

June 17, 2009

Mr. Richard Wittmeier
Senior Vice President, Nuclear Quality
GE Hitachi Nuclear Energy
PO Box 780, M/C A-10
Wilmington, NC 28402

SUBJECT: GE HITACHI NUCLEAR ENERGY RESPONSE TO U.S. NUCLEAR
REGULATORY COMMISSION (NRC) INSPECTION REPORT 05200010/2008-
201, NOTICE OF VIOLATION

Dear Mr. Wittmeier:

Thank you for your April 23, 2009; May 15, 2009; and June 5, 2009; letters in response to the Notice of Violation (NOV) that was discussed in the subject U.S. Nuclear Regulatory Commission (NRC) Inspection Report. We have reviewed your letters and found that your replies to the violations identified in the NOV are generally responsive to our concerns. However, certain aspects of your April 23, 2009, letter need to be addressed in further detail. You are required to respond to this letter and should follow the instructions specified at the end of this letter when preparing your response.

Your response to NOV 05200010/2008-201-04 regarding the corrective action program for Level 1 software error codes, was found to be inadequate in three areas:

First, additional information is requested to clarify when the problem reporting and corrective action requirements of NQA-1-1994, Subpart 2.7, section 8, apply to Engineering Computer Programs (ECPs). The first sentence of section I.B of your response states "error reporting should not be necessary for Level-1 ECPs," while the last paragraph of the same section states "an error in analysis due to a problem with non-Level-2 software would, at a minimum, be treated as a condition adverse to quality. A formal CAR would be required...." Please clarify if the requirements of NQA-1-1994, Subpart 2.7, section 8, apply to Level-1 ECPs. Also, please clarify if error reporting is required when a problem with a Level-1 ECP is discovered. If error reporting is required, please provide the company procedure and section reference governing such reporting.

Second, the last sentence of section II of your response states, "non-Level-2 computer programs have not been developed using the NQA standard...." Please clarify what standard is used for non-Level-2 computer program development.

Third, additional information is requested to clarify when the software procurement requirements of NQA-1-1994, Subpart 2.7, section 10 "Software Procurement," apply. Section III "Planned Corrective Actions" of your response states that "going forward, non-Level-2 software will be required to meet the new (NQA-1-1994, Subpart 2.7, section 10.2) criteria in order to be acceptable for application to design." Please clarify when the requirements of NQA-1-1994, Subpart 2.7, section 10.2 "Software Procurement - Software Developed Not Using Part II," will be applied to Level-1 developmental software once the actions of Section III are implemented. Additionally, please describe any intended connections between software developed under

NQA-1-1994, Subpart 2.7, section 10.2, and software developed under the full NQA-1-1994 standard.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Chief, Quality and Vendor Branch 2, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of this letter. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) additional explanation to address the violation, or if contested, the basis for disputing the violation; (2) the corrective steps that have been taken and the results achieved; and (3) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

If you or your staff has any questions regarding this matter, we will be pleased to discuss them with you.

Sincerely,

/RA/

John A. Nakoski, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

NQA-1-1994, Subpart 2.7, section 10.2, and software developed under the full NQA-1-1994 standard.

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/RA/

John A. Nakoski, Chief
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Office of New Reactors

Docket No.: 05200010/2008-201

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OFFICE	NRO/DCIP/CQVB	NRO/DCIP/CQVB	NRO/DCIP/CQVB: BC
NAME	MMorgan (<i>via email</i>)	DPasquale	JNakoski
DATE	06/16/2009	06/11/2009	06/17/2009

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