

June 26, 2014

MEMORANDUM TO: Anthony Mendiola, Chief
Licensing Processes Branch
Division of Policy
and Rulemaking Division
Office of Nuclear Reactor Regulation

FROM: Kerri A. Kavanagh, Chief */RA/*
Quality Assurance Vendor
Inspection Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

SUBJECT: REQUESTS FOR ADDITIONAL INFORMATION REGARDING THE
TOPICAL REPORT, NEDO-11209, GENERAL ELECTRIC HITACHI
QUALITY ASSURANCE PROGRAM DESCRIPTION, REVISION 11
(TAC NO. MF3792)

The Quality Assurance Vendor Inspection Branch has reviewed the General Electric Hitachi Quality Assurance Topical Report NEDO-11209, "GE Hitachi Nuclear Energy Quality Assurance Program Description," Revision 11 in accordance with the provisions of Standard Review Plan Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants." Based on our review of the document, the staff has determined that additional information is required to complete our review. Our request for additional information is attached.

Enclosure:
Request for Addition Information

CONTACT: Francis X. Talbot, NRO/DCIP
301-415-3146

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DATE	06/25/2014	06/26/2014	06/26/2014

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**REQUEST FOR ADDITIONAL INFORMATION REGARDING
NEDO-11209, "GE HITACHI NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM
DESCRIPTION," REVISION 11
PROJECT NO. 710**

1. In January 2011, the NRC staff approved NEDO-11029, "GE Hitachi Quality Assurance Program Description," Revision 9. In March 2014, General Electric (GE) Hitachi submitted Revision 11 to the NRC, but did not submit Revision 10. GE Hitachi 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, Section 1.1, Section 1.4.2.2, Section 1.4.3.1, and Section 18.4. However, the NRC staff requests that GEH verify that these are all the changes made to the NRC approved NEDO-11209, Revision 9 that were incorporated into NEDO-11209, Revision 10. The staff's purpose is to verify that GE Hitachi's Revision 10 of the Quality Assurance Program Description (QAPD) remained acceptable in accordance with Title 10 of the *Code of Federal Regulation* (10 CFR) 50.4(b)(7)(ii).
2. In the GE Hitachi QAPD, Part II, "QAPD Details," editorial changes were made to Section 2.0, "QUALITY ASSURANCE PROGRAM," Section 2.8, "Quality Assurance Program Description Management," Item 1.
 - Changes that are made to the QAPD that are a reduction in commitment are submitted to the US NRC for review and approval per 10 CFR 50.4(b)(7)(ii).

The staff's review of Section 2.8 determined that 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 approved QAPD are reductions in commitment. The NRC staff requests that GE Hitachi clarify its process of evaluating potential reductions in commitment.

3. The NRC staff determined that GE Hitachi did not make a commitment to the American Society of Mechanical Engineers NQA-1-2008/2009a, Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications." The staff requests clarification on the applicability of Subpart 2.7 to GE Hitachi's quality activities.