July 18, 2008

Mr. Ikuo Otake, Quality Assurance Department Manager
Mitsubishi Heavy Industries
1-1. Wadasaki-Cho 1-Chome, Hyogo-Ku
Kobe, 652-8585, Japan

SUBJECT: NRC INSPECTION REPORT 99901030/2008-201

Dear Mr. Otake:

On May 19–22, 2008, U.S. Nuclear Regulatory Commission (NRC) inspectors conducted an inspection at the Mitsubishi Heavy Industries (MHI) facility in Kobe, Japan. The enclosed report presents the details of that inspection.

This was a limited scope inspection that focused on assessing your compliance with the provisions of Title 10, Part 21 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." While the NRC did review the implementation of portions of your quality assurance (QA) and Part 21 programs, this NRC inspection report does not constitute NRC endorsement of these programs.

The NRC inspectors concluded that the implementation of the inspected portions of MHI's Part 21 and QA programs related to safety-related activities were acceptable. Within the scope of this inspection, no violations or nonconformances were identified.

In accordance with 10 CFR 2.390, "Public Exemptions, Requests for Withholding," the agency will make a copy of this letter, its enclosures, and any associated correspondence 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.

Sincerely,

/RA/
John A. Nakoski, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No. 99901030

Enclosure: Inspection Report 99901030/2008-201

Mr. Ikuo Otake, Quality Assurance Department Manager
Mitsubishi Heavy Industries
1-1. Wadasaki-Cho 1-Chome, Hyogo-Ku
Kobe, 652-8585, Japan

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This was a limited scope inspection that focused on assessing your compliance with the provisions of Title 10, Part 21 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." This NRC inspection report does not constitute NRC endorsement of your overall quality assurance or 10 CFR Part 21 programs.

The NRC inspectors concluded that the control of selected portions of MHI's Part 21 and QA controls regarding its safety-related activities were generally acceptable. Within the scope of this inspection, no violations or nonconformances were identified.

In accordance with 10 CFR 2.390, "Public Exemptions, Requests for Withholding," the agency will make a copy of this letter, its enclosures, and any associated correspondence 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.

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U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION & OPERATIONAL PROGRAMS
VENDOR INSPECTION REPORT

Docket No.:	99901030
Report No.:	99901030/2008-201
Vendor:	Mitsubishi Heavy Industries 1-1. Wadasaki-Cho 1-Chome, Hyogo-Ku Kobe, 652-8585, Japan Phone: +81-78-672-4247 Fax +81-78-672-3145
Vendor Contact:	Ikuo Otake, Quality Assurance Department Manager Phone: +81-78-672-3782 Ikuo_otake@mhi.co.jp
Nuclear Industry:	Mitsubishi Heavy Industries (MHI) manufactures safety-related and American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code items and components. MHI supplies reactor vessels, steam generators, reactor internals, and balance of plant components for the nuclear industry and has provided some of these components to the current U.S. fleet of nuclear reactors as replacement components.
Inspection Dates:	May 19–22, 2008
Inspectors:	Richard McIntyre, NRO/DCIP/CQVB Team Leader Kerri Kavanagh, NRO/DCIP/CQVP Sabrina Cleavenger, NRO/DCIP/CQVB
Approved by:	John A. Nakoski, Chief ***/RA/*** Quality & Vendor Branch 2 Division of Construction Inspection & Operational Programs Office of New Reactors

ENCLOSURE 1

EXECUTIVE SUMMARY

Mitsubishi Heavy Industries
99901030/2008-201

The purpose of this inspection was to assess whether Mitsubishi Heavy Industries (MHI) implemented a quality assurance (QA) program that complies with the requirements of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10, Part 50 of the *Code of Federal Regulations*, "Domestic Licensing of Production and Utilization Facilities," (10 CFR Part 50). The inspection also verified that MHI implemented a program for reporting defects and nonconformances consistent with the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance." This was a limited scope inspection during which the NRC inspectors reviewed portions of the QA program and 10 CFR Part 21 programs that MHI had established and implemented to meet the regulations set forth in 10 CFR Part 21. The inspection was conducted at MHI's facility in Kobe, Japan.

Three members of Japan Nuclear Energy and Safety Organization (JNES) observed the NRC inspection at MHI as part of international cooperative activities conducted under Multinational Design Evaluation Program initiatives to further the sharing of nuclear information and experience.

The NRC inspection bases were the following:

- 10 CFR Part 21
- Appendix B to 10 CFR Part 50

The NRC inspectors implemented Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors" and Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance," during the conduct of this inspection.

There were no NRC inspections performed at MHI's facility in Kobe, Japan prior to this inspection. The results of the inspection are summarized below.

The NRC inspectors reviewed MHI's QA program and implementation activities for the control of purchased material, equipment, and services; inspections; special processes such as welding and non-destructive examination (NDE); procurement document control; and corrective action and nonconformance activities. The NRC inspection team also evaluated MHI's implementation of its 10 CFR Part 21 program for evaluating deviations and reporting of defects that could cause a substantial safety hazard. The NRC inspectors concluded that these portions of MHI's QA and 10 CFR Part 21 programs regarding its safety-related activities were appropriately controlled and implemented.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspectors reviewed the MHI implementing policies and procedures that govern the 10 CFR Part 21 process, including UES-69-020008, "ASME Code Job, Identification and Reporting of Condition Adverse to Safety <Reporting of Defects and Noncompliance (10 CFR Part 21)>," Revision 9, dated May 15, 2008.

The NRC inspectors also reviewed MHI's 10 CFR 21 log and reviewed seven 10 CFR Part 21 evaluations performed by MHI since August 2007 to ensure that the nonconformance report (NCR) and corrective action report (CAR) processes were effective in identifying and evaluating conditions adverse to quality that may require entry into the 10 CFR Part 21 process. The NRC inspectors discussed the MHI 10 CFR Part 21 program with the quality assurance manager and various QA and technical staff and inquired as to how a nonconformance identified as a condition adverse to quality in an NCR or CAR would be evaluated under this program.

The NRC inspectors also sampled the MHI's 10 CFR Part 21 program implementation activities.

b. Observations and Findings

b.1 10 CFR Part 21 Procedure

Procedure number UES-69-020008 outlines the process used at MHI for the reporting of defects and nonconformance 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 from the responsible section manager. Within 60 days of discovery, the safety review team is responsible to determine if the identified deviation is reportable to the NRC. This determination is documented as described in a form provided in Appendix 8 of 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 with in 5 working days if notification of 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 inspectors verified that MHI procedural guidance was adequate to initiate the 10 CFR Part 21 process when an NCR was written that could have an impact on a U.S. facility or a customer of MHI providing equipment or services to a U.S. facility.

b.2 10 CFR Part 21 Implementation

The NRC inspectors 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 the MHI staff was knowledgeable about the conditions that would warrant a 10 CFR Part 21 evaluation. The NRC inspectors also determined that the MHI 10 CFR Part 21 procedure included all the requirements of Part 21 for evaluating and reporting defects and failures to comply. In addition, the NRC inspectors noted that MHI proactively provided training to their suppliers on Part 21 requirements as they relate to those suppliers.

c. Conclusions

The NRC inspectors concluded that the MHI 10 CFR Part 21 program requirements were consistent with the regulatory requirements of 10 CFR Part 21 and were being effectively implemented.

2. Procurement Document Control

a. Inspection Scope

The NRC inspectors reviewed Section 3, "Document Control," Revision 23, dated November 9, 2007 of the MHI Quality Assurance Manual (QAM), Manual Number B91U-N0001, Second Edition, Revision 34, dated November 9, 2007 as it applies to procurement document control to verify compliance with Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50.

The NRC inspectors also reviewed a selection of procurement documents for the South Texas Project (STP) Units 1 and 2 reactor vessel closure head (RVCH) and control rod drive mechanisms (CRDMs) to verify that procurement document control activities were conducted in accordance with MHI requirements and the QA requirements of Appendix B to 10 CFR Part 50.

b. Observations and Conclusions

According to Section 3.5.3 of the MHI QAM, documents revisions shall be controlled in the same manner as the original. In the case of order sheets and order entry check lists, this level of approval rests with the Export Marketing Section (EMS) Manager. The NRC inspectors verified that the STP Unit 1 RVCH and CRDM Order Entry Check List, Revision 10, dated March 17, 2008 and Revision 13, dated May 9, 2008 and the STP Unit 2 for RVCH and CRDM Order Entry Check List, Revision 7, dated March 17, 2008 and Revision 10, dated May 9, 2008 were both reviewed by a team leader in the EMS staff and approved by the EMS Manager in accordance with the MHI QAM. The NRC inspectors also verified that the Unit 1 and Unit 2 Order Sheets, Revisions 6 and 3, respectively, were approved by the EMS Manager. This is consistent with the guidance contained in the MHI QAM.

The NRC inspectors verified that the MHI Submittal Document Control List for the STP Units 1 and 2 RVCH and CRDM included an entry for the receipt of the latest Change Notice, Number 6, received from the customer on March 23, 2006. The NRC inspectors verified that the MHI Received Document Control List for the STP Units 1 and 2 RVCH

and CRDM included an entry for the transmittal of MHI's acknowledgement of the latest Change Notice, Number 6, received from the customer on March 23, 2006. The acknowledgement transmittal was completed on March 24, 2006.

For purchase specifications, the team verified that the quality requirements of MHI and the customer were imposed on the vendor through purchase specifications and quality plans. Section 4 of the MHI QAM requires specific information to be contained in the purchase specification and requires a review of the purchase specification, including changes thereto, by Quality Control (QC) and all other relevant sections. This review is documented on the "Review Request" and is performed to ensure that all requirements of the ASME Code and contract are specified in the purchase specification. The NRC inspectors verified, through an examination of the Review Request, Request Number SO-KAR-05-001, for the San Onofre Nuclear Generating Station (SONGS) Units 2 and 3 Channel Head Purchase Specification, Spec. No. L5-04FZ012, Revision 2, that a review was completed by the Purchase Quality Control Section (PQCS) on January 14, 2005 and by Nuclear Pressure Vessel, Core Internal & Piping Section (NPVPS) on January 13, 2005.

The NRC inspectors verified that Purchase Specification L5-04FZ012, Revision 2, for the purchase of SONGS channel heads and Purchase Specification L5-01EM401, Revision 2, for the purchase of STP replacement closure heads both contained the appropriate requirements for compliance with Appendix B to 10 CFR Part 50, 10 CFR Part 21, and the applicable sections of ASME Code Section III. The purchase specifications also contained the necessary technical requirements and document retention requirements.

c. Conclusions

The NRC inspectors concluded that MHI's policies and procedures for procurement document control comply with the quality assurance requirements of Criterion IV of Appendix B to 10 CFR Part 50 and that MHI personnel were implementing these policies and procedures effectively.

Based on the review activities above, the NRC inspectors concluded that MHI has adequate procedures for the approval, control, and distribution of procurement documents and subsequent changes and that the MHI staff had properly implemented these requirements.

3. Order Entry

a. Inspection Scope

The NRC inspectors reviewed MHI's QAM and implementing policies and procedures governing order entry to verify compliance with the requirements of Criterion III, "Design Control" of Appendix B to 10 CFR Part 50. The NRC inspectors used the following procedures, documents, and records to conduct their review of MHI's order entry program and its implementation:

- MHI Quality Assurance Manual Section 1, "Order Entry and Design Control," Revision 28, dated November 9, 2007

- Order entry documents for the STP Unit 1 RVCH and CRDMs

b. Observations and findings

QAM Section 1 describes MHI's process for receiving customer orders and initiating all required activities to fulfill the applicable ASME Code and contract requirements. QAM Section 1 also provides requirements for establishing a system to control the design process, interfaces, and design changes. Once an order is received, the EMS completes two documents: an order sheet and an order entry checklist. The order sheet identifies the responsible design section, item ordered, delivery date, and scope of work. The order entry checklist provides references for the inquiry, contract, and review documents that describe the order and establishes a list of the concerned sections within the MHI organization. When any change to the checklist occurs, the affected sections identified in the checklist are notified. An order entry control log tracks revisions to the checklist and order sheet.

The EMS manager uses document control lists to track all documents received from and transmitted to the customer; once the contract is obtained, this responsibility is assigned to a project manager and new received and submittal logs are started within the appropriate design section.

The NRC inspectors evaluated MHI's implementation of these measures for the STP Units 1 and 2 RVCH and CRDM (Order No. 25645xx and 25646xx, respectively). The "xx" denotes specific work tasks, i.e. "01 for RVCH work, "11" for CRDM work, and "13" for CRDM dry stepping testing). The NRC inspectors verified that the order entry control log listed each change submitted by the customer and identified the date and method of MHI's response (letter, email, etc.).

The NRC inspectors verified the correct processing of two customer change requests and verified that the change orders were appropriately implemented in the order documents. The NRC inspectors also verified, for a sample of change orders, that all of the concerned MHI department sections identified on the order entry checklist were notified of the change order.

c. Conclusions

The NRC inspectors concluded that the MHI policies and procedures for order entry were consistent with the requirements of Criterion III of Appendix B to 10 CFR Part 50. The NRC inspectors also concluded based on the records reviewed, that MHI personnel were implementing these policies and procedures effectively.

4. Control of Purchased Material, Equipment, and Services

a. Inspection Scope

The NRC inspectors reviewed MHI QA policies and procedures for the control of purchased material, equipment, and services to verify compliance with the quality assurance requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed Section 4 of the MHI QAM, "Procurement Control," Revision 32, dated November 9, 2007. The NRC inspectors also reviewed lower tier guidance for the conduct of vendor audits and surveys, as found in the following procedures:

- Quality Assurance Department Standard BU91-53, " Audit Guideline," Revision 0, dated December 18, 2007

- Purchase Quality Control Section Standard BUH94-06, "Vendor Evaluation Procedure," Revision 9, dated December 11, 2007 (applicable to audits of material and equipment suppliers for nuclear export jobs)

The NRC inspectors reviewed a sample of reports from surveillances that MHI conducted of its suppliers to verify the quality of the material, equipment, and services they supply. The surveillances included audit reports, survey reports, performance assessment reports, and corrective action plan follow-up reports, as applicable, for Japan Steel Works (JSW), Hitachi Metals, Ltd., Sumitomo Metal Industries, Ltd., Kobe Steel, Ltd. Welding Company, and Yokogawa Manufacturing Corporation.

The NRC inspectors reviewed MHI's list of approved vendors, "Qualified Vendor List for ASME Code Job," Revision 33, dated February 23, 2006 to verify that vendors listed within were qualified according to MHI specifications and the list was maintained up-to-date.

The NRC inspectors reviewed lower tier guidance for the development of purchase specifications, as found in the following procedures:

- Section Standard BKC40-N01E, "Procedure for Preparation of Metallic Material Purchase Specification," Revision 1, dated April 10, 1998, and issued by the Core Internal Designing Section (CIDS). This section standard was used to write the purchase specification for the procurement of forgings for CRDM rod travel housings from Hitachi Metals.

- Section Standard BKB40-N01E, "Procedure for Preparation of Metallic Material Purchase Specification," Revision 3, dated April 6, 2001, and issued by the Component Design Section (CDS). This section standard was used to write the purchase specification for the procurement of forgings procured for the STP Units 1 and 2 replacement closure heads from Hitachi Metals.

- Section Standard BKA40-N01, "Procedure for Preparation of Purchase Specification," Revision 0, dated April 15, 1996, and issued by the Steam Generator Designing Section (SGDS). This section standard was used to write the purchase specification for the procurement of four channel heads from Japan Steel Works.

The NRC inspectors reviewed Purchase Quality Control Section Standard BUH94-49, "Source and Receiving Inspection Procedure for Material," Revision 4, dated May 16, 2008 and Section 4 of the MHI QAM to verify that MHI uses receiving inspections to verify that the attributes of purchased items align with procurement documents and that appropriate methods are used to accept basic components from suppliers. The NRC inspectors also reviewed MHI QAM Section 10, "Control of Examination, Test and Inspection," Revision 20 dated November 9, 2007, as it pertains to source and receiving inspections.

In addition, the NRC inspectors evaluated MHI's procurement packages, including the customer certified design and purchase specifications, for the following items: forgings for the STP Replacement RVCH and channel head forgings for SONGS Unit 3 replacement steam generators (RSGs). The NRC inspectors also reviewed a sample of source and receipt inspection packages, including applicable validation documents (Certificates of Conformance (CoCs), Certified Material Test Reports (CMTRs), etc), for the following: the CRDM Latch Housing for the STP Unit 1 RVCH Project, the Replacement RVCH forging for STP Unit 1, and the SONGS Unit 3 RSG Channel Head.

b. Observations and Findings

b1. Policies and Procedures for Vendor Qualification

Section 4 of the MHI QAM describes the process MHI employs for the qualification and evaluation of vendors. ASME Accredited Material Organizations or N type Certificate Holders can be qualified though a verification of the validity of their Quality System Certificate (QSC) and the scope of their work. Other vendors must be qualified via a vendor survey.

According to Section 4 of the QAM, material organizations with QSCs or N/NPT Certificates, while not required to be evaluated by the ASME Code, are surveyed by MHI triennially and evaluated annually. Material organizations without QSCs or N/NPT Certificates are required to be surveyed triennially and audited annually. Vendors who perform ASME Code activities but are not material organizations are surveyed triennially and evaluated annually when an ASME Code activity is ongoing, and vendors for non-Code activities are surveyed triennially and evaluated annually. Annual evaluations may be completed through audits or via a review of vendor-furnished documents, results of previous source and receiving inspections, and/or the results of audits performed by other parties.

Department Standard BU91-53 provides general guidance for the conduct of both internal audits and vendor audits. The standard sets forth the minimum requirements for audit plans, reports, and audit conduct and requires that audit plans be prepared prior to each audit and include an audit checklist to be used for the audit. Reports must be written within 30 days of audit completion and include the following information: background information, conformance of vendor to applicable QA standards and QA requirements of MHI Kobe, adequacy of implementation, and recommendation regarding qualification.

Section Standard BUH 94-06 provides further detail on MHI policies for evaluating the quality control capability of vendors supplying material and equipment. The standard includes templates for the "Checklist for Vendor's Quality Assurance Program" used to identify audit/survey criteria and the "Questionnaire for Performance Assessment" used as a tool for gathering information from vendors for annual evaluations. The questionnaire asks whether, within the past year, the vendor's QAM has changed, if any 10 CFR Part 21 reportable instances have occurred, and what guidance is used for the qualification of NDE personnel. The questionnaire also asks the vendor to list major manufacturing experience completed in the past year in accordance with its QAM and to share the results of audits from other sources.

b2. Review of Vendor Survey Reports

The NRC inspectors selected a sample of vendors from MHI's qualified vendor list (QVL) for review of vendor evaluations, including 1) survey reports for renewal of qualification, 2) annual audit reports, 3) audit reports related to corrective action evaluation, 4) corrective action plan follow-up reports, and 5) performance assessment reports written to document MHI's evaluation of performance assessment questionnaires submitted by vendors in support of annual evaluations. The NRC inspectors verified that the evaluations had been performed in accordance with procedural guidance and provided adequate oversight for items and materials procured by MHI. The vendors reviewed included: Japan Steel Works, Ltd. Muroran Plant for forgings; Hitachi Metals, Ltd. Yasugi Works for forgings; Sumitomo Metal Industries, Ltd. Steel Tube Works for steam generator tubes; Kobe Steel, Ltd. Welding Company Ibaraki Plant for welding materials (for both ASME Code and non-Code activities); and Yokogawa Manufacturing Corporation for calibration services.

The audit and survey reports sampled consisted of single and multi-day surveys with documented objective evidence including references, personnel training and qualification status, inspector observations, test and special process specifications and results, adequacy of procedural controls, and other relevant documentation to support the inspector's conclusions. The NRC inspectors observed that, through the use of a detailed survey and audit check sheet to guide vendor evaluations, MHI was able to adequately evaluate their suppliers' controls for and implementation of Appendix B to 10 CFR Part 50, 10 CFR Part 21, and ASME Section III requirements, as applicable.

For audits and surveys resulting in findings, the NRC inspectors verified that the vendor had established a plan for corrective action, that corrective action had been completed, and that MHI had reviewed and approved the planned corrective action and verified its satisfactory completion. This information was documented on the MHI document "Corrective Action Plan Follow-up Report."

b3. Maintenance of the Qualified Vendor's List

According to QAM Section 4, the Nuclear Plant Quality Assurance Section (NPQAS) has the responsibility for preparing, approving, and distributing the QVL and any revisions thereto. In addition, a review by the Quality Assurance Engineer (QAE) is required prior to final document approval. MHI is informed of changes to their supplier's QAMs through procurement requirements imposed on the suppliers on their certificate of qualification as an approved vendor. Prior to issuing a QAM revision, approved vendors are required to send a copy to MHI for review and approval, after which MHI updates the QVL with the latest revision number and date.

The NRC inspectors observed that MHI was effectively imposing these requirements on its suppliers and maintaining its QVL up-to-date by verifying that an MHI review had been conducted on the following vendor QAM revisions and that these revisions were incorporated into the QVL:

- "Checklist for Vendor's Quality System Program," Document No. UHW-69-08N014, documents Sumitomo Metal Industries' submittal of Revision 35 to their QA manual, QA 3700, dated January 10, 2008. The QVL was updated to reflect this change in Revision 28, dated March 14, 2008.

- "Checklist for Vendor's Quality System Program," Document No. UHW-69-08N019, documents Hitachi Metal's submittal of Revision 4 to their QA manual, QA 36, dated March 11, 2008. The QVL was updated to reflect this change in Revision 29, dated March 26, 2008.

- "Checklist for Vendor's Quality System Program," Document No. UHW-69-08N015, documents Japan Casting and Forging Corporation's submittal of Revision 31 to their QA manual, QA-03, dated April 1, 2008. The QVL was updated to reflect this change in Revision 30, dated April 9, 2008.

b4. Preparation of Purchase Specifications

MHI Section Procedures BKA40-N01, BKB40-N01E, and BKC40-N01E provide specific requirements for the preparation of purchase specifications. The procedures contain similar guidance for purchase specification content, such as requiring the ASME Code class, component type, scope of work, technical requirements, QA program requirements, and requirements for reporting and approving the disposition of nonconformances. The NRC inspectors determined that these procedures provided sufficient guidance to ensure that the necessary technical, quality, and administrative requirements were translated from the certified customer design to the purchase specification.

The NRC inspectors verified that a sample of the requirements identified in Purchase Specification L5-01EM401, Revision 2, for the purchase of closure head forgings from JSW were in compliance with the requirements specified in Westinghouse Design Specification 419A68, Revision 3, "STPNOC Unit 1 Replacement Reactor Vessel Closure Head." The requirements verified included the specific Charpy V-notch test requirements, chemical analysis requirements and acceptance criteria, heat treatment specifications, and visual inspection requirements.

The NRC inspectors also verified that nondestructive examination requirements were properly translated from Southern California Edison SONGS 2/3 Steam Generator Design Specification S023-617-01, Revision 3, to SONGS Unit 3 Replacement Channel Head Forging Purchase Specification L5-04FZ012, Revision 2.

b5. Source and Receiving Inspections

Section 4.3.10 of the MHI QAM requires the QAE or quality control inspector (QCI) to perform source inspections at the vendor as required by the purchase specification and directs the QAE to complete the "Material Inspection Check List." The Material Inspection Check List contains the following: 1) verification that the CMTR aligns with purchase order specifications; 2) verification that the material was produced to the material organization's ASME Quality System Program or a QSP approved by MHI Kobe; 3) characteristics that are required to be verified; 4) the date and signature or stamp of MHI's representative indicating acceptability of the source and receiving inspections; and 5) the date of the inspection and signature or stamp of the authorized nuclear inspector (ANI). The MHI QAM also requires a receipt inspection that includes, as a minimum, verification of item dimensions, visual inspection for damage and cleanliness, and verification of material identification. These activities are performed in

accordance with MHI QAM Section 10, “Control of Examination, Test and Inspection,” Revision 20 dated November 9, 2007.

The NRC inspectors determined that MHI used appropriate methods to accept basic components from its suppliers through a review of Material Inspection Check List Number UHA-STP1-005-02b for the CRDM latch housing for the STP RVH Project, UHA-STP1-014-01A for the Replacement RVCH forging for STP Unit 1, and UHA-SONGS3-024-01a for a SONGS Unit 3 RSG Channel Head. For each of these items, MHI completed a source inspection including, at least, a mechanical test, ultrasonic test, dimensional test, visual inspection, and ID number. The check list also included a verification of the CMTR contents for these packages and the results of MHI’s receiving inspection, which verified objective evidence of purchased items (item appearance, freedom from damage, cleanliness, ID number, quantity, and dimension).

c. Conclusions

The NRC inspectors concluded that the MHI policies and procedures for procurement control were consistent with the quality assurance requirements of Criterion VII of Appendix B to 10 CFR Part 50 and that MHI personnel were implementing these policies and procedures effectively.

The NRC inspectors concluded, based on the records reviewed, that MHI performs periodic audits and evaluations of its suppliers, that the reports for these activities contain sufficient objective evidence to support the (re)qualification of the vendors by MHI, and that MHI maintains an up-to-date list of its qualified vendors. The NRC inspectors also concluded that the requirements set forth in customer design documents were effectively translated into purchase specifications and that purchase specification requirements were successfully verified by MHI through source and receipt inspections and verification of CMTR requirements.

5. Control of Fabrication and Special Processes

a. Inspection Scope

The NRC inspectors reviewed the MHI QAM, the project specific addenda to the QAM, and implementing policies and procedures that govern the control of fabrication and special processes at MHI. These documents included:

- Section 5, “Material Control,” Section 6, “Control of Fabrication Processes,” Section 8, “Control of Welding,” Section 9, “Control of Heat Treatment,” and Section 10, “Control of Examination, Test and inspection,” of the MHI QAM, Second Edition, dated November 9, 2007

- Quality Assurance Program Manuals (Project Addenda) specific to the STP Replacement RVCH Project and the SONGS RSGs

The NRC inspectors also reviewed the applicable section standards and interfaced with personnel from CDS, SGDS, NPQAS, the Component Quality Control Section (CQCS), and the Nuclear Pressure Vessel, Core Internal, and Piping Shop (NPVCIPS).

The NRC inspectors evaluated ongoing activities such as welding, NDE, inspection, and testing for U.S. replacement components. These included STP Unit 1 Replacement RVCH and CRDM penetrations and the SONGS RSG Unit 2B and 3B channel heads. The NRC inspectors reviewed fabrication process sheet (FPS) operations related to an ultrasonic examination (UT) of the SONGS 3B channel head outlet nozzle weld and the liquid penetrant examination (PT) for the SONGS 2B weld joint between the pressure taps and the channel head.

The NRC inspectors reviewed inspection and testing activities for ongoing fabrication of U.S. replacement components. First, the NRC inspectors reviewed the testing documentation for the primary side hydrostatic test conducted for the SONGS Unit 2B RSG. This review included the FPS, inspector qualification records, the hydrostatic test procedure, and the final primary side hydrostatic test record that was completed in April 2008.

The NRC inspectors reviewed all the pertinent activities and documents that were generated to support these fabrication activities to verify compliance with the program requirements and adequate implementation of those requirements, as described below.

b. Observations and Findings

b.1 Policies and Procedures for the Control of Fabrication Processes

The specific QAM sections describe the fabrication, welding, NDE, test, inspection and material control processes for MHI. MHI QAM Section 5 describes the controls applied to assure traceability to material certifications and to prevent the incorrect use of items throughout manufacturing and assembly. QAM Section 6 describes the controls for fabrication, assembling and inspection processes of items to assure these processes are performed in a planned sequence using MHI procedures that meet ASME code and purchase order contract requirements. QAM Section 8 describes the controls of all welding operations to assure compliance with the requirements of Sections III and XI of the ASME code. QAM Section 10 describes the controls for examination, test, and inspection to assure compliance with ASME code and customer purchase order contract requirements.

The Quality Assurance Program Manuals (Project Addenda) for the STP Replacement RVCH Project and the SONGS RSGs provide contract-specific requirements for construction of Replacement RVCHs and CRDMs for STP Units 1 and 2 and RSGs for SONGS Unit 2 and 3.

b.2 Review of Fabrication and Special Process Activities

After reviewing applicable QAM sections and individual section standard documents, the NRC inspectors verified specific manufacturing activities for the STP Unit 1 Replacement RVCH and CRDM penetrations and the SONGS Unit 2 and 3 RSG channel heads. The NRC inspectors determined that the MHI manufacturing process uses the FPS as the method for controlling shop activities. The FPS incorporates witness/hold points for the customer, ANI, and MHI QC and identifies the drawings, specifications, and procedures applicable to the manufacturing activity being performed. The FPS serves to provide shop personnel, including workers, inspectors, and examiners with applicable procedural information as well as operational sequence. The FPS is used as a traveler which also

has the function of a work instruction and check sheet for each operation performed. Finally, the FPS is used for the receipt of material, which includes receipt inspection.

The NRC inspectors determined through review of documents and interviews with personnel that the FPS is developed from applicable design documents and the prepared inspection plan. The initial preparation of the FPS begins with the manufacturing plan and the specific manufacturing process flow diagrams that identify and detail the entire manufacturing process for the specific component being fabricated. Thus, the FPS would include the specific manufacturing or special process activities such as welding, NDE, heat treatment, inspection or test that is to be performed for the specific component, including hold points and witness points for MHI QC, the customer and the ANI.

The NRC inspectors sampled various fabrication and special process activities to verify implementation of the MHI QAM and implementing processes and procedures for the components identified above. These activities included the following areas:

Welding

The NRC inspectors reviewed welding procedure specifications (WPSs), procedure qualification records (PQRs), welding records (WRs), and other welding process documents including welding material traceability for the cladding on the keyway and inner surfaces of the STP Unit 1 RVCH and the cladding of the inner surface of the SONGS Unit 3B RSG channel head. This review included sampling of specific operations identified on the FPS related to welding. The NRC inspectors also verified the qualifications of the welders and welding operators and traced the control of the welding material by heat number from receipt inspection all the way through the FPS welding operation. The NRC inspectors verified compliance with purchase and material specification requirements through a review of the welding CMTRs and verified completion of all required FPS QC, customer, and ANI witness or hold points.

Material Control

In accordance with MHI QAM Section 5, MHI personnel are required to control material in the shop to maintain traceability to the associated material certification documentation (including specification and heat numbers as a minimum). The NRC inspectors verified the implementation of these controls through a review of material control documentation for the welding material described above, for the STP Unit 2 CRDM head penetration material, and for weld material for the SONGS Unit 3B primary inlet nozzle tip. The material control documentation included purchase specification, material inspection checklist, receipt inspection reports, CMTRs and certificates of confirmation of tests (for chemical and physical tests) and the FPS.

In all cases, the NRC inspectors were able to verify that material traceability was clearly indicated to the heat number from initial receipt inspection at MHI completely through FPS shop fabrication activities and was indicated as required on all documents reviewed.

Non-destructive examination (NDE)

Upon review of examination procedures, examiner qualification records, equipment calibration records, and the final documentation results of NDE activities for operations related to a UT of the SONGS 3B channel head outlet nozzle weld and the PT for the SONGS 2B weld joint between the pressure taps and the channel head, the NRC inspectors found that an NCR was issued by MHI QC to document indications identified during the UT for the 3B channel head. The NRC inspectors evaluated the disposition of the NCR and reviewed the corrective actions taken to remove the indication by grinding, PT of the removal area, rework the weld, machining the outlet nozzle for final configuration, final post weld heat treatment, and final UT of the reworked area. The NRC inspectors determined that all NDE activities were performed using established procedures meeting ASME Code requirements and performed by personnel qualified in accordance with MHI procedures.

The NRC inspectors observed the MHI ANI from Hartford Steam Boiler (HSB) Global perform his witness/hold point inspection activities for the SONGS RSG 2B PT examination of the weld joint and found that the activities were performed and documented as required on the FPS.

Inspection and Testing

Upon review of the testing documentation for the primary side hydrostatic test conducted for the SONGS Unit 2B RSG, the NRC inspectors concluded that all test results were within the documented test parameters and were witnessed and signed by the ANI, the customer, and the MHI QC inspectors. This verification was accomplished through examination of the FPS, inspector qualification records, the hydrostatic test procedure, and the final primary side hydrostatic test record.

The NRC inspectors also witnessed the SONGS Unit 2B RSG fit up inspection for the weld joint between the channel head and the nozzle tip. The NRC inspectors concluded that all results for inspection activities were acceptable and conducted in compliance with MHI QAM and fabrication process requirements. In addition to witnessing the fit up inspection, the NRC inspectors' conclusions are based on the review of:

1. the FPS,
2. inspector qualification documentation,
3. inspection tools and measuring and test equipment (M&TE) verification report (calibration records),
4. the fabrication drawing for the channel head,
5. the fit-up inspection procedure, and
6. the final fit-up inspection record that was signed by the customer (SONGS) and the ANI to document that they had witnessed this activity,

c. Conclusions

The NRC inspectors concluded that overall, MHI has established appropriate and effective means to control fabrication activities and special processes such as welding, NDE, inspection, test, and material control for supply of replacement RVCHs and associated CDRMs and RSGs.

Based on a limited review of MHI documentation, direct observations of fabrication, test, and inspection activities, and interviews with MHI personnel, the NRC inspectors determined that the MHI QAM and associated fabrication and special process procedures were being effectively implemented by qualified personnel, using qualified equipment and processes.

6. Nonconforming Materials, Parts, or Components and Corrective Actions

a. Inspection Scope

The NRC inspectors reviewed Section 16, "Control of Nonconforming Items and Activities," and Section 18, "Corrective Action, Preventive Action and Lessons Learned," of the MHI QAM, Second Edition, dated November 9, 2007, which describe the nonconformance and corrective action processes for MHI. The NRC inspectors also reviewed the project specific addenda to the QAM and implementing policies and procedures that govern the control of nonconformances and corrective actions to verify compliance with Criterion XV, "Nonconforming Materials, Part, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. The procedures reviewed included MHI document BU91-51(2), "Over Sea Project Job, Guide Line for Implementation on NCR/CAR," dated February 27, 2008.

The NRC inspectors reviewed the departmental logs of NCRs for all issues associated with the five projects for U.S. utilities and sampled several NCRs concerning unacceptable indications on components being manufactured, suppliers who furnished materials for the manufacture of U.S. components, and damage to locking plates of vane jacking devices and vanes, and displaced bolts. The NRC inspectors also reviewed a sample of corrective actions associated with the departmental logs of CARs for the U.S. components being manufactured at MHI and additional corrective actions identified as a result of internal MHI audits to verify compliance with the program requirements and adequate implementation of those requirements.

b. Observations and Findings

b.1 Policies and Procedures for the Control of Nonconformances and Corrective Action

Section 16 of the MHI QAM describes the process for identifying, documenting, segregating, evaluating, and handling nonconformances and describes the process for notifying affected organizations and customers. Section 18 of the MHI QAM describes the process and elements to be considered in the identification and resolution of significant conditions adverse to quality.

BU91-51(2) defines the MHI employee responsibilities and applicable procedures for handling nonconformances in supplies and services for nuclear facilities. The procedure describes the process for identifying, evaluating, reporting, and correcting nonconformances. The procedure contains multiple process flow diagrams and sample reporting forms that further describe and govern the nonconformance and corrective action processes.

b.2 Review of Nonconformance Reports

The MHI process for identifying and documenting nonconformances is implemented via NCRs in accordance with Figure 1, "Handling Flowchart of Nonconformances," in BU91-51(2). Based on their review of the departmental logs of NCRs and a sample of NCRs, the NRC inspectors observed that each NCR contains a detailed description of the concern and at least one proposed corrective action associated with the identified deficiency. The NRC inspectors verified that the NCRs included the appropriate review and signoff and, when applicable, verified that each corrective action was assigned to a lead organization responsible for its completion.

In addition, the NRC inspectors discussed the nonconformance process with MHI including trend analyses performed for each project on a quarterly basis. The NRC inspectors noted that each individual project trend analysis were then summarized in an overall NCR trend analyses for all projects on a quarterly basis.

b.3 Implementation of Corrective Action Program

As a result of their review of MHI corrective actions, the NRC inspectors noted that most of the corrective actions sampled had been completed in a timely manner as documented on the CARs. The NRC inspectors identified one instance where corrective actions were due two weeks prior to the inspection and had not been completed even though weekly emails were sent to the responsible organization to remind personnel of the due dates. The NRC inspectors discussed this with the vendor and determined that BU91-51(2) did not explicitly define the process for elevating a missed CAR due date to management. However, MHI QA department does have the ability to issue a stop work order of the affected projects if it judges that the severity of the corrective actions requires such action. Based on discussions with MHI QA personnel, the NRC inspectors determined that the MHI QA department was actively pursuing closure of the delinquent CAR and found the actions being taken to be acceptable. The NRC inspectors noted that BU91-51(2) did provide adequate guidance for the review of corrective actions to determine if they are effective in precluding recurrence of the deficiencies.

c. Conclusions

The NRC inspectors concluded that MHI's control of nonconformances and corrective action program requirements were consistent with the regulatory requirements of Criterion XV and Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample reviewed, the NRC inspectors determined that the MHI QAM and associated nonconformance and corrective action procedures were being effectively implemented.

7. Internal Audits

a. Inspection Scope

The NRC inspectors reviewed MHI QAM Section 19, "Internal Audit," Second Edition, dated November 9, 2007, and implementing policies and procedures that govern the internal audit process, including:

- B91U-N0001, "Internal Audit," Revision 18, dated November 9, 2007

- UES-20071181, “2007 Periodic Internal Audit Program,” Revision 2, dated December 23, 2007

These reviews were conducted to verify that MHI’s internal audit controls satisfied Criterion XVIII, “Audits,” of Appendix B to 10 CFR Part 50.

The NRC Inspectors reviewed a selected a sample of audit reports from April 1, 2007 to March 30, 2008 to determine if the audits were being performed in accordance with program requirements.

b. Observations and Findings

b.1 Procedures and Policies Governing the Internal Audit Process

MHI Procedure B91U-N0001 provides a description of the process and requirements for performing internal audits. This procedure further discusses schedules for audit activities, standardized audit techniques, standardized audit reports, and control of the audit process. Internal audits, applied to a complete sector of the manufacturing process (e.g., procurement, quality assurance, purchasing and inspection), are performed for each sector on an annual basis.

MHI Procedure UES-20071181 controls the frequency of internal audits, describes the preparation and content of the audit report, identification and resolution of corrective actions, and closeout of audit findings.

b.2 Implementation of the Internal Audit Process

MHI conducted 27 internal audits in fiscal year 2007 with all audits conducted when originally scheduled. The NRC inspectors noted that although there does not appear to be a time limit for rescheduling internal audits, all audits are required to be completed within the fiscal year. Based on review of audit reports, the associated corrective actions identified, and resolution of those actions completed at the time of the NRC inspection, the NRC inspectors verified that the corrective actions were implemented in a timely manner to respond to any identified findings. The NRC inspectors also verified that the quality assurance manager was cognizant of the findings and of the proposed or completed corrective actions associated with them.

c. Conclusions

The NRC inspectors concluded that MHI’s internal audit program requirements are consistent with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. Based on the limited sample reviewed, the NRC inspectors also determined that the MHI QAM and associated audit procedures were being effectively implemented.

8. Entrance and Exit Meetings

On May 19, 2008, the NRC inspectors presented the inspection scope during an entrance meeting with MHI-Kobe Senior Vice President and General Manager, Shigero Masamori and other MHI personnel.

On May 22, 2008, the NRC inspectors presented the inspection results during an exit meeting with MHI-Kobe Senior Vice President and General Manager, Shigero Masamori and other MHI personnel.

See Attachment 1 for a list of attendees for the entrance and exit meetings.

ATTACHMENT 1

List of Attendees: (1) Entrance Meeting May 19, 2008, (2) Exit Meeting on May 22, 2008

(1)	(2)	Name	Department/Organization
X	X	Glenn Tracy	NRC
X	X	Richard McIntyre	NRC
X	X	Kerri Kavanagh	NRC
X	X	Alan Blamey	NRC
X	X	Sabrina Cleavenger	NRC
X		T. Fukuda	CQCS Department, MHI
X		T. Nakata	PQCS Department, MHI
X		F. Castro	CDS Department, MHI
X		K. Kubo	NCVS Department, MHI
X	X	H. Mizoguchi	TAG Department, MHI
X	X	T. Ozawa	MPS, MHI
X	X	T. Usuda	CQCS, MHI
X	X	G. Abe	SGDS, MHI
X		T. Ota	NSGS, MHI
X	X	T. Kagawa	NSGS, MHI
X	X	N. Sakamoto	CQCS, MHI
X		S. Maeda	NSGS, MHI
X	X	H. Taguchi	NPMPS, MHI
X	X	M. Amano	MPS, MHI
X		T. Fukui	NCVS, MHI
X	X	M. Koyama	SGDS, MHI
X		H. Kamino	CQCS, MHI
X		M. Talongishi	NPVCIPS, MHI
X		J. Kurokawa	NPQAS, MHI
X	X	H. Hirano	PM, MHI
X	X	K. Aizawa	NPQAS, MHI
X		Y. Sano	NPVCIPS, MHI
X		T. Kanabushi	NSGS, MHI
X	X	T. Okamoto	MPMPS, MHI
X	X	S. Yamane	DTS, MHI
X		H. Mimaki	SGDS, MHI
X		H. Kaguchi	Nuclear Plant Component Designing Dept Manager, MHI
X	X	T. Kobayashi	TAG, MHI
X	X	K. Saito	Procurement, MHI
X	X	T. Kodama	PM, MHI
X	X	T. Hoshi	PM, MHI
X		Tsuruta	Lead NDE Level III, MHI
X	X	K. Abe	CIDS, MHI
X	X	Yurugi Kanzaki	CDS, MHI
X	X	Kazuyuki Unate	PQCS, MHI
X		Yoshihisa Tada	CQCS, MHI
X	X	Masayoshi Suzuki	NPQAS, MHI

X	X	Masamori Onozuka	New Plant Engineering, MHI
X	X	J. Namba	Interpreter
X	X	K. Kano	NPQAS, MHI
X	X	S. Koizumi	EMS, MHI
X	X	Y. Okazaki	EMS, MHI
X	X	S. Masamori	MHI Kobe General Manager
X		F. Kono	Nuclear Plant Designing Department, MHI
X	X	T. Kitera	QA Department Manager
X		M. Tsujii	MHI Nuclear Energy Systems Marketing & Administration Department Deputy Manager
X		S. Itoh	Nuclear Power Plant Equipment Mgmt. Dept. Deputy Manager
X	X	K. Hirakawa	QA Department Deputy Manager
	X	T. Tokiami	DTS, MHI
	X	H.G. Domschire	SCE Engineering
	X	T. Nakata	PQCS, MHI
	X	D. Calhoun	SCE Engineering
	X	T. Kimoshita	PQCS, MHI
	X	T. Hashimoto	CDD, MHI
	X	M. Yonoha	QAD, MHI
	X	E. Kadokami	MHI Deputy General Manager
	X	N. Miyakoshi	General Manager of MHI Headquarters QA
	X	T. Walker	STPNOC Quality Manager
	X	R.W. Driscoll	WEC Engineering
	X	S. Babae	Marketing & Administration, MHI
	X	Y. Sagara	MES Manager, MHI
	X	M. Uchida	NPQD Deputy Manager, MHI
	X	T. Saito	NPQAS, MHI
	X	M. Takagishi	NPVCIPS, MHI
	X	Y. Shimokusu	NPEMD Manager, MHI
	X	M. Ono	NPQAS, MHI

Attachment 2

1. PERSONS CONTACTED

Shigero Masamori, Senior Vice President, General Manager
El Kadokami, Deputy General Manager
Ikuo Otake, Manager, Nuclear Energy Systems Quality and Safety Management Dept.
Kyoichi Aizawa, Engineering Manager, Nuclear Plant QA Section, QA Department
Kyoji Kano, Engineering Manager, Nuclear Plant QA Section, QA Department
Norio Sakamoto, Engineer, Component Quality Control Section, QA Department
Ganji Abe, Senior Engineer, Steam Generator Designing Section
Fidel Castro, Acting Manager, Component Designing Section
Masayashi Suzuki, Manager, Overseas Projects Team
Takahiro Nakata, Engineering Manager, Purchase Quality Control Section
Hiroshi Hirano, Project Manager, Nuclear Plant Component Designing Department
Kazuyuki Unate, Manager, Purchase Quality Control Section, QA Department
Takashi Kagawa, Senior Engineer, Nuclear Steam Generator Shop
Tetsuhiko Kodama, Prpject Manager, Nuclear Plant Component Designing Department
Katsuhiko Hirakawa, Deputy Manager, QA Department
Takuya Kitera, Manager, QA Department
Masayoshi Kobatake, Authorized Inspector, Hartford Steam Boiler Global Standards
Robert Driscoll, Resident Principal Engineer, Westinghouse Electric Corporation
David Calhoun, Senior Civil Engineer (SONGS), Southern California Edison
Timothy Walker, Manager of Quality, South Texas Project Nuclear Operating Company

The following JNES representatives observed the inspection:

Masaharu Kudo, Deputy Director – General, Inspection Affairs Division, JNES
Takumi Samukawa, Senior Inspector, Inspection Engineering Group
Hiroyoshi Koizumi, Senior Officer, International Relations Office

2. INSPECTION PROCEDURES USED

Inspection Procedure 43002, “Routine Inspections of Nuclear Vendors”

Inspection Procedure 36100, “Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance”