



HITACHI

GE Hitachi Nuclear Energy

Jerald Head
Senior VP, Regulatory Affairs

3901 Castle Hayne Road
P.O. Box 780
Wilmington, NC 28402
USA

T (910) 819-5692
jerald.head@ge.com

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MFN 11-033

Docket No. 999000003

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

Subject: Reply to a Notice of Nonconformances

References: 1) NRC Nonconformance 99900003/2010-201-01
2) NRC Nonconformance 99900003/2010-201-02
3) NRC Nonconformance 99900003/2010-201-03
4) NRC Report 99900003/2010-201

GE-Hitachi Nuclear Energy Americas LLC (GEH) hereby responds to the Nonconformances, Reference 1 through 3, dated January 20, 2011. The Nonconformances were identified during an NRC inspection, Reference 4, conducted from December 7 to 10, 2011 at our facility by inspectors P. Prescott, Jonathan Ortega-Luciano, Aaron Armstrong, Victor Hall, and Michael Magyar.

Our reply to References 1, 2, and 3 are provided as attachments 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 Russell Bastyr at (910) 819-6240, or myself, if you have any questions or would like to discuss this matter further.

Sincerely,

Jerald Head

Feb. 18, 2010

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Attachment

cc: C. Reda
S. Hamilton
K. Lagesse
H. Madronero
R. Bastyr
J. Stallings
S. Gowdy
H. Neems
P. Campbell

Attachment
Reply to NRC Nonconformance
Docket Number 99900003
Inspection Report No. 99900003/2010-201

This Attachment sets forth the reply of GE-Hitachi Nuclear Energy Americas LLC (GEH) to the NRC's Notice of Nonconformance dated January 20, 2011 relative to NRC Inspection Report 99900003/2010-201 ("the Inspection Report"), Notice of Nonconformance **99900003/2010-201-01** ("the Nonconformance").

The Nonconformance

The Notice of Nonconformance provides the following description:

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states 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 Nuclear Energy Quality Assurance Program Description NEDO-11209-04A, Revision 8, dated March 31, 1989, states in part that, "activities affecting quality, including methods of complying with 10 CFR 50, 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."

GEH's Procedural Requirements and Responsibilities (PR&R) 15, "Nonconforming Materials, Parts, or Components," dated January 8, 2008, states in part that, "This procedure gives the requirements for the identification, documentation, segregation, disposition, and necessary notifications concerning nonconforming material."

GEH's Procedural Responsibilities and Instructions (PRI) 15-5, "Service Component Operation (SCO) Nonconforming Material Control," dated July 27, 2010, is the instruction that described the implementation of nonconforming material contained in PR&R 15. PRI 15-5, Section 4.6.3, states in part that, "if timeliness or effectiveness of other corrective actions creates potential for significant adverse effects on product quality or amount of rework, repair, or scrap, initiate a Corrective Action Request (CAR) per CP-16-01."

Contrary to the above, as of December 10, 2010:

GEH's PRI 15-5 failed to prescribe appropriate quantitative or qualitative acceptance criteria for determining that activities important to safety have been satisfactorily accomplished. Specifically, PRI 15-5 lacked any threshold to initiate the corrective action procedure for nonconforming design issues.

This issue has been identified as Nonconformance 99900003/2010-201-01.B.

GEH's Response to the Notice of Nonconformance

GEH is not contesting the nonconformance and has taken steps to address the issues identified in the Inspection Report. While GEH believes these changes represent an improvement to its program, GEH further believes that its program met the requirements of 10 CFR 50 Appendix B prior to these changes, as explained below.

I. Reason for the Nonconformance

A. Background

It was understood by the current and previous SCO Quality management that the requirements of 10 CFR50 Criterion V, and GEH Nuclear Energy Quality Assurance Program Description NEDO-11209-04A, Revision 8, dated March 31, 1989 were satisfied with the requirement within GEH's Procedural Responsibilities and Instructions (PRI) 15-05, "Service Component Operation (SCO) Nonconforming Material Control," dated July 27, 2010, Section 4.3.3.5, for the SCQ Engineer to review each non-conformance for reportability requirements under 10CFR Part 21 (P&P 70-42). PRI 15-05 section 4.6.3 also required that the SCQ Engineer make a Corrective Action Request (CAR) determination for each IR (non-conformance). If the SCQ Engineer determined that a CAR was required, CP 16-01 "CORRECTIVE ACTION PROCESS" Section 7.1.2 requires a Part 21 applicability determination.

B. Analysis

Although the requirements of Criterion V of 10 CFR Part 50 Appendix B were met with the requirement within PRI 15-05 for a CAR and Part 21 evaluation from the Quality Engineer for each non-conformance, the link to the 10CFR21 could be strengthened to improve the visibility of the Part 21 process. Based on the existing requirements in PRI 15-05, all parts that have been shipped meet the requirements of 10CFR50 Appendix B and the GEH Quality manual, NEDO-11209-04A.

II. Corrective Steps Taken and Results Achieved

- An External Priority B CAR 54003 has been generated, with corrective and preventive actions assigned with deliverable dates entered into the GEH scheduling program.
- To improve the visibility of 10 CFR Part 21 evaluation process, add the guidance for Part 21 applicability to the non-conformance disposition procedure PRI 15-05.
- Update PRI 15-05 to require the SCQ engineers to record the results of the Part 21 applicability review in the non-conformance disposition record.

III. Corrective Steps to Avoid Further Nonconformances

- Provide training for the SCQ Engineers for the new guidance within PRI 15-05.
- Perform an evaluation of other GEH businesses including GNF and GLE to determine similar opportunities to improve the visibility of the 10CFR21 evaluation process.
- Complete the procedural revisions discovered in these evaluations.

IV. Date Full Compliance Achieved

Full implementation of actions are expected to be completed by April 29, 2011

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The Nonconformance

The Notice of Nonconformance provides the following description:

Criterion III,

"Design Control," of Appendix B to 10 CFR Part 50, states in part that, "Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components." Additionally, Criterion III states in part that, "The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculation methods, or by the performance of a suitable testing program."

Chapter 3, "Design Control," of GEH Nuclear Energy Quality Assurance Program Description NEDO-11209-04A, Revision 8, dated March 31, 1989, states in part that, "Design verification is a process for independent review of designs against design requirements to confirm that the designer's methods and conclusions are consistent with the requirements, and that the resulting design is adequate for its specified purpose. Product designs and each application thereof are verified, consistent with contract requirements."

Contrary to the above, as of December 10, 2010:

GEH failed to verify the adequacy of design when performing commercial-grade dedication of electronics. Specifically, GEH's dedication process did not ensure that a technical evaluation was performed for the selection of critical characteristics to provide a link to original environmental and seismic qualifications.

GEH's Response to the Notice of Nonconformance

GEH is not contesting the nonconformance and has taken steps to address the issues identified in the Inspection Report. While GEH believes these changes represent an improvement to its program, GEH further believes that its program met the requirements of 10 CFR 50 Appendix B prior to these changes, as explained below.

I. Reason for the Nonconformance

A. Background

1. I&C personnel failed to perform the Technical Evaluation Worksheet (TEW) evaluation required by EOP 65-2.20 during Technical Approval for Service Order (SO) 1003419.
2. The Dedication Specification associated with SO 1003419, TI 4236, did not provide linkage to the original qualification documentation.
3. There are two formats allowed per engineering procedures to create or update Dedication Specifications, both of which require the TEW process to be followed.
 - a. Technical Evaluation Dedication (TED) – Most commonly used for Electrical & Mechanical parts.
 - b. Test Instruction / Test Procedure – Exclusively used for some Electronics parts.
4. This dual format capability contributed to the inconsistent use of the Technical Evaluation Worksheet by I&C personnel.

B. Analysis

GEH personnel did not perform a complete Technical Approval Evaluation (TA) for SO 1003419, where a TEW would have directed the engineer to perform a selection of critical characteristics and provide linkage to the original Environmental and Seismic Qualifications for the Dedicated Inverter.

Further investigation of Service Orders for Dedicated Electronics items processed between 07/01/2009 and 12/31/2010, showed there were a total of 90 Service Orders. Of these 90 Service Orders, 42 had verifiable TEWs performed or reviewed during the Technical Approval process, and 48 did not have a TEW.

The 48 Service Orders that did not have a TEW involved Electronic parts that used Test Instruction / Test Procedures to document the dedication requirements. The 42 Service Orders that had verifiable TEWs involved Electronic parts that used the Technical Evaluations Dedication Specifications.

The Engineers misinterpreted the procedures and did not understand that the TEW was required for Test Instructions / Test Procedures. Training on the change to the Technical Approval / Dedication Process in mid-2009 was less than adequate.

For all Dedicated items on the 48 Service Orders where a TEW was not performed, including SO 1003419, the actual Dedication of those items was not impacted by the omission of the qualification linkage on the Test Instruction / Test Procedure Dedication Specification as the equipment was fully tested to the specification requirements prior to shipment.

II. Corrective Steps Taken and Results Achieved

- A. The Responsible Engineer who performed the inadequate Technical Approval for SO 1003419 has been counseled concerning this oversight.
- B. Specific training and guidance on the importance of the TEW process has been provided to all Services I&C personnel who have responsibility to perform Technical Approvals in accordance with CP 07-104, Customer Purchase Order Technical Evaluation and Dedication of Commercial Grade Items. CP 07-104 recently superseded EOP 65-2.20 and contains the same requirements for performance of a TEW.
- C. Service Orders for Dedicated Electronics Items, dated from 07/01/2009 to 12/31/2010, have been reviewed for compliance to the required TEW/TED review during Technical Approval. All non-compliant Service Order items (48) have been identified for additional review to meet TEW/TED requirements.

III. Corrective Steps to Avoid Further Nonconformances

- A. CAR 54004 has been initiated to track the following required corrective actions.
 - a. Update Selected Item Drawing and Dedication Spec for Inverter family, DA265A1845, with appropriate original qualification linkages and Critical Characteristics.
 - b. Update Selected Item Drawing and Dedication Specification for parts identified in II.C above.
 - c. Provide training for individuals within Services I&C who may be tasked with the creation or updating of a Dedication Specification. Training will focus on using the TED/TEW process for all updates and new specifications.

IV. Date Full Compliance Achieved

All actions identified above will be completed by June 30, 2011.

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The Nonconformance

The Notice of Nonconformance provides the following description:

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states 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. The instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

Criterion VII, "Control of Purchased Material, Equipment, and Services," states in part that, "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery."

Chapter 7, "Control of Purchased Material, Equipment and Services," of GEH Nuclear Energy Quality Assurance Program Description NEDO-11209-04A, Revision 8, dated March 31, 1989, states in part that, "measures for evaluation, certification, or qualification, and selection of procurement sources by engineering and QA personnel include the use of historical quality performance data, source surveys (including a review of the supplier's QA Program), or source qualification programs."

GEH Policies and Procedures (P&P) 70-14, "Quality Assurance Audit Requirements," dated July 29, 2010, states in part that, "Supplier audits [surveys] of commercial grade calibration suppliers is not required for GEH/GNF/GLE or GEH/GNF/GLE suppliers if the calibration supplier has been assessed and certified by the following accreditation bodies:

- NVLAP [National Voluntary Laboratory Accreditation Program]
- A2LA [The American Association for Laboratory Accreditation]
- ACLASS Accreditation Services [ACLASS]
- Laboratory Accreditation Bureau [LAB]
- International Accreditation Services, Inc. [IAS]

For international suppliers, calibration services purchased from international calibrations suppliers accredited by ILAC [International Laboratory Accreditation Cooperation] are considered to have an equivalent accreditation to NVLAP and A2LA per the ILAC Mutual Recognition Agreement."

Contrary to the above, as of December 10, 2010:

GEH failed to prescribe instructions appropriate to the circumstances. Specifically, P&P 70-14 did not prescribe measures to perform a survey of international calibration services suppliers.

This issue has been identified as Nonconformance 99900003/2010-201-03.

GEH's Response to the Notice of Nonconformance

GEH is not contesting the nonconformance and has taken steps to address the issues identified in the Inspection Report. While GEH believes these changes represent an improvement to its program, GEH further believes that its program met the requirements of 10 CFR 50 Appendix B prior to these changes, as explained below.

I. Reason for the Nonconformance

Guidance provided in the "SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION PROPOSED CHANGE TO THE QUALITY ASSURANCE PROGRAM COMMERCIAL-GRADE CALIBRATION SERVICES ARIZONA PUBLIC SERVICE COMPANY, ET AL. PALO VERDE NUCLEAR GENERATING STATION, UNITS 1, 2, AND 3 DOCKET NOS. 50-528, 50-529, AND 50-530," released under an NRC letter dated September 28, 2005, issued by Daniel S. Collins (NRC), addressed to Gregg Overbeck (APS), with the subject of "PALO VERDE NUCLEAR GENERATING STATION, UNITS 1, 2, AND 3 - APPROVAL OF CHANGE TO QUALITY ASSURANCE PROGRAM (COMMERCIAL-GRADE CALIBRATION SERVICES) (TAC NOS. MC4402, MC4403, AND MC4404)" was incorrectly applied to international calibration suppliers by GEH. This NRC Guidance Letter and the approved regulatory variance are only allowed for Domestic (US) application of this variance. Based on the misinterpretation of the approved NRC variance, GEH incorrectly revised P&P 70-14, "Quality Assurance Audit Requirements," to allow relief from the performance of a survey or audit of international calibration suppliers for placement on the GEH Approved Suppliers List (ASL).

II. Corrective Steps Taken and Results Achieved

P&P 70-14, "Quality Assurance Audit Requirements" was revised to remove the following procedural guidance:

4.2.1.f

"For international suppliers, calibration services purchased from international calibrations suppliers accredited by ILAC are considered to have an equivalent accreditation to NVLAP and A2LA per the ILAC Mutual Recognition Agreement."

4.1.2.h

"Supplier audits of international calibration suppliers are not required for GEH/GNF/GLE or GEH/GNF/GLE suppliers if the calibration supplier has been assessed and certified by the following accreditation bodies:

European Accreditation of Certification (EAC) member bodies:

- Swiss Accreditation Service (SAS - Schweizerische Akkreditierungsstelle)
- Swedish Board for Accreditation and Conformity Assessment (SWEDAC - Styrelsen för Ackreditering och Teknisk Kontroll)
- Spanish Association for Standardization and Certification (AENOR)
- German Physical –Technical Federal Institute (PTB - Pysikalisch-Technische Bundesanstalt)
- Japanese accreditation bodies:
- Japanese National Institutes (mechanical, electrical, electronically, and electric wave)
- Japan Ministry of Economy, Trade and Industry (METI).

For these calibration suppliers, the existence of certification documents shall be confirmed. In absence of certification documents, the calibration supplier's QA manual, including implementing procedures, shall be reviewed to assess that the scope of accreditation satisfies the technical and quality requirements for the nuclear services to be subcontracted. The results of the review shall be documented."

P&P 70-14 now complies with 10CFR 50 Appendix B, criteria V & VII and NEDO 11209, Chapter 7.

III. Corrective Steps to Avoid Further Nonconformances

Determine the effects on the ASL status of International Calibration Suppliers caused by the removal of incorrect guidance in P&P 70-14. If international calibration suppliers are removed from the ASL due to the revision of P&P 70-14, Corrective Actions under the GEH Corrective Action program will be initiated to capture conditions adverse to quality and document the appropriate effects, extents and corrections.

IV. Date Full Compliance Achieved

Full implementation of corrective actions are expected to be completed by June 30, 2011