



**HITACHI**

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MFN 14-057 Supplement 1  
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U.S. Nuclear Regulatory Commission  
Document Control Desk  
Washington, D.C. 20555-0001

**Subject: Revised Response to Request for Additional Information No. 2 Re: General Electric Hitachi (GEH) Quality Assurance Topical Report NEDO-11209, "GE Hitachi Nuclear Energy Quality Assurance Program Description," Revision 11, March 2014 (TAC No. MF3792)**

Reference 1 submitted GE Hitachi Nuclear Energy (GEH) responses to the Nuclear Regulatory Commission (NRC) Requests for Additional Information (RAIs) for NEDO-11209, Revision 11. Subsequent discussions with the NRC staff have caused GEH to revise the response to RAI No. 2. This response replaces the previous response in its entirety. The response includes a substantial change to Section 2.8 of the Topical Report (TR) that will be implemented in the approval (-A) version of the TR.

If you have any questions regarding the enclosed comments, please contact me or Rich Augi ([Rich.Augi@ge.com](mailto:Rich.Augi@ge.com); 910 819 6366).

Sincerely,

James F. Harrison  
Vice President, Fuel Licensing  
Regulatory Affairs  
GE Hitachi Nuclear Energy

Project No. 710

**References:**

1. Letter from JF Harrison (GEH) to Document Control Desk (NRC), Subject: Response to 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, March 2014 (TAC No. MF3792), MFN 14-057, August 29, 2014.

**Enclosures:**

1. Revised Response to Request for Additional Information No. 2 Re: GEH Quality Assurance Topical Report NEDO-11209, Revision 11 – Non-Proprietary Information – Class I (Public)

cc: J. Golla (NRC)  
B.R. Moore (GNF)  
J.G. Head (GEH)  
P.L. Campbell (GEH)  
R. Augi (GEH)  
PLM 001N8521 R3

ENCLOSURE 1

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Revised Response to Request for Additional Information No. 2 Re: GEH  
Quality Assurance Topical Report NEDO-11209, Revision 11

Non-Proprietary Information – Class I (Public)

**RAI 2:**

In the GEH QAPD, Part II, “QAPD Details,” changes were made to Section 2.0, “QUALITY ASSURANCE PROGRAM,” Subsection 2.8, “Quality Assurance Program Description Management,” Item 1, to read as follows:

“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 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 GEH clarify its process of evaluating potential reductions in commitment.

**GEH Response:**

GEH will replace the three numbered sections in Subsection 2.8 “Quality Assurance Program Description Management” with the following two numbered sections in the “-A” version of NEDO-11209 based on the NRC SE:

1. Proposed changes to this QAPD are submitted to the NRC for review and approval per 10 CFR 50.4(b)(7)(ii). The proposed changes will be termed “amendments” to the QAPD and will be presented as markups of the then approved version along with a basis discussion for each change.
2. Upon receipt of the NRC approval of each amendment, the QAPD shall be revised and issued as “NEDO-11209-A” and the revision number incremented. Each NRC approved amendment, with the associated changes, is illustrated in the Revision History located in the front of this document.