

June 6, 2016

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 AMENDMENT TO NEDO-11209-A REVISION 12, "GE HITACHI NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM DESCRIPTION," (CAC NO. MF7028)

Dear Mr. Head:

By letter dated October 14, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15287A009), GE Hitachi Nuclear Energy Americas, LLC (GEH) submitted Amendment to NEDO-11209-A Revision 12, "GE Hitachi Nuclear Energy Quality Assurance Program Description," to the U.S. Nuclear Regulatory Commission (NRC) staff for review.

By letter dated May 6, 2016, an NRC draft safety evaluation (SE) regarding our approval of NEDO-11209-A, Revision 12, was provided for your review and comment (ADAMS Accession No. ML16110A324). By letter dated May 16, 2016, (ADAMS Accession No. ML16137A542) you replied that you had no comments.

The NRC staff has found that Amendment to NEDO-11209-A, Revision 12, is acceptable for referencing in licensing applications for nuclear power plants to the extent specified and under the limitations delineated in the Amendment and in the enclosed final SE. The final SE defines the basis for our acceptance of the Amendment.

Our acceptance applies only to material provided in the subject Amendment. We do not intend to repeat our review of the acceptable material described in the Amendment. When the Amended Topical Report (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 Amended 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 Amendment to TR NEDO-11209-A, Revision 12, 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 will be expected to revise the TR appropriately. Licensees referencing this TR would be expected to justify its continued applicability or evaluate their plant using the revised TR.

Sincerely,

/RA/

Kevin Hsueh, Chief
Licensing Processes Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. 710

Enclosure:
Final SE

cc w/encl: See next page

J. Head

- 2 -

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Final SE

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GE-Hitachi Nuclear Energy Americas

Project No. 710

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FINAL SAFETY EVALUATION BY THE
OFFICE OF NEW REACTORS
OF GENERAL ELECTRIC HITACHI NUCLEAR ELECTRIC, QUALITY
ASSURANCE TOPICAL REPORT NEDO-11209-A, REVISION 12, "GE HITACHI
NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM DESCRIPTION"
(CAC NO. MF7028)

1.0 **INTRODUCTION**

By letter dated October 14, 2015 (Reference 1), General Electric Hitachi Nuclear Energy (GEH) submitted an amendment to Quality Assurance Topical Report (QATR) NEDO 11209-A, Revision 12, "GE Hitachi Nuclear Energy Quality Assurance Program Description," 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 NRC as documented in a safety evaluation report (SER) dated October 20, 2014 (Reference 6).

During its review, the NRC staff determined that additional information was required to complete its review. On February 8, 2016 (Reference 2) and April 11, 2016 (Reference 3), the NRC transmitted two requests for additional information (RAIs) that were necessary complete the staff's review of QATR Revision 12. By letter dated March 2, 2016, and electronic correspondence dated April 15, 2016, GEH responded to the staff's RAIs (Reference 4 and Reference 5).

2.0 **REGULATORY BASIS**

The Commission's 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 a NRC-accepted QA program description from non-licensees (i.e., architect/engineers, nuclear steam system suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC. 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.

Enclosure

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes QA requirements for the design, fabrication, construction, and testing of structures, systems, and components (SSCs) of the facility. The pertinent requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related functions of SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

3.0 EVALUATION

In evaluating the adequacy of the GEH 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," Revision 1, dated August 2015 (Reference 7) 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 (ASME) Standard NQA-1-2008 Edition and the NQA-1a-2009 Addenda, as supplemented by additional regulatory and industry guidance for nuclear operating facilities. ASME Standard NQA-1-2008 Edition 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 Edition and the NQA-1a-2009 Addenda, is endorsed by NRC Regulatory Guide (RG) 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 4.

The proposed changes made to QATR Revision 12, include the following:

- Minor editorial changes spelling corrections, punctuation, administrative improvements, and clarifications to reflect the current organization within General Electric and GEH. The staff verified that the revised GEH QATR continues to ensure that persons and organizations performing quality assurance functions have the required authority and organizational freedom, and remain sufficiently independent from cost and schedule when opposed to safety considerations.
- In addition to the minor editorial changes, GEH added Section 4.4, "Graded Approach to Quality," to PART III, "Supplemental Details," of the QATR. The NRC staff submitted RAI 1 (Reference 2) requesting additional details how GEH planned to implement Section 4.4. GEH's response to RAI 1 (Reference 4) described that the graded approach to quality only applies to non-basic components. For example, it applies to SSCs with a Safety-Related Classification of "S" (Special) in Tier 2 Table 3.2-1 of the Economic Simplified Boiling Water Reactor Design Control Document (ESBWR DCD), Revision 10 dated April 2014, as certified by the US NRC (Reference 8). The ESBWR DCD

elevates many SSCs that would have been classified as “Non-Safety Related” under Appendix B to 10 CFR Part 50, in order to apply more rigorous quality requirements (see Note 5 of Tier 2 Table 3.2-1 of the ESBWR DCD). In addition, GEH in their response described that they may apply the classification of Special to products and services provided to international nuclear power plants not covered by Appendix B to 10 CFR Part 50 or 10 CFR Part 21 to ensure that applicable international regulations, codes, and standards are met. GEH’s use of a graded approach to quality meets the requirements of Appendix B to 10 CFR Part 50 in that GEH applies all applicable Appendix B to 10 CFR Part 50 requirements, as described by ASME in NQA-1-2008 Edition and supplemented by NQA-1a-2009 Addenda, to all basic components as defined by 10 CFR Part 21. The NRC staff found this approach to be acceptable.

- The proposed amendment to QATR Revision 12 also included a commitment to implement the quality assurance program alternative of the Nuclear Energy Institute (NEI) Technical Report NEI 14-05, Revision 1, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated August 2014 (Reference 9). The NRC staff concluded, in an SER dated February 9, 2015 (Reference 10), that NEI 14-05, Revision 1, provided an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50, for using laboratory accreditation by Accreditation Bodies that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

The proposed change was deemed to constitute a reduction in commitment. The NRC staff’s review verified that GEH correctly implemented the requirements of NEI 14-05, Revision 1. NEI 14-05, Revision 1, Section 4, “Purchaser’s Quality Assurance Program,” states, in part, that “Purchasers that rely on the accreditation by ILAC signatories in lieu of commercial-grade surveys are required by 10 CFR Part 50, Appendix B to document this alternative method in their QA Program. A Template for describing the use of the ILAC process in lieu of a commercial-grade survey in a Purchaser’s QA Program is provided in Appendix A. Although a Purchaser is not required to use the Template in Appendix A, all of the actions and steps described in Appendix A need to be included in the Purchaser’s QA Program.”

Section 7.10, “Commitment,” of PART II, “QAPD Details,” was revised to include guidance proposed by GEH to implement the requirements of NEI 14-05, Revision 1. The proposed change to this section, as described, did not address the requirements of this alternative as outlined in NEI 14-05, Revision 1. The NRC staff electronically transmitted RAI 2 (Reference 3) requesting clarification on how GEH planned to meet the requirements of NEI 14-05, Revision 1 in its QATR. In response (Reference 5), GEH revised Section 7.10 to include all the requirements listed in Appendix A of NEI 14-05, Revision 1. The NRC staff found this approach to be acceptable.

3.0 CONCLUSION

The NRC staff used the acceptance criteria of NUREG-0800, Section 17.5 as the basis for evaluating the acceptability of the GEH QATR, NEDO-11209-A, Revision 12 for conformance with the applicable requirements of Appendix B to 10 CFR Part 50. The NRC staff concludes that GEH's Quality Assurance Topical Report NEDO-11209-A Revision 12, follows the NRC guidance contained within and conforms to the format of NUREG-0800, Section 17.5, complies with Appendix B to 10 CFR Part 50 requirements for the QA program, and is therefore, acceptable.

4.0 REFERENCES

1. GE Hitachi Nuclear Energy Amendment to NEDO-11209-A, Revision 12, dated October 14, 2015, "GE Hitachi Nuclear Energy Quality Assurance Program Description" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15287A009).
2. NRC letter to GE Hitachi Nuclear Energy, "Request for Additional Information Regarding Review of Amendment to NEDO-11209-A Revision 12, GE Hitachi Nuclear Energy Quality Assurance Program Description," dated February 8, 2016 (ADAMS Accession No. ML16005A572).
3. NRC electronic correspondence to GE Hitachi Nuclear, "Request for Additional Information Regarding Review of Amendment to NEDO-11209-A Revision 12, "GE Hitachi Nuclear Energy Quality Assurance Program Description," dated April 11, 2016 (ADAMS Accession No. ML16102A443)
4. GE Hitachi Nuclear Energy letter to NRC, "NRC Request for Additional Information Regarding Review of Amendment to NEDO-11209-A Revision 12, GE Hitachi Nuclear Energy Quality Assurance Program Description," dated March 2, 2016 (ADAMS Accession No. ML16063A013)
5. GE Hitachi Nuclear Energy electronic correspondence to NRC, "NRC Request for Additional Information Regarding Review of Amendment to NEDO-11209-A Revision 12, GE Hitachi Nuclear Energy Quality Assurance Program Description," dated April 15, 2016 (ADAMS Accession Nos. ML16106A161).
6. Safety Evaluation of General Electric Hitachi GE Hitachi Nuclear Energy, Quality Management System, Quality Assurance Topical Report, NEDO-11209, Revision 11, Quality Assurance Program Description (TAC NO. MF3792), dated October 20, 2014 (ADAMS Accession No. ML14267A483)
7. NUREG-0800, Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition, Section 17.5 Revision 1, "Quality Assurance

Program Description – Design Certification, Early Site Permit and New License Applicants,” dated August 2015, (ADAMS Accession No. ML15037A441).

8. NUREG-1966 "Final Safety Evaluation Report Related to the Certification of the Economic Simplified Boiling-Water Reactor Standard Design" (ADAMS Accession No. ML14100A304)
9. Submittal of NEI 14-05, Revision 1, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated August 31, 2014 (ADAMS Accession No. ML14245A392).
10. Final Safety Evaluation for Technical Report NEI 14-05, Guidelines for the use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services, Revision 1 dated February 9, 2015 (ADAMS Accession No. ML14322A535)

Principal Contributor: Jonathan Ortega-Luciano, NRO

Date: