November 10, 2010

Mr. Jerald G. Head
Senior Vice President, Regulatory Affairs
GE-Hitachi Nuclear Energy Americas LLC
P.O. Box 780, M/C A-18
Wilmington, NC 28401-0780

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION RE: GE-HITACHI NUCLEAR ENERGY TOPICAL REPORT NEDO-11209, REVISION 9, "GE HITACHI NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM DESCRIPTION" (TAC NO. ME4483)

Dear Mr. Head:

By letter dated June 30, 2010 (Agencywide Documents Access and Management System Accession No. ML101830319), GE-Hitachi Nuclear Energy submitted for U.S. Nuclear Regulatory Commission (NRC) staff review Topical Report NEDO-11209, Revision 9, "GE Hitachi Nuclear Energy Quality Assurance Program Description." Upon review of the information provided, the NRC staff has determined that additional information is needed to complete the review. On October 28, 2010, Russell Bastyr, Nuclear Quality Assurance Leader and Audit Director, and I agreed that the NRC staff will receive your response to the enclosed Request for Additional Information (RAI) questions by December 10, 2010. If you have any questions regarding the enclosed RAI questions, please contact me at 301-415-2365 or Stephen.Philpott@nrc.gov.

Sincerely,

**/RA/**

Stephen S. Philpott, Project Manager
Licensing Processes Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. 710

Enclosure: RAI questions

cc w/encl: See next page

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REQUEST FOR ADDITIONAL INFORMATION

BY THE OFFICE OF NUCLEAR REACTOR REGULATION

REGARDING TOPICAL REPORT

NEDO-11209, REVISION 9, "GE HITACHI NUCLEAR ENERGY

QUALITY ASSURANCE PROGRAM DESCRIPTION"

GE-HITACHI NUCLEAR ENERGY AMERICAS, LLC

PROJECT NO. 710

**Section 1.0 - ORGANIZATION**

**RAI - 1** NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants" (SRP), Section 17.5, "Quality Assurance [(QA)] Program Description [(QAPD)] - Design Certification, Early Site Permit and New License Applicants," Paragraph II.A.3, states in part that the QAPD is to contain an organizational description that addresses the organizational structure, functional responsibilities, levels of authority, and interfaces. The organizational description is to include the onsite and offsite organizational elements that function under the cognizance of the QA program. Topical Report NEDO-11209, Revision 9, Paragraph 1.2.1 states that the organizational structure is shown in Figure 1, "Organizational Structure." Figure 1 is not aligned with the organizational structure described in NEDO-11209, Section 1.2, "Organizational Description." Please provide clarification of the different groups that are in Figure 1 that are not described in Section 1.2 of NEDO-11209, Revision 9.

**RAI - 2** SRP Section 17.5, Paragraph II.A.3, states in part that the QAPD is to contain an organizational description that addresses the organizational structure, functional responsibilities, levels of authority, and interfaces. The organizational description is to include the onsite and offsite organizational elements that function under the cognizance of the QA program. NEDO-11209, Revision 9, Paragraph 1.2.3, makes reference to Figure 2, "Functional Responsibilities." Please provide clarification of the functional responsibilities presented in Figure 2.

**RAI - 3** SRP Section 17.5, Paragraph II.A.5.c, states in part that managers responsible for carrying out the audit functions are to report at a management level sufficiently high to ensure that cost and schedule considerations do not unduly influence decision making. NEDO-11209, Revision 9, Paragraph 1.2.2.3.1, states that the Nuclear Quality Assurance (NQA) Manager has a direct line of communication to the President to discuss quality-related issues. The NQA Manager is not represented nor is the direct line of communication reflected in Figure 1, "Organizational Structure."

ENCLOSURE

Please provide clarification in Figure1 of the location of the NQA Manager and the direct line of communication.

**RAI - 4** SRP Section 17.5, Paragraph II.A.5.c, states in part that managers responsible for carrying out the audit functions are to report at a management level sufficiently high to ensure that cost and schedule considerations do not unduly influence decision making. NEDO-11209, Revision 9, Paragraph 1.2.2.3.4 states in part that the structure is designed to provide sufficient independence for the "Specific Quality Leaders" from cost and schedule when opposed to quality and safety considerations, provides the required independence between the performers and the verifiers, and enables a direct line of communication to top management. Please provide clarification of the term "top management." Please provide clarification in Figure 1 of the location of the "Specific Quality Leaders" and the direct line of communication described in Paragraph 1.2.2.3.4 of NEDO-11209, Revision 9.

**Section 2.0 – Quality Assurance Program**

**RAI - 5** SRP Section 17.5, Paragraph II.S.4, states the qualification requirements for lead auditors. Specifically, Paragraph II.S.4.c requires a lead auditor to have participated in a minimum of five QA audits within a period of time not to exceed three years prior to the date of qualification, one audit of which is a nuclear QA audit within the year prior to qualification or for individuals with related industry experience, demonstrated ability to properly implement the audit process, to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification. NEDO-11209, Revision 9, Paragraph 2.9, commits GE Hitachi Nuclear Energy (GEH) to compliance with NQA-1a-2009, Requirement 2, which contains the requirements for qualification of audit personnel. Please provide clarification if GEH intended to implement this alternative consistent with Section 17.5, Paragraph II.S.4 of the SRP.

**RAI - 6** SRP Section 17.5, Paragraph II.U.2, states in part that the reviewer verify the standards (subparts 2.1 – 2.20) listed in Paragraphs II.U.2.a-h. The "GE Hitachi Nuclear Energy Quality Assurance Program Description Abstract" submitted with NEDO-11209, Revision 9, states that the QAPD has been revised to meet NQA-1, 2008 and NQA-1a-2009 Addenda, in accordance with U.S. Nuclear Regulatory Commission Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 4. Please provide clarification as to whether GEH will implement Part II of NQA-1, 2008 and NQA-1a-2009.

**Section 3.0 – Design Control**

**RAI - 7** SRP Section 17.5, Paragraph II.C.1.j.(1), states that computer program acceptability is pre-verified or the results verified with the design analysis for each application. NEDO-11209, Revision 9, Paragraph 3.4.1, states in part that pre-verified computer programs are controlled to ensure that changes are documented and approved by authorized personnel. When pre-verified computer programs are used, the encoded

mathematical model does not need to be verified. Please specify the criteria for a pre-verified computer program.

**RAI - 8** SRP Section 17.5, Paragraph II.C.1.p, states that where a significant design change is necessary because of an incorrect design, the design process and verification procedure is reviewed and modified as necessary. Please provide clarification regarding the review and modification, as applicable, of the design process where a significant design change is necessary because of an incorrect design.

**Section 13.0 – Handling, Storage, and Shipping**

**RAI - 9** SRP Section 17.5, Paragraph II.M.1, states that marking and labeling instructions for packaging, shipment, handling, and storage of items are required to be established that adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls. NEDO-11209, Revision 9, Paragraph 13.1, states in part that GEH has a program in place that will minimize deterioration of items. Please provide clarification on whether GEH has a sufficient packaging, shipping, handling, and storage program in place to establish controls to indicate the presence of special environments or the need for special controls.

**Section 14.0 – Inspection, Test, and Operating Status**

**RAI - 10** SRP Section 17.5, Paragraph II.N.5, states that temporary modifications, such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point setting, are controlled by approved procedures which include a requirement for independent verification. Please provide clarification if GEH intended to implement this alternative consistent with Section 17.5 of the SRP.

**Section 18.0 – Audits**

**RAI - 11** SRP Section 17.5, Paragraph II.R.3.a, states in part that internal audits of organization and facility activities, conducted before placing the facility in operation, should be performed in such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter. NEDO-11209, Revision 9, Section 18.3.1, states in part that internal audits of organizations and activities are conducted prior to placing a facility in operation and at least once a year subsequently. Please provide clarification as to whether GEH has an audit program in place to ensure that audits of applicable elements of the GEH QA program will be completed at least once a year or at least once during the life of the activity, whichever is shorter.

**RAI - 12** SRP Section 17.5, Paragraph II.R.3.b., states that internal audit frequencies of well established activities, conducted after placing the facility in operation, may be extended one year at a time beyond the two-year interval based on the results of an

annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any function area changes in responsibility, resources or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded and an audit scheduled as soon as practicable. Please provide clarification if GEH intended to implement this alternative consistent with Section 17.5 of the SRP.