Enclosure 2

MFN 12-075

GEH Reply to NRC Notice of Violation Docket Number 05200010/2012-201-01, 05200010/2012-201-02, 05200010/2012-201-03

Public Version

NON-PROPRIETARY VERSION

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GEH Reply to NRC Notice of Violation 05200010/2012-201-01
Docket Number 05200010
Inspection Report No. 05200010/2012-201

This section sets forth the reply of GE-Hitachi Nuclear Energy Americas LLC (GEH) to the NRC's Notice of Violation dated July 6, 2012 relative to NRC Inspection Report 05200010/2012-201 ("the Inspection Report"), Docket Number 05200010/2012-201-01 ("the Violation").

The Violation

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

> Criterion III, "Design Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," 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 calculational methods, or by the performance of a suitable testing program."
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> GEH Quality Assurance Topical Report NEDO-11209-A, "GE Hitachi Nuclear Energy [GENE] Quality Assurance Program Description," dated August 2011, in Section 3.4.1, "Use of Computer Programs," states, in part, that the results of computer programs used for design analysis are verified with each use or pre-verified to show the following: (1) the computer program produces correct solutions for the encoded mathematical model within defined limits for each parameter employed, and (2) the encoded mathematical model produces a valid solution to the physical problem associated with the particular application.
>
> Contrary to the above, as of April 20, 2012, GEH failed to provide adequate design control measures for verifying and validating the adequacy of the ANSYS computer software model used in a dynamic complex analysis. Specifically, the Equipos Nucleares SA (ENSA) test report on the validation of the ANSYS model (1) did not include acceptance criteria for the comparison of the ANSYS results to the target results, (2) did not discuss the basis for the acceptability of the ANSYS model in comparison to acceptance criteria, and (3) did not specify the bias and uncertainty values that would be included in the engineering calculations based on the validation of the ANSYS model.

GEH's Response to the Violation

I. Reason for the Violation

GEH concurs with the violation. A non-conformance assessment conducted by GEH the week of July 23, 2012 determined that GEH design control measures lack specific direction for ensuring the adequacy of suppliers' software quality assurance programs. Two processes are in need of improvement: (1) CP-18-02, "Supplier Audits and Commercial Grade Surveys" does not require the use of a design software audit checklist when auditing suppliers performing

design services. It relies on a more general checklist that covers multiple types of software and software applications. (2) EOP 45-4.00, "Supplier Submitted Supporting Documents," (the process used to review and approve supplier documents for use in GEH design work) does not list design software verification and validation documents as potential documents for GEH Engineering review and approval.

II. Corrective Steps Taken and Results Achieved

Note: At the time of the inspection, GEH used Corrective Action Requests (CARs) to track issues and actions in its Corrective Action Program. GEH has since implemented a new Corrective Action Program and now uses Condition Reports (CRs) to track issues. The content and purpose of CARs and CRs are essentially the same.

Supplier Corrective Action Request (S-CAR) 58401 was written to ENSA on April 19, 2012 requesting that ENSA respond to the software qualification issues identified by the NRC. ENSA is in the process of responding to the Supplier CAR. As part of their response, ENSA has revised the ANSYS software model qualification test report associated with NOV 05200010/2012-201-01, and has re-issued the report to GEH Engineering for review.

III. Corrective Steps to Avoid Further Violations

The following corrective steps will be taken by GEH to strengthen design control measures and avoid similar violations in the future:

- CP-18-02, "Supplier Audits and Commercial Grade Surveys" will be revised to require the use of supplemental software audit checklists when auditing suppliers of safety-related components or services employing software in design activities. See response to Notice of Violation 05200010/2012-201-03 for commitment to develop software audit checklists covering software classifications listed in GEH P&P 70-6.00, "Digital Computer Software Classifications and Quality Requirements".
- EOP 45-4.00, "Supplier Submitted Supporting Documents," will be revised to include review and approval of supplier software verification and validation documents when supplier designs or design services use or rely on software.
- GEH Engineering will review and confirm adequacy of the ANSYS software model qualification test report provided by ENSA as discussed in Section II.

IV. Date Full Compliance Achieved

GEH will complete the corrective actions discussed in Section III by December 31, 2012 to achieve full compliance.

GEH Reply to NRC Notice of Violation 05200010/2012-201-02
Docket Number 05200010
Inspection Report No. 05200010/2012-201

This section sets forth the reply of GE-Hitachi Nuclear Energy Americas LLC (GEH) to the NRC's Notice of Violation dated July 6, 2012 relative to NRC Inspection Report 05200010/2012-201 ("the Inspection Report"), Docket Number 05200010/2012-201-02 ("the Violation").

The Violation

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

> Criterion I, "Quality Standards and Records," of Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 states, in part, that "Structures, systems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed."
>
> [[ ]], "Contract to Provide Steam Dryer Fabrication for [[ ]]," dated March 31, 2007, defines contractual quality requirements, which includes special provisions that impose Appendix B to 10 CFR Part 50, quality assurance requirements, on the [[ ]] steam dryer fabrication.
>
> Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 requires, in part, that "In the case of significant conditions adverse to quality, the measures shall ensure that the cause of the condition is determined and corrective action is 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."
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> GEH Quality Assurance Topical Report NEDO-11209-A in Section 3.2.1.16, states, in part, that "A significant condition adverse to quality (SCAQ) is a failure, malfunction, deficiency, defective item, or nonconformance that, if uncorrected, could have a serious effect on safety or operability. SCAQs are documented, reported to responsible management, their cause is determined and actions to preclude its recurrence are taken."
>
> GEH Common Procedure CP-16-01, Revision 14, "Corrective Action Process," dated February 2, 2012, defines a SCAQ as, "A condition adverse to quality, which, if uncorrected, could have a serious effect on safety or operability."
>
> Contrary to the above, as of April 20, 2012, GEH failed to establish measures to adequately evaluate and determine the cause of a condition and identify corrective actions to preclude recurrence. Specifically, GEH did not provide an adequate evaluation of potential issues resulting from partial joint penetration welds in boiling-water reactor (BWR) steam dryers described in GEH Potentially Reportable Condition PRC 11-71, "Steam Dryer Partial Penetration Welds– [[ ]], dated January 26, 2012. In particular, PRC 11-71 did not

provide a technical evaluation to demonstrate the structural integrity of BWR steam dryers with partial penetration welds, nor did it provide an evaluation of the specific partial penetration welds and their location in the [[ ]] steam dryers, and their likelihood of cracking and the generation of loose parts that could cause a SCAQ. GEH concluded that the presence of loose parts in the reactor coolant and steam systems would not create a substantial safety hazard. In addition, the extent of condition evaluation in PRC 11-71 did not address the plant-specific aspects of the evaluation of potential loose parts from degradation of partial penetration welds in other BWR steam dryers.

GEH's Response to the Violation

I. Reason for the Violation

Note: At the time of the inspection, GEH used Corrective Action Requests (CARs) to track issues and actions in its Corrective Action Program. GEH has since implemented a new Corrective Action Program and now uses Condition Reports (CRs) to track issues. The content and purpose of CARs and CRs are essentially the same.

GEH does not contest the violation. Notably, GEH initiated CAR 57215 in December of 2011, which specifically considered the causes of steam dryer analysis issues. This CAR, and its associated cause evaluation, generated corrective and preventive actions to update analyses and methodology to account for partial penetration welds.

GEH agrees that the documentation within Potentially Reportable Condition PRC 11-71, "Steam Dryer Partial Penetration Welds–[[ ]]," dated January 26, 2012, could have been improved.

PRC 11-71 focused on three major discussion areas: (1) steam dryer general Operating Experience (OE); (2) [[ ]] plant specific OE and Partial Joint Penetration (PJP) welds; and (3) the potential consequences of loose parts from a postulated loss of steam dryer integrity. The loose parts analysis centered on a 2003 GEH analysis of the potential impacts of loose parts[1] from steam dryers, which was subsequently incorporated into a BWRVIP report and reviewed by the NRC. During the inspection, the NRC reviewers stated that the PRC closure documentation over-relied on the loose part discussion to support the conclusions and the evaluation of the extent of condition. CAR 58370 (now CR 619) was written in response to the NRC reviewer concerns.

II. Corrective Steps Taken and Results Achieved

In response to CR 619, an additional, extended evaluation has been performed. The updated evaluation concludes that, based upon extensive operating experience, partial joint penetration welds (as they are applied in [[ ]] and other GEH dryer designs) are not expected to lead to fatigue cracking, degradation, and subsequently generate loose parts that would be considered a potential substantial safety hazard.

[1] GENE-0000-0018-1060-R0, *Technical Assessment* – [[ ]] – *Failure Modes and Effects Evaluation for Steam Dryer Components*, Class III, June 2003.

III. Corrective Steps to Avoid Further Violations

The following corrective steps will be taken by GEH to fully resolve Partial Joint Penetration (PJP) weld concerns:

- Perform an evaluation (e.g., using finite element models) of the [[ ]] PJP welds and analytically determine the fatigue margin.
- Review replacement or modified dryers [[ ]]. If necessary, create additional corrective actions to address any identified deficiencies.

IV. Date Full Compliance Achieved

GEH will complete the corrective actions discussed in Section III by June 28, 2013 to achieve full compliance.

GEH Reply to NRC Notice of Violation 05200010/2012-201-03
Docket Number 05200010
Inspection Report No. 05200010/2012-201

This section sets forth the reply of GE-Hitachi Nuclear Energy Americas LLC (GEH) to the NRC's Notice of Violation dated July 6, 2012 relative to NRC Inspection Report 05200010/2012-201 ("the Inspection Report"), Docket Number 05200010/2012-201-03 ("the Violation").

The Violation

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

> Criterion XVI of Appendix B to10 CFR Part 50 requires, 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."
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> GEH Quality Assurance Topical Report NEDO-11209-A in Section 3.2.1.16, states, in part, that GEH has established the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality (CAQs). Implementing procedures ensure that appropriate actions are initiated following the determination of CAQs in accordance with regulatory requirements. GEH procedures require personnel to identify known CAQs in a timely manner so that corrective actions are adequately documented and not inadvertently nullified by subsequent actions.
>
> CP-16-01 defines a condition adverse to quality as "An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items or non-conformances." Section 7.1.1 assigns responsibility to any employee to "Identify any conditions adverse to quality (CAQ), potential conditions adverse to quality, opportunities for improvement or enhancement, or adverse trends in leading indicators, lagging indicators, or performance indicators as identified in management reviews (such as Quality Control, Safety & Security Culture Council, and Integrity & Compliance Council) by promptly performing the following: Initiate a CAR per Section 7.2 (CAR Initiator)." Section 7.2.2 states, "Initiate a CAR upon discovery from internal or external source."
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> GEH's response letter to NRC NOV 05200010/2008-06, dated April 23, 2009, GEH committed to update GEH (P&P) 70-14, "Nuclear Energy Quality Assurance Audit Requirements," dated December 15, 2011 to establish the methodology to specify the audit criteria specific to the type of software being audited by May 29, 2009.
>
> Contrary to the above, as of April 20, 2012, GEH failed to promptly identify and correct a condition adverse to quality identified in NRC NOV 05200010/2008-06. Specifically, GEH did not initially develop a CAR to document the corrective actions specified in the GEH response letter to NRC NOV 05200010/2008-06, and failed to update GEH P&P 70-14 to establish the methodology to specify the

audit criteria specific to the type of software that is being evaluated consistent with their commitment documented in their response letter.

GEH's Response to the Violation

I. Reason for the Violation

GEH concurs with the violation. GEH committed to revise P&P 70-14, Quality Assurance Audit Requirements, in response to NOV 2008-201-06. In particular, GEH committed to establish the methodology to specify the audit criteria specific to the type of software audited. A non-conformance assessment was performed on June 26, 2012 to determine the cause of this violation. GEH determined that, at the time of the 2008 NRC inspection, no work instruction existed to provide direction for responding to inspections or to track commitments.

II. Corrective Steps Taken and Results Achieved

Note: At the time of the inspection, GEH used Corrective Action Requests (CARs) to track issues and actions in its Corrective Action Program. GEH has since implemented a new Corrective Action Program and now uses Condition Reports (CRs) to track issues. The content and purpose of CARs and CRs are essentially the same.

GEH has generated CAR 58386 (now CR 708) with an action to develop supplemental audit checklists for the software classifications listed in GEH procedure P&P 70-6.00, "Digital Computer Software Classifications and Quality Requirements."

CR 708 also includes action for GEH to revise procedure P&P 70-14, "Quality Audit Requirements," to establish requirements for use of applicable software audit checklists when performing audits of software and related software quality assurance programs.

GEH issued WI-25-102-04, Nuclear Regulatory Inspection Support, on May 19, 2011. The purpose of the procedure is to document the steps required to successfully host NRC inspections at GEH facilities and resolve any concerns noted by NRC inspectors, including the formal response to and closure of inspection findings and violations of NRC regulations. Step 4.3.3 of the work instruction directs initiation of Condition Reports (formerly known as CARs) to track closure of any findings or violations noted in NRC inspection reports.

III. Corrective Steps to Avoid Further Violations

GEH believes that use of WI-25-102-04 will prevent failure to initiate Condition Reports for future NOVs. CAR 58530 (now CR 1074), written in response to this NOV, includes an extent of condition investigation. In addition, GEH will complete the actions associated with CR 708 as discussed in Section II.

IV. Date Full Compliance Achieved

GEH will complete the corrective actions discussed in Section III by December 31, 2012 to achieve full compliance.