



**HITACHI**

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December 9, 2009  
MFN 09-242, Supplement 5

Docket No. 0520010

U. S. Nuclear Regulatory Commission  
Attn: Document Control Desk  
Washington, DC 20555-0001

SUBJECT: Reply to Notices of Violation

REFERENCE: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT  
05200010/2008-201, NOTICE OF VIOLATION TO GENERAL  
ELECTRIC-HITACHI NUCLEAR ENERGY

GE-Hitachi Nuclear Energy (GEH) has received the NRC's letter dated November 9, 2009, providing the results of the staff's evaluation of GEH's responses to the notices of violation. As requested, GEH is providing the clarifications requested in your letter. The attachment should address the identified deficiencies.

I would appreciate an opportunity to discuss this information at your earliest convenience.

Sincerely,

Richard Wittmeier  
Senior Vice President, Quality  
GE Hitachi Nuclear Energy

Attachment:

1. GEH Clarifications – NOV 05200010/2008-201-04

cc: Richard Rasmussen

April 23, 2009

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Jerald Head  
James Klapproth  
Russ Bastyr  
Harold Neems

Attachment 1  
Reply to NRC Notice of Violation 05200010/2008-201-04  
Docket Number 05200010

GEH's Response to the NRC's Letter Dated November 9, 2009

In a letter dated November 9, 2009, NRC rejected GEH's response to NOV 201-04. The NRC staff found that "current application of two corrective action programs to design software during varying circumstances did not meet the requirements of NQA-1-1994, Subpart 2.7, Section 8, for two reasons." The reasons cited were:

1. GEH had not provided a basis for showing that the CAR process meets the specific requirements of NQA-1-1994, Subpart 2.7, Section 8.
2. GEH policies and implementing procedures did not provide adequate guidance to the user to utilize the software error reporting process in all phases of the software life cycle.

Response:

- A) In response to the NRC's concern # 1, GEH evaluated use of the GEH Corrective Action Reporting (CAR) process against the specific requirements of NQA-1-1994, Subpart 2.7, Section 8 for error reporting. The results of this evaluation (shown on Attachment 2) indicate there are two NQA1 requirements, which are outside the scope of the CAR system. These areas are:
- The CAR process does not provide a formal procedure of software problem and corrective action for software errors, and failures.
  - The CAR process does not provide a software configuration management scheme to implement corrections or changes in a controlled manner in accordance with NQA1 Section 5.2.

As a result of this review, GEH will implement the following:

1. GEH will implement a software anomaly and error tracking system, which covers the entire software life cycle.
2. Applicable GEH procedures shall be reviewed to ensure all Software Configuration Management requirements of NQA1 section 5.2 are met for computer calculations used for engineering design.

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B) In response to the NRC's concern # 2, GEH will take the following actions to resolve this concern.

1. GEH will implement a software anomaly and error tracking system, which covers the entire software life cycle. The accompanying procedure will provide adequate guidance on usage of the system throughout the entire software life cycle.
2. Any software utilized in design will require error reporting per the GEH Corrective Action Reporting system, as specified in the response to NOV 05200010/2008-201-03.

These actions will fully resolve the concerns expressed by the NRC in NOV 201-04. GEH will complete these actions by June 1, 2010.

## Attachment 2

### Assessment of NQA1, 2.7, section 8 to GEH Corrective Action Reporting Process

| NQA-1-1994<br>Subpart 2.7<br>Section No. # | NQA-1-1994<br>Subpart 2.7<br>Section Title     | NQA-1-1994 Subpart 2.7 Requirement                                                                                                                           | GEH                                                                                                                                                                                             |
|--------------------------------------------|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8                                          | <b>Problem Reporting and Corrective Action</b> | <b>A formal procedure of software problem and corrective action shall be established for software errors and failures.</b>                                   | Outside scope of CAR process.<br><br>An Anomaly and Error tracking procedure (covering the entire life cycle) is required to fully meet this requirement.                                       |
| 8                                          | Problem Reporting and Corrective Action        | This problem reporting system shall assure that problems are promptly reported to affected organizations to assure formal processing of problem resolutions. | The CAR process provides for prompt notification to affected organizations See CP-16-01 section 7.2.3                                                                                           |
| 8                                          | Problem Reporting and Corrective Action        | Problems in software may be classified by the organization responsible for the evaluation.                                                                   | This is an optional requirement of NQA1 that is implemented within Appendix A of the CAR system<br>See CP-16-01 Appendix A                                                                      |
| 8                                          | Problem Reporting and Corrective Action        | Any classification system shall have defined criteria based on the impact of the software output.                                                            | The CAR process provides a prioritization scheme.<br>See CP-16-01 Appendix A                                                                                                                    |
| 8                                          | Problem Reporting and Corrective Action        | Corrective action by the responsible organization shall assure that:                                                                                         |                                                                                                                                                                                                 |
|                                            |                                                | (a) problems are identified, evaluated, documented, and, if required corrected;                                                                              | Part of CAR process<br>See CP-16-01 section 7.2 & 7.9                                                                                                                                           |
|                                            |                                                | (b) problems are assessed for impact on past and present applications of the software by the responsible organization;                                       | Part of CAR process<br>See CP-16-01 section 7.6.4                                                                                                                                               |
|                                            |                                                | (c) corrections or changes shall be controlled in accordance with Section 5.2; and                                                                           | Outside scope of CAR process.<br><br>A detailed review of the Software Configuration procedures will be conducted and changes made (as required) to ensure full compliance to NQA1 section 5.2. |
|                                            |                                                | (d) preventive actions and corrective actions results are provided to affected organizations.                                                                | Part of CAR process<br>See CP-16-01 section 7.11                                                                                                                                                |