

December 8, 2017

Mr. Jerald G. Head
Senior Vice President, Regulatory Affairs
GE-Hitachi Nuclear Energy Americas, LLC
P.O. Box 780, M/C A-18
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SUBJECT: DRAFT SAFETY EVALUATION FOR PROPOSED AMENDMENT TO
NEDO-11209 REVISION 13, "GE HITACHI NUCLEAR ENERGY QUALITY
ASSURANCE PROGRAM DESCRIPTION" (EPID L-2017-TOP-0058)

Dear Mr. Head:

By letter dated October 6, 2017 (Agencywide Documents Access and Management System Accession No. ML17279A629), GE Hitachi Nuclear Energy (GEH) submitted an amendment to Quality Assurance Topical Report (QATR) NEDO 11209-A, Revision 13, "GE Hitachi Nuclear Energy Quality Assurance Program Description," to the U.S. Nuclear Regulatory Commission (NRC) staff for review. Enclosed is a copy of the NRC staff's draft safety evaluation (SE) for the QATR for GEH's review and comment.

Twenty working days, for the date of this letter, are provided for you to comment on any factual errors or clarity concerns contained in the draft SE. The final SE will be issued after making any necessary changes. The NRC staff's disposition of your comments on the draft SE will be discussed in the final SE.

To facilitate the NRC staff's review of your comments, please provide a marked-up copy of the draft SE showing proposed changes and provide a summary table of the proposed changes.

If you have any questions, please contact Joseph Golla at 301-415-1002.

Sincerely,

/RA Serita Sanders Acting for/

Dennis C. Morey, Chief
Licensing Processes Branch
Division of Licensing Projects
Office of Nuclear Reactor Regulation

Project No. 712

Enclosure:
Draft SE

cc: See next page

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 ASSURANCE PROGRAM DESCRIPTION" (EPID L-2017-TOP-0058)
 DATED: DECEMBER 8, 2017

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GE-Hitachi Nuclear Energy Americas

Project No. 712

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1 DRAFT SAFETY EVALUATION OF GENERAL ELECTRIC HITACHI NUCLEAR ENERGY,
2 QUALITY ASSURANCE TOPICAL REPORT NEDO-11209-A, REVISION 13, "GE HITACHI
3 NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM DESCRIPTION"

4 (EPID L-2017-TOP-0058)

5
6 1.0 INTRODUCTION
7

8 By letter dated October 6, 2017 (Ref. 1), General Electric Hitachi Nuclear Energy (GEH)
9 submitted an amendment to Quality Assurance Topical Report (QATR) NEDO 11209-A,
10 Revision 13, "GE Hitachi Nuclear Energy Quality Assurance Program Description," to the
11 U.S. Nuclear Regulatory Commission (NRC) for review and approval in accordance with the
12 provisions of Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.4(b)(7)(ii). GEH
13 proposed that this updated QATR would replace the current QATR for GEH, which was
14 approved by NRC as documented in a safety evaluation (SE) dated June 6, 2016 (Ref. 2).
15

16 2.0 REGULATORY BASIS
17

18 The Commission's regulatory requirements related to Quality Assurance (QA) programs for non-
19 licensees are set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.4(b)(7)(ii).
20 This regulation requires that a change to a NRC-accepted QA program description from
21 non-licensees (i.e., architect/engineers, nuclear steam system suppliers, fuel suppliers,
22 constructors, etc.) must be submitted to the NRC. The NRC will review the proposed QATR for
23 acceptability to ensure the applicable requirements of Appendix B to 10 CFR Part 50 will be
24 satisfied.
25

26 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing
27 Plants," to 10 CFR Part 50 establishes QA requirements for the design, fabrication,
28 construction, and testing of structures, systems, and components (SSCs) of the facility. The
29 pertinent requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the
30 safety-related functions of SSCs and include designing, purchasing, fabricating, handling,
31 shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining,
32 repairing, refueling, and modifying.
33

34 3.0 EVALUATION
35

36 In evaluating the adequacy of the GEH QATR, the NRC staff used the guidance contained in
37 NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear
38 Power Plants," SRP Section 17.5, "Quality Assurance Program Description – Design
39 Certification, Early Site Permit and New License Applicants," Revision 1, dated August 2015
40 (Ref. 3) hereafter referred to as standard review plan (SRP) Section 17.5, which provides
41 acceptance criteria for design certification, early site permit, combined operating license,
42 construction permit, and operating license applicants. SRP Section 17.5 is based on American
43 Society of Mechanical Engineers (ASME) Standard NQA-1-2008 Edition and the NQA-1a-2009
44 Addenda, as supplemented by additional regulatory and industry guidance for nuclear operating
45 facilities. ASME Standard NQA-1-2008 Edition and the NQA-1a-2009 Addenda, upon which the
46 GEH QATR is based, incorporated the supplemental guidance into a single document, and is,
47 therefore, in alignment with SRP Section 17.5. In addition, NQA-1-2008 Edition and the

1 NQA-1a-2009 Addenda, is endorsed by NRC Regulatory Guide 1.28, "Quality Assurance
2 Program Requirements (Design and Construction)," Revision 4.

3
4 The proposed changes made to GEH's QATR, Revision 13, include minor editorial changes and
5 changes to the organizational structure within GEH. In a conference call held on November 9,
6 2017, GEH staff provided clarification for organizational changes regarding the reporting
7 structure of the Profit and Loss (P&L) Business Leaders, Nuclear Oversight Quality, and P&L
8 Quality Leaders. GEH clarified that the dotted lines between P&L Business leaders and P&L
9 Quality leaders and the dotted lines between Nuclear Oversight Quality and P&L Quality
10 leaders, as shown in Figure 1 of Revision 13 to the QATR, provide flexibility for the
11 management of resources in implementing the quality requirements set forth in the QATR;
12 however, Nuclear Oversight Quality maintains responsibility for the final release of products to
13 the customer.

14
15 The NRC staff verified that the revised GEH QATR continues to ensure that persons and
16 organizations performing quality assurance functions have the required authority and
17 organizational freedom, and remain sufficiently independent from cost and schedule when
18 opposed to safety considerations.

19 20 4.0 CONCLUSION

21
22 The NRC staff used the acceptance criteria of NUREG-0800, Section 17.5 as the basis for
23 evaluating the acceptability of the GEH QATR, NEDO-11209-A, Revision 13 for conformance
24 with the applicable requirements of Appendix B to 10 CFR Part 50. The NRC staff concludes
25 that GEH's QATR, NEDO-11209-A, Revision 13, follows the NRC guidance contained within
26 and conforms to the format of NUREG-0800, Section 17.5, complies with Appendix B to 10 CFR
27 Part 50 requirements for the QA program and, therefore, is acceptable.

28 29 5.0 REFERENCES

- 30
31 1. GE Hitachi Nuclear Energy Amendment to NEDO-11209-A, Revision 13, October 6, 2017,
32 "GE Hitachi Nuclear Energy Quality Assurance Program Description" (Agencywide
33 Documents Access and Management System (ADAMS) Accession No. ML17279A629).
34
35 2. Safety Evaluation of General Electric Hitachi GE Hitachi Nuclear Energy, Quality
36 Management System, Quality Assurance Topical Report, NEDO-11209, Revision 12, Quality
37 Assurance Program Description (CAC NO. MF7028), June 6, 2016 (ADAMS Accession
38 No. ML16138A359).
39
40 3. NUREG-0800, Standard Review Plan for the Review of Safety Analysis Reports for Nuclear
41 Power Plants: LWR Edition, Section 17.5 Revision 1, "Quality Assurance Program
42 Description – Design Certification, Early Site Permit and New License Applicants,"
43 August 2015 (ADAMS Accession No. ML15037A441).
44

45 Principal Contributor: Ashley Ferguson, NRO

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47 Date: December 8, 2017