

July 23, 2012

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

SUBJECT: NRC INSPECTION REPORT NO. 05200021/2012-201 AND NOTICE OF VIOLATION

Dear Mr. Ogata:

From June 5, 2012 through June 8, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Engine Systems, Inc. (ESI) facilities in Rocky Mount, NC. The purpose of the limited-scope inspection was to verify that Mitsubishi Heavy Industries, Ltd (MHI) effectively implemented quality assurance (QA) processes and procedures for testing activities performed in support of the U.S. Advanced Pressurized-Water Reactor design certification application. The inspection focused on assessing compliance with the provisions of selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulation* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The enclosed report presents the results of this inspection. This NRC inspection report does not constitute NRC endorsement of MHI's overall QA program.

Based on the results of this inspection, the NRC determined that four Severity Level IV violations of NRC requirements occurred. The NRC evaluated the violations in accordance with the agency's Enforcement Policy, which is available on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

These violations are cited in the enclosed Notice of Violation (Notice) and circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because the NRC inspection team identified an example in which MHI failed to adequately oversee the implementation of ESI's test control, corrective action, nonconformance and training programs in accordance with Appendix B to 10 CFR Part 50.

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

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC's Public Document Room or from

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

Sincerely,

/RA/

Kerri A. Kavanagh, Chief
Quality Assurance Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 05200021

Enclosures:

1. Notice of Violation
2. Inspection Report No. 05200021/2012-201 and Attachment

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

Sincerely,

/RA/

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NOTICE OF VIOLATION

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

Docket No.: 05200021
Inspection Report No. 2012-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection of Mitsubishi Heavy Industries, Ltd. (MHI) conducted at the Engine Systems, Inc. (ESI) facilities in Rocky Mount, NC, on June 5, 2012 through June 8, 2012, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are described below:

- A. Criterion III, "Design Control," 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 also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components.

Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization."

MHI QAM, UES-20080022, "Change Control," Revision 5, dated October 13, 2011, states, in part, that, "changes to final designs and nonconforming items dispositioned use-as-is or repair shall be justified and subject to design control measures commensurate with those applied to the original design. When any changes to design inputs or outputs are made, the changes shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based. Evaluation shall be documented, even though the changes do not affect any of the design outputs."

Contrary to the above, as of June 8, 2012, MHI failed to ensure adequate evaluation of design control changes for gas turbine generators (GTG) testing activities. Specifically, MHI did not perform a design change evaluation for the GTG's compressor discharge hose replacement that failed during prototype testing and failed to ensure the design change was included in final design documentation.

This issue has been identified as Violation 05200021/2012-201-01.

This is a Severity Level IV violation (Section 6.5.d of the NRC Enforcement Policy)

- B. Criterion XI, "Test Control" of Appendix B to 10 CFR Part 50 states, in part, that, "a test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents."

MHI MUAP-07024-P, "Qualification and Test Plan of Class 1E Gas Turbine Generator System," Revision 2, dated on October 10, 2010, Section 4, "Principal Design Criteria,"

describes the scheduled maintenance activities as requirements for two design conditions of the GTGs.

Contrary to the above, as of June 8, 2012, MHI, which has the overall responsibility for the test program, failed to include scheduled maintenances in the test procedure as required by the two design conditions of the GTG. Specifically, MHI failed to send ESI the adequate fuel nozzle cleaning procedure prior to the start and load acceptance test, and approved the test procedure 8001517-FTP without including the scheduled maintenance.

This issue has been identified as Violation 05200021/2012-201-02.

This is a Severity Level IV violation (Section 6.5.d of the NRC Enforcement Policy).

- C. Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, states in part, that "the program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

MHI QAM, UES-20080022, "Training and Indoctrination," Revision 5, dated February 14, 2012, states in part, that, "Personnel performing or managing activities affecting quality shall receive training and indoctrination to assure suitable proficiency in assigned activities. Indoctrination shall assure knowledge in the required general criteria including applicable codes, regulations, standards, and company procedures, applicable quality assurance program elements, job responsibilities, and authority."

Section 2 of ESI's QAM, "Quality System," 5th Edition Revision 0, dated July 13, 2007, states in part, "Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities." ESI's QAM also states, "Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed. The need for a formal training program shall be determined and such training activities shall be conducted as required to qualify personnel who perform inspections and tests."

ESI's Procedure, QTP-100, "Indoctrination and Training Procedure," Revision 4, dated April 24, 2006, states, in part, that, "Training in accordance with the Training Matrix shall be scheduled and completed within a two (2) week period. Records of completion shall be transmitted back to the person responsible for maintaining the Training Matrix. Training Matrix shall be updated at completion of training. This update must include date training was completed."

Contrary to the above, as of June 8, 2012, MHI, which has the overall responsibility for training activities, failed to ensure that ESI personnel performing safety-related GTG testing activities had completed required training. Specifically, ESI failed to ensure personnel performing inspection and test activities for the safety-related GTG testing had completed required training and maintain training records in accordance with ESI's procedure QTP-100.

This issue has been identified as Violation 05200021/2012-201-03.

This is a Severity Level IV violation (Section 6.5.d of the NRC Enforcement Policy).

- D. 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."

Criterion V, "Instructions, Procedures and Drawings," 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 QAM, UES-20080022, Revision 5, dated February 14, 2012, "Corrective Action, Preventive Action and Lessons Learned," states, in part, that, "Conditions adverse to quality shall be identified promptly and corrected as soon as practical." The QAM also states, "These measures shall be extended to the performance of subcontractor's corrective and preventive action measures."

Section 14.1 of ESI's QAM, "Corrective Action," 5th Edition, Revision 0, dated July 13, 2007, states, in part, that, "When a significant condition adverse to quality occurs, ESI take(s) actions to eliminate the cause in order to prevent reoccurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. ESI has established and maintains a documented procedure that defines the requirements for reviewing and determining the cause nonconformities, evaluating the need for action to ensure that nonconformities do not reoccur, determining, and implementing action needed, records of the results of action taken and reviewing corrective action taken."

ESI's procedure QCP-301, "Control of Nonconforming Conditions and Corrective Actions and 10 CFR 21 Reportable Conditions," Revision 22, dated November 15, 2011, states, in part, that, "Engineering shall review the nonconforming condition and determine if a 10 CFR Part 21 evaluation is required. This determination shall be completed within 7 working days of the NCR initiation date. The engineer shall document this determination by entering 'yes' or 'no' beside the '10 CFR 21 is required?' box on the NCR form."

Contrary to the above, as of June 8, 2012, MHI, which has the overall responsibility for corrective action for GTG testing activities, failed to ensure that ESI followed procedures to promptly identify and correct conditions adverse to quality. Specifically, ESI engineering did not complete reviews to determine if a 10 CFR Part 21 evaluation is required for nonconformances as required by the ESI QT-100 procedure within the 7-day period.

This issue has been identified as Violation 05200021/2011-201-04.

This is a Severity Level IV violation (Section 6.5.d of the NRC Enforcement Policy).

In accordance with the provisions of 10 CFR 2.201, "Notice of Violation," MHI is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality Assurance Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation. This

reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

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

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

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

Dated at Rockville, MD, this 23th day of July 2012.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND
OPERATIONAL PROGRAMS**

Docket No.: 05200021

Report No.: 05200021/2012-201

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

Applicant Contact: Mr. Ryan Sprengel
Lead Licensing Engineer

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

Inspection Dates: June 5-8, 2012

Inspectors: Paul Prescott NRO/DCIP/CQAB Team Leader
Aixa Belen-Ojeda NRO/DCIP/CQAB
Aaron Armstrong NRO/DCIP/CQMV
Paul Coco NRO/DCIP/CQMV

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

EXECUTIVE SUMMARY

Mitsubishi Heavy Industries, Ltd.
05200021/2012-201

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

MHI performed plant specific US-APWR gas turbine generator (GTG) qualification testing activities. MHI contracted Engine Systems Inc. (ESI) to perform the testing.

The NRC based its inspection on the following:

- Appendix B to 10 CFR Part 50

During this inspection, the NRC inspection team implemented Inspection Procedure (IP) 35034, "Design Certification Testing Inspection," as supplemented by IP 35017, "Quality Assurance Implementation Inspection."

With the exception of the four violations described below, the NRC inspection team concluded that ESI is effectively implementing its QA program in support of MHI's US-APWR DC testing activities.

Training and Qualification

The NRC inspection team identified one violation associated with MHI's failure to implement the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. Violation 05200021/2012-201-03 involved MHI's failure to ensure that ESI personnel performing safety-related GTG testing activities had completed the required training and maintain training records in accordance with ESI's document QTP-100.

Control of Purchased Equipment, Materials, and Services

The NRC inspection team concluded that the implementation of MHI's and ESI's programs for control of purchased equipment, materials and services is consistent with the regulatory requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services" of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that MHI, and ESI are effectively implementing their policies and procedures in support of MHI's US-APWR DC testing activities. No findings of significance were identified.

Test Control

The NRC inspection team identified two violations associated with MHI's failure to implement the requirements of Criterion III, "Design Control," and of Criterion XI, "Test Control," of

Appendix B to 10 CFR Part 50. Violation 05200021/2012-201-01 involved MHI's failure to perform a design change evaluation for GTG testing activities. Violation 05200021/2012-201-02 involved MHI's failure to send ESI the fuel nozzle cleaning procedure prior to the start and load acceptance test and approved the test procedure without including the scheduled maintenance.

Control of Measuring and Test Equipment

The NRC inspection team concluded that the implementation of ESI's control of measuring and test equipment program is consistent with the regulatory requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that ESI is effectively implementing its policies and procedures in support of MHI's US-APWR GTG testing activities. No findings of significance were identified.

Nonconforming Materials, Parts or Components and Corrective Actions

The NRC inspection team identified one violation associated with MHI's failure to implement the requirements of Criterion XVI, "Corrective Action" of Appendix B to 10 CFR Part 50. Violation 05200021/2012-201-04 involved MHI's failure to ensure that ESI engineering complete reviews to determine if a 10 CFR 21 evaluation is required for nonconformances as required by the ESI QCP-301 procedure within the 7-day period.

Quality Assurance Records

The NRC inspection team concluded that the implementation of MHI's and ESI's QA records programs is consistent with the regulatory requirements of Criterion XVII, "Quality Assurance Records;" of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that MHI and ESI are effectively implementing its policies and procedures in support of MHI's US-APWR DC testing activities. No findings of significance were identified.

REPORT DETAILS

1. Training and Qualification of Personnel

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed the implementation of Mitsubishi Heavy Industries' (MHI's) and Engine Systems, Inc's. (ESI's) quality assurance (QA) programs for training and qualification of personnel in support of MHI's prototype testing for the U.S. Advanced Pressurized Water Reactor (US-APWR) gas turbine generator (GTG). Specifically, the NRC inspection team reviewed the policies and implementing procedures governing the implementation of MHI's and ESI's programs for training and qualification of personnel to verify compliance with the regulatory requirements of Criterion II, "Quality Assurance Program," 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". In addition, NRC inspection team also discussed these programs with the management and technical staff of MHI and ESI.

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

- Engine Systems Inc., "Quality Assurance Manual," 5th Edition Revision 0, dated July 13, 2007
- Engine Systems, Inc, QTP-100, "Indoctrination and Training Procedure," Revision 4, dated April 24, 2006

b. Observations and Findings

b.1 Policies and Procedures

Section 18 of ESI's Quality Assurance Manual (QAM) provides guidance for the identification of training requirements for personnel performing activities affecting quality.

ESI's QTP-100 describes the methods used for indoctrination and training of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained. It also explains that all personnel trainings are done in accordance with the Training Matrix.

b.2 Implementation of the Training and Qualification Program

The NRC inspection team reviewed training records for ESI personnel performing safety-related testing activities in support of MHI's GTG qualification testing. The NRC inspection team verified that ESI personnel performing GTG testing activities were trained to the implementing procedures.

QTP-100 requires every employee to have the initial indoctrination conducted by the department manager. This indoctrination includes an overview of the quality program, core procedures, departmental objectives, and training program objectives. Records of completion are tracked in the Training Matrix. On the required completion date, the QA manager, shall notify the department manager of uncompleted training notifications. Notifications are sent to the affected managers each week until the training has been completed.

The NRC inspection team examined the Training Matrix for the personnel performing the safety-related GTG testing. During the review of training records for ESI employees, the NRC inspection team noted that three ESI employees were not trained in the required procedures. Specifically, one ESI employee was not trained to procedures QCP-301, "Control of Nonconforming Conditions and Corrective Actions and 10 CFR 21 Reportable Conditions," Revision 22, dated November 15, 2011. The QA Manager stated the employee would be trained on QCP 301 in the near future. The Training Matrix for the other two ESI quality control (QC) employees involved in safety-related testing activities indicated they were not trained to QCP-600, "Measuring and Test Equipment Calibration and Control," Revision 19, dated July 16, 2010. The NRC inspection team discussed the training of the QC employees with the QA manager. The QA manager informed the NRC inspection team that the two QC employees had been trained; however, the records that documented their training were lost and were not documented on the Training Matrix. The QA manager subsequently provided the NRC inspection team with replacement forms documenting training of the two ESI QC employees. The NRC inspection team identified this issue as Violation 05200021/2012-201-03

c. Conclusions

The NRC inspection team concluded that MHI/ESI did not implement its training program consistent with the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. The NRC inspection team issued Violation 05200021/2012-201-03 for MHI's/ESI's failure to ensure that safety-related GTG testing personnel received required training and maintained training records in accordance with ESI's procedure QTP-100.

2. Control of Purchased, Material, Equipment and Services

a. Inspection Scope

The NRC inspection team reviewed the implementation of MHI's and ESI's QA programs for control of purchased material, equipment, and services in support of MHI's prototype testing for the US-APWR GTG. Specifically, the NRC inspection team reviewed the policies and implementing procedures to verify compliance with the regulatory requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed these programs with management and technical staff of MHI and ESI.

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

- MHI UES-20080022, "Quality Assurance Manual (QAM) Nuclear Safety Related for Non ASME Code Job," Revision 5, dated October 13, 2011
- Purchase Order (PO) MNP-0546 from MHI to ESI: "US-APWR Gas Turbine Generator for Class 1E Testing Requirements," Revision 2, dated November 10, 2009
- Technical Specification Requirement 4GGUAP-20080012 from MHI to ESI: "Gas Turbine Generator Class 1E Qualification Program," Revision 5
- PO 85038A8 from MHI to Kawasaki: "Supporting Testing"

- Technical Specification Requirement 4GG-UAP-20080022, from MHI to Kawasaki: “US-APWR Gas Turbine Generator for Class 1E Testing Requirements Specification,” Revision 2
- Engine Systems Inc., “Quality Assurance Manual,” 5th Edition Revision 0, dated July 13, 2007
- PO 95332 from ESI to Teledyne Brown Engineering, Inc. (TBE) dated May 17, 2011
- Technical Specification Requirement 8001517, from ESI to TBE, “Purchase Specification for Teledyne Brown Engineering, Inc. for Mitsubishi Heavy Industries Emergency Gas Turbine Generator Set IEEE-387 Prototype Build,” Revision 0, dated December 10, 2009

b. Observations and Findings

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

Section 4 of MHI’s QAM establishes the measures and governing procedures to control the procurement of items and services to ensure conformance to specified requirements. It also describes the process for source evaluation, selection, and annual evaluation of vendors.

Section 6 of ESI’s QAM provides guidance for the applicable design basis and other requirements necessary to assure adequate quality is included or referenced in documents for procurement of items and services. Additionally, suppliers are selected and approved based on their ability to meet prescribed criteria and audited or surveyed as required by specifications or contract requirements.

b.2 Implementation of the Procurement Process

The NRC inspection team reviewed PO MNP-0546 from MHI to ESI for the conduct of prototype testing for the US-APWR GTG. Section 5 of the PO required that engineering and testing services be provided in accordance with ESI’s QA program and imposed 10 CFR Part 21. Section 5 also specified that the GTG package be commercial-grade. As outlined in Technical Specification 4GG-UAP-20080012, MHI provided the configuration of what was within the scope of testing. MHI supplied a Kawasaki M1T-33 gas turbine power section including two gas turbine engines, dual single output gearbox, turbine controller and generator controller. MHI also supplied the generator from Kato Engineering. The Technical Specification outlined ESI’s role for the test as supplying the test procedure, conducting the test, documenting the test results and providing the qualification reports.

The MHI Technical Specification 4GG-UAP-20080022 to Kawasaki stated that the GTG was not to be supplied as a basic component or dedicated. Kawasaki supplied the GTG to International Standards Organization (ISO)-9000/2000 requirements. The MHI PO 85038A8 requested that Kawasaki provide a technician to support and verify the adequacy of the testing conducted by ESI. The NRC inspection team ensured that the Kawasaki technician’s training was current.

ESI contracted TBE to provide the detailed GTG package design. The conceptual design was expanded to include details for additional component and piping layout (fuel oil, lube oil, starting air, and post operation purge air) within the enclosure. TBE worked with ESI and the enclosure vendor ACS Engineering to provide detailed fabrication drawings. TBE also was responsible for

the overall seismic qualification of the GTG assembly. This included qualification activities to be performed by TBE on structural and piping systems as well as coordination and independent review of analysis performed by outside vendors contracted by ESI. Wyle Laboratories did the seismic qualification of the GTG while ESI did the generator oil system and lubricating oil cooler fan.

No findings of significance were identified in the NRC inspection team's review of MHI's and ESI's implementation of the procurement process associated with the GTG.

b.3 External Audits

The NRC inspection team reviewed the external audits to verify the implementation of MHI's and ESI's audit programs. The NRC inspection team verified that plans identifying the audit scope, focus, and applicable checklist criteria had been prepared and approved before the initiation of the audit activity. In addition, the NRC inspection team verified that qualified lead auditors and auditors performed the external audits.

The NRC inspection team reviewed the following audit reports related the prototype GTG testing:

- MHI audit of ESI, document number UEQ-UAP-200110005, dated June 9, 2011
- MHI audit of ESI dated May 30, 2008
- ESI audit of Wyle Laboratories in Huntsville, AL dated March 3, 2011
- ESI audit of TBE in Huntsville, AL dated May 11, 2010
- ESI audit of TBE dated May 3, 2011
- ESI., "Quality Assurance Manual," 5th Edition Revision 0, dated July 13, 2007
- PO 95332 from ESI to TBE dated May 17, 2011

The NRC inspection team confirmed that the audit reports contained a review of the relevant QA criteria in Appendix B to 10 CFR Part 50 for the activities performed by the individual suppliers as well as documentation of pertinent supplier guidance associated with each criterion. For audits resulting in findings, the NRC inspection team verified that the supplier had established a plan for corrective action and that MHI or ESI had reviewed and approved the corrective action and verified its satisfactory completion and proper documentation. For ESI, the NRC inspection team verified that all of the corrective actions had been implemented.

No findings of significance were identified in the NRC inspection team's review of MHI's and ESI's implementation of the audit process.

b.4 Auditor Training and Qualification

The NRC inspection team reviewed set the training and qualification records of lead auditors and auditors for MHI and ESI and confirmed that auditing personnel had completed all required

training and maintained qualification and certification in accordance with MHI's and ESI's policies and procedures

No findings of significance were identified in the NRC inspection team's review of MHI's and ESI's implementation for auditor training and qualification.

c. Conclusions

The NRC inspection team concluded that the implementation of MHI's and ESI's programs for the control of purchased material, equipment, and services is consistent with the regulatory requirements of Criterion VII of Appendix B to 10 CFR Part 50. Based on the sample of documents reviewed, the NRC inspection team concluded that MHI and ESI were effectively implementing their policies and procedures in support of MHI's prototype testing for the US-APWR GTG. No findings of significance were identified.

3. Test Control

a. Inspection Scope

The NRC inspection team reviewed the implementation of MHI's and ESI's QA program for test control in support of MHI's prototype testing for the US-APWR GTG. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of test control to verify compliance with the regulatory requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed the test control program with the management and technical staff of MHI, and ESI.

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

- MHI UES-20080022, "Quality Assurance Manual (QAM) Nuclear Safety Related for Non ASME Code Job," Revision 5, dated October 13, 2011
- Engine Systems Inc., "Quality Assurance Manual," 5th Edition Revision 0, dated July 13, 2007
- Engine Systems Inc. 8001517-FTP, "Factory Test Procedure for Emergency Gas Turbine Generator" Revision 2 dated November 24, 2010
- Engine Systems Inc. 8001517-FTR, "Qualification Test Report for Emergency Gas Turbine Generator Mitsubishi Heavy Industries" Revision 2, dated December 06, 2011
- Transmittal Letter from MHI to ESI, "Transmittal of Gas Turbine Generator Class 1E Qualification Program Instruction for Cleaning Work of Fuel Nozzle 7BG-UAP-20100072," dated November 11, 2010
- MHI MUAP-07024-P, "Qualification and Test Plan of Class 1E Gas Turbine Generator System," Revision 2 dated October 10, 2010
- MHI DWG No. 7BG-UAP-20100028, "Gas Turbine Class 1E Qualification Program Operation & Maintenance Manual of Gas Turbine Engine," Revision 0, dated April 1, 2010

- Engine Systems Inc. EP-203, "Design Verification," Revision 2 dated November 1, 2004

b. Observations and Findings

b.1 Policies and Procedures

Section 1 of MHI's QAM establishes the measures and governing procedures to control design changes and nonconforming items dispositioned as use-as-is or repair.

Section 4.6 of ESI's QAM identifies the qualification test control activities for testing safety-related items that are required to demonstrate compliance with regulatory and contract requirements. Section 10 of ESI's QAM identifies the test procedure requirements and control.

EP-203 identifies the guidance for performing design verification of nuclear safety-related projects. The design verification includes check for review and approval responsibilities, test objectives, system configuration, environmental conditions, acceptance criteria, data collection, a method for conducting the test, and a reference section.

Test procedure 8001517-FTP outlines the plan and procedures for testing GTG for the US-APWR. This document also includes the test objectives and scope, acceptance criteria, configuration, equipment, and data measurement.

Test report 8001517-FTR documents the GTG qualification testing activities for the US-APWR. This document includes the description of equipment, test results, analysis and evaluation of results.

MUAP-07024-P is the technical report submitted to the NRC that describes the design criteria, the design features, and testing and qualification requirements for the Class 1E GTG units for the US-APWR.

b.2 Gas Turbine Generator Qualification Testing

The NRC inspection team reviewed and evaluated test procedures, test analysis and test results associated with the US-APWR GTG qualification testing. The equipment qualification was to be executed in accordance with MHI's MUAP-07024-P, IEEE Standard 387-1995 "Standard Criteria for Diesel Generator Units Applied as Standby Power Supply for Nuclear Power Generating Stations," as augmented by the US APWR Design Control Document (DCD) and "Interim Staff Guidance on the Review of Nuclear Power Plant Designs using Gas Turbine Driven Standby Emergency Alternating Current Power System," DC/COL-ISG-021.

The qualification testing requirements of the prototype GTG consisted of start and load acceptance tests, load capability test, and margin tests. The start and load acceptance tests establish the capability of the GTG unit to start and accept load for 150 consecutive times within the required period of time followed by continued operation until temperature equilibrium is obtained. The load capability test demonstrates the capability of the GTG unit to carry the rated loads at rated power factor for the period of time indicated, and to successfully reject the load. The margin test demonstrates the GTG unit capability to start and carry loads that are greater than the magnitude of the most severe step load within the plant design load profile, including step changes above base load.

ESI developed test procedure 8001517-FTP which consisted of a preliminary inspection and testing of the GTG prototype, setup of the interfaces, controls, data acquisition systems, auxiliaries, and equipment qualification. The NRC inspection team verified that the test procedures appropriately incorporated the testing requirements and were approved by MHI.

The acceptance criteria were met in establishing the conditions to achieve qualifying test runs. The test log maintained an adequate sequence of events and procedural verifications in every step. The log also included safety-related testing equipment calibration information and traceability, pictures of the test setup, and testing data to support each qualifying test run.

The body of the test report discussed the results of the test and any nonconformances during the testing and their impact on the test results. The NRC inspection team noted that the test report indicated that three issues occurred during the testing, were captured within the ESI nonconformance report (NCR) process and included in the report. The three issues are discussed below.

During the Start and Load Acceptance Test, it was noted that on start #128 there was a severe failure of one of ESI's 375 KVAR reactive load banks. The failure resulted in a large load transient applied to the GTG for a short period of time which initiated an under speed trip from the program logic controller. As result, the GTG automatically shut down before getting to an equilibrium condition. This incident was evaluated as a failure of the nonsafety-related reload bank for testing; therefore, in accordance with IEEE Standard 387, ESI was able to repeat it while maintaining the requirement of sequential starts. This was tracked in NCR #5598.

The load capability test required the GTG to be running for 22 hours at 100% rated load. During the test, several small load bank failures occurred causing the applied load to be less than 100 percent of the rated load as required by IEEE Standard 387. ESI recorded the amount of time that 100% load was not achieved and added additional time to the test. ESI's engineers proved analytically that the time added at 100 percent load met the requirements of IEEE Standard 387 to achieve the required load over time. In addition, MHI evaluated and approved the results of the NCR. This was tracked in NCR #5549.

The NRC inspection team noted that during the same load capability test, ESI initiated NCR #5628, "Compressor Discharge Hose Failure during Load Capability Test," dated December 20, 2010. The NCR stated that a failure of the hose connected to the engine #1 compressor discharge and pressure gauge had occurred. The root cause for the failure was the high temperatures experienced at the compressor discharge hose connection. This issue did not invalidate the load capability test. After the completion of the test, the hose at the compressor discharge connection was replaced with ¼ inch stainless steel tubing, which allowed the heat to dissipate in the tubing before reaching the hose. The NCR #5628 was closed on the same day it was initiated.

According to the US-APWR DCD Section 3.2 "Classification of Structures, Systems, and Components," the GTG is considered safety-related. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, states, in part, that design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design. The NRC inspection team asked MHI's and ESI's personnel for the design change evaluation and noted that neither of them had performed any design change evaluation. The NRC inspection team identified this issue as Violation 0520021/2012-201-01. Also, the NRC inspection team discussed with MHI and ESI how the design change was going to be tracked and included in the final design documentation.

The NRC inspection team noted that the test report had fuel nozzle cleaning maintenance documented. The maintenance was performed on the engines every 50 starts following the manufacturer's recommendations. However, this maintenance was not captured in the test procedure as a requirement and was not included in the ESI test plan. The NRC inspection team discussed the maintenances with MHI. MHI stated that scheduled maintenance was mentioned in MHI's qualification and test plan MUAP-07024-P and a fuel nozzle cleaning procedure was included in MHI's maintenance manual, DWG No. 7BG-UAP-20100028. Also, MHI provided ESI a version of the maintenance procedure on November 11, 2010, in the middle of the start and load acceptance testing. After the review of the documents mentioned, the NRC inspection team noted that the fuel nozzle procedure included in DWG No. 7BG-UAP-20100028 differed with the version of the procedure sent to ESI for use during the qualification testing.

The IEEE Standard 387 requirements state that tests performed for verification of a scheduled maintenance procedure required during start and load acceptance tests, can be conducted and testing can be resumed without penalty as long as the maintenance procedure is defined prior to conducting the start and load acceptance tests. MHI failed to evaluate the impact of the maintenance activity on the GTG prior to conducting the tests. Additionally, MHI sent a new fuel nozzle cleaning procedure after the start and load acceptance test started, and approved the test procedure 8001517-FTP without including the scheduled maintenance in it.

The NRC inspection team reviewed MUAP-07024-P and noted that in Section 4 "Principal Design Criteria," the scheduled maintenance activities are a requirement for two design conditions of the GTGs. Criterion XI, "Test Control" of Appendix B to 10 CFR Part 50, states in part, that "a test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in-service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in the applicable design documents." The maintenance activity is applicable under all design conditions for which the equipment is expected to function, and not completing the maintenance can contribute to operational transients or component failures, jeopardizing its ability to perform satisfactorily in-service and therefore should have been identified in the written test procedure. The NRC inspection team identified this issue as Violation 05200021/2012-201-02.

c. Conclusions

The NRC inspection team concluded that MHI did not implement its test control programs consistent with the requirements of Criterion XI, "Test Control;" and Criterion III, "Design Control" of Appendix B to 10 CFR Part 50. The NRC inspection team issued Violation 05200021/2012-201-01 for MHI's failure to perform a design change evaluation for GTG testing activities and Violation 05200021/2012-201-02 for MHI's failure to include the scheduled maintenance in the test procedure.

4. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed the implementation of MHI's and ESI's QA program for the control of measuring and test equipment (M&TE) in support of MHI's prototype testing for the US-APWR GTG. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation to verify compliance with the regulatory requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed the test control program with the management and technical staff of MHI and ESI.

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

- Engine Systems Inc., "Quality Assurance Manual," 5th Edition Revision 0, dated July 13, 2007
- QCP-600, "Measuring and Test Equipment Calibration and Control," Revision 19, dated July 15, 2010
- ESI survey of J.A. King & Company, LLC., October 13, 2010

b. Observations and Findings

b.1 Policies and Procedures

Section 11 of ESI's QAM establishes the measures and governing procedures for the control of M&TE as required by regulations. QCP-600 establishes measures to ensure tools, gages, instruments, and other M&TE used are properly calibrated and controlled

b.2 Implementation of Control of Measuring and Test Equipment

The NRC inspection team verified that the M&TE sampled had appropriate calibration records and that the M&TE used in the testing was calibrated using procedures traceable to known industry standards, and that calibration results were recorded, reviewed, and verified by test personnel. Calibration records indicated the calibration procedure to be used, the as found and as left conditions, the accuracy required, the date of calibration and due date for recalibration, and the applicable National Institute of Standards and Technology traceable reference equipment used in the calibration. In addition, the NRC inspection team reviewed the audit report performed by ESI to J.A. King & Company, LLC and verified that the survey covered the services provided.

Conclusions

The NRC inspection team concluded that the implementation of ESI's program for the control of M&TE is consistent with the regulatory requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. Based on the sample of documents reviewed, the NRC inspection team concluded that ESI is effectively implementing its policies and procedures in support of the prototype testing for the US-APWR GTG. No findings of significance were identified.

5. Nonconforming Materials, Parts or Components and Corrective Actions

a. Inspection Scope

The NRC inspection team reviewed the implementation of the MHI's and ESI's QA program for the control of nonconformances and its corrective action program in support of MHI's prototype testing for the US-APWR GTG. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of ESI's program for control of nonconformances and its corrective action program to verify compliance with the regulatory requirements of Criterion XV, "Nonconforming Material, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed the control of nonconformances and corrective action programs with the management and technical staff of MHI, and ESI.

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

- ESI's "Quality Assurance Manual," Revision 0, dated August 12, 2007
- ESI's procedure QCP-301, "Control of Nonconforming Conditions and Corrective Actions and 10 CFR 21 Reportable Conditions," Revision 22, dated November 15, 2011
- Nonconforming Condition Report (NCR) # 5408, "Receipt Inspection Discrepancies in Air Start Manifold," dated August 23, 2010
- NCR #5409, "Generator Assembly Jacking Bolt," dated August 23, 2010
- NCR #5424, "Acoustic Enclosure Assembly," dated September 1, 2010
- NCR #5533, "Automatic Voltage Regulator Defective," dated October 25, 2010
- NCR #5549, "Load Banks Failure During GTG Load Capability Test," dated November 1, 2010
- NCR #5598, "Load Bank Failure during GTG Start and Load Acceptance Test," dated December 1, 2010
- NCR #5628, "Compressor Discharge Hose Failure during Load Capability Test," dated December 20, 2010
- NCR #7121, "Acoustic Enclosure Assembly Drop in to GTG Air Intake," dated May 31, 2012

b. Observations and Findings

b.1 Policies and Procedures

Section 13 of ESI's QAM established the process for products that do not conform to specified requirements. These products are documented, identified, and segregated, where practical, to prevent inadvertent use or installation.

Section 14 of ESI's QAM establishes the process for significant conditions adverse to quality and actions taken to eliminate causes to prevent recurrence. The section ensures corrective actions are appropriate to address the effects of the nonconformities. This section also establishes and maintains a documented procedure that defines the requirements for reviewing nonconformities, cause of nonconformities, evaluating the need for action, and ensuring the nonconformities do not recur.

QCP-301 describes the methods ESI uses to identify, control, document, and resolve for conditions or items that do not conform to specified requirements. The procedure also describes the methods used to ensure significant conditions adverse to quality are promptly identified and corrected. This includes the method of reporting defects and noncompliances to the NRC in accordance with 10 CFR Part 21.

b.2 Implementation of Control of Nonconformances and Corrective Action and Programs

The NRC inspection team reviewed the documentation from the safety-related GTG testing activities, which was completed at the time of this inspection. The NRC inspection team verified that issues had been accurately documented in NCRs and screened in accordance with QCP-301. Also, the NRC inspection team noted that ESI had not issued any condition adverse to quality reports for the MHI GTG testing activities. QCP-301 requires Engineering to review the NCR to determine if a 10 CFR Part 21 evaluation is required. The engineer shall document this determination by entering "yes" or "no" beside the box marked "10 CFR 21 is required?" on the NCR form. This determination shall be completed within 7 working days of the NCR initiation date. The NRC inspection team noted two examples in which ESI failed to do a review to determine if a Part 21 evaluation was required in the 7-day period, as specified by their procedure. The two examples are NCR #5409, which was initiated on August 23, 2010, with the determination review completed on September 20, 2010, and NCR #5424, which was initiated on September 1, 2010, with the determination review completed on September 23, 2010.

Based on the two examples above, the NRC inspection team concluded that ESI failed to meet the requirements of Criterion V, "Instructions, Procedures and Drawings," and Criterion XVI of Appendix B to 10 CFR Part 50. ESI also failed to follow procedures to promptly identify and correct conditions adverse to quality. Specifically, the ESI engineering department did not complete reviews to determine if a 10 CFR Part 21 evaluation is required for NCRs as required by ESI QCP-301 within the 7-day period. The NRC inspection team identified this issue as Violation 05200021/2012-201-04.

c. Conclusions

The NRC inspection team concluded that ESI did not implement its corrective action program consistent with the regulatory requirements of Criterion XVI, "Corrective Action," and Criterion V, "Instructions, Procedures and Drawings," of Appendix B to 10 CFR Part 50. Based on the sample of documents reviewed, the inspection team issued Violation 05200021/2012-201-04 for ESI's failure to complete the determination if a 10 CFR Part 21 evaluation is required for the nonconformances as required by ESI QCP-301 within the 7-day period.

6. Quality Assurance Records

a. Inspection Scope

The NRC inspection team reviewed the implementation of the MHI's and ESI's QA program for the control of QA records in support of MHI's prototype testing for the US-APWR GTG. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of ESI's program for control of QA records to verify compliance with the regulatory requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team also discussed the control of QA records with the management and technical staff of MHI and ESI

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

- ESI, "Quality Assurance Manual," Revision 0, dated August 12, 2007
- ESI Procedure QCP-700, "Quality Assurance Records," Revision 9, dated February 3, 2010

b. Observations and Findings

b.1 Policies and Procedures

Section 16 of ESI's QAM provides guidance for the protection, maintenance, distribution, retention, and disposition of QA records.

Procedure QCP-700 establishes guidance for the classification, receipt, control and status of records, retention, storage, preservation, and safekeeping of all record types generated by ESI.

b.2 Implementation of Quality Assurance Records Process

The NRC inspection team reviewed a sample of records, procedures, and testing data used for identification, receipt control, processing, retention, and safekeeping for all documented records generated in support of MHI's GTG testing. During this review, the NRC inspection team verified that ESI had implemented a QA records program that provided adequate measures for the identification, classification, validation, and distribution controls of records. In addition, the NRC inspection team interviewed responsible ESI staff as part of its evaluation of the ESI QA records program. The NRC inspection team noted that ESI's policies and implementing procedures provided the necessary guidance for the administration, identification, receipt, storage, preservation, safekeeping, and disposition of all records.

c. Conclusions

The NRC inspection team concluded that the implementation of ESI's QA records program is consistent with the regulatory requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. Based on the sample of documents reviewed, the NRC inspection team determined that ESI is effectively implementing its policies and procedures in support of MHI's US-APWR GTG testing. No findings of significance were identified.

Entrance and Exit Meetings

On June 5, 2012, the NRC inspection team presented the inspection scope during an entrance meeting with MHI, the Mitsubishi Nuclear Energy System (NMES), and ESI personnel. On June 8, 2012, the NRC inspection team presented the inspection results during an exit meeting with MHI, MNES, and ESI personnel.

ATTACHMENT 1

1. PERSONS CONTACTED

NAME	COMPANY	ENTRANCE MEETING	EXIT MEETING	INTERVIEWED
Takashi Fukuda	MHI	X	X	X
Katsuhisa Takaura	MHI	X	X	X
Kazunori Inoue	MHI	X	X	X
Shinji Niida	MHI	X	X	X
Vann Mitchell	MNES	X	X	X
Hideki Tanaka	MNES	X	X	X
Shinji Kawanago	MNES	X	X	X
John Manno	KES	X		
Tom Horner	ESI	X	X	X
Dan Roberts	ESI	X	X	X
Paul Johnson	ESI	X	X	X
Brad Abernathy	ESI	X	X	X
Robin L Weeks	ESI	X		
Paul Prescott	NRC	X	X	
Aaron Armstrong	NRC	X	X	
Paul Coco	NRC	X	X	
Aixa Belen-Ojeda	NRC	X	X	

2. INSPECTION PROCEDURES USED

Inspection Procedure (35034, "Design Certification Testing Inspection," dated January 27, 2010

Inspection Procedure 35017, "Quality Assurance Implementation Inspection," dated July 29, 2008.

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
05200021/2012-201-01	Opened	NOV	Criterion III
05200021/2012-201-02	Opened	NOV	Criteria XI
05200021/2012-201-03	Opened	NOV	Criteria II
05200021/2012-201-04	Opened	NOV	Criteria XVI