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MFN 09-779

Docket Number 05200010

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

Subject: Reply to Notice of Violation, NRC Inspection Report 5100010/2009-201

References: 1) NRC Notice of Violation Docket Number 05200010/2009-201-01, 05200010/2009-201-02, 05200010/2009-201-03
2) NRC Inspection Report 05200010/2009-201

GE-Hitachi Nuclear Energy Americas LLC (GEH) hereby responds to the Notice of Violation, Reference 1, dated November 12, 2009. The violation was identified during an NRC inspection, Reference 2, conducted from September 14 -18, 2009 at our facility by inspectors Y. Diaz-Castillo, S. Cleavenger, C. Hinson, I. Berrios, B. Broadhead.

Our reply to Reference 1 is 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 me at (910) 819-6240 if you have any questions or would like to discuss this matter further.

Sincerely,

A handwritten signature in cursive script that reads "Richard D. Wittmeier". The signature is written in black ink on a white background.

Richard Wittmeier

Attachment 1, 2, 3

cc: R. Ramussen (NRC)
Jerry Head
James Klapproth
Harold Neems
Russell Bastyr

Attachment 1
Reply to NRC Notice of Violation
Docket Number 05200010
Inspection Report No. 05200010/2009-201

This Attachment sets forth the reply of GE-Hitachi Nuclear Energy Americas LLC (GEH) to the NRC's Notice of Violation dated November 12, 2009 relative to NRC Inspection Report 05200010/2009-201 ("the Inspection Report"), Docket Number 05200010/2009-201-01 ("the Violation").

The Violation

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

Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50 states, in part, that "the applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance (QA) program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions. The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

Section 2.3.1 of GEH's Policy and Procedure 70-30, "Personnel Proficiency in Quality

Related Activities," dated August 4, 2003, stated that records may be retained in an employee's file, as separate file or as a centralized computer database.

Section 2.5 of GEH's Engineering Operating Procedure 75-5.00, "Quality and Technical

Training," Revision 15, dated May 11, 2009, stated that training assignment and completion records for GEH personnel shall be recorded and maintained in a centralized database and controlled as a Quality Information System.

Contrary to the above, as of September 18, 2009, the GEH QA program did not provide procedural guidance for managing the centralized computer database.

Furthermore, as of September 18, 2009, there were 12 databases used to control training records, six of which had been migrated to a new centralized database in accordance with the requirements of procedures 70-30 and 75-5.00. Although a procedure is currently in development for the new centralized database, GEH is currently using multiple databases for which no procedure exists on how to manage these databases.

GEH's Response to the Violation

I. Reason for the Violation

GEH agrees that multiple databases are being used for which job aids and training are in place but for which there are no GEH procedures issued. GEH

has reviewed existing databases to obtain a complete view of all existing training databases. The review of these systems shows that training has been documented and maintained. Job aids and training have been provided to the administrators of existing systems. These systems are operated in a controlled manner, though it is not documented in a procedure.

II. Corrective Steps Taken and Results Achieved

The following near-term steps were taken in response to the Violation while the corrective action process changes described in Section III, below, are being developed and implemented:

Our investigation of all existing training databases showed that the administrators of each system to ensure records are maintained were handling administration adequately. The administrators of each system had been provided a combination of job aids and training.

III. Corrective Steps to Avoid Further Violations

As documented in CAR #49456 the following steps are being taken:

- (a) Updated P&P 70-30 to incorporate the requirement that the administration of training databases be documented in a procedure and that training records be maintained as quality records
- (b) Create and issue Nuclear work instructions for the administration of the myLearning system
- (c) Create and issue Nuclear work instructions for all Nuclear training systems.
- (d) Train administrative personnel on newly created work instructions

IV. Date Full Compliance Achieved

The actions described in Section III above will be in place no later than March 15, 2010.

Attachment 2
Reply to NRC Notice of Violation
Docket Number 05200010
Inspection Report No. 05200010/2009-201

This Attachment sets forth the reply of GE-Hitachi Nuclear Energy Americas LLC (GEH) to the NRC's Notice of Violation dated November 12, 2009 relative to NRC Inspection Report 99900003/2009-201 ("the Inspection Report"), Docket Number 99900003/2009-201-02 ("the Violation").

The Violation

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

Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 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. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Engineering Operating Procedure (EOP) 30-5.00, "Supplier Design Services Document Review," Revision 10, dated March 20, 2009, required GEH engineers and/or managers performing receipt inspections to verify that "all necessary inputs were correctly identified and applied" in design packages received from suppliers and to document this review by checking a box on form NEO-866, "Review/Acceptance of Purchased Design Service Documents," dated March 2007.

Section VII, "Control of Purchased Material, Equipment, and Services," of the GE Nuclear Energy Quality Assurance Program Description," Revision 8, dated March 31, 1989 required, as a minimum, a triennial audit and annual evaluations of safety related suppliers and stated that "When an evaluation is performed, the results are documented and approved by responsible QA personnel. This evaluation considers pertinent factors, such as: the results of previous audits; history of performance of product and/or purchased service; effectiveness of implementation of the supplier's QA Program; and the importance, complexity, and quality requirements of the item or service concerned."

Contrary to the above:

1. EOP 30-5.00 failed to provide adequate guidance for personnel to verify that "all necessary inputs were correctly identified and applied" in design packages received from suppliers (i.e., which inputs are necessary, how to

verify that they were correctly identified and applied, etc.). The NRC inspectors found that the GEH engineers who performed receipt inspections of calculations had varying interpretations of the intent of this statement, and as such, were implementing the requirement inconsistently.

2. GEH did not perform an adequate review of the work performed by Empresarios Agrupados Internacional, S.A. (EA) between October 2007 and October 2008 to justify EA's continued status as an approved supplier. The latest supplier QA Program Evaluation conducted by GEH of EA, dated October 9, 2008, was inadequate in that the following sections of the evaluation were marked "N/A," even though there were 5 CARs issued as a result of the 2007 EA audit, one CAR for errors in calculations, and 7 receipt inspections that should have been evaluated and documented on the annual evaluation:

- Results of previous source verifications, audits, and receiving inspections.
- Nature and severity of corrective action requests (CARs) including evaluation of supplier's responsiveness to and effectiveness of corrective action programs.
- Review and evaluate the supplier's furnished documents and records such as Certificates of Conformance, nonconformance notices, and corrective actions.

GEH's Response to the Violation

I. Reason for the Violation

Item 1

GEH Engineering Operating Procedure EOP 30-5.00, Supplier Design Services Documentation Review, directs the engineer conducting receipt inspection of design services documentation to confirm, "the necessary inputs were correctly identified and applied." The direction is given for both interim reviews (step 4.2.2.c.) and final reviews (step 4.3.5.c). This direction is open to interpretation, and further guidance describing the extent of the reviews does not exist in EOP 30-5.00 or in form NEO-866, which is used to document review/acceptance of purchased design service documents.

The lack of clarity and specificity around this procedural requirement led to the variance in answers received by NRC inspectors when GEH engineers were asked about application of the confirmation steps.

Item 2

GEH 2008 Annual Evaluation performed of Empresarios Agrupados used form RC-0876A governed by procedure AG-003 (Supplier Audits and Surveys). The process to update and maintain GEH Approved Supplier List (ASL) was at that time governed by AG-002. This dual procedural basis and lack of clear instructions to complete the forms caused the Supplier Quality Engineer to miss CARs that resulted from the 2007 audit as well as the evaluation of the receiving inspection forms performed in the interval 2007-2008. These deficiencies were identified internally at GE prior to the NRC inspection and GEH has already taken measure to clarify and simplify the procedural requirements.

II. Corrective Steps Taken and Results Achieved

Item 1

GEH has gathered the additional information necessary from Empresarios Agrupados to respond to NRC RAI 12.2-19 SO3, which raised the need for explanations of increased dose rates calculated for a dropped fuel bundle in GEH's response to RAI 12.2-19 SO2. This information has been provided to the NRC in GEH letter MFN 09-498, issued on August 10, 2009. In addition, necessary changes have been made to the ESBWR DCD Revision 6 chapter 12 figures and text based on the revised Empresarios Agrupados analyses and report.

DRF 0000-0104-9040 contains the design information used to complete the response to NRC RAI 12.2-19 SO3. The completed receipt inspection form (NEO 866) is located in nefile 0103-1742.

Item 2

Empresarios Agrupados (EA) Annual Evaluation was performed on October 09, 2009 using the new and updated instructions and form for annual evaluation. This assessment includes evaluation of Supplier CARs issued to EA, as well as a thorough review of the receipt inspection forms performed during the last calendar year and supplier furnished documents.

Records of this annual evaluation are maintained per GEH policy. This action has been documented in GEH Corrective Action Report 49455. As result of this evaluation Empresarios Agrupados remains on the GEH Approved Supplier as active supplier with restrictions for GEH to perform a peer review of engineering calculations and document it as part of the receiving inspection form (NEO 866).

III. Corrective Steps to Avoid Further Violations

Item 1

GEH Engineering benchmarked the industry, and determined to take the following steps to avoid further violations:

- EOP 30-5.00 and form NEO 866 steps requiring confirmation of “necessary inputs” are being revised to read “the design inputs and customer technical requirements, as defined in the purchase order (PO), were applied in the design documents.” These steps will be further clarified to direct the responsible engineer to compare the design inputs and customer technical requirements transmitted to the supplier to those used in the design documentation. (Using the phrase “design inputs and customer technical requirements” instead of “ necessary inputs” provides additional clarification as this terminology is used in other GEH engineering design procedures.)
- GEH will provide training on the EOP 30-5.00 and form NEO 866 revisions described above to engineers who conduct receipt inspections of supplier provided design documentation.

Item 2

CP-07-02 “Supplier Approval”, Rev 9 (9/17/09) has been implemented to improve the guidance to perform Supplier Annual Evaluation and to update the annual evaluation form to include specific provisions for receipt inspection evaluation. Additionally CP-18-02 “Supplier Audits and Surveys” Rev 4 (10/26/09) has been issued to incorporate more rigorous process and standardization across the business related to Supplier Audits and Commercial Grade Surveys. Finally the new created position of Audit Director is taking the lead to enhance the lead auditor training including industry issues awareness with the goal to improve the quality of supplier quality oversight.

IV. Date Full Compliance Achieved

Item 1

GEH will implement the procedure and form changes as described by March 15, 2010.

Item 2

All corrective actions have been implemented as of October 26, 2009.

Attachment 3
Reply to NRC Notice of Violation
Docket Number 05200010
Inspection Report No. 05200010/2009-201

This Attachment sets forth the reply of GE-Hitachi Nuclear Energy Americas LLC (GEH) to the NRC's Notice of Violation dated November 12, 2009 relative to NRC Inspection Report 05200010/2009-201 ("the Inspection Report"), Docket Number 05200010/2009-201-03 ("the Violation").

The Violation

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

Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

Appendix A, "Priority Level of CARs," of Corrective Action procedure CP-16-01, "Corrective Action Process," Revision 5, dated May 1, 2009, stated the definition of a Priority Level A, a Significant Condition Adverse to Quality (SCAQ), as "a condition adverse to quality, which, if uncorrected, could have a serious effect on safety or operability." Appendix A of CP-16-01 also required that for a SCAQ, an identification of causal factors, an independent root cause investigation, and an extent of condition evaluation be performed. Appendix A also required that preventive actions be taken in order to prevent recurrence.

Contrary to the above, CAR 48406, opened in response to the radiation shielding error associated with the MCNP energy spectrum, was not appropriately classified as a Priority Level A, a SCAQ, and did not include an identification of causal factors, an independent root cause investigation, and an extent of condition. CAR 48406 should have been classified as a Priority Level A instead of a Priority Level C because:

1. The error could have had a serious effect on worker safety given the potential for a personnel overexposure in the event of a fuel drop accident, and
2. The significant increase in the radiation zoning designation for the upper drywell had a significant negative effect on operations by no longer permitting continuous operations in the upper drywell during refueling operations and restricting access to this area.

GEH's Response to the Violation

I. Reason for the Violation

GEH Engineering performed a root cause analysis on the inappropriate prioritization of CAR 48406. The root cause analysis identified the following root causes for event:

- GEH form CP-16-01-04, CAR Prioritization Level Decision Tree, does not provide guidance for evaluating prioritization criteria for CARs written against design licensing documentation for new products and plants. Without this additional guidance, those involved in the CAR process distinguish between existing, licensed designs and designs being submitted for licensing. In particular, design licensing documentation should be treated as though the “regulatory life” of the referenced design begins with docketing of the licensing document.
- CP-16-01, Corrective Action Process, does not include consideration of Supplier CARs by the CAR Oversight Group during the group’s review of GEH and GNF CARs. Although consideration of Supplier CARs would not have resulted in raising the priority of CAR 48406, it could have identified the history and trend in work product errors by Empresarios Agrupados Internacional, S.A. (EA) within a week of the initiation of CAR 48406. Recognition of the trend would have led to full review of the effects and extents of cause(s) associated with the EA errors.

II. Corrective Steps Taken and Results Achieved

Response to NRC RAI 12.2-19 SO3, which was the genesis of CAR 48406, was issued under MFN 09-498 on August 10, 2009 and the necessary changes have been made to the ESBWR DCD Revision 6 chapter 12 figures and text based on the revised EA analyses and report.

DRF 0000-0104-9040 contains the design information used to complete the response to NRC RAI 12.2-19 SO3. The completed receipt inspection form (NEO 866) is located in nefile 0103-1742.

CAR 48406 has been re-opened and prioritized as a Significant Condition Adverse to Quality CAR (Priority A).

III. Corrective Steps to Avoid Further Violations

GEH Engineering will complete the Response Analysis for CAR 48406, and perform a Root Cause Analysis of how the explanation for the increased dose rate provided by EA was not provided in GEH's response to RAI 12.2-19 SO2. The Root Cause Analysis will include an investigation of the extent of condition and the extent of cause identified by the analysis.

GEH form CP-16-01-04, CAR_Prioritization Level Decision Tree, will be revised to provide guidance for evaluating priority criteria for CARs written against design licensing documentation for new products and plants. The new guidance will state that such documents should be treated as though the "regulatory life" of the referenced design begins with docketing of the licensing document when determining CAR priority.

CP-16-01, Corrective Action Process, will be revised to direct the CAR Oversight Group to include consideration of Supplier CARs when evaluating corrective action requests for trends.

Corrective Action Program training will be revised to include the changes to for CP-16-01-04 and CP-16-01 discussed above.

A Lessons Learned will be created and distributed to GEH employees establishing expectations and clear guidance on evaluating priority criteria for CARs written against design licensing documentation for new products and plants. This Lessons Learned will be covered at upcoming CAR Screener, CAR Oversight Group and CAR Critique meetings to ensure Screeners and members of the Oversight and Critique groups are familiar with the expectations.

IV. Date Full Compliance Achieved

The corrective steps to avoid further violation will be completed by March 31, 2010.