



HITACHI

GE Hitachi Nuclear Energy

Richard Wittmeier
Senior Vice President
Nuclear Quality

P.O. Box 780 M/C A-10
3901 Castle Hayne Road
Wilmington, NC 28402

T 910 819-6240
Richard.Wittmeier@ge.com

April 9, 2009
MFN 09-237

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

Subject Reply to a Notice of Nonconformance

References: 1) NRC Notice of Nonconformance Docket Number 99900003/2009-201-02
 2) NRC Inspection Report 99900003/2009-201

GE Hitachi Nuclear Energy Americas LLC (GEH) hereby responds to the Notice of Nonconformance, Reference 1, dated March 13, 2009. The nonconformance was identified during an NRC inspection, Reference 2, conducted from January 27 thru January 30, 2009 at our facility by inspectors V. Hall, Aaron Armstrong and P. Prescott.

Our reply to Reference 1 is provided as an attachment to this letter.

The NRC inspection report comments and suggestions are helpful to us in our constant efforts to improve our programs, to ensure continued quality assurance of our products and processes, and to ensure our compliance with NRC regulations and license conditions.

Please contact me on (910) 819-6240 if you have any questions or would like to discuss this matter further.

Sincerely,

Richard Wittmeier

Attachment

cc: Jerry Head
 James Klapproth
 Kevin Walsh
 Harold Neems

IE09
WR

Attachment
Reply to NRC Notice of Nonconformance
Docket Number 99900003
Inspection Report No. 99900003/2009-201

This Attachment sets forth the reply of GE Hitachi Nuclear Energy Americas LLC (GEH) to the NRC's Notice of Nonconformance dated March 13, 2009 relative to NRC Inspection Report 99900003/2009-201 ("the Inspection Report"), Docket Number 99900003/2009-201-02 ("the Nonconformance").

The Nonconformance

The Notice of Nonconformance provides the following description of the Nonconformance:

"Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states in that "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

"Chapter 5, "Instructions, Procedures, and Drawings," of GEH Quality Assurance Program Description NEDO-11-209-04A, Revision 8, dated March 31, 1989, states in part that, "activities affecting quality, including methods of complying with 10CFR50, Appendix B, are delineated, accomplished, and controlled by such documents as policies, procedures, operating instructions, design specifications, shop drawings, planning sheets, test and inspection procedures, and standing instructions."

"Contrary to the above, as of January 30, 2009:

GEH failed to adequately document the engineering justification used to dedicate commercial-grade items. Two examples of inadequate documentation were:

1. GEH's dedication specifications and associated documents failed to provide an adequate link to original environmental and seismic qualifications.

2. GEH failed to adequately document its process for taking credit for Underwriters Laboratory (UL) certifications to verify material as part of the dedication process.”

“This issue has been identified as Nonconformance 9900003/2009-201-02.”

GEH's Response to the Notice of Nonconformance

GEH is not contesting the Nonconformance per the NRC statement that “GEH failed to adequately document the engineering justification used to dedicate commercial-grade items.” While GEH engineering expertise has provided adequate engineering justification for commercial grade dedication, the documentation for such items needs to be improved to provide additional clarity.

GEH has taken corrective steps to immediately address the issues identified in the Inspection Report where they may affect product quality, and has established a clear path forward to provide adequate documentation for commercial grade dedication engineering justification.

I. Reason for Nonconformance

The overall root cause for this nonconformance is procedural adequacy. Specifically, lack of adequate documentation in the dedication process is associated with procedures not providing sufficient guidance on documentation requirements. The following discusses the specific examples referenced in the NRC report.

A. Qualification Linkage:

1. GEH Engineering Operating Procedure (“EOP”) EOP 65-2.20, “ Customer PO Technical Evaluation and Dedication of Commercial Grade Items”, provides procedural guidance on the creation of Dedication Specifications. GEH procedure EOP 65-2.20 also provides direction on the selection and verification of critical characteristics. Engineering Service Instruction (“ESI”) 20-9.00, “Dedication Specification Generation” provides instructions for the generation of Dedication Specifications. The Technical Evaluation Worksheet (TEW) was implemented effective August 5, 2008 (Reference EOP 65-2.20, Revision 18) and these work sheets provide documentation of the technical evaluation performed in preparing the specification for commercial grade dedication.

2. Although the introduction of the Technical Evaluation Work Sheets improved the documentation of the technical evaluation, GEH has determined that the Technical Evaluation Work Sheets did not provide sufficient guidance on documenting Seismic and Environmental Qualification ("EQ") linkages to original plant equipment, parts and components. As such, additional preventive actions and improvements have been defined, as detailed in Sections II and III below.

B. UL Certification

1. EOP 65-2.20 and ESI 20-9.00 have historically not provided guidance on the use and acceptance of critical characteristics based on National Code Standards such as UL.

2. As a result of an internal audit GEH issued internal Corrective Action Request ("CAR") 46966 in November of 2008. This CAR identified, "Use and acceptance of UL verified critical characteristics in the GEH dedication program is not documented in EOP 65-2.20 or ESI 20-9.00."

3. The corrective actions for CAR 46966 were underway but not fully implemented at the time of the NRC inspection. These actions include updating EOP 65-2.20 and ESI 20-9.00 to provide more detail on the use of National Codes and Industry Standards, such as UL, as part of the dedication acceptance process.

4. Since the NRC inspection, an additional corrective action is planned to provide additional guidance in the TEW. The TEW will require justification of use of National Codes and Industry Standards, such as UL, if selected as a method to verify a Critical Characteristic, as identified in Section III.B.2.

II. Corrective Steps Taken and the Results Achieved

- A. On February 2, 2009 the day after the NRC Exit Meeting, an internal meeting was held with all affected engineering personnel responsible for preparing dedication specifications and the concerns raised by the NRC inspection were reviewed. The primary purpose of the meeting was to communicate the NRC concerns. It was stated that a detailed plan would be developed to address these concerns, and that in the interim, engineers were directed to provide additional focus on providing adequate documentation supporting the technical evaluation and qualification linkage.

- B. On February 5, 2009 CAR 47489 was issued as a result of the NRC inspection based on the discussions during the NRC Exit Meeting. The CAR was later revised once the NRC Report (NO. 99900003/2009-201) was received.
- C. On February 17 and February 19, 2009 a formal root cause analysis was performed by a cross-functional GEH team. The root cause analysis report is attached to CAR 47489.
- D. On March 7, 2009, CAR 47489 response (including the associated root cause analysis) was completed and the evaluation of the effect of this condition was completed based on reviewing dedication specifications of prior parts shipped, and also dedication specifications in process for the purpose of determining if there was a concern with the product quality. The conclusion of the effects of this condition was that there is no effect on product quality because linkage to the qualification test was confirmed by reviewing the engineering documentation. Therefore, the technical basis for selecting the critical characteristics, acceptance criteria, test frequency and test method identified in the dedication specification as well as linkage to qualification is not a concern.
- E. Additional steps were taken to validate the conclusion of the CAR effects and extents after the NRC report was received. On March 24 through March 26, 2009, commercial grade dedicated shipments were held and documentation reviewed to provide additional assurance that linkage to the qualification test existed. All product was accepted and released for shipment.
- F. On March 30, 2009 the NRC report was reviewed with all affected engineering personnel and the upcoming corrective and preventative actions identified on CAR 47489 were reviewed; reference Preventive Action #1 of CAR 47489.

III. Corrective Steps that will be taken to Avoid Further Non conformances

- A. The following corrective actions were identified as a result of the root cause analysis.
 - 1. EOP 65-2.20 and ESI 20-9.00 are being revised to provide more guidance on the use of National Codes and Industry Standards, such as UL, as part of the dedication acceptance process. Reference CAR 46966.
 - 2. ESI 20-9.00 is being revised to include a detailed explanation of sampling

plan criteria in accordance with EPRI TR-017218, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process". Reference CAR 47489.

- B. Preventive Action #2 of CAR 47489, requires that the Technical Evaluation Work Sheet be revised to provide clarification as follows:
1. Clarify the requirements for documenting linkage to the originally qualified part or assembly. The specific changes will be as follows:
 - Addition of all references and their file locations that are necessary to clearly link the current part to the original test or qualification report.
 - Addition of a requirement to list all superseded part / model numbers from the tested part to the currently sold part.
 - Addition of a requirement to clearly identify all critical subcomponents that are necessary to ensure qualification.
 - Addition of a clear qualification summary statement with a conclusion that specifically states that the current part number is qualified to a specific qualification report.
 2. Additionally, the TEW format will be modified to clearly document the explanation of the basis for selecting the critical characteristics, acceptance criteria, test frequency and test method. Included is a requirement to document justification of use of National Codes and Industry Standards, such as UL, if selected as a method to verify a Critical Characteristic. Reference Preventive Action #2 of CAR 47489.
- C. Preventive Action #3 of CAR 47489 reviews the changes to EOP 65-2.20, ESI 20-9.00 and the TEW with all affected engineering personnel.

IV. Date when Full Compliance will be Achieved

The corrective and preventative actions described will be completed on or before April 30, 2009.