



HITACHI

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July 17, 2009
MFN 09-242, Supplement 3

Docket No. 0520010

SUBJECT: Reply to Notices of Violation

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

Dear Mr. Nakoski:

GE-Hitachi Nuclear Energy (GEH) has received the NRC's letter dated June 17, 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 052000010/2008-201-04

cc: Jerald Head
James Klapproth
Mark Harvey
Harold Neems

Attachment 1

GEH Clarifications – NRC Notice of Violation 05200010/2008-201-04

Docket Number 05200010

A Summary of GEH's April 23, 2009 Response

Clarifications Requested by the NRC

I. Error Reporting

The text of the NRC's request reads as follows:

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 an 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.

GEH offers the following clarifications:

Engineering Computer Programs have one of 4 levels. Each level represents a different phase in the ECP life cycle, as follows:

Level 1 – ECPs in the development phase. Level 1 ECPs have not yet been pre-verified and approved for design usage. Any such usage in design requires:

- 100% independent verification of the results
- Unique designator to indicate non certified level

Level 2 – ECPs pre-verified and approved for design usage

Level 3 – ECPs previously at Level 2, but not latest version

Level 4 – Retired ECPs

Engineering Computer Programs that have been designated as Level 2 ECPs are developed and verified under the GEH program in compliance with NQA-1-1994 subpart 2.7. Level 2 ECPs have been tested across their intended range of applicability. Under the GEH design control process, verification of analyses performed using Level 2 ECPs requires only confirmation that the inputs are correct and that the application of the software is consistent with its approved purpose. Level 2 ECPs require problem reporting per NQA-1-1994, Subparts 2.7, Section 8. GEH considers problem reporting as defined under Subpart 2.7 a requirement for Level 2, 3, and 4 ECPs.

ECP Level 1 is a life cycle phase, and is only intended to designate software undergoing the development and certification processes. Once certified, Level 1 ECP software is

elevated to Level 2. It is not the intent of the GEH program to have ECP software remain at Level 1.

As a general rule, Level 1 code will not be utilized for design activities. However, when business conditions dictate usage of software prior to certification, 100% independent verification of the analyses performed using the code is required for each application of the code. Identification of conditions adverse to quality subsequent to verification of the analyses will be dispositioned with the 10CFR 50, Appendix B, Criteria 16 Correction Action Program implemented at GEH.

Therefore, under the GEH process, the requirements of Subpart 2.7, Section 8, "Problem Reporting and Corrective Action," are not applicable to Level 1 ECPs due to their developmental status and independent verification requirements.

II. Standards for Non-Level-2 ECPs

The text of the NRC's request reads as follows:

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.

GEH offers the following clarifications:

All active Engineering Computer Programs (regardless of level) shall meet NQA-1-1994 or its equivalent NQA-2-1990. No other standards are utilized for ECP software.

III. Procurement

The text of the NRC's request reads as follows:

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.

GEH offers the following clarifications:

Software obtained externally to GE intended for ECP applications, (e.g. Commercial Off The Shelf Software (COTS)) used in the design process will be placed through the same process to achieve Level 2 certification as the internally developed ECP software.

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.

GEH offers the following clarifications:

All ECP software will be certified using the process defined in section II of NQA-1-1994.