January 24, 2008

Mr. Keith Paulson
Senior Technical Manager
Mitsubishi Nuclear Energy Systems, Inc.
4350 Northern Pike, Suite 301
Monroeville, PA 15146

SUBJECT: SAFETY EVALUATION REPORT FOR MITSUBISHI HEAVY INDUSTRIES US-APWR TOPICAL REPORT NUMBER PQD-HD-19005, REVISION 1, "QUALITY ASSURANCE PROGRAM (QAP) DESCRIPTION FOR DESIGN CERTIFICATION OF THE US-APWR"

Dear Mr. Paulson:

By letter dated January 26, 2007, as supplemented by letters dated March 7, and August 30, 2007, Mitsubishi Heavy Industries, LTD. (MHI), submitted Topical Report PQD-HD-19005, Revision 0, "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR," to the U.S. Nuclear Regulatory Commission (NRC) staff. On October 15, 2007, MHI responded to the NRC staff's request for additional information and provided Revision 1 of Topical Report PDQ-HD-19005 to the NRC staff. The MHI QAP topical report covers the activities associated with the Design Certification (DC) of the US-APWR.

The NRC staff has reviewed this topical report and has found that Topical Report PDQ-HD-19005, Revision 1 is acceptable for use by MHI for the US-APWR DC activities to the extent specified and under the limitations delineated in the topical report and in the enclosed safety evaluation. The safety evaluation defines the basis for acceptance of the topical report. Our acceptance applies only to material provided in the subject topical report. We do not intend to repeat our review of the acceptable material described in the topical report for the review of the DC.

In accordance with the guidance provided on the NRC website, http:/www.nrc.gov/about-nrc/regulatory/licensing/topical-reports.html, we request that MHI publish an accepted version of this topical report within 90 days. The accepted version of this topical report shall incorporate this letter and the enclosed safety evaluation after the title page. Also, the accepted version must include the NRC staff's request for additional information and your responses to these questions. The accepted version shall include a "-A" (designating accepted) following the topical report identification symbol PQD-HD-19005.

If future changes to the NRC's regulatory requirements affect the acceptability of this topical report, MHI will be expected to revise the topical report appropriately, or justify its continued use.

Sincerely,
/RA/

Larry J. Burkhart, Acting Chief
US-APWR Projects Branch
Division of New Reactor Licensing
Office of New Reactors

Project No. 0751

cc: See next page

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SAFETY EVALUATION REPORT BY THE OFFICE OF NEW REACTORS

REGARDING MITSUBISHI HEAVY INDUSTRIES (MHI) TOPICAL REPORT

MHI PQD-HD-19005, REVISION 1, "QUALITY ASSURANCE PLAN (QAP)

DESCRIPTION FOR DESIGN CERTIFICATION OF THE US-APWR"

1.0 INTRODUCTION

By letter dated January 26, 2007 (Reference 1), as supplemented by letters dated March 7, (Reference 2) and August 30, 2007 (Reference 5), Mitsubishi Heavy Industries, LTD. (MHI), submitted Topical Report PQD-HD-19005, Revision 0, "Quality Assurance Program (QAP) Description for Design Certification of the US-APWR," in accordance with the guidance of Draft NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," (SRP) Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," (Reference 3). Additionally, on October 15, 2007 (Reference 6), MHI provided Revision 1 of Topical Report PDQ-HD-19005 to the NRC staff. The MHI QAP topical report covers the activities associated with the Design Certification (DC) of the US-APWR. The QAP is based on the applicable portions of both Appendix B to *Title 10 of the Code of Federal Regulations* (10 CFR) Part 50 and American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Applications," (Reference 4) that are relevant to the US-APWR DC project.

2.0 REGULATORY EVALUATION

The Commission's regulatory requirements related to quality assurance (QA) programs are set forth in 10 CFR 52.47(a)(19) and Appendix B to 10 CFR Part 50 (Appendix B).

10 CFR 52.47(a)(19) requires, in part, that a DC application contain the technically relevant information in a final safety analysis report that describes the facility, presents the design bases and the limits on its operation, and present a safety analysis of the structures, systems, and components (SSCs) and of the facility as a whole, and must include a description of the QAP to be applied to the design of the SSCs of the facility. 10 CFR 52.47(a)(19) further requires that the description of the QAP for a nuclear power plant include a discussion of how the applicable requirements of Appendix B will be satisfied.

10 CFR Part 50, Appendix B establishes QA requirements for the design, fabrication, construction, and testing of SSCs of the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

3.0 EVALUATION

In evaluating the adequacy of the format and level of detail of the QAP, the NRC staff followed Draft SRP Section 17.5 for guidance. Draft SRP Section 17.5 provides an outline of a QAP for DC, early site permit, combined license, construction permit, and operating license applicants. Draft SRP Section 17.5 was developed using ASME NQA Standard NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance for nuclear operating facilities. The Draft SRP Section 17.5 became final, with no significant changes, in March 2007, which was then used by the NRC staff to complete the review of the MHI QAP.

3.1 QAP Overview

In PQD-HD-19005, Revision 1, MHI specified the quality control requirements for MHI Nuclear Energy Systems Headquarters (MHI-NESH) activities affecting the US-APWR DC.

3.1.1 Organization

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.A, for providing an organizational description that includes an organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAP implementation. The MHI QAP establishes independence between the organization performing checking functions and the organization responsible for performing the function. In addition, the MHI QAP provides for management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. Responsibility and authority for planning, establishing, and implementing an effective overall QAP are clearly described and defined. MHI may delegate all or part of these activities for which they are responsible to others but retains responsibility for the QAP.

In the QAP, MHI commits to implement the quality standards described in NQA-1-1994, Basic Requirement 1 and Supplement 1S-1, for establishing supplemental requirements for organization, without further clarifications or exceptions.

3.1.2 QA Program

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.B, for establishing the necessary measures to implement a QA program to ensure that the design of the nuclear power plant is in accordance with governing regulations and license requirements. The QA program is comprised of those planned and systematic actions necessary for establishing the safety classification of SSCs, and for determining the quality group classification, applicable quality standards, and the seismic design classification of SSCs commensurate with their respective safety classification. A list or a system identifying SSCs and activities, to which the QAP applies, is maintained at the appropriate facility.

The MHI QAP provides measures to assess the adequacy of the QAP and to ensure its effective implementation, at least once each year or at least once during the life of the activity, whichever is shorter. In addition, consistent with SRP Section 17.5, paragraph II.B.8, the QAP applies a grace period of 90 days to activities that must be performed on a periodic basis. The grace period does not allow the “clock” for a particular activity to be reset forward. However, the “clock” for an activity is reset backwards by performing the activity early.

The MHI QAP follows the guidance of SRP Section 17.5, paragraphs II.S and II.T, for describing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAP to assure that suitable proficiency is achieved and maintained. The MHI QAP provides the minimum training requirements for all personnel responsible for the implementation of the QAP.

In the QAP, MHI commits to implement the quality standards described in NQA-1-1994, Basic Requirement 2 and Supplements: 2S-1, for establishing supplemental requirements for qualification of inspection and test personnel; 2S-3, for establishing supplemental requirements for qualification of QAP audit personnel; and 2S-4, for establishing supplemental requirements for qualification for personnel indoctrination and training, with the following alternatives or exceptions to 2S-3.

- As an alternative to the requirement of NQA-1-1994, Supplement 2S-3, that prospective lead auditors must have participated in a minimum of five audits in the previous 3 years, MHI QAP states that the prospective Lead Auditor shall demonstrate his/her ability to properly implement the audit process, as implemented by the company, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification. The NRC staff finds this alternative is consistent with SRP Section 17.5, paragraph II.S.4.c and, therefore, is acceptable.

3.1.3 Design Control

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.C, for establishing the necessary measures to control the design, design verification, and analysis activities of safety-related items and services that are subject to the provisions of the QAP. The MHI QAP design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces with the applicant and its suppliers. These provisions ensure that the design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions). In addition, the MHI QAP provides for design documents to be reviewed by individuals knowledgeable in QA to ensure that the documents contain the necessary QA requirements.

In the QAP, MHI commits to implement the quality standards described in NQA-1-1994, Basic Requirement 3 and Supplements: 3S-1, for establishing the program for design control and verification; 11S-2, for establishing supplemental requirements for computer program testing; and Subpart 2.7 for the standards for computer software QA controls, without further clarifications or exceptions.

3.1.4 Procurement Document Control

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.D, for establishing the necessary administrative controls and processes to ensure that applicable regulatory, technical, and QA program requirements are included or referenced in procurement documents. Applicable technical, regulatory, administrative, quality and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21) are invoked for procurement of items and services.

In the QAP, MHI commits to implement the quality standards described in NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, for establishing supplemental requirements for procurement document control, with the following alternatives and exceptions:

- As an alternative to NQA-1-1994, Supplement 4S-1, Section 2.3, which states that procurement documents must require suppliers to have a documented QA program that implements NQA-1-1994, Part I, the QAP requires that suppliers have a documented QA program that is determined to meet Appendix B and the MHI QAP, as applicable to the circumstances of the procurement. Appendix B, Criterion IV, "Procurement Document Control," requires suppliers to have a QA program consistent with Appendix B. The NRC staff finds this alternative is consistent with SRP Section 17.5, paragraph II.D.2.d. and therefore, acceptable.

- The QAP provides for procurement documents to allow the supplier to work under the MHI QAP, including implementing procedures, in lieu of the supplier having its own QA program. Criterion IV of Appendix B requires suppliers to have a QA program consistent with Appendix B. The NRC staff finds this alternative is consistent with SRP Section 17.5, paragraph II.D.2.d. and therefore, acceptable.

- As an alternative to NQA-1-1994, Supplement 4S-1, Section 3, which requires procurement documents to be reviewed before award of the contract, the QAP proposes to conduct the QA review of procurement documents through review of the applicable procurement specification, including the technical and quality procurement requirements, before contract award. In addition, procurement document changes (e.g., scope, technical, or quality requirements) will also receive QA review. The NRC staff evaluated this proposed alternative and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change. Therefore, the NRC staff concluded that this alternative is acceptable.

- Procurement documents for commercial-grade items that the applicant will procure as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated. This alternative is acceptable since it is consistent with NRC staff guidance contained in Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products,” dated March 21, 1989, and Generic Letter 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs,” dated April 9, 1991, as delineated in SRP Section 17.5, paragraphs II.U.1.c and II.U.1.d.

3.1.5 Instructions, Procedures, and Drawings

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.E, for establishing the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed, in accordance with documented instructions, procedures, and drawings.

In the QAP, MHI commits to implement the quality standards described in NQA-1-1994, Basic Requirement 5 for establishing procedural controls without further clarifications or exceptions.

3.1.6 Document Control

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.F, for establishing the necessary measures and governing procedures to control the preparation, review, approval, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled. Measures are provided to assure that documents, including revisions or changes, are reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated. A list of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

In establishing provisions for document control, MHI, in the QAP, commits to implement the quality standards described in NQA-1-1994, Basic Requirement 6 and Supplement 6S-1, for establishing supplemental requirements for document control, without further clarifications or exceptions.

3.1.7 Control of Purchased Material, Equipment, and Services

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.G, for establishing the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The program provides measures for evaluating prospective suppliers and selecting only qualified suppliers. In addition, the program provides for auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services.

The program provides for acceptance actions, such as source verification, receipt inspection, post-installation tests, and review of documentation, such as certificates of conformance, to ensure that the procurement, inspection and test requirements have been satisfied before relying on the item to perform its intended safety function. Dedication of commercial-grade items and/or services for safety-related applications may be procured from suppliers given that an evaluation of the suitability of the item or service for nuclear applications is performed by the MHI technical and QA organizations. The critical characteristics of the item or service are determined and documented as part of this evaluation and special methods shall be established to provide assurance that the item or service specified is the item or service received. If needed, these special quality verification methods may include inspections, tests, commercial grade surveys, or evaluations of the supplier.

In establishing procurement verification control, MHI, in the QAP, commits to implement the quality standards described in NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, for establishing supplemental requirements for control of purchased items and services, with the following clarifications and exceptions:

- The MHI QAP proposes that other 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the National Institute of Standards and Technology (NIST), and other State and Federal agencies that may provide items or services to MHI Nuclear Energy Systems Headquarters (MHI-NESH) not be required to be evaluated or audited.

  The NRC staff acknowledges that 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the NIST, and other State and Federal agencies perform work under acceptable quality programs, and no additional audit or evaluation is required. The NRC staff

determined that this exception is acceptable as documented in a letter to Edwin Hatch Nuclear Power Station on March 20, 2000 (Reference 7). MHI-NESH is still responsible for ensuring that the items or services procured conform to the applicable Appendix B program, ASME Boiler and Pressure Vessel Code requirements, and other regulatory requirements and commitments. MHI-NESH is also responsible for ensuring that procured items or services are suitable for the intended application and for documenting an evaluation. To this extent on this basis, the NRC staff finds this proposed exception acceptable.

- As an alternative to NQA-1-1994, Supplement 7S-1, Section 8.1, in terms of the requirement for documents to be available at the site, the MHI QAP proposes that documents may be stored in approved electronic media under the applicant's or supplier's control and not physically located at the plant site, as long as they are accessible from the respective nuclear facility. Following completion of the construction period, sufficient as-built documentation will be turned over to the MHI-NESH to support operations. The NRC staff determined that this alternative meets Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services." Criterion VII requires documentary evidence that items conform to procurement documents to be available at the nuclear facility before installation or use. Therefore, this provision, which would allow for accessing and reviewing the necessary procurement documents at the site before installation and use, would meet this requirement.

3.1.8 Identification and Control of Materials, Parts, and Components

This element is not applicable to the MHI US-APWR DC application and has not been reviewed or approved by the NRC staff.

3.1.9 Control of Special Processes

This element is not applicable to the MHI US-APWR DC application and has not been reviewed or approved by the NRC staff.

3.1.10 Inspection

MHI-NESH does not perform inspection activities as part of the US-APWR DC application. However, the MHI QAP describes the MHI requirements for suppliers who perform inspection activities associated with the US-APWR DC application. In establishing inspection requirements, MHI, in the QAP, commits to require suppliers to implement the quality standards described in NQA-1-1994, Basic Requirement 10 and Supplement 10S-1, without further clarifications or exceptions.

3.1.11 Test Control

MHI-NESH does not perform test activities as part of the US-APWR DC application, except for computer program testing. However, the MHI QAP describes the MHI requirements for suppliers who perform testing activities associated with the US-APWR DC application. In establishing provisions to ensure that computer software used in applications affecting safety are prepared, documented, verified and tested, and used such that the expected outputs are obtained and configuration control maintained, MHI, in the QAP, commits to implement the quality standards described in NQA-1-1994, Supplement 11S-2, for establishing supplemental requirements for computer program testing, and Subpart 2.7, without further clarifications or exceptions.

3.1.12 Control of Measuring and Test Equipment

MHI-NESH does not control measuring and test equipment as part of the US-APWR DC application. However, the MHI QAP describes the MHI requirements for suppliers who control measurement and test equipment associated with the US-APWR DC application.

In establishing provisions for control of measuring and testing equipment, MHI, in the QAP, commits to require its suppliers to implement the quality standards described in NQA-1-1994, Basic Requirement 12 and Supplement 12S-1, for establishing supplemental requirements for control of measuring and test equipment, with the following clarifications and exceptions:

- The MHI QAP clarifies that the out-of-calibration conditions, described in paragraph 3.2 of Supplement 12S-1 of NQA-1-1994, refer to cases where the measuring and test equipment are found to be out of the required accuracy limits (i.e., out of tolerance) during calibration. The NRC staff determined that the clarification for the out-of-calibration conditions is consistent with the objective outlines in supplement 12S-1 and, therefore, is acceptable.

- As an alternative to the NQA-1-1994, Subpart 2.4, Section 7.2.1, calibration labeling requirements, the MHI QAP proposes that the required calibration information be maintained in suitable documentation traceable to the device for measuring and testing equipment which is impossible or impractical to mark because of equipment size or configuration. This alternative is consistent with the NRC staff guidance provided in SRP 17.5, paragraph II.L.3, and, therefore, is acceptable.

3.1.13 Handling, Storage, and Shipping

This element is not applicable to the MHI US-APWR DC application and has not been reviewed or approved by the NRC staff.

3.1.14 Inspection, Test, and Operating Status

This element is not applicable to the MHI US-APWR DC application and has not been reviewed or approved by the NRC staff.

3.1.15 Nonconforming Materials, Parts, or Components

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.O, for establishing the necessary measures to control items, including services, that do not conform to specified requirements, to prevent inadvertent use. Nonconformances are evaluated for impact on the services or resultant documentation, to ensure that the final condition does not render the service, activity, or documentation unacceptable or indeterminate. Results of evaluations of conditions adverse to quality are analyzed to identify quality trends, documented, and reported to upper management in accordance with applicable procedures.

In addition, the MHI QAP provides for establishing the necessary measures to implement a reporting program in accordance with the requirements of 10 CFR, Part 21 “Reporting of Defects and Noncompliance.”

In establishing measures for nonconforming material, MHI, in the QAP, commits to implement the quality standards described in NQA-1-1994, Basic Requirement 15 and Supplement 15S-1,

for establishing supplemental requirements for the control of nonconforming items, without further clarifications or exceptions.

3.1.16 Corrective Action

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.P, for establishing the necessary measures to promptly identify, control, document, classify, and correct conditions adverse to quality. The MHI QAP requires personnel to identify known conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality are documented and reported to responsible management. In case of suppliers working on safety-related activities, or similar situations, MHI-NESH may delegate specific responsibility for the corrective action program, but MHI-NESH maintains responsibility for the program's effectiveness.

In addition, the MHI QAP provides for establishing the necessary measures to implement a reporting program in accordance with the requirements of 10 CFR Part 21.

In establishing a corrective action program, MHI, in the QAP, commits to implement the quality standards described in NQA-1-1994, Basic Requirement 16, without further clarifications or exceptions.

3.1.17 QA Records

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.Q, for establishing the necessary measures to ensure that sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and retrievable.

When using electronic records storage and retrieval systems, the MHI QAP provides for compliance with NRC guidance provided in NRC Generic Letter 88-18, “Plant Record Storage on Optical Disks,” Regulatory Issue Summary (RIS) 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media,” and associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guidelines (TG) 11-1998, TG 15-1998, TG 16-1998, and TG 21-1998.

In establishing provisions for records, MHI, in the QAP, commits to implement the quality standards described in NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, for establishing supplemental requirements for QA records, with the following clarification or exception:

- As an alternative to the NQA-1-1994, Supplement 17S-1, Section 4.2(b), requirements for records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers, the MHI QAP proposes that hard records be stored in steel cabinets or on shelving in containers, except that methods other than binders, folders, or envelopes may be used to organize records for storage. By letter dated September 1, 2005 (Reference 8), the NRC staff determined that this proposed alternative was acceptable for Nuclear Management Company, LLC. As such, the NRC staff finds this proposed alternative acceptable.

3.1.18 QA Audits

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.R, for establishing the necessary measures to implement audits to verify that activities covered by the QAP are performed in conformance with the requirements established. The audit program is also reviewed for effectiveness as part of the overall audit process. The MHI QAP provides for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of program and procedures, and to determine if they are meaningful and comply with the overall QAP. Internal audits are performed with a frequency to assure that an audit of all applicable QA program elements is completed within a period of once per calendar year or at least once during the life of the activity, whichever is shorter. External audits determine the adequacy of a supplier's and contractor's QAP. Audit results are documented and reviewed by the responsible management. Management responds to all audit findings and initiates corrective action where indicated. In addition, where corrective action measures are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means, is conducted to verify implementation of assigned corrective action.

In establishing the audit program, MHI, in the QAP, commits to implement the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1, for establishing supplemental requirements for audits, without further clarifications or exceptions.

3.2 Nonsafety-Related SSC QA Control

3.2.1 Nonsafety-Related SSCs - Significant Contributors to Plant Safety

The MHI QAP follows the guidance of SRP Section 17.5, paragraph II.V.1, for establishing specific program controls applied to nonsafety-related SSCs that are significant contributors to plant safety, for which Appendix B is not applicable. The MHI QAP applies specific controls to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSCs a significant contributor to plant safety consistent with applicable sections of the QAP.

3.2.2 Nonsafety-Related SSCs Credited for Regulatory Events

In establishing the quality requirements for nonsafety-related SSCs credited for regulatory events, the MHI QAP follows the guidance of SRP Section 17.5, paragraph II.V.2, and MHI commits to implement the following regulatory guidance:

- The quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants," dated April 2001.

- The quality requirements for anticipated transient without scram (ATWS) equipment in accordance with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," dated January 16, 1985.

- The quality requirements for station blackout (SBO) equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in Regulatory Guide 1.155," Station Blackout," dated August 1988.

3.3 Regulatory Commitments

The MHI QAP follows the guidance of SRP Section 17.5, Paragraph II.U, for establishing QA program commitments. Furthermore, in Part IV of the QAP, MHI commits to comply with the following NRC Regulatory Guides and other QA standards to supplement and support the QAP.

- Regulatory Guide 1.26, Revision 4, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," dated March 2007.

- Regulatory Guide 1.29, Revision 4, "Seismic Design Classification," dated March 2007.

- ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Part I and II, as described above in Sections 3.1.1 through 3.1.18 of this Safety Evaluation Report (SER).

- ANSI/ASME NQA-1-1994 Edition, Subpart 2.7, “Quality Assurance Requirements of Computer Software for Nuclear Facility Application.”

- Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides, as described in Section 3.1.17 of this SER.

4.0 CONCLUSION

The MHI QAP follows the NRC guidance and conforms to the format of SRP Section 17.5. The NRC staff used the acceptance criteria of SRP Section 17.5 as the basis for evaluating the acceptability of the MHI QAP in conformance with the provisions of 10 CFR 52.47(a)(19) and Appendix B to 10 CFR Part 50. On the basis of the NRC staff’s review of the MHI QAP, the NRC staff concludes that:

- The MHI QAP adequately describes the authority and responsibility of management and supervisory personnel, performance/verification personnel, and self-assessment personnel.

- The MHI QAP adequately provides for organizations and persons to perform verification and self-assessment functions with the authority and independence to conduct their activities without undue influence from those directly responsible for costs and schedules.

- The MHI QAP adequately applies to activities and items that are important to safety.

- The MHI QAP adequately establishes controls that, when properly implemented, comply with the requirements of 10 CFR Part 52, Appendix B to 10 CFR Part 50, and 10 CFR Part 21, consistent with the criteria contained in SRP Section 17.5, and in the relevant regulatory guidance.

On the basis of its review, the NRC staff concludes that the MHI QAP adequately describes the MHI QA program. Accordingly, the NRC staff concludes that the MHI QAP complies with the applicable NRC regulations and industry standards and can be used by MHI for DC activities associated with the US-APWR.

5.0 REFERENCES

1. Kaneda, M., MHI, LTD., to D.B. Matthews, USNRC, “Quality Assurance Program (QAP) Description for Design Certification of the Mitsubishi Heavy Industries, LTD. US-APWR,” January 26, 2007 (ADAMS Accession No. ML070330446).

2. Kaneda, M., MHI, LTD., to D.B. Matthews, USNRC, “A Summary Table Comparing U.S. and Japanese Quality Assurance Requirements for Nuclear Facilities,” March 7, 2007 (ADAMS Accession No. ML070670452).

3. NUREG-0800, " Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, “Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," March 2007

4. American Society for Mechanical Engineers (ASME). NQA-1-1994 Edition, “Quality Assurance Requirements for Nuclear Facility Applications.” New York. 1994.

5. Kaneda, M., MHI, LTD., to D.B. Matthews, USNRC, Response to NRC’s Questions for Topical Report PQD-HD-19005 (R0) “Quality Assurance Program (QAP) Description For Design Certification of the US-APWR,” August 30, 2007 (ADAMS Accession No. ML072490419).

6. Kaneda, M., MHI, LTD., to D.B. Matthews, USNRC, Revised version of the Topical Report entitled "Quality Assurance Program (QAP) Description For Design Certification of the US-APWR," October 15, 2007 (ADAMS Accession No. ML072970115).

7. Letter from NRC to Southern Nuclear Operating Company; Edwin I. Hatch Nuclear Power Station, Units 1 and 2 RE: Approval of Relief Request RR-27, Third 10-year Interval Inservice Inspection Program (TAC NOS. MA6163 and MA6164), March 20, 2000 (ADAMS Accession No. ML003693241).

8. Letter from NRC to Nuclear Management Company, LLC; Approval of Change to the Nuclear Management Company Quality Assurance Topical report (TAC NOS. MC7585, MC7587, MC7588, MC7589, MC7590, MC7591, MC7592), September 1, 2005 (ADAMS Accession No. ML052430024).

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