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U.S. Nuclear Regulatory Commission
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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)

This letter transmits the GE Hitachi Nuclear Energy (GEH) responses to the Nuclear Regulatory Commission (NRC) Requests for Additional Information (RAIs) for NEDO-11209, Revision 11 (Reference 1).

If you have any questions regarding the enclosed comments, please contact me or Rich Augi (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 Joseph A. Golla (NRC) to Jerald G. Head (GEH), Subject: 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 14-055, August 18, 2014.

Enclosures:

1. Response to Request for Additional Information 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)

ENCLOSURE 1

MFN 14-057

Response to Request for Additional Information Re: GEH Quality
Assurance Topical Report NEDO-11209, Revision 11

Non-Proprietary Information – Class I (Public)

RAI 1:

In January 2011, the U.S. Nuclear Regulatory Commission (NRC) staff approved NEDO-11029, “GE Hitachi Quality Assurance Program Description,” Revision 9. In March 2014, General Electric Hitachi (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, Section 1.1, Section 1.4.2.2, Section 1.4.3.1, and Section 18.4. 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 GEH’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).

GEH Response:

GEH has provided Attachment 1 to this document which lists all the changes from Revision 9 to Revision 10.

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:

The basis for the GEH request for this process option originates in our understanding of the NRC’s approach in dealing with non-licensee Quality Assurance (QA) programs. It is clear in 10 CFR 50.4(b)(7)(ii) that a change to an approved program has to be submitted, but it isn’t clear that NRC review and approval is always required. Two examples, in particular, led to the requested item being added to our revision request. First, in the approval letter for another vendor’s Quality Management System (QMS) ([ML12338A515](#)), it is clear that the NRC review utilizes, in part, 10 CFR 50.54(a)(4) to determine the acceptability of changes to a non-licensee QMS program. Second, the Safety Evaluation Report provided by the NRC for Revision 9 of NEDO-11209 ([ML112140602](#)) contained the following paragraph in the Regulatory Evaluation section (bold text added for emphasis):

*The NRC 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 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.*

The phrase “When requested” implied that further review and approval by the NRC staff was contingent upon a specific request. GEH interpreted these two examples to mean that we should submit all changes but only request NRC review and approval of those that failed a detailed screening criteria as discussed below.

GEH has drafted Section 2.8 based upon 10 CFR 50.54 (3) and will use a screening process to evaluate potential reductions in commitment that are in line with 10 CFR 50.54 (3).

1. The first category of changes is administrative in nature: improvement and clarifications, spelling corrections, punctuation, or editorial items.
2. The second category of changes are based upon NRC acceptance of other standards:

- 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;
 - The use of a QA alternative or exception approved by an NRC safety evaluation (SE), provided that the bases of the NRC approval are applicable to GEH; and
 - The elimination of QA program information that duplicates language in QA regulatory guides and QA standards to which GEH is committed.
3. The third category is focused on organizational changes:
- The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;
 - The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text; and
 - 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.
4. The fourth category is intended to cover changes in the QAPD in Part III that are made to address international standards changes. NEDO-11029 Revision 11 Section 2.8(g) currently states:

“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).”

GEH proposes to make the following changes in the “-A” version of NEDO-11209 Revision 11:

- Move the international standards from Part IV, “Regulatory Commitments” to Part III;
- Create a new section in Part III “Supplemental Details”: Section 7.0 “References”; and
- NEDO-11209 Part II Section 2.8 (g) would be changed to read:
“Any change to Part III, “Supplemental Details” that do not entail NRC related standards (i.e. ISO 9001, KTA-1401, GS-R-3).”

RAI 3:

The NRC staff determined that GEH 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 GEH’s quality activities.

GEH Response:

GEH will include a commitment to NQA-1-2008/2009a, Subpart 2.7, “Quality Assurance Requirements of Computer Software for Nuclear Facility Applications” in Sections 3.10 and 11.6 of the “-A” version of NEDO-11209 based on the NRC SE.

**Attachment 1: GEH Quality Assurance Program Description NEDO-11209 Revision 9
Mapping to Revision 10**

Revision 9 Section	Revision 9 Section Description	Revision 10 Summary of Change
	Disclaimer	No change
	Revision History	Updated
	Table Of Contents	Updated
	Acronyms & Abbreviations	Added EHS, GSC, SCAQ in Revision 10 In Revision 10, Removed NQA from Acronyms & Abbreviations.
	Introduction	No change
	Scope	No change
SECTION 1	Organization	No change
1.1	General	Clarified QAPD adherents Removed organizational elements table
1.2	Organizational Description	No change
1.2.1	Organizational Structure	Updated to reflect 2012 organizational structure
1.2.1.1	P&Ls	Updated to reflect 2012 organizational structure
1.2.1.2	Support Organizations	Updated to reflect 2012 organizational structure
1.2.1.3	Quality	Updated to reflect 2012 organizational structure
1.2.2	Management Positions	No change
1.2.2.1	President and Chief Executive Officer	Wording change in first paragraph, removed duplicate text on establishment of GEH QA policy. Added that the President additionally reports to GE Power and Water.
1.2.2.2	Business Leaders for P&L's and Support Organizations	No change
1.2.2.3	Quality Leader	Removed NQA & Support Services title, combined them into Quality Programs Combined P&L and Support Quality Leaders into "Organization Specific Quality Leaders" Added Continuous Improvement
1.2.3	Functional Responsibilities	No change
1.2.4	Interface responsibilities	No change
1.3	All Employees and contractors	No change
1.4	Authority to Stop Work	Removed NQA title and added Quality Assurance Organization
1.5	Delegation Outside the GEH	No change

Revision 9 Section	Revision 9 Section Description	Revision 10 Summary of Change
	Organization	
1.6	Commitment	No change
Figure 1	Organizational Structure	Updated figure for 2012 organization
Figure 2	Functional Responsibilities	Replaced table with new table reflecting 2012 organization
SECTION 2	QUALITY ASSURANCE PROGRAM	No change
SECTION 3	DESIGN CONTROL	No change
SECTION 4	PROCUREMENT DOCUMENT CONTROL	No change
SECTION 5	PROCEDURES, INSTRUCTIONS, AND DRAWINGS	No change
SECTION 6	DOCUMENT CONTROL	No change
6.1	General	No change
6.2	Review and Approval of Documents	No change
6.3	Changes to Documents	No change
6.4	Temporary Documents	Clarified to current process for all temporary changes
6.5	Commitment	No change
SECTION 7	CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES	
7.1	General	No change
7.2	Supplier Evaluation and Selection	No change
7.3	Proposal/Bid Evaluation	No change
7.4	Control of Supplier Generated Documents	No change
7.5	Control of Supplier Nonconformances	Removed conditionality of nonconformance reporting from #4
7.6	Acceptance of Items or Service	No change
7.7	Supplier Performance Evaluation	No change
7.8	Commercial Grade Items and Services - Dedication	No change
7.9	Records	No change
7.10	Commitment	Eliminated 1st bullet exception to Requirement 7 Editorial changes
SECTION 8	IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS	No change
SECTION 9	CONTROL OF SPECIAL	No change

Revision 9 Section	Revision 9 Section Description	Revision 10 Summary of Change
	PROCESSES	
SECTION 10	INSPECTION	
10.1	General	No change
10.2	Inspection Personnel	Clarified to include how activities are defined
10.3	Planning	No change
10.4	Final Inspection	No change
10.5	Records	Editorial/layout changes
10.6	Commitment	No change
SECTION 11	TEST CONTROL	Some editorial changes throughout section
SECTION 12	CONTROL OF MEASURING AND TEST EQUIPMENT	No change
SECTION 13	HANDLING, STORAGE, AND SHIPPING	No change
SECTION 14	INSPECTION, TEST, AND OPERATING STATUS	No change
SECTION 15	NONCONFORMING MATERIALS, PARTS, OR COMPONENTS	
15.1	General	No change
15.2	Identification and Control	No change
15.3	Disposition	Eliminated 2nd sentence in Rework and Repair definition to align with current procedure requirements Editorial changes
15.4	Re-examination	No change
15.5	Commitment	No change
SECTION 16	CORRECTIVE ACTION	No change
SECTION 17	QUALITY ASSURANCE RECORDS	Editorial changes
SECTION 18	AUDITS	
18.1	General	No change
18.2	Personnel	No change
18.3	Audit Documentation	Editorial changes
18.4	Internal Audits	Updated to reflect 2012 organization change responsibility for Internal Audits
18.5	Supplier Audits	No change
18.6	Audit Response and Follow-up	No change
18.7	Commitment	No change
APPENDIX A	REGULATORY COMMITMENTS	No change