Quality Assurance Program (QAP) Description For Design Certification of the US-APWR

PQD-HD-19005-A

Topical Report

Process/Program Owner:
General Manager
of Nuclear Energy Systems Quality & Safety Management Department

Version Number **Revision 0** Effective Date 2/25/'08

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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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August 30, 2007

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Washington, DC 20555-0001

Attention: Mr. David B. Matthews

Project No.0751
MHI Ref: UAP-HF-07110

Subject: Response to NRC's Questions for Topical Report PQD-HD-19005(R0) "Quality Assurance Program (QAP) Description For Design Certification of the US-APWR".

With this letter, Mitsubishi Heavy Industries, LTD. (MHI) transmits to the U.S. Nuclear Regulatory Commission (NRC) the documents entitled "Response to NRC's Questions for Topical Report PQD-HD-19005(R0) "Quality Assurance Program (QAP) Description For Design Certification of the US-APWR" in response to the NRC's questions for the topical report. In the enclosed documents, MHI provides our responses following to NRC's comments and questions. If necessary, MHI may revise our topical report.

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

Sincerely,

M. Kaneda

Masahiko Kaneda,
General Manager- APWR Promoting Department
Mitsubishi Heavy Industries, LTD.

Enclosures:
Enclosure1 - Response to NRC's Questions for Topical Report PQD-HD-19005(R0) "Quality Assurance Program (QAP) Description For Design Certification of the US-APWR"

CC: S. M. Coffin
S. R. Monarque
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Enclosure 1

UAP-HF-07110, Rev.0

US-APWR

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 2007

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 2007

Introduction

Quality Assurance Program (QAP) Description For Design Certification of the US-APWR (PQD-HD-19005 R0) is the top-level MHI policy document which presents MHI's overall philosophy regarding achievement and assurance of quality and assigns major functional responsibility and authorities. The QAP, which was submitted to the NRC on January 26, 2007 includes administrative controls that meet 10 CFR 50, Appendix B and 10 CFR 52, and is based on the requirements of American Society of Mechanical Engineers (ASME) standards NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications". Since the submission of the reports, MHI has been asked questions by the NRC staffs. This report summarizes our response to those questions regarding the Quality Assurance Program (QAP) Description.

QUESTION-1

Draft Standard Review Plan (SRP) 17.5, dated September 22, 2006, paragraph II.A.1 states that at the most senior management level, the applicant or holder is to issue a written quality assurance program (QAP) description that establishes the quality policy and commits the organization to implement it. Revision 0 of the MHI-NESH QAP topical report is signed by the Executive Vice President of MHI-NESH. The Executive Vice President of MHI-NESH is not at the most senior management level according to the MHI-NESH QAP topical report. The MHI-NESH QAP topical report must be signed by the President of MHI or his/her designee.

Response

The title of Dr. Uratani, Executive Vice President of MHI-NESH should be corrected to as described below:

General Manager, Nuclear Energy Systems Headquarters Executive Vice President & Representative Director of Mitsubishi Heavy Industries, Ltd.

It is noted that he is at the most senior management level for MHI-NESH. Therefore, we will keep him as Approver of the QAP description.

QUESTION-2

10 CFR 52.47 (a)(19) requires that the applicant of a standard design certification (DC) include a quality assurance program description (QAPD) to be applied to the design of structures, systems, and components of the facility that satisfies the applicable portions of Appendix B to 10 CFR Part 50. Part I, Section 1.1 of the MHI-NESH QAP topical report provides information on activities to which the QAP applies.

a. For consistency with the above regulations, the staff needs clarification of the overall scope (e.g., DC) that applies or to which the QAP could apply, in addition to the list of activities already mentioned.

b. The QAP states that "the QAP may be applied to certain activities where regulations other than 10 CFR [Part] 50 establish QAP requirements for activities within their scope." Since application of this QAP will mainly be under the requirements of 10 CFR Part 52, and by reference to 10 CFR Part 50, the staff determined that it would be appropriate that the QAP include 10 CFR Part 52 in the statement. The staff recommends "the QAP may be applied to certain activities where regulations other than 10 CFR *Part* 50 *and 10 CFR Part 52* establish QAP requirements for activities within their scope."

Response

a. MHI will add the words “Design Certification” in the first sentence of MHI - NESH QAP Part I, Section 1.1 as indicated below.

1.1 Scope / Applicability

This QAP applies to Design Certification activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

b. MHI will add the regulation name "10 CFR Part52" in the first paragraph of MHI - NESH QAP Part I, Section 1 and in the second paragraph of MHI - NESH QAP Part I, Section 1.1 as indicated below.

< The first paragraph of MHI - NESH QAP Part I, Section 1 >
The MHI-NESH US-APWR Project Quality Assurance Program (QAP) is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for plants designed by MHI-NESH. The QAP describes the methods and establishes QAP and administrative control requirements that meet 10 CFR Part 50, Appendix B and 10 CFR Part 52. The QAP is based on the requirements of ASME NQA–1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as specified in this document.

< The second paragraph of MHI - NESH QAP Part I, Section 1.1 >
Safety-related systems, structures, and components, under the control of the QAP, are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAP may be applied to certain activities where regulations other than 10 CFR Part 50 and 10 CFR Part 52 establish QAP requirements for activities within their scope.

QUESTION-3

Draft SRP 17.5, paragraph II.A.1, states that at the most senior management level, the applicant or holder is to issue a written QAPD that establishes the quality policy and commits the organization to implement it. The MHI-NESH QAP states that the Executive Vice President reports to the President of MHI with respect to all matters. As such, the President, MHI, should designate the Executive Vice President, MHI-NESH, as the senior position that is responsible for overall implementation of the quality assurance program. The MHI-NESH QAP should have a statement documenting the designation.

Response

The response is the same as the one of Item1.

QUESTION-4

Draft SRP Section 17.5, paragraph II.A.4, states that there should be independence between the organization performing checking functions from the organization responsible for performing the functions. In order to satisfy the Three Mile Island (TMI)-related requirement contained in 10 CFR 50.34(f)(3)(iii)(A), clarify how MHI-NESH will implement measures to control the independence of organizations consistent with Section 17.5, paragraph II.A.4, of the SRP.

Response

MHI will add the Section about QA organizational independency to MHI - NESH QAP Part II, Section 1 as described below.

1.6 Quality Assurance Organizational Independence

For the design certification, independence shall be maintained between the organization or organizations performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

QUESTION-5

Draft SRP Section 17.5, paragraph II.A.7, states that management ensures that the size of the QA organization is commensurate with its duties and responsibilities. In order to satisfy the TMI-related requirement contained in 10 CFR 50.34(f)(3)(iii)(F), clarify how MHI-NESH will implement measures to ensure that the size of the QA organization is commensurate with its duties and responsibilities.

Response

MHI will add one paragraph about the size of QA organization just after the first paragraph of MHI - NESH QAP Part II, Section 1 as described below.

SECTION 1 ORGANIZATION

This Section describes the MHI-NESH organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAP implementation.
The organizational structure includes corporate and design functions for the development of the US-APWR. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of this QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

The General Manager of Nuclear Energy Systems Headquarters is responsible to size the Quality Assurance organization commensurate with the duties and responsibilities assigned.

QUESTION-6

Draft SRP Section 17.5, paragraph II.B.1, states that management implementing portions of the QAPD should assess the part of the program for which they are responsible and assure is effective implementation at least once each year or at least once during the life of the activity, which ever is shorter, or may extend it to once every two years. Section 2 of the MHI-NESH QAP states that senior management is regularly apprised of audit results evaluating the adequacy of implementation of the QAP through the audit functions described in the Section 18, Audits, of the QAP. Section 2.3 of the MHI-NESH QAP states that reviews of the status and adequacy of the US-APWR Project QA program and its implementation will be conducted on an ongoing basis via senior management review of quality assurance audit reports. In addition, Section 18.1 of the MHI-NESH QAP provides measures to assess the effective implementation of the program at least once a year or at least once during the life of the activity, which ever is shorter. Clarify how the MHI-NESH QAP will provide for these requirements consistently throughout the MHI-NESH QAP and consistent with Section 17.5 of the draft SRP.

Response

MHI will revise MHI - NESH QAP Part II, Section 2.3 as described below.

2.3 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the QA program or portions thereof, assess the adequacy of that part of the program for which they are responsible and assure its effective implementation at least once each year or at least once during the life of the activity, which ever is shorter.

QUESTION-7

Section 2, page 7 of the MHI-NESH QAP, states that the objective of the QAP is to assure that MHI-NESH nuclear generating plants are designed, constructed, and operated in accordance with governing regulations and license requirements. The MHI-NESH QAP is for the design certification of the US-APWR and therefore, should not be applied to construction and operation. The staff recommends removing "constructed and operated" from the first sentence of the second paragraph of page 7 of the MHINESH QAP.

Response

MHI will remove "constructed and operated" from the first and the third sentence of the second paragraph of page 7 of the MHI - NESH QAP.

QUESTION-8

Draft SRP Section 17.5, paragraph II.B.8, states that "a general grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general grace period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early." Section 2 of the MHI-NESH QAP incorporates a grace period of 25% to be applied to provisions that are required to be performed on a periodic basis. In addition, the statement in the MHI-NESH QAP does not discuss the "clock" portion of this approved exception to NQA-1-1994. The MHI-NESH QAP should adopt the entire exception as stated in draft SRP Section 17.5, paragraph II.B.8, or justify why partial adoption of the exception is acceptable.

Response

MHI will revise the paragraph just before MHI - NESH QAP Part II, Section 2.1 as described below.

> Delegated responsibilities may be performed under a supplier's or principal contractor's QAP, provided that the supplier or principle contractor has been approved as a supplier in accordance with the QAP. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principle contractor's QAP and implementing procedures. In addition, routine interfaces with project personnel assure that quality expectations are met.
>
> A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early. Audits schedules are based on the month in which the audit starts.

QUESTION-9

Draft SRP Section 17.5, paragraph II.S.2, states the qualification requirements for individuals responsible for managing the implementation of the QA plan. Section 2.5 of the MHI-NESH QAP provides the minimum qualification of the Engineer of NESQD and the Engineer of APPD. However, these qualifications do not provide for requirements for management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures.

Clarify how the MHI-NESH QAP will address these requirements consistent with Section 17.5 of the draft SRP.

Response

MHI will apply the qualification requirements that Draft SRP Section 17.5, paragraph II.S.2 states to only the qualification of QA Manager.
So, MHI will revise the second paragraph of MHI - NESH QAP Part II, Section 2.5 as described below.

> The minimum qualifications of the General Manager of NESQD are that he or she holds an engineering or related science degree and has a minimum of four years of related experience (3 of the 4 years must include 2 years of nuclear power plant experience) and 1 year of supervisory or management experience. One year of experience performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a cases-by-case basis and approved and documented by senior management.

QUESTION-10

Draft SRP Section 17.5, paragraph II.S.3, states the qualification requirements for individuals responsible for planning, implementing, and maintaining the QA plan. Clarify how the MHI-NESH QAP will provide for these requirements consistent with Section 17.5 of the draft SRP.

Response

MHI will add one paragraph about the qualification at the end of MHI - NESH QAP Part II, Section 2.5 as described below.

> The minimum qualifications of the individuals responsible for planning, implementing and maintaining the programs for the QAPD are that each has a high school diploma or equivalent and has a minimum of one year of related experience. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

QUESTION-11

Section 2.7 of the MHI-NESH QAP states that MHI commits to requiring suppliers to establish and perform inspection and test personnel qualification in accordance with NQA-1-1994 and Supplement 2S-1. Clarify why this commitment is necessary.

Response

MHI recognizes this commitment is not necessary and will delete it.

QUESTION-12

Draft SRP Section 17.5, paragraph II.D.3, states, in part, that changes made as a result of bid evaluations or pre-contract negotiations are incorporated into the procurement documents, and the review of such changes and their effects are completed prior to

contract award. Section 4.1 of the MHI-NESH QAP establishes a commitment to NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, and includes clarifications and exceptions to these requirements. As an exception, the template proposes that "the quality assurance review of procurement documents is satisfied through review of the applicable procurement specifications, including the technical and quality procurement requirements, prior to bid or award of contract." This exception does not specify if procurement documents as well as changes to procurement documents will be part of the proposed quality assurance review. Clarify how the proposed quality assurance review of procurement documents includes the considerations delineated in Section 17.5 of the draft SRP.

Response

MHI will add one sentence at the end of the third paragraph in MHI - NESH QAP Part II, Section 4.1, NQA-1-1994, Supplement 4S-1 as described below.

- Section 3 of this supplement 4S-1 requires procurement documents to be reviewed prior to bid or award of contract. The quality assurance review of procurement documents is satisfied through review of the applicable procurement specification, including the technical and quality procurement requirements, prior to bid or award of contract. Procurement document changes (e.g., scope, technical or quality requirements) will also receive the quality assurance review.

QUESTION-13

Draft SRP Section 17.5, paragraph II.F.9.b, states that document control measures provide for coordination and control of interface documents. The MHI-NESH QAP does not provide measures for coordinating and controlling interface documents. Clarify how the MHI-NESH QAP addresses coordination and control of interface documents consistent with Section 17.5 of the draft SRP.

Response

MHI will add one provision to the first paragraph of MHI - NESH QAP Part II, Section 6 as described below.

SECTION 6 DOCUMENT CONTROL

MHI-NESH has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to assure that correct documents are being employed. The control system (including electronic systems used to make documents available) shall be documented and shall provide for (a) through (f) below:

(a) identification of documents to be controlled and their specified distribution;
(b) a method to identify the correct document (including revision) to be used and control of superseded documents;
(c) Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;
(d) review of documents for adequacy, completeness, and correctness prior to approval and issuance.
(e) a method for providing feedback from users to continually improve procedures and work instructions.
(f) coordinating and controlling interface documents and procedures.

QUESTION-14

Section 7.1, page 18 of the MHI-NESH QAP, states that industry programs such as those applied by ASME, NUPIC, or other established utility groups are used as input or the basis for supplier qualification whenever appropriate. These programs are for utilities to share auditing resources. Since MHI-NESH is not an utility, clarify how this example is applicable to the QAP for the US-APWR.

Response

MHI will delete the phrase "Nuclear Procurement Issues Committee (NUPIC), or other established utility groups," in the fourth paragraph of MHI - NESH QAP Part II, Section 7.1.

QUESTION-15

Draft SRP Section 17.5, paragraph II.G.9.c, states that measures for evaluation and selection of procurement sources, and the results therefrom, are documented and included in supplier's technical and quality capability as determined by a direct evaluation of its facilities and personnel and the implementation of its QA program. The MHI-NESH QAP does not provide measures for evaluating the supplier's implementation of a QA program. Clarify how the MHI-NESH QAP addresses evaluation of a supplier's implementation of a QA program consistent with Section 17.5 of the draft SRP.

Response

MHI will add one measure to assure the quality of purchased items and services to MHI - NESH QAP Part II, Section 7.1 as described below.

- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

QUESTION-16

Draft SRP Section 17.5, paragraph II.L.8, states that for procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation (A2LA) are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance, provided that certain conditions are met. One of the conditions, paragraph II.L.8.c, states that the use of the alternative method is limited to the National Voluntary Accreditation Program (NVLAP) and A2LA, as recognized through the mutual recognition arrangement of the International Laboratory Accreditation Program (ILAC). Section 7.2 of the MHI-NESH QAP proposes to use this alternative method with a calibration laboratory accredited by NVLAP or A2LA as recognized by NVLAP through a Mutual Recognition Arrangement (MRA). An MRA is a generic term referring to a conformity assessment process. For assessment of calibration laboratories, the NRC has found the ILAC MRA to be an acceptable alternative. The alternative does not include MRAs administered under other programs. Clarify which MRA the MHI-NESH QAP proposes to use.

Response

MHI will revise MHI - NESH QAP Part II, Section 7.2, NQA-1-1994, Supplement 7S-1, (3), as described below.

(3) A documented review of the supplier's accreditation shall be performed and shall include a verification of each of the following:

- The calibration laboratory holds an accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) or by the American Association for Laboratory Accreditation (A2LA) as recognized by NVLAP through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).
- The accreditation is based on ANS/ISO/IEC 17025.
- The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.

QUESTION-17

Draft SRP Section 17.5, paragraph II.L.8, states that for procurement of commercial grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the A2LA are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance, provided that certain conditions are met. Paragraph II.L.8.h also states that the proposed alternative is limited to domestic (within the United States) calibration service suppliers. Clarify how the MHI-NESH QAP will implement the procurement of commercial-grade calibration services consistent with Section 17.5, paragraph II.L.8.h, of the draft SRP.

Response

MHI understands NRC's comment. But, MHI will delete the description about Commercial Grade Items and Services exceptions in Design Certification.

[For Reference]

- For the procurement control of commercial-grade calibration services in Japan for safety-related application, supplier audits by MHI or MHI supplier are performed. MHI-Takasago R&D Center has already performed the audits.
- MHI considered that MHI would use MHI - NESH QAP Part II, Section 7.2 to the supplier of commercial-grade calibration services in United States. But, there has not been and will not be such a supplier in United States at Design Certification.

QUESTION-18

In lieu of Section 8.1 of NQA-1-1994, Supplement 7S-1, regarding documents to be available at the site, the MHI-NESH QAP proposes to consider documents that may be stored in approved electronic media under the company or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Describe the process and measures that will be implemented to ensure that the validity, integrity, and accessibility of documents stored in approved electronic media under company or supplier control and not physically located on site. Explain how this alternative meets the requirements of NQA-1 for procurement documents required to be available at the site.

Response

MHI will add two sentences to the description of this exception in MHI - NESH QAP Part II, Section 7.2, NQA-1-1994, Supplement 7S-1 as described below.

For the design certification, the design output including the design performed by supplier will be controlled by MHI. So these documents are available at the design organization offices.

- For Section 8.1, MHI-NESH considers documents that may be stored in approved electronic media under MHI-NESH or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to MHI-NESH to support operations. The MHI-NESH records management system will provide for timely retrieval of necessary records.

QUESTION-19

10 CFR 21.2(a)(3) states that the regulations in Part 21 apply to each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for a design certification rule under part 52 of this chapter. Draft SRP Section 17.5, paragraphs II.U.1.d and II.U.1.e require verification that the applicant commits to the most recent revision of Generic Letters (GLs) 89-02 and 91-05, with regards to commercial-grade items or services. Clarify how the MHI-NESH QAP will commit to GLs 89-02 and 91-05 consistent with Section 17.5 of the draft SRP, or provide justification for their exclusion.

Response

MHI understands NRC's comment. But, MHI will delete the description about Commercial Grade Items and Services exceptions in Design Certification.

QUESTION-20

Section 15.1 of the MHI-NESH QAP provides for measures "that implement a reporting program which conforms to the requirements of 10 CFR 50.55(e) and/or 10 CFR [Part] 21 during construction and 10 CFR Part 21 during operations." 10 CFR 50.55(e) does not apply to design certifications. In addition, as described in item 19 above, design certification is within the scope of 10 CFR Part 21. Clarify how the MHI-NESH QAP will provide measures for reporting of defects and noncompliance during design certification consistent with 10 CFR Part 52 requirements.

Response

MHI will revise MHI - NESH QAP Part II, Section15.1 as described below.

MHI-NESH will establish the necessary measures and governing procedures that implement a reporting program which conforms to the requirements of 10 CFR 52 and/or 10 CFR 21 during design certification.

QUESTION-21

Section 16.1 of the MHI-NESH QAP provides for measures "that implement a program to identify, evaluate and report defects and non-compliances in accordance with 10 CFR 50.55(e) and/or 10 CFR [Part] 21, as applicable." 10 CFR 50.55(e) does not apply to design certifications. Clarify how the MHI-NESH QAP will provide measures for identification, evaluation, and reporting of defects and noncompliance during design certification consistent with 10 CFR Part 52 requirements.

Response

MHI will revise MHI - NESH QAP Part II, Section16.1 as described below.

MHI-NESH has in-place the necessary measures and governing procedures that implement a program to identify, evaluate and report defects and non-compliances in accordance with 10 CFR 52 and/or 10 CFR Part 21, as applicable. Such a reporting program applies to safety-related activities and services performed by MHI-NESH and/or MHI-NESH suppliers / sub-suppliers providing input to DC application development.

QUESTION-22

Draft SRP Section 17.5, paragraph II.Q.4, states that document access controls, user privileges, and other appropriate security controls must be established. The MHI-NESH QAP does not provide measures for security control of records. Clarify how the MHI-NESH QAP will implement measures to provide document access controls and security controls consistent with Section 17.5 of the draft SRP.

Response

MHI will add the words "access controls, security controls" and "user privileges" as the requirements for record administration in MHI - NESH QAP Part II, Section17 as described below.

SECTION 17 QUALITY ASSURANCE RECORDS

MHI-NESH shall establish the necessary measures and governing procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for MHI-NESH and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, security controls, user privileges, and final disposition.

QUESTION-23

Draft SRP Section 17.5, paragraph II.Q.5, states, in part, that design documentation and records include not only the final design documents, such as drawings and specifications, and revisions thereto, but also documentation which identifies the important steps, including sources of design inputs that support the final design. The MHI-NESH QAP does not provide measures for incorporation of documentation of design input sources that support the final design as part of the record retention program. Clarify how the MHI-NESH QAP will implement measures to control design records consistent with Section 17.5 of the draft SRP.

Response

Though the requirements about design documentation and records are addressed in MHI-NESH QAP Part II, Section 3.2, MHI will add the same requirements in MHI - NESH QAP Part II, Section17.1 as described below.

17.1 Record Retention

Measures are required to be established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. MHI-NESH maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses and computer programs) and the sources of input

that support the final output. Such records and their retention times are defined in appropriate procedures. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

QUESTION-24

Section 18.1, page 31 of the MHI-NESH QAP, states that during the early portions of US-APWR Project activities, audits will focus on areas including, but not limited to, procurement and corrective action. Since the scope of the MHI-NESH QAP is design certification, design control should be added to the list of focus areas during the early phases of the US-APWR activities. Otherwise, justify why design control should not be added.

Response

MHI will add "design control" as the focus on area at early portion of US-APWR Project activities in MHI - NESH QAP Part II, Section18.1 as described below.

18.1 Performance of Audits

Internal audits of selected aspects of licensing, design phase are performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed. During the early portions of US-APWR Project activities, audits will focus on areas including, but not limited to, design control, procurement, and corrective action. Functional areas of an organization's QA program for auditing include at a minimum verification of compliance and effectiveness of implementation of internal rules, procedures (e.g., design, procurement, surveillance, test), regulations, programs for training, retraining, qualification and corrective actions associated record keeping.

QUESTION-25

Draft SRP Section 17.5, paragraph II.R.10, states that when any work carried out under the requirements of the QA program is delegated to others, the work is to be audited by the QA audit program. Clarify how the MHI-NESH QAP will provide measures to address the audit of QA program requirements delegated to others, consistent with Section 17.5 of the draft SRP.

Response

Work delegated to others would be controlled either under MHI-NESH QAP (internal audit) or under a contract (supplier audit). MHI will add "and /or services" in MHI - NESH QAP Part II, Section18.1 b, just above 18.2 NQA-1-1994 Commitment, as described below.

b. Audits of suppliers of safety-related components and/or services are conducted as described in Section 7.1.

18.2 NQA-1-1994 Commitment

.....

QUESTION-26

Draft SRP Section 17.5, paragraph II.R.11, provides guidance to conduct procurement audits of suppliers. The guidance states, in part that: (1) the supplier's QA program is audited on a triennial basis, (2) the triennial period starts when the first audit is performed, and, (3) an audit is initially performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. Section 18.1 of the MHI-NESH QAP makes reference to Section 7.1 of the MHINESH QAP for the description of measures established for audits of safety-related component suppliers. Section 7.1 of the MHI-NESH QAP states that qualified suppliers are audited on a triennial basis. Clarify how the MHI-NESH QAP will implement the full supplier audit controls consistent with Section 17.5 of the draft SRP.

Response

MHI will revise the provision to cover full supplier audit control in MHI - NESH QAP Part II, Section7.1 as described below.

7.1 Acceptance of Items or Services

MHI-NESH establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity and the frequency of procurement. Verification actions include testing, as appropriate, during design, fabrication and construction activities. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.

- Prospective suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. Qualified suppliers are audited as follows:
  1) the supplier's QA program is audited on a triennial basis
  2) the triennial period starts when the first audit is performed
  3) an audit is initially performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

  In addition, if a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. MHI-NESH may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet MHI-NESH requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

QUESTION-27

Part III of the MHI-NESH QAP is titled "Regulatory Treatment of Non-Safety Systems (RTNSS)." Draft SRP Section 17.5, paragraph II.V.1, also includes the Reliability Assurance Program (RAP). Both RTNSS and RAP are identified as being significant contributors to plant safety in the Commission's policy on nonsafety-related structures, systems, and components (SSCs). Clarify how the MHI-NESH QAP will implement nonsafety-related SSC quality controls for the Reliability Assurance Program.

Response

MHI will revise Part III of MHI-NESH QAP described as follows.

1) Revise the title of Part III
2) The words "significant contributors to plant safety" is used instead of RTNSS and RAP
2) Divide Part III to two portions
3) Part III-1) includes Section1 to Section18, and Section 19 in original QAP is changed to Part III-2)

PART III NONSAFETY-RELATED SSC QUALITY CONTROL

PART III-1) Nonsafety Related SSCs - Significant Contributors to Plant Safety

Specific program controls are applied to nonsafety-related SSCs, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAP are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The following clarify the applicability of the QA Program to the nonsafety-related SSCs and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for nonsafety-related SSCs.

Section 1 Organization

The verification activities described in this part may be performed by the MHI-NESH line organization, the QA organization described in Part II is not required to perform these functions.

.....

Section 18 Audits

MHI-NESH shall establish measures for line management to periodically review and document the adequacy of the process and take any necessary corrective action, audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the

comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 18).

PART III-2) Nonsafety-Related SSCs Credited for Regulated Events

MHI-NESH commits to implement quality requirements to the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Operating Nuclear Power Plants."
MHI-NESH commits to implement quality requirements to ATWS requirement in accordance with Generic Letter 85-06 "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."
MHI-NESH commits to implement quality requirements to ATWS requirement in accordance with 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 System and Equipment," in RG 1.155, "Station Blackout."

QUESTION-28

Draft SRP Section 17.5, paragraph II.V.1.b, provides the quality assurance program controls required for non-safety related SSCs that are identified as being significant contributors to plant safety. Paragraph II.V.1.b states that the supplier's procedures describe the quality controls applied to the subject equipment. Part III, Section 2 of the MHI-NESH QAP states that "suppliers of these SSCs or related services may [emphasis added] describe the quality controls applied in appropriate procedures, [and] a new or separate QA program is not required." Clarify how the proposed statement of the supplier's quality assurance program controls are consistent with Section 17.5 of the draft SRP.

Response

MHI will delete the word "may" and revise the paragraph of MHI-NESH QAP Part III, Section 2, as described below.

Section 2 QA Program

MHI-NESH QA requirements for nonsafety-related SSCs are contained in this QAP and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. These suppliers need not a new or separate QA program.

QUESTION-29

Draft SRP Section 17.5, paragraph II.U.1, states that the applicant commits to the most recent revision of the regulatory guides (RGs). Part IV of the MHI-NESH QAP commits to revision 3 of RGs 1.26 and 1.29. Both of these RGs were revised in March 2007. Justify why the MHI-NESH QAP does not commit to the latest revisions of these RGs consistent with Section 17.5 of the draft SRP.

Response

MHI will commit to the latest revisions of RGs 1.26 and 1.29 in MHI-NESH QAP Part IV.

Regulatory Guides:

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

Regulatory Guide 1.26 defines classification of systems and components.

MHI-NESH commits to the applicable regulatory position guidance provided in this latest revision of regulatory guide for US-APWR project.

Regulatory Guide 1.29, Revision 4, March 2007 – Seismic Design Classification

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

MHI-NESH commits to the applicable regulatory position guidance provided in this latest revision of regulatory guide for US-APWR project.

Revision History

Revision	Page	Description
0	All	Original issued Topical Report Number PQD-HD-19005 Rev.1 "Quality Assurance Program (PQD) Description For Design Certification of the US-APWR" was revised in accordance with Safety Evaluation Report dated January 24, 2008 as Original Issuance of Topical Report Number PQD-HD-19005-A Rev.0 "Quality Assurance Program (PQD) Description For Design Certification of the US-APWR".

POLICY STATEMENT

Nuclear Energy Systems Headquarters in Mitsubishi Heavy Industries, Ltd. (MHI-NESH) shall design and procure nuclear plants in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the U.S. Code of Federal Regulations (CFR) and applicable laws and regulations of the state and local governments.

The MHI-NESH US-APWR Project Quality Assurance Program is the Quality Assurance Program (QAP) provided in this document and the associated implementing documents. Together they provide for control of MHI-NESH activities that affect the quality of safety related nuclear plant structures, systems, and components and include all planned and systematic activities necessary to provide adequate confidence that such structures, systems, and components will perform satisfactorily in service. The QAP may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements.

The QAP is the top-level policy document that establishes the manner in which quality is to be achieved and presents MHI-NESH's overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the Quality Assurance Program.

Compliance with the QAP and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the MHI-NESH Quality Assurance Program.

Signed Y. Uratani 2/25/'08
Y. Uratani

General Manager, Nuclear Energy Systems Headquarters
Executive Vice President & Representative Director
of Mitsubishi Heavy Industries, Ltd.

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PART I INTRODUCTION

SECTION 1 GENERAL

The MHI-NESH US-APWR Project Quality Assurance Program (QAP) is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for plants designed by MHI-NESH. The QAP describes the methods and establishes QAP and administrative control requirements that meet 10 CFR Part 50, Appendix B and 10 CFR Part 52. The QAP is based on the requirements of ASME NQA–1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as specified in this document.

The QAP is defined by the NRC approved regulatory document that describes the Quality Assurance Program elements, along with the associated implementing documents. Procedures and instructions that control US-APWR Project activities are developed prior to commencement of activities. (See section 2.6 of Part II for additional information) Business policies of MHI-NESH establish high level responsibilities and authority for carrying out administrative functions which are outside the scope of the QAP.

Procedures establish practices for certain activities which are common to all MHI-NESH organizations performing those activities such that the activity is controlled and carried out in a manner that meets QAP requirements. Organization specific procedures establish detailed implementation requirements and methods, and may be used to implement the business policies of MHI-NESH or be unique to particular functions or work activities.

1.1 Scope / Applicability

This QAP applies to Design Certification activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

Designing Testing Licensing Procuring
Inspecting

Safety-related systems, structures, and components, under the control of the QAP, are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAP may be applied to certain activities where regulations other than 10 CFR Part 50 and 10 CFR Part52 establish QAP requirements for activities within their scope.

The policy of MHI-NESH is to assure a high degree of availability and reliability of its nuclear plants while ensuring the health and safety of its workers and the public. To this end, selected elements of the QAP are also applied to certain equipment and activities that are not safety-related, but support safe, economic, and reliable plant operations, or where other NRC guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

PART II QAP DETAILS

SECTION 1 ORGANIZATION

This Section describes the MHI-NESH organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAP implementation. The organizational structure includes corporate and design functions for the development of the US-APWR. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of this QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

The General Manager of MHI-NESH is responsible to size the Quality Assurance organization commensurate with the duties and responsibilities assigned.

The MHI-NESH US-APWR Project organization is responsible for US-APWR plant licensing, engineering, procurement and development activities. There are several organizations within MHI-NESH which implement and support the QAP.

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting the US-APWR Project QA Program. The MHI-NESH organization and the US-APWR Project organization are shown in Figures II.1-1 and II.1-2 respectively.

1.1 General Manager of MHI-NESH

The General Manager of MHI-NESH, who is assigned the most senior management of MHI-NESH and Executive Vice President & Representative Director of MHI as a resolution of board of directors, is responsible for all aspects of design of MHI-NESH's nuclear plants. The General Manager of MHI-NESH is also responsible for all technical and administrative support activities provided by MHI-NESH. The General Manager of MHI-NESH directs the General Manager of Nuclear Energy Systems Engineering, the General Manager of APWR Promoting Department and General Manager of Nuclear Energy Systems Quality & Safety Management Department in fulfillment of their responsibilities. The General Manager of MHI-NESH reports to the President of Mitsubishi Heavy Industries, Ltd. with respect to important business matters.

1.2 APWR Promoting Department (APPD)

US-APWR Project in MHI-NESH organization is responsible for US-APWR plant licensing, engineering and procurement activities.

1.2.1 General Manager of APPD (APPD Manager)

The APPD Manager reports to the General Manager of MHI-NESH and is responsible for the administration of the US-APWR QAP. The APPD Manager also directs the planning and development of the APPD staff, and organization resources.

1.3 Nuclear Energy Systems Engineering Center (N-Center)

The N-Center organization is responsible for engineering and licensing.

1.3.1 General Manager of N-Center (N-Center Manager)

The N-Center Manager reports to the General Manager of MHI-NESH and is responsible for the administration of engineering and nuclear fuel under the QAP. As shown in Figure II.1-2, for

the US-APWR, the General Manager of N-Center takes project direction from the General Manager of APPD.

1.3.2 General Manager of Reactor Core Engineering Department (RCE Manager)

The RCE Manager reports to the N-Center Manager and is responsible for the engineering of Basic Design of Fuel & Core under the QAP.

1.3.3 General Manager of Reactor Safety Engineering Department (RSE Manager)

The RSE Manager reports to the N-Center Manager and is responsible for the engineering of Safety Analysis under the QAP.

1.3.4 General Manager of Water Reactor Engineering Department (WRE Manager)

The WRE Manager reports to the N-Center Manager and is responsible for the engineering of Basic Design of System, I&C and Plant under the QAP.

1.3.5 Group Manager of Planning & Administration Group (P&A-G Manager)

The P&A-G Manager reports to the N-Center Manager and is responsible for the administration of engineering and general affairs for N-Center under the QAP.

1.4 Nuclear Energy Systems Quality and Safety Management Department (NESQD)

The MHI-NESH Quality Assurance Organization is responsible for independently planning and performing activities to verify the development and effective implementation of the MHI-NESH QAPs including but not limited to US-APWR Project , engineering, licensing, document control, corrective action program and procurement that support new nuclear plant generation.

1.4.1 General Manager of NESQD (NESQD Manager)

The NESQD Manager reports to the General Manager of MHI-NESH for the design activities and is responsible for developing and maintaining the MHI-NESH QAP, evaluating compliance to the program and managing the QA organization resources.

Also the NESQD Manager is responsible for the development and verification of implementation of the QAP described in this document. The NESQD Manager is responsible for assuring compliance with regulatory requirements and procedures through audits and technical reviews; for monitoring organization processes to ensure conformance to commitments and licensing document requirements; for ensuring that vendors providing quality services to MHI-NESH are meeting the requirements of 10 CFR 50, Appendix B

through MHI-NESH vendor audits. The NESQD Manager has sufficient independence from other US-APWR Project priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas necessary regarding MHI-NESH US-APWR Project activities. The NESQD Manager may make recommendations to the US-APWR Project management regarding improving the quality of work processes. If the NESQD Manager disagrees with any actions taken by the US-APWR Project organization and is unable to obtain resolution, the NESQD Manager shall bring the matter to the General Manager of MHI-NESH who will determine the final disposition.

1.5 Authority to Stop Work

Quality assurance personnel have the authority, and the responsibility, to stop work in progress which is not being done in accordance with approved procedures or where safety or SSC integrity may be jeopardized. This extends to work performed by suppliers furnishing safety-related services to MHI-NESH.

1.6 Quality Assurance Organizational Independence

For the design certification, independence shall be maintained between the organization or organizations performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review / verification.

1.7 NQA-1-1994 Commitment

In establishing its organizational structure, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 1 and Supplement 1S-1.

Figure II.1-1

MHI-NESH Organization

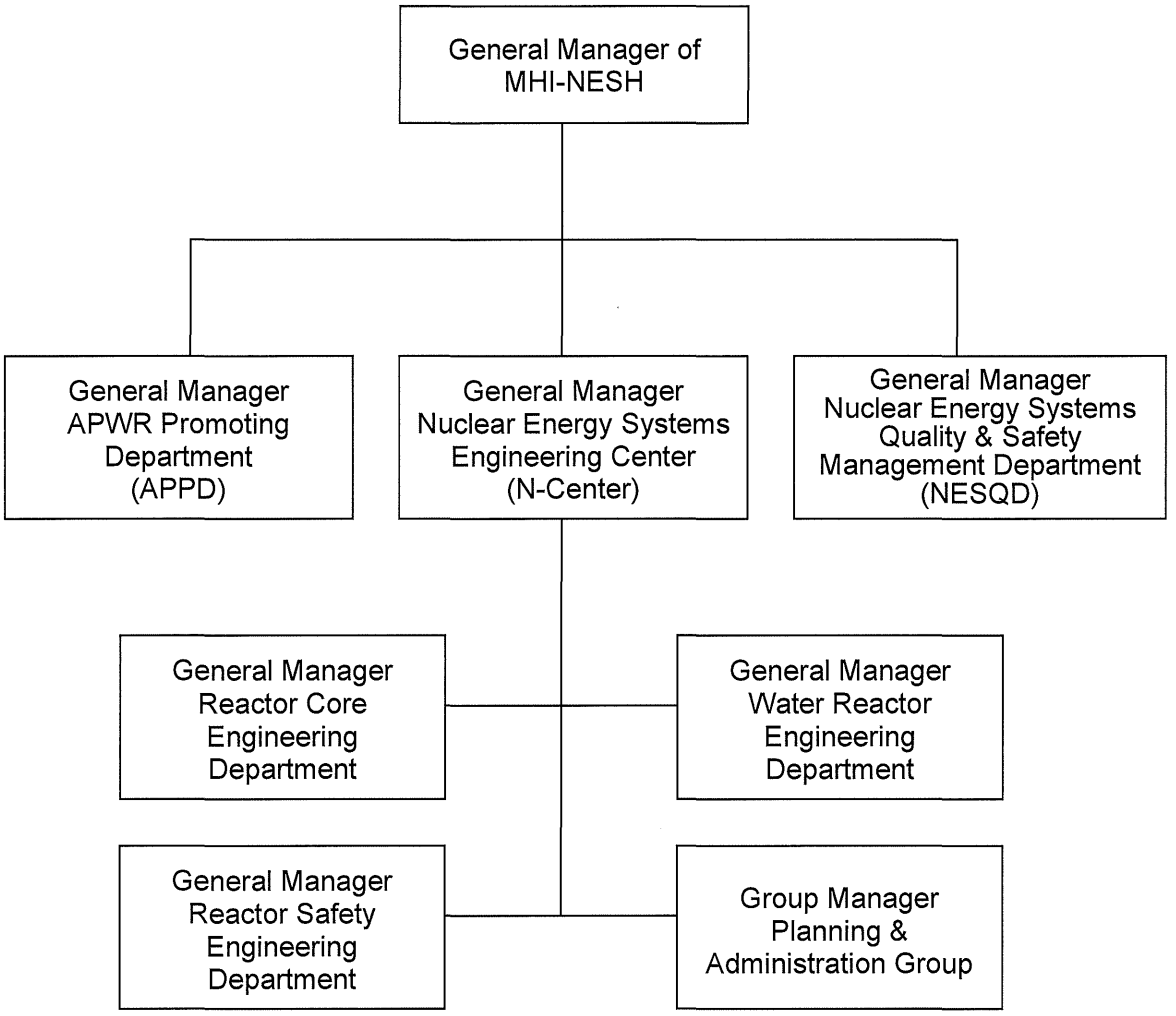
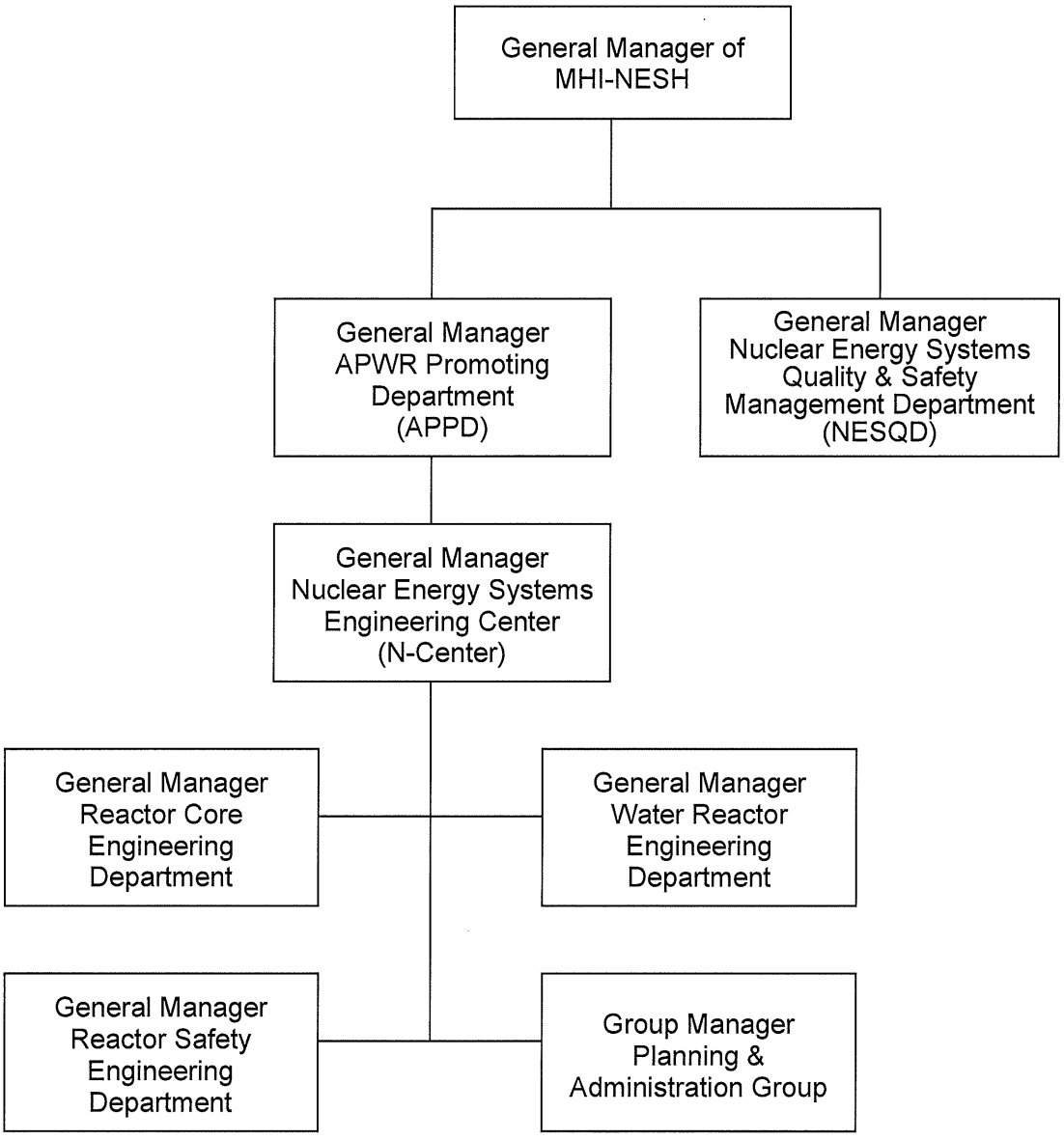


Figure II.1-2

US-APWR Project Organization



SECTION 2 QUALITY ASSURANCE PROGRAM

MHI-NESH has established the necessary measures and governing procedures to implement the QAP as described in the QAP. MHI-NESH is committed to implementing the Quality Assurance Program in all aspects of work that are important to the safety of the nuclear plants as described and to the extent delineated in this QAP. Further, MHI-NESH ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. This QAP also applies to certain nonsafety-related structures, systems, components and activities to a degree consistent with their importance to safety. Senior management is regularly apprised of audit results evaluating the adequacy of implementation of the QAP through the audit functions described in the Audit Section of this QAP.

The objective of the QAP is to assure that MHI-NESH nuclear generating plants are designed in accordance with governing regulations and license requirements. The program is based on the requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as further described in this document. The QAP applies to those quality-related activities that involve the functions of safety-related structures, systems, and components (SSCs) associated with the design and licensing of new nuclear power plants. A list identifying SSCs and activities to which this program applies is maintained at the appropriate facility. Regulatory Guide 1.26 is used as a basis for this list. Cost and scheduling functions do not prevent proper implementation of the QAP.

Specific program controls are applied to non-safety related SSCs, for which 10CFR50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAP are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

Delegated responsibilities may be performed under a supplier's or principal contractor's QAP, provided that the supplier or principle contractor has been approved as a supplier in accordance with the QAP. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principle contractor's QAP and implementing procedures. In addition, routine interfaces with project personnel assure that quality expectations are met.

A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early. Audits schedules are based on the month in which the audit starts.

2.1 Responsibilities

Personnel who work directly or indirectly for MHI-NESH are responsible for the achievement of acceptable quality in the work covered by this QAP. This includes those activities delineated in Part I, Section 1.1 of this QAP. MHI-NESH personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the

QAP are performed as directed by documented instructions, procedures and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used. The NESQD Manager is responsible to verify that processes and procedures comply with QAP and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2 Delegation of Work

MHI-NESH retains and exercises the responsibility for the scope and implementation of an effective QAP. Positions identified in the Organization Section of this QAP may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the level appropriate for its nature and effect, and with any necessary technical advice or review.

2.3 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the QA program or portions thereof, assess the adequacy of that part of the program for which they are responsible and assure its effective implementation at least once each year or at least once during the life of the activity, which ever is shorter.

2.4 Issuance and Revision to Quality Assurance Program

Administrative control of the QAP during design certification will be in accordance with 10 CFR 50.55(f), as appropriate. Changes to the QAP are evaluated by the Engineer of NESQD to ensure that such changes do not degrade previously approved quality assurance controls specified in the QAP. This document shall be revised as appropriate to incorporate additional QA commitments. New revisions to the document will be reviewed, at a minimum, by the Senior Engineer of NESQD and approved by the NESQD Manager.

Changes to QAP will be submitted for review as specified in § 50.4.
The submittal of a change to the quality assurance program description will include all pages affected by that change and will be accompanied by a forwarding letter identifying the change, the reason for the change, and the bases for concluding that the revised program incorporating the change continues to satisfy the criteria of Appendix B of 10CFR50 and the quality assurance program description commitments previously accepted by the NRC.

A copy of the forwarding letter identifying the changes will be maintained as a facility record for three years.

Changes to the quality assurance program description will be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

2.5 Personnel Qualifications

Personnel assigned to implement elements of the QAP shall be capable of performing their assigned tasks. To this end MHI-NESH establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QAP to assure that suitable proficiency is achieved and maintained. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable MHI-NESH procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAP elements to be employed. Records of personnel training and qualification are maintained.

The minimum qualifications of the General Manager of NESQD are that he or she holds an engineering or related science degree and has a minimum of four years of related experience (3 of the 4 years must include 2 years of nuclear power plant experience) and 1 year of supervisory or management experience. One year of experience performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a cases-by-case basis and approved and documented by senior management.

The minimum qualifications of the individuals responsible for planning, implementing and maintaining the programs for the QAPD are that each has a high school diploma or equivalent and has a minimum of one year of related experience. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

2.6 Legacy Issue

The US-APWR design is based on the design of the Japanese-APWR. The J-APWR design was completed in accordance with a prior version of MHI's QA program, which was based on Japanese Guidelines. The requirements of the Japanese Guidelines have been compared to the QA requirements of 10CFR50, Appendix B, ASME NQA-1-1994 and Standard Review Plan 17.5 and were found to be very similar. Certain test activities completed under research and development relied on alternative controls allowed by the Japanese Guidelines, but not addressed in the U.S. requirements. These test activities are evaluated in accordance with a procedure to provide reasonable assurance that the completed design work satisfies 10CFR50, Appendix B.

2.7 NQA-1-1994 Commitment / Exceptions

- In establishing qualification and training programs, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-3 and 2S-4, with the following clarifications and exceptions:

  - NQA-1-1994, Supplement 2S-2

    - This Supplement is not applicable at this time (DC application).

  - NQA-1-1994, Supplement 2S-3

    - The requirement that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years is replaced by the following, "The prospective lead auditor shall demonstrate his/her ability to properly implement the audit process, as implemented by MHI-NESH, 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."

SECTION 3 DESIGN CONTROL

MHI-NESH has established and implements a process to control the design, design changes and of items that are subject to the provisions of this QAP. The design process includes provisions to control design inputs, outputs, changes, interfaces, records and organizational interfaces within MHI-NESH and with suppliers. These provisions assure that 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) so that the final design output can be related to the design input in sufficient detail to permit verification. Design change processes and the division of responsibilities for design-related activities are detailed in MHI-NESH and supplier procedures. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution and revision of design inputs and outputs.
Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the MHI-NESH design organization or by other organizations so authorized by MHI-NESH.

Design documents are reviewed by individuals knowledgeable in QA to ensure the documents contain the necessary QA requirements.

3.1 Design Verification

MHI-NESH design processes provide for design verification to ensure that items and activities subject to the provisions of this QAP are suitable for their intended application, consistent with their effect on safety. Design changes are subjected to these controls, which include verification measures commensurate with those applied to original plant design.

Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state-of-the-art, and the similarity with previously proven designs. This includes design inputs, design outputs and design changes. Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for item's intended use.

MHI-NESH normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, manufacture or construction. When such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function.

If existing qualification test results are proposed for use in the US-APWR design, test results will be re-evaluated using the procedure described in section 2.6 above.

3.2 Design Records

MHI-NESH maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses and computer programs) and the sources of input that support the final output.

Plant design drawings reflect the properly reviewed and approved configuration of the plant.

3.3 Computer Application and Digital Equipment Software

The QAP shall govern the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated nonsafety-related applications. MHI-NESH and suppliers shall be responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures shall require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software and revision thereto shall be documented and approved by authorized personnel. This QAP shall also be applicable to the administrative functions associated with the maintenance and security of computer hardware where such functions are considered essential in order to comply with other QAP requirements such as QA records.

3.4 NQA-1-1994 Commitment

In establishing its program for design control and verification, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 3, and Supplement 3S-1 and the standards for computer software contained in Subpart 2.7.

SECTION 4 PROCUREMENT DOCUMENT CONTROL

MHI-NESH has established the necessary measures and governing procedures to assure that purchased items and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

- Where original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to assure that interfaces, interchangeability, safety, fit and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.

- Applicable technical, regulatory, administrative, quality and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under MHI's QA program).

Reviews of procurement documents shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4.1 NQA-1-1994 Commitment

In establishing controls for procurement, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 4S-1

  - Section 2.3 of this Supplement 4S-1 includes a requirement that procurement documents require suppliers to have a documented QAP that implements NQA-1-1994, Part 1. In lieu of this requirement, MHI-NESH may require suppliers to have a documented supplier QAP that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of the procurement.

  - With regard to service performed by a supplier, MHI-NESH procurement documents may allow the supplier to work under the MHI-NESH QA program, including implementing procedures, in lieu of the supplier having its own QA program.

- Section 3 of this supplement 4S-1 requires procurement documents to be reviewed prior to bid or award of contract. The quality assurance review of procurement documents is satisfied through review of the applicable procurement specification, including the technical and quality procurement requirements, prior to bid or award of contract. Procurement document changes (e.g., scope, technical or quality requirements) will also receive the quality assurance review.

- Procurement documents for Commercial Grade Items that will be dedicated by MHI-NESH as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated.

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

MHI-NESH has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAP as described in the QAP. Such documents are prepared and controlled according to Part II, Section 6 of this QAP. In addition, means are provided for dissemination to the staff of instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

5.1 Procedure Adherence

The MHI-NESH policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Part II, Section 6 of this QAP. Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require

(1) the written procedure to be present and followed step-by-step while the task is being performed,
(2) the user to have committed the procedure steps to memory,
(3) verification of completion of significant steps, by initials or signatures or use of check-off lists.

Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks that are infrequently performed, and tasks where steps must be performed in a specified sequence.

5.2 Procedure Content

The established measures address the applicable content of procedures as described in the introduction to Part II of NQA-1-1994. In addition, procedures governing tests and inspections will include as applicable, initial conditions and prerequisites for the performance of the activity.

5.3 NQA-1-1994 Commitment

In establishing procedural controls, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 5.

SECTION 6 DOCUMENT CONTROL

MHI-NESH has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to assure that correct documents are being employed. The control system (including electronic systems used to make documents available) shall be documented and shall provide for (a) through (e) below:

(a) identification of documents to be controlled and their specified distribution;
(b) a method to identify the correct document (including revision) to be used and control of superseded documents;
(c) Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;
(d) review of documents for adequacy, completeness, and correctness prior to approval and issuance.
(e) a method for providing feedback from users to continually improve procedures and work instructions.
(f) coordinating and controlling interface documents and procedures.

The types of documents to be controlled include:

(a) drawings such as design, construction, installation, and as-built drawings;
(b) engineering calculations
(c) design specifications
(d) purchase orders and related documents
(e) vendor-supplied documents
(f) audit, surveillance, and quality verification/inspection procedures
(g) inspection and test reports
(h) instructions and procedures for activities covered by this QAP
(i) nonconformance reports and corrective action reports
Personnel from the QA organization review and concur with quality-related procedures associated with design.

6.1 Review and Approval of Documents

Documents shall be reviewed for adequacy by qualified persons other than the preparer. Prior to issuance or use, documents including revisions thereto, shall be approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval. Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor

changes that do not require such a review and approval and the persons who can authorize such a classification shall be clearly delineated in implementing procedures.

6.3 NQA-1-1994 Commitment

In establishing provisions for document control, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

MHI-NESH has established the necessary measures and governing procedures to control the procurement of items and services to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services.

7.1 Acceptance of Item or Service

MHI-NESH establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity and the frequency of procurement. Verification actions include testing, as appropriate, during design, fabrication and construction activities. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.

- Prospective suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. Qualified suppliers are audited as follows:
  1) the supplier's QA program is audited on a triennial basis
  2) the triennial period starts when the first audit is performed
  3) an audit is initially performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

  In addition, if a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period.
  MHI-NESH may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet MHI-NESH requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, certificates of conformance, and document reviews

(including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by the Purchaser with appropriate input from the Supplier and be completed to ensure that procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.

- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.

- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

7.2 NQA-1-1994 Commitment

In establishing procurement verification controls, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 7S-1

  – MHI-NESH considers that other 10 CFR 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to MHI-NESH plants are not required to be evaluated or audited.

  – For Section 8.1, MHI-NESH considers documents that may be stored in approved electronic media under MHI-NESH or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to MHI-NESH to support operations. The MHI-NESH records management system will provide for timely retrieval of necessary records.

SECTION 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

This section is not applicable at this time (DC application).

SECTION 9 CONTROL OF SPECIAL PROCESSES

This section is not applicable at this time (DC application).

SECTION 10 INSPECTION

MHI-NESH does not perform inspection activity in the DC stage. Suppliers will perform this activity. So MHI-NESH requires suppliers to perform following items.

Suppliers shall establish the necessary measures and governing procedures to implement inspections that assure items, services and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Inspection may also be applied to items, services and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results shall be documented.

Inspection Program

The inspection program establishes inspections (including surveillance of processes), as necessary to verify quality:
(1) at the source of supplied items or services,
(2) in-process during fabrication at a Supplier's facility,
(3) for final acceptance of fabricated and/or installed items,
(4) upon receipt of items for a facility.

The inspection program establishes requirements for planning inspections, such as the group or discipline responsible for performing the inspection, where inspection hold points are to be applied, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and include qualified inspectors or engineers. Inspection plans are based on, as a minimum, the importance of the item to the safety of the facility, the complexity of the item, technical requirements to be met, and design specifications. Where significant changes in inspection activities for the facilities are to occur, management responsible for the inspection programs evaluate the resource and planning requirements to ensure effective implementation of the inspection program.

Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as: reject, acceptance, and reinspection results; and the person(s) performing the inspection.

Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

Inspector Qualification

Suppliers of MHI-NESH shall establish qualification programs for personnel performing quality inspections. The qualification program requirements are described in Section 2 of this QAP. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

10.1 NQA-1-1994 Commitment

– MHI-NESH commits to require suppliers to establish inspection requirements in accordance with NQA- 1-1994, Basic Requirement 10 and Supplement 10S-1.

SECTION 11 TEST CONTROL

MHI-NESH does not perform test activity except for under mentioned 11.2 in the DC stage. Suppliers will perform this activity. So MHI-NESH requires suppliers to perform following items.

Tests are performed according to applicable procedures that include, consistent with the effect on safety,
(1) instructions and prerequisites to perform the test,
(2) use of proper test equipment,
(3) acceptance criteria, and
(4) mandatory verification points as necessary to confirm satisfactory test completion.
Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, retesting is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

The tests are performed and results documented in accordance with applicable technical and regulatory requirements. The test programs ensure appropriate retention of test data in accordance with the records requirements of this QAP. The personnel performing or evaluating tests are qualified in accordance with the requirements established in Section 2 of this QAP.
Tests previously completed will be evaluated using the procedure described in section 2.6.

11.1 NQA-1-1994 Commitment

MHI-NESH commits to require suppliers to establish provisions for testing in accordance with NQA-1-1994, Basic Requirement 11 and Supplement 11S-1.

11.2 NQA-1-1994 Commitment for Computer Program Testing

MHI-NESH establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that the expected output is obtained and configuration control maintained. To this end MHI-NESH commits to compliance with the requirements of NQA-1-1994, Supplement 11S-2 and Subpart 2.7 to establish the appropriate provisions.

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

MHI-NESH does not perform the control of measuring and test equipment in the DC stage. Suppliers will perform this activity. So MHI-NESH requires suppliers to perform the following items.

Suppliers shall establish the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gages, tools, reference and transfer standards, and nondestructive examination equipment. Commercial-grade calibration services shall be controlled as described in Section 7 of this QAP.

12.1 NQA-1-1994 Commitment / Exceptions

MHI-NESH commits to require suppliers to establish provisions for control of measuring and test equipment, in accordance with NQA-1-1994, Basic Requirement 12 and Supplement 12S-1:

- The out of calibration conditions described in paragraph 3.2 of Supplement 12S-1 refers to when the M&TE is found out of the required accuracy limits (i.e. out of tolerance) during calibration.

- Measuring and test equipment are not required to be marked with the calibration status where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

This section is not applicable at this time (DC application).

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

This section is not applicable at this time (DC application).

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

MHI-NESH has established the necessary measures and governing procedures to control items, including services, which do not conform to specified requirements to prevent inadvertent installation or use. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements dispositioned repair or use-as-is, shall be subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with MHI-NESH procedures, regulatory requirements, and industry standards.

15.1 Reporting Program

MHI-NESH will establish the necessary measures and governing procedures that implement a reporting program which conforms to the requirements of 10 CFR 52 and 10 CFR 21 during design certification.

15.2 NQA-1-1994 Commitment

In establishing measures for nonconforming materials, parts, or components, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 15, and Supplement 15S-1.

SECTION 16 CORRECTIVE ACTION

MHI-NESH has established the necessary measures and governing procedures to promptly identify, control, document, classify and correct conditions adverse to quality. MHI-NESH procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. MHI-NESH procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, MHI-NESH documents establish the requirements for documentation and timely evaluation of the issue.
Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

In the case of suppliers working on safety-related activities, or other similar situations, the licensee may delegate specific responsibilities of the Corrective Action program but the licensee maintains responsibility for the program's effectiveness.

16.1 Reporting Program

MHI-NESH has in-place the necessary measures and governing procedures that implement a program to identify, evaluate and report defects and non-compliances in accordance with 10 CFR 52 and 10 CFR Part 21, as applicable. Such a reporting program applies to safety-related activities and services performed by MHI-NESH and/or MHI-NESH suppliers / sub-suppliers providing input to **DC** application development.

16.2 NQA-1-1994 Commitment

In establishing provisions for corrective action, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 16.

SECTION 17 QUALITY ASSURANCE RECORDS

MHI-NESH shall establish the necessary measures and governing procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for MHI-NESH and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, security controls, user privileges, and final disposition.

17.1 Record Retention

Measures are required to be established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. MHI-NESH maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses and computer programs) and the sources of input that support the final output. Such records and their retention times are defined in appropriate procedures. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

17.2 Electronic Records

When using electronic records storage and retrieval systems, MHI-NESH complies with NRC guidance Generic Letter 88-18, "Plant Record Storage on Optical Disks." MHI-NESH will manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18 and associated NIRMA Guidelines TG 11-1998, TG15-1998, TG16-1998, and TG21-1998.

17.3 NQA-1-1994 Commitment / Exceptions

In establishing provisions for records, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 17S-1
  - Supplement 17S-1, section 4.2(b) requires records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. For hard-copy records maintained by MHI-NESH, the records are suitably stored in steel file cabinets or on shelving in containers, except that methods other than binders, folders or envelopes may be used to organize the records for storage.

SECTION 18 AUDITS

MHI-NESH has established the necessary measures and governing procedures to implement audits to verify that activities covered by this QAP are performed in conformance with the requirements established. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

18.1 Performance of Audits

Internal audits of selected aspects of licensing, design phase are performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed. During the early portions of US-APWR Project activities, audits will focus on areas including, but not limited to, design control, procurement, and corrective action. Functional areas of an organization's QA program for auditing include at a minimum verification of compliance and effectiveness of implementation of internal rules, procedures (e.g., design, procurement, surveillance, test), regulations, programs for training, retraining, qualification and corrective actions associated record keeping. The audits are scheduled on a formal preplanned audit schedule. The audit system is reviewed periodically and revised as necessary to assure coverage commensurate with current and planned activities. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the NESQD Manager.

The MHI-NESH is responsible for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures (by representative sampling), and to determine if they are meaningful and comply with the overall QAP. External audits determine the adequacy of supplier and contractor quality assurance program.

The results of each audit are reported in writing to the responsible section manager, or designee, as appropriate. Additional internal distribution is made to other concerned management levels in accordance with approved procedures.

Management responds to all audit findings and initiates corrective action where indicated. 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.

Internal Audits

a. Internal audits should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter.

Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of this QAP; regulations; provisions for training, retraining, qualification, and performance of personnel performing activities covered

by this QAP; corrective actions taken following abnormal occurrences; and, observation of the performance of activities including associated record keeping.

b. Audits of suppliers of safety-related components and/or services are conducted as described in Section 7.1.

18.2 NQA-1-1994 Commitment

In establishing the independent audit program, MHI-NESH commits to compliance with NQA-1-1994, Basic Requirement 18 and Supplement 18S-1.

PART III NONSAFETY-RELATED SSC QUALITY CONTROL

PART III-1) Nonsafety Related SSCs - Significant Contributors to Plant Safety

Specific program controls are applied to non-safety related SSCs, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAP are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The following clarify the applicability of the QA Program to the nonsafety-related SSCs and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for nonsafety-related SSCs.

Section 1 Organization

The verification activities described in this part may be performed by the MHI-NESH line organization , the QA organization described in Part II is not required to perform these functions.

Section 2 QA Program

MHI-NESH QA requirements for nonsafety-related SSCs are contained in this QAP and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. These suppliers need not a new or separate QA program.

Section 3 Design Control

MHI-NESH shall establish design control measures to ensure that the contractually established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer's work.

Section 4 Procurement Document Control

Procurement documents for items and services obtained by or for MHI-NESH shall include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

Section 5 Instructions, Procedures, and Drawings

MHI-NESH shall provide documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed shall provide an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

Section 6 Document Control

MHI-NESH shall establish controls for the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superceded or obsolete documents.

Section 7 Control of Purchased Items and Services

MHI-NESH shall establish measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

Section 8 Identification and Control of Purchased Items

This section is not applicable at this time (DC application).

Section 9 Control of Special Processes

This section is not applicable at this time (DC application).

Section 10 Inspection

MHI-NESH does not perform inspection activity in the DC stage. Suppliers will perform this activity. So MHI-NESH requires the suppliers to perform following items.

Suppliers shall establish documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by personnel in the line organization through the independent verification (IV)/ simultaneous verification (SV), or similar process that utilizes knowledgeable personnel to perform the verification function.

Section 11 Test Control

MHI-NESH does not perform test in the DC stage. Suppliers will perform this activity. So MHI-NESH requires the suppliers to perform following items.

Suppliers shall establish measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

Section 12 Control of Measuring and Test Equipment (M&TE)

MHI-NESH does not perform the control of measuring and test equipment in the DC stage. Suppliers will perform this activity. So MHI-NESH requires the suppliers to perform following items.
Suppliers shall establish measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use.

Section 13 Handling, Storage, and Shipping

This section is not applicable at this time (DC application).

Section 14 Inspection, Test, and Operating Status

This section is not applicable at this time (DC application).

Section 15 Control of Nonconforming Items

MHI-NESH shall establish measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

Section 16 Corrective Action

MHI-NESH shall establish measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

Section 17 Records

MHI-NESH shall establish measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

Section 18 Audits

MHI-NESH shall establish measures for line management to periodically review and document the adequacy of the process and take any necessary corrective action, audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 18).

PART III-2) Nonsafety-Related SSCs Credited for Regulated Events

MHI-NESH commits to implement quality requirements to the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Operating Nuclear Power Plants."
MHI-NESH commits to implement quality requirements to ATWS requirement in accordance with Generic Letter 85-06 "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."
MHI-NESH commits to implement quality requirements to ATWS requirement in accordance with 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 System and Equipment," in RG 1.155, "Station Blackout."

PART IV REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides and the other quality assurance standards which have been selected to supplement and support the MHI-NESH QAP. MHI-NESH commits to compliance with these standards to the extent described herein. Commitment to a particular Regulatory Guide or other QA standard does not constitute a commitment to the Regulatory Guides or QA standards that may be referenced therein.

Regulatory Guides:

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

Regulatory Guide 1.26 defines classification of systems and components.

MHI-NESH commits to the applicable regulatory position guidance provided in this latest revision of regulatory guide for US-APWR project.

Regulatory Guide 1.29, Revision 4, March 2007 – Seismic Design Classification

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

MHI-NESH commits to the applicable regulatory position guidance provided in this latest revision of regulatory guide for US-APWR project.

Standards:

ASME NQA-1-1994 Edition – Quality Assurance Requirements for Nuclear Facility Applications

MHI-NESH commits to NQA-1-1994, Parts I and II, as described in the foregoing sections of this document.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)

MHI-NESH commits to NIRMA TGs as described in section 17 of this document.