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**HITACHI**

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June 5, 2009  
MFN 09-242, Supplement 2

U. S. Nuclear Regulatory Commission  
Attn: Document Control Desk  
Washington, DC 20005-0001

**SUBJECT:** Revised Response to Notice of Violation

**REFERENCE:** NRC Inspection Report 05200010/2008-201  
Notice of Violation to GE Hitachi Nuclear Energy

In letter MFN 09-242 dated April 23, 2009, GE Hitachi Nuclear Energy ("GEH") responded to the referenced NRC inspection report. Attachment 1 concerned Notice of Violation 08200010/2008-201-01, to which GEH responded, indicating that GEH contested the violation based on information provided in the response. In subsequent discussions with the NRC and internally, GEH has determined that a revision to the original response is warranted and GEH no longer contests the violation. The revised GEH response is provided in Attachment 1.

Please let me know if you have any question relating the information contained herein.

Sincerely,

Richard Wittmeier  
Sr. Vice President  
Nuclear Quality

cc: Jerald Head  
James Klopproth  
Mark Harvey  
Russ Bastyr  
Harold Neems  
John Nakoski (NRC)

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**Attachment 1**  
**Reply to NRC Notice of Violation 05200010/2008-201-01**

**Docket Number 05200010**

***The Notice of Violation***

The Notice of Violation provides the following description of the violation:

Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of Part 21 of Title 10 of the Code of Federal Regulations, "Reporting of Defects and Noncompliance" (10 CFR Part 21), requires, in part, that each individual, corporation, partnership, dedicating entity, or other entity subject to 10 CFR Part 21 adopt procedures to evaluate deviations and failures to comply as soon as practicable in order to identify defects and failures to comply associated with substantial safety hazards.

Section 7.7.3 of GNF CP 23-01, "Engineering Computer Programs," Revision 1, dated February 14, 2006, states that GEH internal users of software are to document and report to GEH Computer Department any engineering computer program technical usage problems, including potential errors.

Section 7.6.2 of GNF CP 23-01, states that GEH Computer Department documents all problems in engineering computer program problem reports and transmits them to the design and development organization managers for evaluation.

Section 7.7.6 of GNF CP 23-01, states that during the evaluation process, the problem is to be evaluated for any potential reportable conditions in accordance with the requirements of GNF P&P 70-42, "Reporting of Defects and Non-Compliance under 10 CFR Part 21," dated September 25, 2008.

Contrary to the above, as of December 19, 2008, GEH failed to perform a Part 21 evaluation when another GEH organization indicated that a software problem had impacted their use of the code. Specifically, GEH Engineering Computer Program problem report 2007-20 reported usage problems with the application of the GEXL critical quality boiling length correlation built into the TRACG code and was not adequately forwarded to GEH Nuclear Quality Assurance for Part 21 processing. As a result, GEH failed to document the evaluation of Engineering Computer Program problem report 2007-20 for potential safety concerns, and subsequent Part 21 reporting.

### **GEH's Revised Response**

This revised response replaces the response in Reference 1 in its entirety.

Processing of Engineering Computer Program ("ECP") Problem Report 2007-20 did not result in objective evidence that 10 CFR Part 21 was considered, which equates to a failure to document an action. However, the identified problem did not constitute a condition reportable under 10 CFR Part 21.

### **Reason for the Violation**

GEH agrees that procedure GEH/GNF CP-23-01 did not require the GEH technical reviewer to document the results of the evaluation for determining reportable conditions:

- GEH/GNF CP-23-01 requirement: For Type A problems,<sup>1</sup> engineers in the role of Engineering Computer Program "Users" are required to perform the following: "During the evaluation process, the ECP problem will be evaluated for any potentially reportable conditions in accordance with the requirements of GNF P&P 70-42 or GEH P&P 70-42 and initiate action if appropriate."

Under the GEH process in place at the time of the NRC inspection, unless a problem report was escalated for further evaluation, there was no specific requirement to document objective evidence of the assessment of a review for 10 CFR Part 21 concerns. This condition was the result of weaknesses in procedure CP 23-01 and the GEH/GNF 70-42 in place at the time.

### **Corrective Actions Taken**

The problem with the ECP Problem Report process lacking proper documentation has been corrected through actions taken to:

- (1) change the ECP Problem Report process to require that the initiation of an ECP Problem Report results in the coincident initiation of a Corrective Action Report ("CAR"), and
- (2) change the CAR and 10 CFR Part 21 processes to require an individual initiating a CAR for a condition adverse to quality to determine whether it involves a deviation or failure to comply potentially associated with a substantial safety hazard at the time the CAR is initiated and to document the determination in the CAR.

In this manner, action taken to implement Section 7.7.6 of GEH/GNF CP 23-01 will be documented in the associated CARs. See also References 1 and 3 for details of these actions.

### **Planned Corrective Actions**

The actions taken ensure that the action required by Section 7.7.6 of CP-23-01 will be documented.

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<sup>1</sup> GEH and GNF engineers classify software errors as Type A or Type B; i.e., those that have an impact on calculated numerical results or those that do not, respectively.

**Date When Full Compliance Will Be Achieved**

Corrective actions for ECP Problem Report concerns have been implemented by the actions already completed, as described above.

**References:**

1. MFN 09-242, Richard Wittmeier (GEH) to the US NRC Document Control Desk, "Reply to Notices of Violation," April 23, 2009.
2. MFN 09-242, Supplement 1, Richard Wittmeier (GEH) to the US NRC Document Control Desk, "Reply to a Notice of Violation," May 15, 2009.
3. MFN 09-236, Richard Wittmeier (GEH) to the US NRC Document Control Desk, "Reply to a Notice of Violation," April 9, 2009.