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Document Control Desk
U.S. Nuclear Regulatory Commission
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"

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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

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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

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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.

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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.