-N02-01" was revised and the following were described in the revised Certificate:

- In order for Assigned Personnel to be able to visually recognize what shall be done, the distinctions between "Annual Evaluation" and "Triennial Re-evaluation" were made clear.

MHI Takasago performed indoctrination and training of related employees on this issue.
MHI Kobe will verify completion of the revised Certificate "QMS91-N02-01" and the indoctrination and training.
(Verification on the correction of the Certification Records of all Test Personnel has been completed at the time of NRC Inspection.
This is not significant condition adverse to quality and there was no impact on any testing results.)

4. Date when full compliance will be achieved

Corrective steps have been completed by MHI Takasago.
MHI Kobe will complete above confirmation by the end of October, 2011.

NOV-C (NRC Identification No. 05200021/2011-202-03)

1. Content of NOV

Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50 states, in part, "Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix."

MHI Takasago's QAM TA QMS91-N01, Revision 12, Section 4, "Procurement Document Control," Step 1 states, in part, that "The procurement document (Ordering Specification) shall be submitted to the supplier at the time of placement of order." TA QMS91-N01, Section 7, "Control of Purchase Material, Equipment, and Services," Step 7.1, "Procurement Plan," states, in part, that "The assigned person in charge of the relevant unit shall prepare a procurement document (Ordering Specification) to correctly convey the requirements to the supplier." MHI Procurement Specification 5BE-UAP-20110010-R2, "USAPWR Sump Strainer Downstream Effect Core Inlet Blockage Test (Part 2) Procurement Specification," Revision 2, dated July 6, 2011, requires that MHI Takasago perform testing activities in accordance with Appendix B to 10 CFR Part 50 and with 10 CFR Part 21, "Reporting of Defects and Noncompliance."

Contrary to the above, as of July 25, 2011, MHI failed to establish measures to ensure the implementation of applicable requirements associated with procurement document control. Specifically, MHI failed to do the following:

- implement requirements specified in MHI report TA QMS91-N01 for the preparation and submittal of an ordering specification (Purchase Specification Form QMS91-N01-10) to MHI's subsuppliers of measurement and test equipment (M&TE)
- require its subsuppliers to provide M&TE and calibration services as a safety-related activity as required by MHI Procurement Specification 5BE-UAP-20110010-R2.

2. Reason for violation

During procurements of M&TE and Calibration Services, MHI Takasago did not use the Purchase Specification Form "QMS91-N01-10" for M&TE and Calibration Services which is required by TA QMS91-N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual."

Furthermore, MHI Takasago verified that Subsuppliers did not officially receive the requirements for Safety-Related Activities.

Even though it is required in the QA Manual TA QMS91－N01, Revision 12, Section 4 "Procurement Document Control" that the Purchase Specification Form "QMS91-N01-10" shall be used; however, it was not specified in the QA Manual to use this Purchase Specification Form for Procurement of M&TE Calibration Services.

3. Corrective steps that have been taken and results achieved, Corrective steps that will be taken to avoid further violation

MHI Takasago obtained the Certificates of Conformance for the past Procurements of Calibration Services which indicated compliance with the requirements for Safety-Related Activities. (This has been verified at the time of NRC Inspection.)

MHI Takasago revised TA QMS91－N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual," and described the following in the Revised Manual.

- The Purchase Specification Form, "QMS91-N01-10" shall be used for Procurements of M&TE and Calibration Services.
- Specified the Requirements of "10 CFR 50 Appendix B" and "10 CFR 21" in the Purchase Specification Form, "QMS91-N01-10".

MHI Takasago performed indoctrination and training of related employees on this issue.
MHI Kobe will perform verification and approval of the Revision of MHI Takasago's QA Manual TA QMS91－N01.
(This is not significant condition adverse to quality and there was no impact on any testing results.)

4. Date when full compliance will be achieved

Corrective steps have been completed by MHI Takasago.
MHI Kobe will complete above confirmation by the end of October, 2011.

NOV-D (NRC Identification No. 05200021/2011-202-04)

1. Content of NOV

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...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."

MHI Takasago's QAM TA QMS91-N01, Revision 12, Section 7, Subpart 7.2, "Selection of Supplier," describes the methods for evaluating suppliers of safety-related material, equipment, or services. Step 7.2.2.b.1 of TA QMS91-N01 requires, in part, that the evaluation of the supplier be based on "the results of checking of the supplier's present quality record, which has been documented to enable objective evaluation."

Contrary to the above, as of July 25, 2011, MHI failed to conduct adequate oversight of its suppliers to verify that its suppliers' quality programs adequately met established procurement requirements. Specifically, MHI failed to document adequate objective evidence to support multiple audit conclusions and to verify all relevant quality assurance criteria within the scope of its suppliers' quality assurance program.

2. Reason for violation

1) MHI Takasago verified that the items for "Handling, Storage and Shipping" were excluded from the Checklist for External Audits. The cause of the exclusion was the misunderstanding of MHI Takasago that the requirements of Criterion XIII, "Handling, Storage and Shipping," of Appendix B to 10 CFR Part 50 applied to Basic Components only.

2) MHI Takasago left check-boxes for some of the items blank in the column for objective evidence in the Audit Checklist. The cause of the blank check-boxes is that the procedure regarding how to describe in the Checklist was not made clear.

3. Corrective steps that have been taken and results achieved, Corrective steps that will be taken to avoid further violation

1) MHI Takasago revised QMS91－N06-03, "Audit Check Sheet". Revised portions are as follows:
   - Deleted the words "quality records are not necessary"
   - Added the words "Handling, Storage, and Shipping"

2) A Procedure regarding how to describe requirements in the Checklist shall be established.

(This is not significant condition adverse to quality and there was no impact on any testing results.)

4. Date when full compliance will be achieved

MHI Takasago will complete the corrective actions by the end of October, 2011.

MHI Kobe will complete the above confirmation by the middle of November, 2011.

NOV-E (NRC Identification No. 05200021/2011-202-05)

1. Content of NOV

Criterion X, "Inspection," of Appendix B to 10 CFR Part 50 states, in part, that "A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity."

MHI Procurement Specification 5BE-UAP-20110010-R2, Revision 2, requires that MHI Takasago perform testing activities in accordance with Appendix B to 10 CFR Part 50 and 10 CFR Part 21 requirements. In addition, 5BE-UAP-20110010-R2 invoked the requirement that testing activities be conducted in accordance with American Society of Mechanical Engineers Nuclear Quality Assurance (NQA)-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications."

NQA-1-1994, Section 10, "Inspection," Subsection 6.1, "In-process inspection," states, in part, that "inspection of items in-process or under construction shall be performed for work activities where necessary to verify quality." In addition, Subsection 6.2, "Combined Inspection and Monitoring," Step 6.2.1 states, in part, that "a combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process."

Contrary to the above, as of July 25, 2011, MHI failed to conduct adequate oversight of testing activities to verify that its quality programs adequately met established procurement requirements. Specifically, MHI failed to perform in-process inspections of ongoing core inlet blockage test activities and had not developed formal plans to implement monitoring of core inlet blockage test activities as required in support of the design certification application for the U.S. Advanced Pressurized-Water Reactor.

2. Reason for violation

It was MHI Takasago's understanding that Inspections to be performed at Takasago were "Inspections prior to Shipping" only.

The cause was that MHI Takasago did not correctly understand the requirements of NQA1-1994, Section 10.

3. Corrective steps that have been taken and results achieved, Corrective steps that will be taken to avoid further violation

MHI Takasago inspected the performance of subject Downstream Testing which is part of CIB Test.

MHI Takasago revised TA QMS91－N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual," and described the following in the revised Manual.

- When preparing Quality Plans, Inspection Steps shall be designated as "Hold Point".
- Inspection Timing shall be verified by the QA Section.
- Inspection Timing shall correspond to Test Activities and Inspections shall be performed at the Testing Station.

MHI Takasago performed indoctrination and training of related employees on this issue.
MHI Kobe will perform verification and approval of the Revision of QA Manual "TA QMS91－N01" of MHI Takasago.
(This is not significant condition adverse to quality and there was no impact on any testing results.)

4. Date when full compliance will be achieved

Corrective steps have been completed by MHI Takasago.
MHI Kobe will complete above confirmation by the end of October, 2011.

NOV-F (NRC Identification No. 05200021/2011-202-06)

1. Content of NOV

Criterion XIII, "Handling, Storage and Shipping," of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration."

Contrary to the above, as of July 25, 2011, MHI Takasago's QAM, TA QMS91-N01, Revision 12, Section 13, "Handling, Storage, and Shipping," failed to establish measures to control handling and storage of M&TE. Specifically, MHI failed to establish controls for M&TE associated with downstream testing for the design certification application for the US-APWR.

2. Reason for violation

MHI Takasago verified the statement in TA QMS91-N01, Revision 12, Section13, saying "MHI Takasago does not manufacture equipment to be used for Nuclear Facilities; therefore, this Section is not applicable to MHI Takasago."

Misunderstanding that the requirements of Criterion XIII, "Handling, Storage, and Shipping," of Appendix B to 10 CFR Part 50, were only applicable to Basic Components was the root cause of the problem.

3. Corrective steps that have been taken and results achieved, Corrective steps that will be taken to avoid further violation

MHI Takasago revised TA QMS91－N01, "Takasago R&D Center Nuclear Energy R&D Quality Assurance Manual" and described the following in the Revised Manual.

- Provision for "Handling, Storage, and Shipping" regarding M&TE in Section 12.
- Provision for "Handling, Storage, and Shipping" regarding Test Equipment in Section 13.

MHI Takasago performed indoctrination and training of related employees on this issue.

MHI Kobe will perform verification and approval of the Revision of "QA Manual TA QMS91－N01" of MHI Takasago.

(This is not significant condition adverse to quality and there was no impact on any testing results.)

4. Date when full compliance will be achieved

Corrective steps have been completed by MHI Takasago.

MHI Kobe will complete above confirmation by the end of October, 2011.