FINAL SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

TOPICAL REPORT NEDO-11209, REVISION 9

"GE HITACHI NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM DESCRIPTION"

GE HITACHI NUCLEAR ENERGY

PROJECT NO. 710

1.0 INTRODUCTION AND BACKGROUND

By letter dated June 30, 2010 (Reference 1), as supplemented by letter dated December 10, 2010 (Reference 2), GE Hitachi Nuclear Energy (GEH) submitted Topical Report (TR) NEDO-11209, Revision 9, "GE Hitachi Nuclear Energy Quality Assurance Program Description [QAPD]," (hereafter referred to as the Quality Assurance Topical Report (QATR)) to the U.S. Nuclear Regulatory Commission (NRC) for review and approval in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.4(b)(7)(ii). GEH proposed that this updated QATR would replace the current QATR for GEH, which was approved by the NRC as documented by letter dated March 31, 1989 (Reference 4).

2.0 REGULATORY EVALUATION

The NRC regulatory requirements related to quality assurance (QA) programs for non-licensees are set forth in 10 CFR 50.4(b)(7)(ii). This regulation requires that a change to an NRC-accepted QATR from non-licensees (i.e., architect/engineers, nuclear steam supply system (NSSS) suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC. When requested, the NRC will review the proposed QATR for acceptability to ensure the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes QA requirements for the design, construction and operation of structures, systems, and components (SSCs) of the facility. The relevant requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related functions of those SSCs including their design, purchase, fabrication, handling, shipping, storage, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modification.

3.0 TECHNICAL EVALUATION

3.1 Background

The proposed QATR is similar in many respects to previous submittals approved for licensees in accordance with NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description

[QAPD] – Design Certification, Early Site Permit and New License Applicants" (hereafter SRP 17.5). The original QAPD was based largely on commitments to the following: (1) Appendix B of 10 CFR Part 50, (2) Regulatory Guide (RG) 1.28, "Quality Assurance Program Requirements (Design and Construction)," (3) ANSI N45.2-1971, "Quality Assurance Program Requirements for Nuclear Power Plants," and (4) applicable sections of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code.

This QATR is based on ASME Nuclear Quality Assurance (NQA) Standard NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications" and NQA-1a-2009 Addenda. The QATR is organized into eighteen basic sections corresponding to the quality requirements delineated in Appendix B to 10 CFR Part 50 and is responsive to both Appendix B, as applicable, and the regulatory guidance set forth in RG 1.28, Revision 4. GEH considers the collective requirements of the QATR and Standards NQA-1-2008 and NQA-1a-2009 Addenda equivalent to the NRC staff guidance in SRP 17.5. SRP 17.5 outlines the NRC staff review of a standardized QA program and is based on the following documents: (1) ASME Standard NQA-1 (1994 Edition); (2) RG 1.8, "Qualification and Training of Personnel for Nuclear Power Plants;" (3) RG 1.28, "Quality Assurance Program Requirements (Design and Construction);" (4) RG 1.33, "Quality Assurance Program Requirements (Operation);" and (5) NRC Review Standard 002, "Processing Applications for Early Site Permits." The review approach of SRP 17.5 has previously been used by the NRC staff for evaluating the NQA-1-1994 standard as the basis for a QA Program.

The significant changes to the QA program in the GEH QATR are: (1) a commitment to NQA-1-2008 and NQA-1a-2009 Addenda (hereafter collectively NQA-1) as the basis for the QA Program, and (2) other changes made by GEH to allow for the use of new technology and methods not available in 1989. In the NRC staff's request for additional information (RAI)-6, the NRC staff requested that GEH provide a clarification as to whether the proposed QATR will implement Part II of NQA-1. In its response, GEH stated that Appendix A of the QATR was revised to clarify that the proposed QATR commits to Part I in its entirety and Part II for those activities within GEH's scope as an NSSS supplier as described in contract specific quality plans.

3.2 Evaluation

The NRC staff evaluated the adequacy of the QATR in describing how the requirements of Appendix B to 10 CFR Part 50 will be satisfied. The format and content of the QATR were evaluated in accordance with the guidance of SRP 17.5, which provides a basis for the NRC staff review of QA programs based on Standard NQA-1-1994. The acceptability of the level of detail provided by the QATR is in part determined by its adequacy in addressing the acceptance criteria of SRP 17.5.

3.2.1 Format and Content of the QATR

The format used for the NRC staff evaluation followed the sequence of the 18 criteria of Appendix B and corresponding provisions of NQA-1. The QATR provides guidance for establishing a top-level policy document that defines the quality requirements and assigns major functional responsibilities. The GEH QATR applies to work involving SSCs for nuclear power plants and fuel reprocessing plants that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. It is incumbent upon the client to identify the specific QA requirements that must be met for the scope of activities.

3.2.1.1 Organization

The QATR is the top-level policy document that establishes GEH's overall methodology regarding achievement and assurance of quality. Implementing documents provide more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QATR. Compliance with the QATR and implementing documents is mandatory for all GEH employees and contractors performing activities related to safety.

The QATR describes the organizational structure, functional responsibilities, and levels of authority and interfaces for establishing, executing, and verifying QA program implementation. GEH services are organized into business groups and functional support groups. This organizational structure can be categorized in three main elements: Profit & Loss Center (P&L), Support Organization, and Quality, which all report to the President. The P&L organization is comprised of several areas with financial responsibility for delivery of products and services. The support groups facilitate the activities of the P&L. The quality organization is responsible for providing oversight. In RAI-1 and RAI-2, the NRC staff requested descriptions of the different groups in Figure 1, "Organizational Structure" and Figure 2, "Functional Responsibilities," that were not described under the organization description. In its response, GEH revised the "organization description" and Figure 1 and Figure 2 to be more detailed and consistent with the use of organizational terminology.

The President and Chief Executive Officer (hereafter the "President") of GEH ensures that the size of the QA Division is commensurate with its duties and responsibilities. Policy, project instructions, and governing company standards are established to control quality-related activities. Specific implementing procedures are established to control activities in compliance with the requirements of the program. In RAI questions 3 and 4, the NRC staff requested that GEH show the location within its organization of the NQA Manager and the "Specific Quality Leaders" in Figure 1 and demonstrate how GEH planned to implement a direct line of communication between the NQA Manager, Specific Quality Leaders, and the President. In its response, GEH revised the organization description and Figure 1 to be more detailed about how a direct line of communication will be established with this revised QATR.

In establishing its organizational structure, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion I, and with NQA-1, Requirement 1. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH under this QAPD and concluded that the controls for the organizational structure meet the guidance in SRP 17.5.

3.2.1.2 QA Program

GEH has established the necessary measures and governing procedures to implement the QA Program described in the QATR. GEH policy makes compliance with the program mandatory for all employees and contractors performing quality-related activities. The QATR applies to work performed on safety-related SSCs that are within the scope of 10 CFR Part 50, Appendix B. The program is binding on all companies that have adopted this QATR including participating organizations, the President, all employees, and contractors whose activities may influence quality.

QA personnel monitor activities affecting quality and evaluate them in accordance with acceptance criteria to ensure satisfactory performance. These criteria are outlined in the implementing procedures. The President reviews the overall status and adequacy of the QA

Program. Managers review those portions of the program related to their area of responsibility to ensure effective implementation. These reviews take place at least once each fiscal year or at least once during the life of the activity whichever is shorter.

Personnel working directly or indirectly for GEH are responsible for the achievement of acceptable quality in their work covered by the QATR. Activities governed by the QA Program are performed as directed by documented instructions, procedures, and drawings that have a level of detail appropriate for the activity's complexity and effect on safety. The President establishes QA policy and objectives.

The President has delegated to the QA Manager the responsibility for providing and maintaining the QA Program policy and direction and for coordinating and verifying its implementation on projects. Personnel assigned to implement elements of the QA Program shall be capable of performing their assigned tasks. GEH establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QA Program to assure that suitable proficiency is achieved and maintained. Quality-related activities that require qualification of personnel are controlled by written procedures and only those personnel who have met the requirements are permitted to perform these activities.

In establishing its QA Program, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion II and NQA-1, Requirement 2. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for the program meet the guidance in SRP 17.5.

3.2.1.3 Design Control

GEH has established the necessary measures and governing procedures to control the design and design changes of items that are subject to the provisions of the QATR. The engineering organizations of the companies that have adopted this QATR have overall responsibility for the control of the design process from its inception to the final result. The design process includes provisions to control design inputs, outputs, changes, verification, interfaces, organizational interfaces, and records. Design change control follows the same review process as the original design. Procedures provide guidance and specify methods for performing design verification. Design verification reviews are performed by qualified personnel other than those who performed the original design. Design analyses are required to be sufficiently detailed to permit design verification without recourse to the originator.

In RAI-7, the NRC staff requested that GEH describe the criteria established by the QATR for a pre-verified computer program. In its response, GEH stated that paragraph 3.4.1 of the QATR was revised to include the criteria to be implemented by GEH to verify the result of computer programs used for design analysis. During design reviews, design documents are reviewed against requirements of the applicable design criteria and/or other supporting documents in accordance with procedures established by the design organization conducting the reviews.

In RAI-8, the NRC staff requested that GEH describe the process to be used if a significant design change is necessary as a result of an incorrect design. In its response, GEH stated that paragraph 3.6 was added to the QATR to address this particular situation. Responsibility to initiate and approve any required design changes is assigned to the same groups or organizations that reviewed and approved the original design documents. The design change control procedure requires documentation of the change and approval by the responsible engineering organization.

In establishing provisions for design control, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion III and NQA-1, Requirement 3. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for design meet the guidance in SRP 17.5.

3.2.1.4 Procurement Document Control

GEH has established the necessary measures and governing procedures to verify that a statement of the scope of work to be performed and other requirements necessary to ensure quality are included or referenced in GEH-originated documents for procurement of equipment, materials, components, and services. GEH procurement documents include information and requirements such as the following:

(1) statement of the scope of work, applicable regulatory standards and code requirements, drawings, test and inspection requirements, and information that describe the items or services to be furnished;

(2) reference to the supplier's documented QA Program that has been reviewed and determined to meet the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the circumstances of the procurement. Alternately, suppliers may work to the GEH QA Program and implementing procedures;

(3) acceptance and/or rejection criteria;

(4) identification of QA records to be controlled, maintained, retained and/or delivered to GEH for information, review or approval (retention times and disposition requirements are specified for records to be retained); and

(5) provisions for the supplier to submit nonconformances together with their recommended disposition (use as is, reject, rework, or repair), including the technical justification, to GEH for review and approval and, if required, recommendation of disposition to the client.

Procurement documents are prepared, reviewed, and approved by the appropriate disciplines and issued in a sequence of steps prescribed in accordance with standard operating procedures prior to release for fabrication, construction, or installation of items or performance of services. A changes and/or revisions to a procurement document are subject to the same level of review and approval as the original procurement document.

In establishing controls for procurement documents, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion IV and NQA-1, Requirement 4. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for the procurement documents meet the guidance in SRP 17.5.

3.2.1.5 Instructions, Procedures, and Drawings

GEH has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed and performed in accordance with procedures, work instructions, or drawings of a type appropriate for the circumstances and include quantitative or qualitative acceptance criteria to implement the QA Program as described in the QATR. GEH implementing procedures and/or work instructions are prepared to describe the activity to a level

of detail that is based on one or more of the following: the complexity of the task, the need to ensure consistent and acceptable results, the significance of the item, the work environment, or worker proficiency and ability.

In establishing procedural controls, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion V and NQA-1, Requirement 5. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for instructions, procedures, and drawings meet the guidance in SRP 17.5.

3.2.1.6 Document Control

GEH 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 ensure that correct documents are being employed. The program and implementing procedures include measures which ensure that documents, including changes, are reviewed for adequacy and inclusion of quality requirements and approved for release by authorized personnel. GEH maintains a listing of all controlled documents that identify the current revision. The list is available to all personnel in order to determine the appropriate document for use.

In establishing document controls, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion VI, and NQA-1, Requirement 6. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the provisions for the document control program meet the guidance in SRP 17.5.

3.2.1.7 Control of Purchased Material, Equipment, and Services

GEH has established the necessary measures and procedures to ensure that purchased items and services are clearly and adequately specified in procurement documents, and that suppliers are capable of producing items and furnishing services that conform to procurement document requirements. Controls shall provide for the following, as appropriate:

(1) provisions for supplier evaluation,

(2) review of procurement requirements, and

(3) surveillance of the supplier.

In establishing a program for the control of items and services, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion VII and NQA-1, Requirement 7 with exceptions or alternatives. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the program for the control of purchased material, equipment, and services meets the guidance in SRP 17.5.

3.2.1.7.1 Evaluation of GEH's QA Program Proposed Clarifications, Exceptions, or Alternatives

GEH proposed a revised version of NQA-1, Part I, Requirement 7, Section 600, "Control of Supplier Nonconformance," paragraph 600(b). GEH rewrote the paragraph to remove the generalized title of "Purchaser" and customized it to GEH requirements of the QATR.

The NRC staff reviewed the proposed revision of Paragraph 600(b) located in the second paragraph of Section 7.5, “Control of Supplier Nonconformances,” of the QATR. The NRC staff found this alternative acceptable based on the guidance in SRP 17.5, Paragraph II.G.14. This section states that the “purchaser is required to approve the supplier’s recommended disposition and technical justification for nonconformances.” The NRC staff found the GEH alternative equivalent to the NRC staff guidance.

GEH considers 10 CFR Part 50 licensees, Authorized Nuclear Inspection Agencies (AIAs), the National Institute of Standards and Technology (NIST), or other state and federal agencies, which may provide items or services to GEH, as not requiring evaluation or audit.

The NRC staff determined that neither NQA-1 or SRP 17.5 have requirements or guidance stating that licensees, an AIA, NIST, or other state and federal agencies providing items or services, be evaluated or audited. Therefore, the NRC staff determined that GEH’s proposal of not evaluating such entities is acceptable.

GEH proposed that when purchasing commercial-grade calibration services from a domestic calibration laboratory, procurement source evaluation and selection measures do not need to be performed, provided that certain conditions, as stated in the QATR, Section 7.10, are met. The NRC staff determined that the QATR wording was equivalent to the guidance in SRP 17.5, paragraphs II.L.8.a.-i. Therefore, the NRC staff found the GEH alternative equivalent to the NRC staff’s guidance.

GEH proposed that requirements for control of commercial-grade items and services will be established in GEH documents using 10 CFR Part 21 and the guidance of Electric Power Research Institute NP-5652 as discussed in Generic Letter (GL) 89-02 and GL 91-05. Dedication is outside the scope of NRC staff guidance provided in SRP 17.5. Subpart 2.14 of NQA-1 addresses commercial-grade items. GEH proposed controls do not contradict the requirements in NQA-1 or any NRC staff guidance on commercial-grade dedication. Therefore, the NRC staff found the proposed alternative equivalent to the NRC staff’s guidance.

3.2.1.8 Identification and Control of Materials, Parts, and Components

GEH has the necessary measures and governing procedures for the identification and control of materials, parts, and components to prevent the shipment or use of incorrect or defective items. This includes controls for consumable materials and items with a limited shelf life. The identification of items is maintained throughout fabrication, erection, installation, and use, such that the item can be traced to its documentation, consistent with the item’s effect on safety.

Identification is maintained throughout the life of the product, component, part, or item. Identification is accomplished using heat numbers, part numbers, serial numbers, or other appropriate means. The identification is located either on the item or on records traceable to the item. Locations and methods of identification are selected so as not to affect the function or quality of the item.

In establishing provisions for identification and control of items, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion VIII and NQA-1, Requirement 8. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for the identification and control of materials, parts, and components meet the guidance in SRP 17.5.

3.2.1.9 Control of Special Processes

GEH has established the necessary measures and governing procedures to ensure that special processes such as welding, heat treating, and nondestructive examination are controlled. These provisions include ensuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Special processes are performed in accordance with applicable codes, standards, specifications, criteria, or other established requirements. Special processes are those where the results are highly dependent on the control of the process, the skill of the operator, or both, and for which the specified quality cannot be readily determined by inspection or test of the final product.

In establishing measures for the control of special processes, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion IX and NQA-1, Requirement 9. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for special processes meet the guidance in SRP 17.5.

3.2.1.10 Inspection

GEH has established the necessary measures and governing procedures to implement inspections that ensure items, services, and activities affecting safety meet established requirements and conform to documented instructions, procedures, and drawings. Types of inspections may include, but are not limited to: source, in process, final, receipt, maintenance, modification, in-service and operations. Inspections are carried out by properly qualified personnel independent of those who performed or directly supervised the work. Inspection results are documented by the inspector and reviewed by authorized personnel qualified to evaluate the inspection.

In establishing inspection requirements, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion X and NQA-1, Requirement 10. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for inspection activities meet the guidance in SRP 17.5.

3.2.1.11 Test Control

GEH has established the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QATR will be tested for qualifying, demonstrating, or ensuring the quality of procured items or services. The GEH test program includes provisions for ensuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. Test results are documented and evaluated by the responsible organization to assure that the test requirements have been satisfied.

Additionally, GEH has established and implemented provisions to ensure that computer software used in applications affecting safety is prepared, documented, verified, tested, and used such that the expected output is obtained and configuration control is maintained.

In establishing test control requirements, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XI and NQA-1, Requirement 11. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the test control requirements meet the guidance in SRP 17.5.

3.2.1.12 Control of Measuring and Test Equipment

GEH has established the necessary measures and governing procedures to control the calibration, maintenance, storage and use of measuring and test equipment. The procedures cover equipment such as indicating and actuating instruments and gauges, tools, reference and transfer standards, and nondestructive examination equipment. Measuring and test equipment are calibrated at prescribed intervals whenever the accuracy of the measuring and test equipment is suspect, or prior to use. This activity is controlled by an approved procedure that requires adequate documentation of calibration.

In establishing a measuring and test equipment calibration program, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XII and NQA-1, Requirement 12. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for measuring and test equipment meet the guidance in SRP 17.5.

3.2.1.13 Handling, Storage, and Shipping

GEH established the necessary measures and governing procedures to control the handling, storage, packaging, shipping, clearing, and preservation of items to prevent inadvertent damage or loss and to minimize deterioration. Items are appropriately marked and labeled during packaging, shipping, handling and storage to identify, maintain and preserve the item's integrity and indicate the need for special controls. Special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels and temperature levels) are provided when they are required to maintain acceptable quality.

In RAI-9, the NRC staff requested GEH to describe the controls they have in place to minimize the deterioration of items under special environmental conditions. In its response, GEH stated that Paragraph 13.3 of the QATR was revised to include controls that will be implemented under special environmental conditions to minimize deterioration of items.

In establishing provisions for handling, storage, and shipping, GEH commits to compliance with Appendix B to10 CFR Part 50, Criterion XIII and NQA-1, Requirement 13. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for handling, storage, and shipping meet the guidance in SRP 17.5.

3.2.1.14 Inspection, Test, and Operating Status

GEH has established the necessary measures and governing procedures to identify the inspection and test status of individual items and for indicating the operating status of equipment, such as valves and switches. Implementing procedures specify the authority for the application and removal of these status indicators. In RAI-10, the NRC staff requested GEH to clarify if the scope of the QATR will establish requirements to control temporary modifications, such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point settings. In its response, GEH stated that the QATR is not intended to include these requirements because independent verification of temporary modifications is applicable to operating plants and is outside of GEH's scope as an NSSS supplier. The inspection and test status is maintained through the use of physical location, status indicators (such as tags, markings, shop travelers, stamps, and inspection records), or other suitable means.

In establishing measures for control of inspection, test, and operating status, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XIV and NQA-1, Requirement 14. As

set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for the inspection, test, and operating status meet the guidance in SRP 17.5.

3.2.1.15 Nonconforming Materials, Parts, or Components

GEH has established the necessary measures and governing procedures to control items that do not conform to specified requirements and to prevent inadvertent test, installation, or use. GEH's controls provide for identification, documentation, evaluation, segregation when practical, disposition of nonconforming items, and notification to affected organizations. Nonconforming items are identified by marking, tagging, or other methods not detrimental to the item, on the item, the container, or the package containing the item. Nonconformance evaluation and disposition are defined in implementing procedures. Personnel performing evaluations to determine a disposition are qualified to:

(1) demonstrate competence in the specific area they are evaluating,

(2) possess an adequate understanding of the requirements, and

(3) access pertinent background information.

Nonconformances to design requirements dispositioned "use-as-is" or "repair" are subject to design control measures commensurate with those applied to the original design.

In establishing provisions for nonconforming material, parts, or components, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XV and NQA-1, Requirement 15. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for handling nonconforming material, parts, or components meet the guidance in SRP 17.5.

3.2.1.16 Corrective Action

GEH has established the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality (CAQs). Implementing procedures ensure that appropriate actions are initiated following the determination of CAQs in accordance with regulatory requirements. GEH procedures require personnel to identify known CAQs in a timely manner so that corrective actions are adequately documented and not inadvertently nullified by subsequent actions. Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance. Significant conditions and trends adverse to quality are reported to the appropriate level of management.

In establishing corrective action requirements, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XVI and NQA-1, Requirement 16. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for corrective action meet the guidance in SRP 17.5.

3.2.1.17 QA Records

GEH has established 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 for the records retention program and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, and final disposition.

Additionally, GEH has established the necessary provisions for the generation, distribution, use, maintenance, storage, and disposition of quality records in electronic media. GEH procedures identify the acceptable media on which electronic records are created and stored.

In establishing a QA records program, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XVII, NQA-1, Requirement 17, Generic Letter 88-18, and RIS 2000-18. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for QA records meet the guidance in SRP 17.5.

3.2.1.18 Audits

GEH has established the necessary measures and governing procedures to verify compliance with QA Program requirements, to verify that performance criteria are met, to determine the effectiveness of the program, and to provide a comprehensive independent evaluation of activities and procedures covered by this QATR. GEH utilizes a system of planned audits and surveillances to verify compliance and assess the effectiveness of all aspects of GEH's program and implementing procedures. Audits are performed in accordance with written procedures or checklists by qualified personnel who do not have direct responsibility for performing the activities being audited. An audit schedule is documented at the beginning of each year to document the planned, periodic coverage of internal functions performing quality-related activities and evaluation of the performance of suppliers.

In RAI-11, the NRC staff requested that GEH describe the QA measures used to ensure that audits of covered activities within the scope of the QATR will be completed at least once per year or at least once during the life of the activity. In its response, GEH stated that Paragraph 18.3.1 of the QATR was revised to address this requirement by adding the following sentence: "Activities with durations of less than one year are audited at least once during the life of the activity." GEH's audit schedule is reviewed periodically and revised to ensure that coverage is current.

In establishing an audit program, GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XVIII, NQA-1, Requirement 18 and RIS 2000-18. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the controls for the audit program meet the guidance in SRP 17.5.

4.0 CONCLUSION

The NRC staff evaluated GEH's QATR (Reference 5) submittal and the supplemental correspondence. The NRC staff concludes that GEH's QA Program description, including alternatives, adequately addresses the requirements of Appendix B to 10 CFR Part 50 and is acceptable.

5.0 REFERENCES

1. Letter from GEH to NRC, MFN 10-181, "Revised Version of the GE Hitachi, Nuclear Energy, Topical Report NEDO 11209, entitled 'GE Hitachi Nuclear Energy Quality Assurance Program Description,'" dated June 30, 2010. ADAMS Accession No. ML101830319.

2. Letter from GEH to NRC, MFN 10-354, "Response to NRC RAIs on GE Hitachi Nuclear Energy Topical Report NEDO-11209, Revision 9," dated December 10, 2010. ADAMS Accession No. ML103480313.

3. Letter from NRC to GEH, "Request for Additional Information Re: GE-Hitachi Nuclear Energy (GEH) Topical Report NEDO-11209, Revision 9, 'GE Hitachi Nuclear Energy Quality Assurance Program Description' (TAC No.4483)," dated November 10, 2010. ADAMS Accession No. ML103090076.

4. Letter from NRC to GE Nuclear Energy, "Acceptance of Amendment 8 to General Electric Company (GE) QA Topical Report," dated March 31, 1989. ADAMS Accession No. ML022810092.

5. TR NEDO-11209, Revision 9, "GE Hitachi Nuclear Energy Quality Assurance Program Description," dated December 9, 2010. ADAMS Accession No. ML103480314.

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