

January 16, 2015

Mr. Jerald G. Head  
Senior Vice President, Regulatory Affairs  
General Electric-Hitachi  
Nuclear Energy Americas, LLC  
P.O. Box 780, M/C A-18  
Wilmington, NC 28401-0780

SUBJECT: FINAL SAFETY EVALUATION FOR GENERAL ELECTRIC HITACHI NUCLEAR ENERGY AMERICAS, LLC TOPICAL REPORT NEDO-11209, "GE HITACHI NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM DESCRIPTION," REVISION 11 (TAC NO. MF3792)

Dear Mr. Head:

By letter dated March 31, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14090A330), GE Hitachi Nuclear Energy Americas, LLC (GEH) submitted Topical Report (TR) NEDO-11209, "GE Hitachi Nuclear Energy Quality Assurance Program Description" Revision 11, to the U.S. Nuclear Regulatory Commission (NRC) staff for review.

By letter dated November 14, 2014, an NRC draft safety evaluation (SE) regarding our approval of NEDO-11209, Revision 11, was provided for your review and comment (ADAMS Accession No. ML14316A349). The NRC staff's disposition of the GEH comments on the draft SE are presented in the attachment to the final SE enclosed with this letter.

The NRC staff has found that NEDO-11209, Revision 11, is acceptable for referencing in licensing applications for nuclear power plants to the extent specified and under the limitations delineated in the TR and in the enclosed final SE. The final SE defines the basis for our acceptance of the TR.

Our acceptance applies only to material provided in the subject TR. We do not intend to repeat our review of the acceptable material described in the TR. When the TR appears as a reference in license applications, our review will ensure that the material presented applies to the specific plant involved. License amendment requests that deviate from this TR will be subject to a plant-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC website, we request that GEH publish the approved TR NEDO-11209, Revision 11, within three months of receipt of this letter. The approved version shall incorporate this letter and the enclosed final SE Supplement after the title page. Also, it must contain historical review information, including NRC requests for additional information and your responses. The approved version shall include an "-A" (designating approved) following the TR identification symbol.

J. Head

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If future changes to the NRC's regulatory requirements affect the acceptability of this TR, GEH and/or licensees referencing it will be expected to revise the TR appropriately, or justify its continued applicability for subsequent referencing.

Sincerely,

*/RA/*

Aby S. Mohseni, Deputy Director  
Division of Policy and Rulemaking  
Office of Nuclear Reactor Regulation

Project No. 710

Enclosure: Final Safety Evaluation

cc w/encl: See next page

J. Head

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**NRR-106**

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GE-Hitachi Nuclear Energy Americas

Project No. 710

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SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS  
GENERAL ELECTRIC (GE) HITACHI NUCLEAR ENERGY AMERICAS, LLC.  
QUALITY MANAGEMENT SYSTEM, QUALITY ASSURANCE TOPICAL REPORT  
NEDO-11209, REVISION 11 "GE HITACHI NUCLEAR ENERGY QUALITY  
ASSURANCE PROGRAM DESCRIPTION" PROJECT NO. 710

1.0 INTRODUCTION

By letter dated March 31, 2014 (Reference 1), GEH submitted quality management system (QMS) quality assurance (QA) topical report (QATR) NEDO-11209, Revision 11, "GE Hitachi Nuclear Energy Quality Assurance Program Description [QAPD]," 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 January 11, 2011 (Reference 5).

2.0 REGULATORY BASIS

The NRC regulatory requirements related to 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 nuclear facilities. 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

In evaluating the adequacy of the GEH QMS QATR, the NRC staff used the guidance contained in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," SRP Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," dated March 2007 (Reference 4) hereafter referred to as standard review plan (SRP) Section 17.5, which provides acceptance criteria for design certification, early site permit, combined operating license, construction permit, and operating license applicants. SRP Section 17.5 is based on American Society of Mechanical Engineers

ENCLOSURE

(ASME) Standard NQA-1-1994 Edition, as supplemented by additional regulatory and industry guidance for nuclear operating facilities. ASME Standard NQA-1-2008 and the NQA-1a-2009 Addenda, upon which the GEH QATR is based, incorporated the supplemental guidance into a single document, and is therefore in alignment with SRP Section 17.5. In addition, NQA-1-2008 and the NQA-1a-2009 Addenda, hereafter referred to as NQA-1-2008, is endorsed by NRC Regulatory Guide (RG) 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 4.

### 3.1 BACKGROUND

The proposed GEH QMS QATR is similar in many respects to previous submittals approved for licensees in accordance with NUREG-0800, Section 17.5. The original QAPD was based largely on commitments to the following: (1) Appendix B of 10 CFR Part 50, (2) 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 ASME Boiler and Pressure Vessel Code.

This QATR is based on GEH commitment to 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and 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 NQA-1-2008 and NQA-1a-2009 Addenda equivalent to the NRC staff guidance in SRP Section 17.5.

NUREG-0800, SRP Section 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 Section 17.5 has previously been used by the NRC staff for evaluating the NQA-1-1994 standard as the basis for a QA Program.

### 3.2 EVALUATION

The NRC staff evaluated the adequacy of the GEH QMS 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 Section 17.5, which provides a basis for the NRC staff's review of QA programs based on the NQA-1-2008 Standard. 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 Section 17.5.

In January 2011, the U.S. NRC staff approved NEDO-11029, "GE Hitachi Quality Assurance Program Description," Revision 9. In March 2014, GEH submitted

Revision 11 to the NRC, but did not submit Revision 10. GEH provided Enclosure 2, "Roadmap for NEDO-11209, Revision 11," which covered NEDO-11209, Revision 9 mapping to Revision 10 and 11. In the Table, the NRC staff identified five changes made in NEDO-11209, Revision 10, to Section 1.1, Section 1.4.2.2, Section 1.4.3.1, and Section 18.4.

On August 18, 2014, the NRC staff requested that GEH (Reference 6) verify that these were all the QA changes made to NRC approved NEDO-11209, Revision 9, that were incorporated into NEDO-11209, Revision 10. The NRC staff's purpose was to verify that GEH's Revision 10 of the QAPD remained acceptable in accordance with 10 CFR 50.4(b)(7)(ii). This was Request for Additional Information (RAI) 1. On August 29, 2014, GEH responded to RAI 1 (Reference 7). The NRC staff confirmed that all of the QA changes made in GEH NEDO-11209, Revision 10, were acceptable and incorporated into GEH NEDO-11209, Revision 11. This resolved RAI 1.

### 3.2.1 Format and Content of the QATR

The format used for the NRC staff's 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 vendor QA scope of work activities.

#### 3.2.1.1 ORGANIZATION

In Part II, "QAPD Details," Section 1.0, "ORGANIZATION," GEH made the following organizational changes: (1) added ISO9001 and GS-R-1 industry guidance; (2) added Nuclear Fuels & Services subsection 1.3.1.1; (3) added Nuclear Plant Projects subsection 1.3.1.2; (4) modified Nuclear Oversight Organization in subsection 1.3.2 to add support organizations; (5) renamed "Nuclear Oversight" in subsection 1.3.3 with added support organizations; (6) removed duplicate items in subsection 1.4.1 for the President and Chief Executive Officer, and moved duplicate items to the GEH QAPD Statement of Policy and added responsibility items 2 and 4; (7) renamed the "Quality Leader," as the Nuclear Oversight Senior Vice President," and added responsibility items 2, 3, and 5; (8) renamed the "Nuclear Quality Assurance Leader," as the "Quality Oversight Leader in subsection 1.4.2.1 with clarified responsibilities for this position; (9) modified the responsibilities to remove audit functions for Profit and Loss Quality Leaders in subsection 1.4.3.1; (10) added the Sourcing General Manager in subsection 1.4.4; (11) added the responsibilities of employees and contractors in Section 1.5; (12) updated organizational structures and clarified conditions for issuing a "stop work;" in Section 1.6; and (13) added section with delegation authority inside the GEH Organization in Section 1.7.

In Section 1.8, "Commitments," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion I, and NQA-1-2008 and NQA-1a-2009, Addenda, Requirement 1. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in

QAPD Section 1.0 and concluded that the controls for the organizational structure meet the guidance in SRP Section 17.5, Section A, "ORGANIZATION (Criteria I)."

### 3.2.1.2 QUALITY ASSURANCE PROGRAM (QAP)

In Part II, "QAPD Details," GEH made changes to QAPD Section 2.0, "QUALITY ASSURANCE PROGRAM." The NRC staff reviewed and found acceptable the minor editorial changes to QAPD Sections 2.1, "General," through 2.7, "Grace Period." However, GEH made significant QAP management changes to QAPD Section 2.8, "Quality Assurance Program Description Management." Specifically, changes to QAPD Section 2.8 included:

1. Changes that are made to the QAPD are submitted to the NRC for review and approval per 10 CFR 50.4(b)(7)(ii).
2. In addition to QAP changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:
  - (a) The use of a QA standard approved by the NRC which is more recent than the QA standard in the QAPD at the time of the change;
  - (b) The use of a QA alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to GEH;
  - (c) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;
  - (d) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;
  - (e) The elimination of QAP information that duplicates language in quality assurance RGs and QA standards to which GEH is committed;
  - (f) Organizational revisions that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations; and
  - (g) Any change to Part III, "Supplemental Details," or Part IV, "References," that do not entail NRC related standards (i.e., ISO 9001, KTA-1401, GS-R-3).

The NRC staff reviewed the regulations in 10 CFR 50.54(a)(3)(i) through 10 CFR 50.54(a)(3)(vi) and determined that GEH QAPD Section 2.8, Items (a) through (f) noted above, are not applicable to GEH since GEH is an NSSS vendor, not a licensee. The

requirements of 10 CFR 50.4(b)(7)(ii) for changes to a vendor's QA program do not permit vendors to evaluate whether or not changes to an NRC accepted vendor QAPD are reductions in commitment. The NRC staff requested that GEH clarify its process for evaluating potential reductions in commitment. On August 18, 2014, the NRC staff sent GEH NRC RAI 2 on this issue (Reference 6).

On August 29, 2014, GEH responded to RAI 2 (Reference 7). On September 11, 2014, the NRC staff conducted a conference call with GEH to clarify GEH's use of 10 CFR 50.54(a)(3) and 10 CFR 50.54(a)(4). The NRC staff reiterated an Office of General Counsel interpretation on the applicability of this regulation. On September 23, 2014, GEH again responded to RAI 2 by removing use of the regulations in 10 CFR 50.54(a)(3) and 10 CFR 50.54(a)(4) for QA reductions in commitments (Reference 8). GEH submitted changes to the GEH QAPD, Revision 11, appropriately applying the regulation in 10 CFR 50.4(b)(7)(ii). This resolved RAI 2.

With respect to Part III, "Supplemental Details," and Part IV, "References," that do not involve NRC regulations or related standards (i.e., ISO 9001, GS-R-3, KTA-1401, and GS-R-3), the NRC staff determined that GEH may use these industry standards at their own discretion without prior NRC review and approval as long as these industry standards do not conflict with 10 CFR Part 50, Appendix B, for safety related components.

In GEH QATR QAPD Section 2.9, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion II, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 2. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 2.0 and concluded that the controls for the QAP meet the guidance in SRP Section 17.5, Section B, "QUALITY ASSURANCE PROGRAM (Criteria II)."

### 3.2.1.3 DESIGN CONTROL

In Part II, "QAPD Details," GEH made changes to Section 3.0, "DESIGN CONTROL." The NRC staff reviewed and found acceptable editorial changes to the QAPD which added: (1) Sections 3.2, "Design Inputs," (2) Subsection 3.3.3, "Design Results;" bullet items 4, 5, and 6; (3) Subsection 3.4.3, "Design and Development Review;" (4) Subsection 3.5.4, "Extent of Design Verification;" added item 1 with the words "state of the art;" (5) Subsection 3.5.6, "Design and Development Validation," and (6) Section 3.6, "Change Control," added items 7 and 8.

In GEH QATR QAPD Section 3.10, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion III, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 3. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 3.0 and concluded that the controls for design meet the guidance in SRP Section 17.5, Section C, "DESIGN CONTROL AND VERIFICATION (Criteria III)."

#### 3.2.1.4 PROCUREMENT DOCUMENT CONTROL

In Part II, "QAPD Details," GEH made minor editorial changes to Section 4.0, "PROCUREMENT DOCUMENT CONTROL." In Section 4.5, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion IV, NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 4. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 4.0 and concluded that the controls for procurement documents meet the guidance in SRP Section 17.5, Section D, "PROCUREMENT DOCUMENT CONTROL (Criteria IV)."

#### 3.2.1.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

In Part II, "QAPD Details," GEH made minor editorial changes to GEH QAPD Section 5.0, "INSTRUCTIONS, PROCEDURES AND DRAWINGS." In Section 5.4, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion V, NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 5. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 5.0 and concluded that the controls for instructions, procedures, and drawings meet the guidance in SRP Section 17.5, Section E, "INSTRUCTIONS, PROCEDURES, AND DRAWINGS (Criteria V)."

#### 3.2.1.6 DOCUMENT CONTROL

In Part II, "QAPD Details," GEH made minor editorial changes to GEH QAPD Section 6.0, "DOCUMENT CONTROL." In Section 6.5, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion VI and NQA-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 6. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 6.0 and concluded that the controls for documents meet the guidance in SRP Section 17.5, Section F, "DOCUMENT CONTROL (Criteria VI)."

#### 3.2.1.7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

In Part II, "QAPD Details," GEH made changes to Section 7.0, "CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES."

1. In GEH QATR QAPD Section 7.10, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion VII, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 7, with the following exceptions:
  - GEH considers 10 CFR Part 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 GEH, as not requiring evaluation or audit.
  - When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:

- The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the GEH QAP and technical provisions. At a minimum, the purchase document will require that the calibration certificate/report include identification of the laboratory equipment/standard used.
  - The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
  - A documented review of the supplier's accreditation will be performed and will include a verification of each of the following:
    - The calibration laboratory holds a domestic accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP), the American Association for Laboratory Accreditation (A2LA), ACLASS Accreditation Services, Laboratory Accreditation Bureau (LAB), International Accreditation Services (IAS) or Perry Johnson Laboratory Accreditation, Inc. (PJLA) as recognized through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).
    - The accreditation is based on ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories".
    - The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.
2. The GEH program for dedication of commercial-grade items commits to be consistent with the following:
- NQA-1a-2009, Subpart 2.14,
  - EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications", 6/88 as endorsed and modified by the following NRC Generic Letters (GLs):
    - GL 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products (3/89)
    - GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs" (4/91)

As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 7.0 and concluded that the controls for purchased material, equipment, and services, including controls for commercial-grade calibration services and commercial-grade dedication, meet the guidance in Section 17.5. Section G, "CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES (Criteria VII)," Item 12b,

“Accreditation to ANSI/ISO/IEC 17025,” and Section V, “QA Program Commitments,” to GL 89-02 and GL 91-05.

3.2.1.8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

In Part II, “QAPD Details,” GEH made minor editorial changes to Section 8.0, “IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS.” In Section 8.6, “Commitment,” GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion VIII, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 8. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 8.0 and concluded that the controls for purchased material, parts, and components meet the guidance in SRP Section 17.5, Section H, “IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS (Criteria VIII).”

3.2.1.9 CONTROL OF SPECIAL PROCESSES

In Part II, “QAPD Details,” GEH made minor editorial changes to Section 9.0, “CONTROL OF SPECIAL PROCESSES.” In GEH QATR QAPD Section 9.6, “Commitment,” GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion IX, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 9. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 9.0 and concluded that the control of special processes meets the guidance in SRP Section 17.5, Section I, “CONTROL OF SPECIAL PROCESSES.”

3.2.1.10 INSPECTION

In Part II, “QAPD Details,” GEH made minor editorial changes to GEH QAPD Section 10.0, “INSPECTION.” In Section 10.6, “Commitment,” GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion X, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 10. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 10.0 and concluded that the controls for inspections meet the guidance in SRP Section 17.5, Section J, “INSPECTION.”

3.2.1.11 TEST CONTROL

In Part II, “QAPD Details,” GEH made minor editorial changes to Section 11.0, “TEST CONTROL.” In Section 11.6, “Commitment,” GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XI and NQA-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 11. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 11.0 and concluded that controls for tests meet the guidance in SRP Section 17.5, Section K, “TEST CONTROL.”

#### 3.2.1.12 CONTROL OF MEASURING AND TEST EQUIPMENT

In Part II, "QAPD Details," GEH made minor editorial changes to GEH QAPD Section 12.0, "CONTROL OF MEASURING AND TEST EQUIPMENT." In Section 12.6, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XII, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 12. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 12.0 and concluded that the control of measuring and test equipment meets the guidance in SRP Section 17.5, Section L, "CONTROL OF MEASURING AND TEST EQUIPMENT."

#### 3.2.1.13 HANDLING, SHIPPING, AND STORAGE

In Part II, "QAPD Details," GEH made no changes to GEH QAPD Section 13.0, "HANDLING, SHIPPING, AND STORAGE." In Section 13.6, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XIII, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 13. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 13.0 and concluded that the controls for handling, shipping and storage meet the guidance in SRP Section 17.5, Section M, HANDLING, STORAGE, AND SHIPPING."

#### 3.2.1.14 INSPECTION, TEST, AND OPERATING STATUS

In Part II, "QAPD Details," GEH made no changes to Section 14.0, "INSPECTION, TEST, AND OPERATING STATUS." In Section 14.3, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XIV, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 14. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 14.0 and concluded that the controls for inspections, tests, and operating status meet the guidance in SRP Section 17.5, Section N, "INSPECTION, TEST, AND OPERATING STATUS."

#### 3.2.1.15 NONCONFORMING MATERIAL AND COMPONENTS

In Part II, "QAPD Details," GEH made minor editorial changes to Section 15.0, "NONCONFORMING MATERIAL AND COMPONENTS." In Section 15.5, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XV, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 15. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 15.0 and concluded that the controls for nonconforming material and components meet the guidance in SRP Section 17.5, Section O, "NONCONFORMING MATERIAL AND COMPONENTS."

#### 3.2.1.16 CORRECTIVE ACTION

In Part II, "QAPD Details," GEH made minor editorial changes to Section 16.0, "CORRECTIVE ACTION." In Section 16.5, Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XVI, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 16. As set forth above, the NRC staff reviewed the QA

measures to be implemented by GEH in QAPD Section 16.0 and concluded that the controls for corrective action meet the guidance in SRP Section 17.5, Section P, "CORRECTIVE ACTION."

### 3.2.1.17 QUALITY ASSURANCE RECORDS

In Part II, "QAPD Details," GEH made minor editorial changes to Section 17.0, "QUALITY ASSURANCE RECORDS." In GEH QATR QAPD Section 17.8, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XVII, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 17, GL 88-18, "Plant Records and Storage on Optical Disk," and Regulatory Information Summary (RIS) 2008-18, "Guidance on Managing Quality Assurance Records in Electronic Media." As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 17.0 and concluded that the controls for QA records meet the guidance in SRP Section 17.5, Section Q, "QUALITY ASSURANCE RECORDS."

### 3.2.1.18 AUDITS

In Part II, "QAPD Details," GEH made minor editorial changes to Section 18.0, "AUDITS." In GEH QATR QAPD Section 18.7, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XVIII, NQA-1-2008 and the NQA-1a-2009 Addenda, Requirement 18. As set forth above, the NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 18.0 and concluded that the controls for audits meet the guidance in SRP Section 17.5, Section R, "AUDITS."

### 3.2.1.19 GEH QATR QAPD, Part IV, REGULATORY COMMITMENTS

In Part IV, "REGULATORY COMMITMENTS," GEH commits to the following regulations and guidance documents in Part I and II:

- 10 CFR Part 50, Appendix B
- ASME NQA-1-2008 and the NQA-1a-2009, 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.
- 10 CFR Part 21
- 10 CFR Part 70, Subpart D (70.22(f)) for licensing of special nuclear material
- 10 CFR Part 71
- 10 CFR Part 72, Subpart G for storage of radioactive material and waste
- Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs) as endorsed by US NRC RIS 2000-18
- EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications" (as endorsed and modified by US NRC GL 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products")
- ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories"

- RG 1.28, Revision 4, 2010 – “Quality Assurance Program Requirements (Design and Construction)”
- GL 88-18, “Plant Record Storage on Optical Disks”
- GL 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products”
- GL 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs”
- RIS 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media”

The NRC staff found that GEH did not commit to ASME NQA-1-2008 and NQA-1-2009a Addenda, Subpart 2.7, “Quality Assurance Requirements of Computer Software for Nuclear Facility Applications.” On August 18, 2014, the NRC staff requested additional information from GEH (Reference 6) to verify if GEH quality activities should include ASME NQA-1-2008/2009a Edition, Subpart 2.7. This was RAI 3.

On August 29, 2014, in GEH’s response to RAI 3 (Reference 7), GEH stated that “GEH will include a commitment to NQA-1-2008/2009a, Subpart 2.7, “Quality Assurance Requirements of Computer Software for Nuclear Facility Applications,” in Section 3.10 and 11.6 of the “A” (Approved Version) of NEDO-12209. Based on this GEH response, the NRC staff determined that RAI 3 is resolved.

#### 4.0 CONCLUSIONS

The NRC staff evaluated GEH’s QATR QAPD, Revision 11 (Reference 1), reviewed the previous GEH submittal letter (Reference 2) on GEH QATR QAPD, Revision 9 (Reference 3) and the NRC approval letter and safety evaluation for GEH QATR QAPD, Revision 9 (Reference 5). The NRC staff concludes that GEH provided adequate responses (Reference 7 and 8) to resolve three NRC staff RAIs (Reference 6) in Sections 3.2.1.2 and 3.2.1.19 of this safety evaluation. The NRC staff also concludes that GEH’s QATR QAPD, Revision 11, including QA alternatives, adequately addresses the requirements of Appendix B to 10 CFR Part 50 and is acceptable.

#### 5.0 REFERENCES

1. Letter from GE Hitachi Nuclear Energy (GEH) to NRC, MFN 14-108, Quality Assurance Topical Report (QATR) NEDO-11209, “GE Hitachi Nuclear Energy Quality Assurance Program Description,” Revision 11, dated March 31, 2014 (ADAMS Accession No. ML14090A330).
2. Letter from GE Hitachi Nuclear Energy (GEH) to NRC, MFN 10-354, “Response to NRC RAIs on GE Hitachi Nuclear Energy QATR NEDO-11209, Revision 9, “GE Hitachi Nuclear Energy Quality Assurance Program Description,” dated December 10, 2010 (ADAMS Accession No. ML103480313).

3. GEH QATR NEDO-11209, "GE Hitachi Nuclear Energy Quality Assurance Program Description," Revision 9, dated December 9, 2010 (ADAMS Accession No. ML103480314).
4. NRC NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," dated March 2007 (ADAMS Accession No. ML06319009)
5. NRC Approval Letter for GEH QATR QAPD, Revision 9, dated January 11, 2011 (ADAMS Accession No. ML110110473)
6. NRC Letter to GEH, Request for Additional information RE: General Electric Hitachi (GEH) Quality Assurance Topical Report NEDO-11209, "GE Hitachi Nuclear Energy Quality Assurance Program Description," Revision 11, August 18, 2014 (TAC No. MF3792) (ADAMS Accession No. ML14217A387)
7. Letter from GEH to NRC, MFN 14-057, "GEH Response to NRC Request for Additional Information 2, dated August 29, 2014 Re: GE Hitachi (GEH) Quality Assurance Topical Report (QATR) NEDO-11209, GE Hitachi Nuclear Energy Quality Assurance Program Description," Revision 11, March 2014 (TAC No. MF3792) (ADAMS Accession No. ML14241A433)
8. Letter from GEH to NRC, MFN 14-057, Supplement 1, "GEH Response to RAI No. 2, dated September 23, 2014, RE: GEH QATR NEDO-11209, GEH Nuclear Energy QAPD," Revision 11, March 2014 (TAC No. MF3792) (ADAMS Accession No. ML14266A382).

Attachment: Resolution of Comment

Principal Contributor: Francis X. Talbot

Date:

**RESOLUTION OF COMMENTS BY THE OFFICE OF NUCLEAR REACTOR**

**REGULATION ON DRAFT SAFETY EVALUATION FOR**

**TOPICAL REPORT NEDO-11209, REVISION 11,**

**“GE HITACHI NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM**

**DESCRIPTION”**

**(TAC NO. MF3792)**

<b>Location</b>	<b>Comment</b>	<b>NRC Disposition</b>
Page 6, Section 3.2.1.3 “Design Control”	Item (3) Subsection 3.4.2, “Design and Development Review;” should be Subsection 3.4.3.	Comment accepted. Change made in final SE.