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

PQD-HD-19005

Topical Report

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2	See Description	1. Revised to add Kobe Works in MHI to perform jobs such as stress analysis. Revised page: 2 to 8 2. The words "MHI-NESH" were replaced with the words "MHI-NESD" at related portions. Revised page: all 3. Revised as the results of the discussion for appropriate expression and the correction of editorial error. Revised page: 1, 9 to 11, 15, 18, 21, 24, 25, 33, 36 4. This revision does not represent a reduction of commitments described in the Safety Evaluation Report dated January 24, 2008.
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Revision History

Revision	Page	Description
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8	iv, v, 2 to 7	1. Revised in accordance with the change of the organization on April 1, 2014. The structure and name of the organization: Rearranged the management and designing organization without functional change.

POLICY STATEMENT

Energy & Environment in Mitsubishi Heavy Industries, Ltd. (MHI-EE) 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-EE 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-EE 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-EE'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-EE Quality Assurance Program.

Signed E. Kadokami / May 9. '14

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PART I INTRODUCTION

SECTION 1 GENERAL

The MHI-EE 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-EE. 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-EE 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-EE 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-EE 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-EE 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.

The definitions provided in ASME NQA-1, 1994 Part I Section I.4 apply to select terms as used in this document.

PART II QAP DETAILS

SECTION 1 ORGANIZATION

This Section describes the MHI-EE 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 MHI-EE US-APWR Project organization is responsible for US-APWR plant licensing, engineering, procurement and development activities. There are several organizations within MHI-EE 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-EE organization and the US-APWR Project organization are shown in Figures II.1-1 and II.1-2 respectively.

1.1 Senior General Manager and General Managers of Nuclear Energy Systems Division (NESD) of MHI-EE

The Senior General Manager of NESD of MHI-EE, who is assigned the most senior management of NESD of MHI-EE, is responsible for all aspects of design of MHI-EE's nuclear plants. The Senior General Manager of NESD of MHI-EE is responsible for the overall implementation of the Quality Assurance Program in MHI-EE. The Senior General Manager of NESD of MHI-EE is also responsible for all technical and administrative support activities provided by MHI-EE and contractors. The Senior General Manager of NESD of MHI-EE directs the Manager of APWR Project and the Directors of Reactor Core and Safety Engineering Department, Nuclear Electrical, Instrumentation & Control Engineering Department, Nuclear Plant Designing Department, Advanced Nuclear Plant Designing & Fuel Cycle Engineering Department, and Nuclear Plant Component Designing Department in fulfillment of their responsibilities. The Senior General Manager of NESD of MHI-EE is responsible to size the Quality Assurance organization commensurate with the duties and responsibilities assigned. The Senior General Manager of NESD of MHI-EE reports to the President of Mitsubishi Heavy Industries, Ltd. with respect to important business matters. The Senior General Manager of NESD of MHI-EE may delegate the above activities to the General Managers of NESD of MHI-EE.

1.1.1 APWR Project

APWR Project (APP) is responsible for US-APWR plant licensing, engineering and procurement activities.

1.1.1.1 Manager of APWR Project (APP Manager)

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

1.1.2 Engineering and Designing Departments

Engineering and Designing Departments are responsible for engineering and licensing. As shown in Figure II.1-2, for the US-APWR, the Directors of the Engineering and Designing Departments take project direction from the APP Manager.
The Engineering and Designing Departments Directors report to the APP Manager and are responsible for the administration of engineering and nuclear fuel under the QAP. The Engineering and Designing Departments Directors establish necessary written procedures to perform the activity in accordance with the requirements described in this QAP.

1.1.2.1 Director of Reactor Core & Safety Engineering Department (Director of RCSED)

The Director of RCSED reports to the APP Manager and is responsible for the engineering of Basic Design of Fuel & Core and Safety Analysis under the QAP.

1.1.2.2 Director of Nuclear Electrical, Instrumentation & Control Engineering Department (Director of NEICED)

The Director of NEICED reports to the APP Manager and is responsible for the engineering of Basic Design of I&C and Electrical System under the QAP.

1.1.2.3 Director of Nuclear Plant Designing Department (Director of NPDD)

The Director of NPDD reports to the APP Manager and is responsible for the piping design and the engineering of Basic Design of System and Plant under the QAP.

1.1.2.4 Director of Advanced Nuclear Plant Designing & Fuel Cycle Engineering Department (Director of ANPDFCED)

The Director of ANPDFCED reports to the APP Manager and is responsible for engineering and design of radioactive waste disposal system under the QAP.

1.1.2.5 Director of Nuclear Plant Component Designing Department (Director of NPCDD)

The Director of NPCDD reports to the APP Manager and is responsible for engineering and design of components under the QAP.

1.2 Quality Assurance

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

1.2.1 Director of Nuclear Energy Systems Safety & Quality Management Department (Director of NESSQMD)

The Director of NESSQMD reports to the Senior General Manager of NESD of MHI-EE for the design activities and is responsible for developing and maintaining the MHI-QAPD and the MHI-EE written procedures to perform the activity in accordance with the requirements described in this QAP, evaluating compliance to the programs and managing the QA organization resources.

The Director of NESSQMD has sufficient authority, access to work areas, and organizational freedom to:

(a) identify quality problems;
(b) initiate, recommend, or provide solutions to quality problems through designated channels;
(c) verify implementation of solutions; and
(d) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

Also, the Director of NESSQMD has sufficient independence from cost and schedule considerations.

The Director of NESSQMD has the overall responsibility for MHI-QAPD and performs the following functions to administer the activities in MHI-EE;

(a) to analyze the collected nonconformance(s), corrective action(s) and audit results, and provide the guideline to prevent the recurrence
(b) to confirm the activities in MHI-EE through reviewing, auditing and/or monitoring.

The Director of NESSQMD is responsible to assure that the activities in MHI-EE meet the requirements in this QAPD and that the MHI-EE written procedures correctly implement the requirements included in the QAPD. The Director of NESSQMD 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, parts, and materials to MHI-EE are meeting the requirements of 10 CFR 50, Appendix B through vendor audits. The Director of NESSQMD has sufficient independence to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas necessary regarding US-APWR Project activities in MHI-EE. The Director of NESSQMD may make recommendations to the US-APWR Project management regarding improving the quality of work processes. If the Director of NESSQMD disagrees with any actions taken by the US-APWR Project organization and is unable to obtain resolution, the Director of NESSQMD shall inform the Senior General Manager of NESD of MHI-EE who will determine the final disposition.

1.3 Authority to Stop Work

Quality assurance personnel in NESSQMD 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-NESD.

1.4 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.

1.6 NQA-1-1994 Commitment

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

Figure II.1-1

MHI-EE Organization

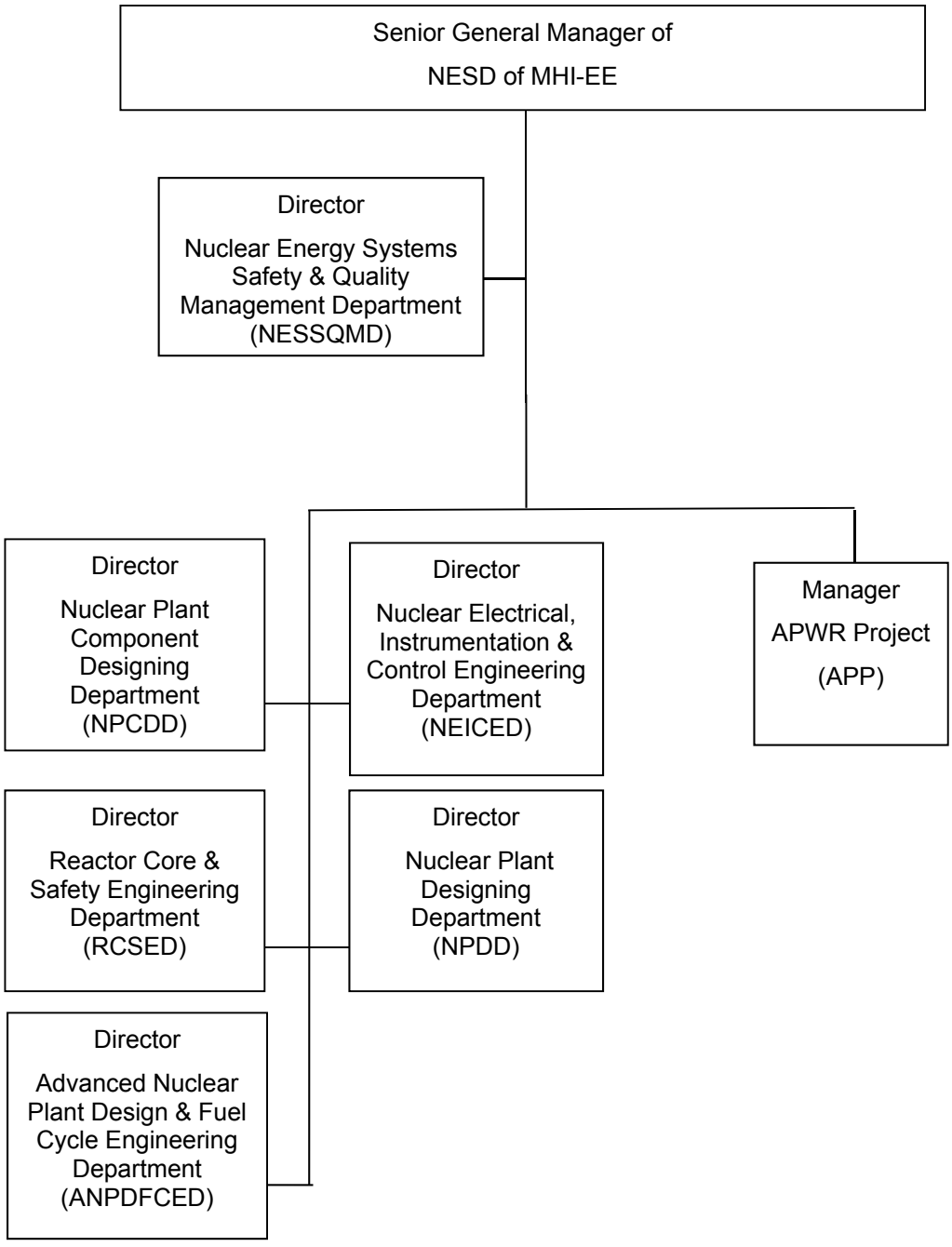
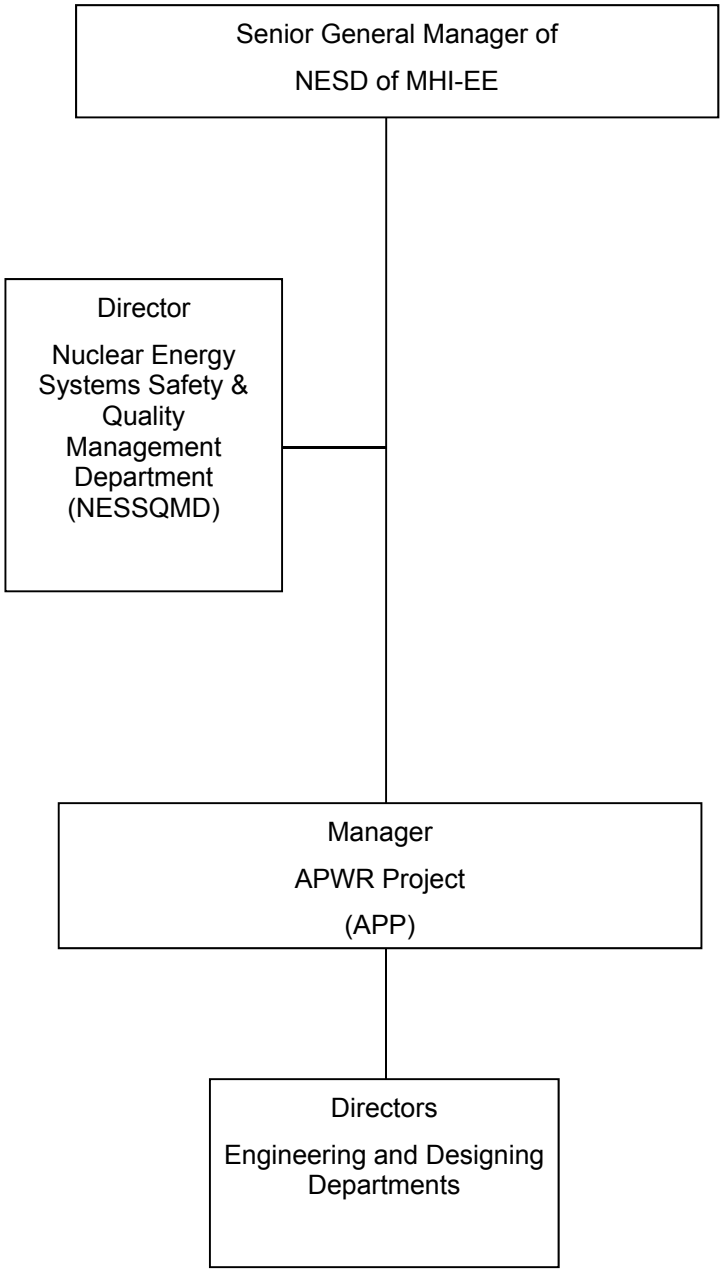


Figure II.1-2

US-APWR Project Organization



SECTION 2 QUALITY ASSURANCE PROGRAM

MHI-EE has established the necessary measures and governing procedures to implement the QAP as described in the QAP. MHI-EE 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-EE 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-EE 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.

As described in Part III of this 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 the supplier’s personnel provide added assurance 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-EE 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-EE 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 Director of NESSQMD 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-EE 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 to assure its effective implementation at least once each year or at least once during the life of the activity, whichever 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 NESSQMD 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 NESSQMD and approved by the Director of NESSQMD.

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-EE 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-EE 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 Director of NESSQMD are an engineering or related science degree and a minimum of four years of related experience with at least two years of nuclear power plant experience. During the four years, the individual shall have at least one year of supervisory or management experience, and 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-EE 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-EE, 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-EE 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-EE 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-EE 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-EE design organization or by other organizations so authorized by MHI-EE.

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

3.1 Design Verification

MHI-EE 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-EE 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-EE 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 non-safety-related applications. MHI-EE 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-EE 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-EE 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 / Exceptions

In establishing controls for procurement, MHI-EE 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-EE 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-EE procurement documents may allow the supplier to work under the MHI-EE 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-EE 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-EE 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-EE 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-EE commits to compliance with NQA-1-1994, Basic Requirement 5.

SECTION 6 DOCUMENT CONTROL

MHI-EE 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.

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-EE commits to compliance with NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

MHI-EE 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-EE 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-EE may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet MHI-EE 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 / Exceptions

In establishing procurement verification controls, MHI-EE 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-EE 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-EE plants are not required to be evaluated or audited.

  – For Section 8.1, MHI-EE considers documents that may be stored in approved electronic media under MHI-EE 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-EE to support operations. The MHI-EE 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-EE does not perform inspection activity in the DC stage. Suppliers will perform this activity. So MHI-EE 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.

10.1 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 includes 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 re-inspection 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.

10.2 Inspector Qualification

Suppliers of MHI-EE 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.

10.3 NQA-1-1994 Commitment

– MHI-EE 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-EE does not perform test activity except for under mentioned 11.2 in the DC stage. Suppliers will perform this activity. So MHI-EE 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-EE 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-EE 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-EE 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-EE does not perform the control of measuring and test equipment in the DC stage. Suppliers will perform this activity. So MHI-EE 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-EE 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, with the following clarifications and exceptions:

- 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-EE 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-EE procedures, regulatory requirements, and industry standards.

15.1 Reporting Program

MHI-EE 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-EE commits to compliance with NQA-1-1994, Basic Requirement 15, and Supplement 15S-1.

SECTION 16 CORRECTIVE ACTION

MHI-EE has established the necessary measures and governing procedures to promptly identify, control, document, classify and correct conditions adverse to quality. MHI-EE 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-EE 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-EE 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-EE 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-EE and/or MHI-EE suppliers / sub-suppliers providing input to DC application development.

16.2 NQA-1-1994 Commitment

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

SECTION 17 QUALITY ASSURANCE RECORDS

MHI-EE 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-EE 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-EE 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-EE complies with NRC guidance Generic Letter 88-18, “Plant Record Storage on Optical Disks.” MHI-EE 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-EE 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-EE, 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-EE 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 Director of NESSQMD.

The MHI-EE 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.

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-EE commits to compliance with NQA-1-1994, Basic Requirement 18 and Supplement 18S-1.

PART III NON-SAFETY-RELATED SSC QUALITY CONTROL

PART III-1) Non-safety-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 non-safety-related SSCs and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for non-safety-related SSCs.

Section 1 Organization

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

Section 2 QA Program

MHI-EE QA requirements for non-safety-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-EE 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-EE 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-EE 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-EE 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 superseded or obsolete documents.

Section 7 Control of Purchased Items and Services

MHI-EE 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-EE does not perform inspection activity in the DC stage. Suppliers will perform this activity. So MHI-EE 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 are performed by knowledgeable personnel who may be in the same line organization as those performing the activity in question, and are, at a minimum, as qualified as the person who performed the activity.

Section 11 Test Control

MHI-EE does not perform test in the DC stage. Suppliers will perform this activity. So MHI-EE 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-EE does not perform the control of measuring and test equipment in the DC stage. Suppliers will perform this activity. So MHI-EE 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-EE 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-EE shall establish measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

Section 17 Records

MHI-EE 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-EE 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) Non-safety-Related SSCs Credited for Regulated Events

MHI-EE 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-EE commits to implement quality requirements to ATWS equipment in accordance with Generic Letter 85-06 “Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related.”
MHI-EE commits to implement quality requirements for 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 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-EE QAP. MHI-EE 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-EE 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-EE 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-EE 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-EE commits to NIRMA TGs as described in section 17 of this document.