

July 6, 2012

Jerald G. Head, Senior Vice President
Regulatory Affairs
GE Hitachi Nuclear Energy
PO Box 780 M/C A-18
Wilmington, NC 28402-0780

SUBJECT: NRC INSPECTION REPORT 05200010/2012-201 AND NOTICE OF VIOLATION

Dear Mr. Head:

On April 16–20, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the General Electric-Hitachi (GEH) Nuclear Energy facility in Wilmington, NC. The enclosed report presents the results of that inspection.

This was a limited scope inspection that focused on assessing GEH's compliance with selected portions 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." The inspection focused on the design of spent fuel pool racks, and design calculations related to structures, systems, and components and associated codes used in the development of the economic simplified boiling-water reactor (ESBWR) design certification. This NRC inspection report does not constitute NRC endorsement of GEH's overall quality assurance (QA) program.

Based on the results of this inspection, the NRC has determined that three violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because a review of GEH's QA program documentation and implementation identified that (1) GEH failed to provide an adequate evaluation of partial joint penetration welds in the [[]] steam dryers described in PRC 11-71, "Evaluation, Steam Dryer Partial Penetration Welds—[[]]," dated January 26, 2012, which could cause a significant condition adverse to quality from the generation of loose parts, (2) GEH, and its contractor Equipos Nucleares SA (ENSA), failed to provide adequate design controls to meet the requirements in Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 for verification and validation of the ANSYS computer software for a dynamic complex analysis, and (3) GEH failed to develop and implement corrective actions to meet the requirements in Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 to update QA audit procedures and checklists for computer software used in safety-related applications for design engineering, instrumentation and control, simulation, and machinery software control.

Information on aspects of the GEH steam dryers and ESBWR design are summarized in this letter and its enclosures to avoid disclosure of proprietary material. This letter and its enclosures will be withheld for 5 days from the date of issuance to allow you to identify any information you consider to be proprietary. If you consider any information in this letter or its enclosures to be proprietary, you must submit a timely request to the NRC to

withhold that information in accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice."

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine if further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

Sincerely,

/RA/

Kerri A. Kavanagh, Chief
Quality Assurance Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 05200010

Enclosures:

1. Notice of Violation
2. Inspection Report No. 05200010/2012-201

J. Head

- 2 -

withhold that information in accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice."

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine if further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

Sincerely,

/RA/

Kerri A. Kavanagh, Chief
Quality Assurance Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 05200010

Enclosures:

1. Notice of Violation
2. Inspection Report No. 05200010/2012-201

DISTRIBUTION:

LDudes J Luehman ASakadales RidsNroDcipCevb/Cqab
Timothy.Enfinger@ge.com

ADAMS Accession No.: ML12187A102

NRC-001

OFFICE	NRO/DCIP/CQAB	NRO/DCIP/CQAB	NRO/DE/CIB	R-II/EICS
NAME	FTalbot	TKenzia	TScarbrough	AAllen
DATE	07/05/2012	07/05/2012	07/05/2012	07/05/2012
OFFICE	NRO/DCIP/CEVB	NRO/DCIP/CAEB	NRO/DCIP/CQAB	
NAME	GGalletti	Tim Frye	KKavanagh	
DATE	07/05/2012	07/05/2012	07/06/2012	

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

GE Hitachi Nuclear Energy
PO Box 780 M/C A-18
Wilmington, NC 28402-0780

Docket Number 05200010
Inspection Report Number 2012-201

During an NRC inspection conducted on April 16–20, 2012, at the General Electric–Hitachi (GEH) Nuclear Energy facility in Wilmington, NC, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 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.”

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.

These issues have been identified as Notice of Violation (NOV) 05200010/2012-201-01.

This is a Severity Level IV violation (Section 6.5.d).

- B. 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 requirement, 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.”

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.

These issues have been identified as Notice of Violation 05200010/2012-201-02.

This is a Severity level IV violation (Section 6.5.d).

- C. Criterion XVI of Appendix B to 10 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 nonconformances are promptly identified and corrected.”

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."

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.

These issues have been identified as Notice of Violation 05200010/2012-201-03.

This is a Severity Level IV violation (Section 6.5.d).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," GEH is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to Chief, Quality Assurance Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this notice of violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violations" and should include for each violation: (1) the reason for the violation or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please

provide the level of protection, described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 6th day of July 2012.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION & OPERATIONAL PROGRAMS
VENDOR INSPECTION REPORT**

Docket No.: 05200010

Report No.: 05200010/2012-201

Vendor: General Electric–Hitachi (GEH) Nuclear Energy
3901 Castle Hayne Road
Wilmington, NC 28401

Vendor Contact: Tim Enfinger
Senior Licensing Engineer
Regulatory Affairs
GE Hitachi Nuclear Energy
910-819-4881
Timothy.Enfinger@ge.com

Background: The U.S. Nuclear Regulatory Commission (NRC) under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” is conducting a design certification review of GEH’s economic simplified boiling-water reactor (ESBWR). The NRC Inspection Team focused its inspection on the spent fuel pool rack design calculations and associated codes and standards, the ESBWR steam dryer design, follow up from previous NRC inspection report findings, and the GEH audit program.

Inspection Dates: April 16–20, 2012

Inspection team:	Greg Galletti,	NRO/DCIP/CVEB	Team Leader
	Francis Talbot	NRO/DCIP/CQAB	Inspector
	Thomas Kendzia	NRO/DCIP/CQAB	Inspector in Training
	Alma Allen	NRC Region II/EICS	Region II Inspector
	Thomas Scarbrough	NRO/DE/CIB	Technical Specialist

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

EXECUTIVE SUMMARY

General Electric-Hitachi Nuclear Energy
05200010/2012-201

The purpose of this inspection was to review General Electric-Hitachi (GEH) Nuclear Energy's quality assurance (QA) program and its implementation as it relates to radiation shielding calculations and associated codes implemented in support of the economic simplified boiling-water reactor (ESBWR) design. The inspection was conducted at GEH's facility in Wilmington, NC.

The NRC inspection basis was 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."

The NRC inspection team implemented Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection," in combination with IP 43002, "Routine Inspections of Nuclear Vendors," during the conduct of this inspection.

Prior to this inspection, two previous NRC inspections were performed, one in September 2009 (05200010/2009-201) and one in December 2008 (05200010/2008-201), as part of an ESBWR design certification review at GEH's facility in Wilmington, NC. As part of this inspection, the NRC inspection team followed up and verified that GEH resolved inspection findings in NRC Inspection Report (IR) 05200010/2008-201 and IR 05200010/2009-201. The inspection team verified that GEH resolved six notices of violation (NOVs) in IR 05200010/2008-201 and three NOVs in IR 05200010/2009-201.

With the exception of the areas described below, the NRC inspection team concluded that GEH's QA policies and procedures were in compliance with the applicable requirements of Appendix B to 10 CFR Part 50 and that GEH personnel were implementing these policies and procedures effectively.

10 CFR Part 21 Program

The NRC inspection team concluded that GEH is implementing its 10 CFR Part 21 program consistent with the regulatory requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance." Based on the limited sample of documents it reviewed, the NRC inspection team also determined that GEH is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

Design Control

The NRC inspection team reviewed policies and procedures and evaluated a sample of design and procurement documents, including design specifications and test reports, related to the ESBWR fuel storage racks (FSR) and steam dryers to assess GEH's implementation of their design control process. The NRC inspection team identified violation 05200010-2012-201-01 for GEH's failure to provide adequate design controls for verification and validation of the ANSYS computer software model used in a dynamic complex analysis.

Corrective Action

The NRC inspection team reviewed GEH policies and procedures for work orders, incident classification and investigation (associated with GE Hitachi Global Nuclear Fuels [GNF]), supplier nonconforming material, engineering and PRA changes, licensing document error resolution, nuclear customer issue resolution, and employee concerns to ensure that conditions adverse to quality were properly identified and dispositioned in accordance with regulations.

The NRC inspection team identified violation 05200010/2012-201-02 for GEH's failure to evaluate properly a potential significant condition adverse to quality (SCAQ). Specifically, GEH did not provide an adequate evaluation of potential issues resulting from partial joint penetration welds in [[]] steam dryers described in PRC 11-71, which could cause a SCAQ from the generation of loose parts.

The NRC inspection team identified violation 05200010-2012-201-03 for GEH's failure to implement corrective actions related to NRC NOV 05200010/2008-201-06 regarding the establishment of a methodology to specify the audit criteria specific to the type of software being audited

Audits

The NRC inspection team concluded through a review of (1) GE Hitachi Global Nuclear Fuel (GNF) and GEH Nuclear Quality Assurance (NQA) internal audit plans and reports and (2) three external audit reports of GEH and GEH corrective actions taken from findings in these audits that GEH's QA program requirements for audits are consistent with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed General Electric-Hitachi (GEH) Nuclear Energy policies and implementing procedures governed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," to verify compliance with this regulatory requirement. Specifically, the NRC inspection team focused on the GEH nonconformance, corrective action, and customer feedback process to verify that they provided for entry into the GEH 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation," evaluation and reporting process. A sample of corrective action reports (CARs) were reviewed to verify that the screening to perform a 10 CFR Part 21 evaluation and reporting was performed correctly. In addition, the NRC inspection team evaluated a sampling of the 10 CFR Part 21 postings for compliance with the requirements of 10 CFR 21.6, "Posting Requirements."

Within the scope of this area of the inspection, the NRC inspection team reviewed the 10 CFR Part 21 procedures and records listed in Section 5 of this report. The NRC inspection team also conducted interviews of GEH and ENSA staff as noted in Section 6.

b. Postings

The NRC inspection team verified that GEH had a controlled list of postings and physically verified that 6 (of the 44 onsite) posted notices were in place as required. GEH uses the option (10 CFR 21.6.b) to post Section 206 of the Energy Reorganization Act of 1974, and a description of the regulation and GEH procedure that implement the regulation, and the name of the individual to whom reports can be made, and the location where the regulation and implementing procedure can be examined.

b.1 10 CFR Part 21 Procedures

GEH Procedure P&P 70-42, "Reporting of Defects and Noncompliance Under 10 CFR Part 21," Revision 14, dated January 24, 2012, establishes the requirements for compliance with the regulatory requirements of 10 CFR Part 21. This document defines the responsibilities, timelines, and actions for identifying and evaluating deviations and failures to comply, the process for reporting defects, and posting requirements. GEH performs the 10 CFR Part 21 evaluation by initiating a potential safety concern (PSC) or a potential reportable concern (PRC). A PSC is used if GEH is unsure if a deviation or failure to comply exists, and a PRC is initiated if a deviation or failure to comply is determined to exist. The timetable for the PSC is 14 days (to determine if a PRC exists) to support meeting the 60-day requirement if a reportable condition exists. Normally GEH initiates a PSC/PRC from a CAR through GEH Common Procedure CP-16-01, "Corrective Action Process," Revision 14, dated February 10, 2012. If a PSC/PRC is initiated without a CAR, one is initiated as part of the process. The GEH procedures for nonconformances and customer feedback do not provide a separate review for initiating a PSC/PRC, but they do provide for initiating a CAR (discussed in the

corrective action section of this report). The NRC inspection verified that the procedural requirements for reporting meet the regulatory requirements.

The NRC inspection team reviewed a selection of issues, including nonconformances, customer feedback forms, and corrective action reports, and verified that PSC/PRCs were being initiated when appropriate. The NRC inspection team reviewed a selection of PSCs and PRCs to check the adequacy of the evaluations and verify that the time requirements for evaluation or reporting required by 10 CFR Part 21 were being met. The NRC inspection team noted that the GEH process notifies the initiator of the PSC or PRC (or the initiator of the CAR) of the final determination, and allows for the initiator to question the determination. During the inspection, it was noted that two open PRC evaluations were sent back to the initiator, who had questioned the disposition of the issues. The inspection team determined that the process allows for such additional information to be provided and is not being used to extend the evaluation time. The NRC inspection team noted that the PSC/PRC evaluations contained good detail.

b.2 Sampling of Purchase Orders to Verify Compliance with 10 CFR 21.31

The NRC inspection team reviewed a sample of purchase orders (POs) to verify that GEH had implemented a program consistent with the requirements described in 10 CFR 21.31, "Procurement Documents," which specify the applicability of 10 CFR Part 21 in POs for safety-related services. The NRC inspection team verified that GEH imposed the requirements of 10 CFR Part 21 on qualified suppliers with programs that met the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

c. Conclusions

The NRC inspection team concluded that GEH is implementing its 10 CFR Part 21 program consistent with the regulatory requirements. Based on the limited sample of documents it reviewed, the NRC inspection team also determined that GEH is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

2. Design Control

a. Inspection Scope

The NRC inspection team reviewed GEH policies and procedures and their implementation for the control of the design of the ESBWR FSRs to ensure compliance with the quality assurance (QA) requirements in Appendix B to 10 CFR Part 50. For example, the inspection team reviewed the PO, design specification, procedures, work instructions, contractor procedures, CARs, audit reports, and licensing topical reports applicable to the ESBWR FSRs. The inspection team discussed the policies and procedures with representatives of GEH and its contractor ENSA.

The documents reviewed as part of this inspection are listed at the end of this report. Within the scope of this area of the inspection, the NRC team reviewed the design

control procedures and records listed in Section 5 of this report. The NRC inspection team also conducted interviews of GEH and ENSA staff as noted in Section 6.

b. Observations and Findings

The inspection team found that the design process for the ESBWR FSRs was conducted in a planned, controlled manner that effectively establishes and controls design inputs, outputs, analyses, records, and organizational interfaces. The inspection team also found that design activities and related changes were accomplished in accordance with approved procedures.

The ESBWR FSR design specification (GEH 26A7031) included requirements for design, fabrication, materials, inspection and testing, delivery, and documentation for the ESBWR FSRs. For example, the specification required the FSRs to be designed to specific codes and standards (e.g., the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (BPV Code)) and applicable NRC regulatory guides. The specification stated that the ESBWR FSRs are classified as Safety Class N (Nonsafety-related), Safety-Related Classification S (Special), and Seismic Category I. The QA requirements of Appendix B to 10 CFR Part 50 apply to the design, fabrication, testing, and inspection of the ESBWR FSRs. The design life is specified as 60 years, except for replacement items (such as seals and gaskets). The design conditions specified that the spent FSRs must be designed, fabricated, inspected, and tested to meet the requirements of American National Standards Institute/American Nuclear Society (ANSI/ANS)-57.2, "Design Requirements for Light Water Reactor Spent Fuel Storage Facilities at Nuclear Power Plant," dated 1983.

The new FSRs are designed, fabricated, inspected, and tested to the requirements of ANSI/ANS-57.3, "Design Requirements for New Fuel Storage Facilities at Light Water Reactor Plants," dated 1983. The specification requires that a full array of loaded spent FSRs be designed to be subcritical by at least 5 percent delta k. The specification states that the FSR design shall provide sufficient natural convection coolant flow to adequately remove decay heat and maintain local coolant temperature in any storage cavity (within the rack and at rack exit) below specific temperatures during both normal and abnormal conditions. The specification requires the FSRs to be designed to withstand the loads resulting from building response spectra indicated in the specification. The specification required that the stress in the structural components of the FSRs not to exceed the allowable stress levels given in the ASME BPV Code, Section III, Subsection NF. The rack modules are designed to be stable for all conditions and to counteract the tendency to overturn from horizontal and vertical loads. The specification provides requirements for accidental equipment drop. The specification requires that all equipment be designed to perform its intended function, considering environmental conditions, postulated design conditions, and natural phenomena. The specification requires that all equipment be capable of operating during and after the application of specified loads and loading combinations considering the most adverse combination of the environmental, seismic, or dynamic conditions, and specified loading combinations. The specification requires that all materials used in the construction of the rack must be specified in accordance with the applicable American Society for Testing and Materials (ASTM) and ASME specifications.

GEH CP-04-107, "Order Placement," Revision 4.1, dated April 12, 2012, includes requirements for controlled procurement of material, services, and labor, including

application of technical, engineering, customer, and quality requirements on POs. The procedure specifies roles and responsibilities, procedural steps for procurement, description of requirements, defining technical requirements, and quality requirements. GEH WI-04-107-08, GEH Attachment T Preparation Instruction,” dated May 17, 2011, provides instructions for preparing and completing Attachment T, “Technical, Quality and Administrative Requirements for Order Placement.” GEH WI-04-107-01, “Item Master File–Item Create Instructions,” Revision 1, dated April 5, 2011, provides instructions for using the tracking system for a new material or product item in the GEH Oracle Item Master File.

GEH issued Standard PO 437001935 for design and analyses of the ESBWR FSRs to its contractor, ENSA. A completed Attachment T form provided requirements for the design and analyses of the ESBWR FSRs. The statement of work (SOW) specified three rack designs as spent fuel racks for the spent fuel pool, spent fuel racks for the buffer pool, and new fuel racks for the buffer pool. The SOW stated that the analyses shall be performed based on the requirements of Specification 26A7032, with the exception of the criticality analysis, which was not part of the work scope. ENSA obtained services from subcontractors in meeting the PO. The PO defined special quality requirements that impose Appendix B to 10 CFR Part 50, QA requirements, and 10 CFR Part 21, notification requirements, on the FSR design and fabrication activities. The NRC inspection team evaluated the application of the requirements in the ESBWR FSR design specification from GEH to ENSA and the ENSA subcontractors. GEH NEDO-33260, “Quality Assurance Requirements for Suppliers of Equipment and Services to the ESBWR Project,” dated January 2012, defines the QA requirements for suppliers of equipment and services to the ESBWR project.

The inspection team evaluated the audit process for control of the design from GEH to ENSA and the ENSA subcontractors. The inspection team reviewed GEH P&P 70-14, “Nuclear Energy Quality Assurance Audit Requirements,” dated December 15, 2011,” which defines the QA audit program requirements for GEH and suppliers. The inspection team reviewed the results of a GEH audit of its contractor ENSA in GEH Supplier Audit Report No. “ENSA-2011-01, Audit Checklist,” dated July 8, 2011, and the resolution of audit findings. The inspection team also reviewed ENSA GP 08.03, Revision 16, “Suppliers Audits,” dated June 29, 2011, which specifies requirements for audits of suppliers of material, items, and services. The inspection team also sampled the results of an ENSA audit of its subcontractors (CTC and Principia) and the resolution of audit findings.

The inspection team selected for review a sample of CARs related to the design of the ESBWR FSRs. In particular, the inspection team reviewed CARs #55530 to #55535 and their resolution. The inspection team found that the CARs had been properly prioritized and dispositioned in accordance with GEH procedures and comply with Appendix B to 10 CFR Part 50.

The inspection team reviewed the policies and procedures of GEH and its contractor ENSA for the control of computer software used in the design of the ESBWR FSRs for compliance with Appendix B to 10 CFR Part 50. GEH NEDO-11209-A, Section 3.4.1, “Use of Computer Programs,” states 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. GEH CP-03-04, Revision 7, "Technical Reviews," dated February 1, 2011, establishes guidelines, responsibilities, and instructions for identification, execution, and documentation of technical reviews and associated actions in support of design and development processes. GEH CP-23-01, "Engineering Computer Programs," dated January 19, 2012, defines the responsibilities, requirements, and deliverables for the control of computer programs that GEH uses. Section 4.7.1 of GEH CP-23-01 states that when using computer programs in design activities, GEH cognizant staff shall only apply approved computer programs and are responsible for documenting (a) verification of input, (b) confirmation that the use is within the application range of the computer program, and (c) confirmation of computer program status.

The completed GEH audit checklist, dated July 8, 2011, reviewed by the inspection team, specified that ENSA had performed verification and validation of commercial software to ensure that the programs are correct and adequate. ENSA GP 05.09, "Validation and Verification of the Design & Analysis Computer Programs," dated September 22, 2010, requires verification and validation for the application of computer software in design activities. The inspection team reviewed sample calculation packages by GEH and ENSA to demonstrate the specific applicability of computer software for the design of the ESBWR FSRs. In particular, the inspection team reviewed the verification and validation of computer software MCNP-05P by GEH and ANSYS by ENSA. The NRC accepted the use of computer software MCNP-05P developed by the Los Alamos National Laboratory in its safety evaluation report (SER) on GEH NEDC-33374P-A, Revision 4, "Safety Analysis Report for Fuel Storage Racks Criticality Analysis for ESBWR Plants," dated September 2010, which described the criticality analysis for the ESBWR FSRs. The inspection team reviewed the consideration of error notifications for computer software by GEH and ENSA. The team noted that GEH was undergoing a self-assessment plan (ENG-2012-04) to determine the impact of errors identified in computer software. The inspection team identified a concern with the process that GEH and ENSA implemented for verification and validation of the adequacy of computer software for its use in engineering applications.

Specifically, GEH, and its contractor ENSA, failed to provide adequate design controls for verification and validation of the ANSYS computer software model used in a dynamic complex analysis. In particular, the ENSA report on the validation of the ANSYS model for a dynamic complex analysis (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. The NRC inspection team identified this issue as violation 05200010/2012-201-01. The NRC inspection team also noted that during the initial evaluation of ENSA by GEH or subsequent periodic self-assessments performed by ENSA of their internal programs, neither GEH nor ENSA identified the inadequacy of the ENSA methodology for verifying and validating computer software. On April 19, 2012, GEH initiated a supplier CAR (S-CAR #58401) to ENSA, and an internal CAR #58404 to address these issues.

The NRC inspection team reviewed the process GEH used for the verification of engineering services that its contractor ENSA provided. GEH EOP 45-4.00, Revision 22, "Supplier Submitted Supporting Documents," dated December 30, 2011, defines the responsibilities and procedural requirements for review and approval of

supporting documents submitted by suppliers of material, equipment, and services. GEH CP-07-103, Revision 5.1, "Inspection Requirements for Procured Items," dated November 17, 2011, provides inspection requirements of safety-related material, commercial-grade items, and nonsafety-related material. GEH reviewed the technical capability of ENSA before issuing the PO for the design of the ESBWR FSRs. GEH conducted audits of ENSA's engineering activities to provide confidence in the implementation of the QA requirements. GEH engineers reviewed the contractor submittals for the design of the ESBWR FSRs with a receipt checklist and prepared the GEH licensing topical reports (LTRs) on the design of the ESBWR FSRs. The NRC accepted GEH LTRs NEDO-33373-A, Revision 5, "Dynamic, Load-Drop and Thermal-Hydraulic Analyses for ESBWR Fuel Racks," dated October 2010, and NEDC-33374P-A on dynamic, load-drop, and thermal-hydraulic analyses and criticality analysis for ESBWR fuel racks in SERs dated October 20 and September 21, 2010, respectively. The inspection team compared the ESBWR FSR design specification to the applicable LTRs for incorporation of the design requirements into the engineering analyses. For example, the inspection team compared the FSR design specification and LTRs for FSR material, ASME BPV Code requirements, fuel assembly design and weight, enrichment assumptions, and criticality criteria. The inspection team observed that a specific checklist for GEH engineering staff review of technical reports that its contractors submitted would provide a more clear indication of receipt review of engineering services.

The NRC inspection team reviewed the process GEH established to control changes to the design for the ESBWR FSRs. GEH NUPI-030-05, Revision 3.1, "Engineering Design Change Control," dated November 30, 2011, specifies requirements for changes to the design of ESBWR components. GEH WI-06-118-05, Revision 1.1, "NPP Licensing Document Error Resolution," dated January 9, 2012, addresses resolution of errors identified in licensing documents submitted to the NRC. The inspection team discussed the design change process with GEH engineers and reviewed a sample of design change packages. The inspection team found that the design change control board includes GEH personnel across multiple disciplines to address cross-cutting issues for design changes. The inspection team found the GEH engineering design change process satisfied the requirements in Appendix B to 10 CFR Part 50.

c. Conclusions

The NRC inspection team concluded that GEH's program requirements for design control are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of design documentation reviewed, the NRC inspection team determined that GEH's Quality Assurance Program Description (QAPD) and associated design control were being effectively implemented with the following exception.

The NRC inspection team identified violation 05200010-2012-201-01 for GEH's failure to provide adequate design controls for verification and validation of the ANSYS computer software model used in a dynamic complex analysis.

3. Corrective Action

a. Inspection Scope

The NRC inspection team reviewed GEH's QA policies and implementing procedures that govern the corrective action process to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed GEH policies and procedures for work orders, incident classification and investigation (associated with GE Hitachi Global nuclear Fuels [GNF]), supplier nonconforming material, engineering and PRA changes, licensing document error resolution, nuclear customer issue resolution, and employee concerns to ensure that conditions adverse to quality were properly identified and dispositioned in accordance with regulations. The NRC inspection team also followed up on corrective actions from NRC findings in two previous 10 CFR Part 21 and QA inspections of the GEH ESBWR Design Certification (DC) in NRC Inspection Reports 05200010/2008-201 and 05200010/2009-201, completed in December 2008 and September 2009, respectively.

The NRC inspection team reviewed a selection of the corrective actions reports to verify implementation of the process in accordance with regulations and GEH procedures. In addition, the NRC inspection team observed the weekly meeting for review of new CARs and interviewed various GEH engineers, supervisors, and management personnel about the corrective action process.

Within the scope of this area of the inspection, the NRC inspection team reviewed the GEH corrective action procedures and records as noted in Section 5 of this report. The NRC inspection team also conducted interviews of GEH and ENSA staff as noted in Section 6.

b. Observations and Findings

b.1 GEH Corrective Action Program Personnel Interviews and Training

The NRC inspection team conducted interviews at GEH with employees from plant analysis and new plants engineering. The interviews were conducted to determine if employees have a working knowledge of the CAP and if issues adverse to quality were being identified and entered into the CAP. Most of the staff interviewed understood that issues adverse to quality were to be entered through the GEH Web site using the commitment tracking system (CTS), which generates a CAR. Individuals interviewed indicated that, when using CTS to initiate a CAR, they are required to describe the issue, assign a priority level to the issue, perform a cause analysis (dependent on the priority level), and propose a resolution for the issue. The CAR is then electronically routed to the appropriate reviewers for action and, ultimately, for final disposition. The few staff members who had never entered a CAR in CTS were not familiar with how to initiate a CAR in CTS, but they readily referenced CP-16-01, "Corrective Action Process," the applicable work procedure, and felt that they could easily enter a CAR if needed. Individuals who had never entered a CAR did state that if they had any issues or concerns, they would discuss them with their supervisor and a collaborative decision would be made on how to best address the issue. The NRC inspection team verified that the GEH had performed training on the CAR process and maintained training records.

b.2 NRC Review of GEH Policies and Procedures for the Corrective Action Program

Section 16 of GEH's QAPD provided a general description of GEH's corrective action program. Section 16 of NEDO-33260 indicated that GEH suppliers and sub-suppliers must have and implement a QA program conforming to the basic requirements of Section 16 of the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-1994.

CP-16-01 established the GEH process for identifying correcting conditions adverse to quality, significant conditions adverse to quality, and enhancements and recommendations. GEH classifies the CARs as priority A-significant condition adverse to quality, B-condition adverse to quality, C-broke/fix, and D-enhancement. For all CARs, the initiator recommends a prioritization and if a PSC/PRC is required, this is then verified by the CAR screener and the oversight group. Cause and actions for all CARs to be taken have to be determined within 30 days and the final corrective action for A, B, and C priorities are required to be completed within 90 days unless management approves a long-term action. A cause analysis, identification of causal factors, and extent of condition are required for A, B, and C priorities. A and B priorities require an effectiveness review (to prevent recurrence), and for A priorities, the cause analysis must be a root cause analysis.

The NRC inspection team verified GEH policies and procedures for work orders, supplier nonconforming material, engineering and PRA changes, licensing document error resolution, nuclear customer issue resolution, and employee concerns that required CARs for conditions adverse to quality, or for issues that could not be conditions adverse to quality. The NRC inspection team verified that issues in these processes were identified in CARs or were not conditions adverse to quality by performing a detailed review of a sample of the CARs. For CP-27-107, "Incident Classification and Investigation," Revision 0, March 1, 2012, which is the nuclear fuel fabrication nonconformance process, there is no tie to the CAR process for conditions adverse to quality. GEH stated the employees receive training on initiating CARs for conditions adverse to quality if a product that could be delivered would be affected. The reviews of the 2011 log for these issues, and the CAR log of all fuel issues that could affect the purchaser, appeared to be captured in the CAR process. The NRC inspection team observed that of the GEH processes reviewed, the CP-27-107 process had several significant issues in it, which although they were not released from GEH to a purchaser, they could be considered conditions adverse to quality. GEH initiated CAR #58409 to address this procedural issue.

b.3 Implementation of the GEH Corrective Actions Program

The NRC inspection team observed a weekly CAR Oversight Group meeting that is held to review new CARs. The NRC inspection team noted that the Oversight Group consisted of personnel with diverse backgrounds, demonstrated a questioning attitude, and provided input on whether the issue could be a repeat of some other issue seen at GEH. The NRC team observed that the initial CAR reviews did not include a specific look to determine if the CAR was a repeat of a prior significant condition adverse to quality. GEH identified that it uses the effectiveness review to prevent recurrence of issues. From the NRC inspection team's review of portions of the CAR database, there does not appear to be a

recurrence of a previous SCAQ for the ESBWR CARs reviewed. GEH initiated CAR 58408 to evaluate screening of new CARs for repeat issues.

The NRC inspection team performed a detailed review of 56 (2-A, 16-B, 29-C, and 9-D) CARs and their associated documentation (cause, corrective, and preventative action). The NRC team selected these issues from the last 3 years of CARs associated with the ESBWR to verify adequate determination of priority, need for a PSC/PRC, cause determination, corrective action preventative action, and timeliness of response. A review of the root cause determination was performed for the two significant conditions adverse to quality. The NRC inspection team noted that several CAR corrective actions were closed out in the CAR system and incorporated into system-specific tracking systems used for issues to be resolved as part of the tier 2 system engineering to be performed on the ESBWR. This appears to provide adequate tracking of the issues. Some CARs were responded to after the assigned due date. GEH identified this issue previously GEH and a CAR was issued. The CAR effectiveness review on resolving the late CAR response issue was still open, as the CAR program lead stated that the issue had not been resolved. The NRC inspection team did not identify any significant conditions adverse to quality or conditions adverse to quality that were excessively late by reviewing the currently open CAR list (which included corrective and preventative actions).

b.4 [[] Steam Dryer Cracking Evaluation and Reporting Issue

During an audit of the ESBWR steam dryer analysis in March 2012, the NRC staff identified a concern about no evaluation by GEH for a possible significant safety hazard (10 CFR Part 21) for partial penetration welds in the [[]] steam dryers in light of cracking on the [[]] steam dryers after one cycle of operation and the GEH decision to replace the partial penetration welds on the Grand Gulf steam dryer with full penetration welds versus re-performing the steam dryer analysis. During this inspection, the NRC inspection team conducted a detailed review of the GEH CAR #57240 and PRC 11-71 on BWR steam dryer partial penetration welds at the [[]] nuclear power plant.

The detailed analysis for GEH CAR #57240 was documented in PRC 11-71, in which GEH summarized its evaluation of potential issues resulting from partial joint penetration (PJP) welds in BWR steam dryers, and reached a conclusion on whether the condition was a substantial safety hazard and reportable under 10 CFR Part 21. PRC 11-71 discusses the bases, inputs, and assumptions for the evaluation. For example, PRC 11-71 states the evaluation approach taken was [[

]]. The conclusion references BWR Vessel and Internals Project (BWRVIP) Report BWRVIP-06-A, "Safety Assessment of BWR Reactor Internals," dated March 2002, and the corresponding NRC safety evaluation report (SER) dated February 17, 2011, for an analysis of loose parts in the reactor coolant and steam systems. [[

]]. PRC 11-71 adds that no additional actions are necessary to support its conclusions.

The NRC inspection team found that PRC 11-71 did not describe an adequate evaluation to provide reasonable assurance that the [[]] steam dryers would maintain their structural integrity to avoid the generation of loose parts in consideration of the presence of partial penetration welds in BWR steam dryers. [[

]], without performing a specific analysis on the consequences. The NRC inspection team considers the presence of loose parts in the RV without a specific analysis a significant condition adverse to quality in accordance with Criterion XVI of Appendix B to 10 CFR Part 50.

The inspection team noted that a GEH engineering manager prepared PRC 11-71 instead of a member of the GEH engineering staff with technical expertise in partial penetration welds in steam dryers. The NRC has indicated in SERs for power uprates (NRC letter dated March 2, 2006, from Richard Ennis, NRC Office of Nuclear Reactor Regulation, to Michael Kansler, Entergy Nuclear Operations, Inc., forwarding "Vermont Yankee Nuclear Power Station – Issuance of Amendment Re: Extended Power Uprate", and NRC NUREG-0800 (Revision 3, March 2007), "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 3.9.5, "Reactor Pressure Vessel Internals," Appendix A, "NRC Review of Potential Adverse Flow Effects in Nuclear Power Plant Systems,"), that steam dryers must be designed to maintain their structural integrity to avoid generating loose parts in the reactor coolant and steam systems. The NRC SER on BWRVIP-06 provides general acceptance of the BWRVIP evaluation of potential consequences of loose parts in reactor systems. The NRC safety evaluation specifies that plant-specific considerations are needed when loose parts are considered at a specific nuclear power plant.

The NRC inspection team found several inadequacies in the GEH consideration of the presence of partial penetration welds in BWR steam dryers described in PRC 11-71. In particular, GEH did not perform a specific evaluation of the possible generation of loose parts related to partial penetration welds in BWR steam dryers until NRC staff raised the issue in December 2011. PRC 11-71 does not provide a technical evaluation to demonstrate the structural integrity of BWR steam dryers with partial penetration welds, [[

]]. PRC 71-11 does not provide an evaluation of the specific partial penetration welds and their location in the [[]] steam dryers, and their likelihood of cracking and generating loose parts. The extent of condition evaluation in PRC 11-71 does not address the plant-specific aspects of the evaluation of potential loose parts from degradation of partial penetration welds in BWR plants other than [[]]. The inspection team determined that the GEH evaluation of partial penetration welds in BWR steam dryers fails to meet the requirements in Criterion XVI of Appendix B to 10 CFR Part 50. On April 17, 2012, GEH initiated CAR #58370 to address the concerns about PRC 11-71 that the NRC inspection team raised. The NRC inspection team identified this issue as violation 05200010/2012-201-02.

The NRC inspection team also found that the GEH evaluation in PRC 11-71 of partial penetration welds in BWR steam dryers is inconsistent with applicable NRC safety evaluations and SRP guidance on steam dryer analysis on the importance of maintaining the structural integrity of the steam dryer to avoid the generation of loose parts in the reactor and steam systems.

b.5 NRC Follow Up on GEH Notices of Violation in NRC Inspection Reports 05200010/2008-201 and 05200010/2009-201

The NRC inspection team reviewed a large number of GEH changes made to GEH policies and procedures (P&P), common procedures (CPs), engineering operations procedures (EOPs), work instruction (WIs), GEH internal and external audit findings, and GEH QA CARs used to resolve corrective actions related to NRC findings in NRC Inspection Reports 05200010/2008-201 and 05200010/2009-201. The NRC inspection team found that GEH completed corrective actions, including revisions to the procedures identified in the GEH responses to NRC NOVs; therefore, NOVs 05200010/2008-201-01 through 05 and 05200010/2009-201-01 through 03 are resolved.

The inspection team also found that GEH had not completed corrective actions to resolve NOV 05200010/2008-201-06. In NOV 05200010/2008-201-06, NRC inspection team noted that: (1) P&P 70-14 did not contain any guidance for inspecting computer software; and (2) the GEH audit checklists did not differentiate between engineering design, instrumentation and control (I&C), plant simulation, or machinery control software.

In GEH's response letter to the NOV 05200010/2008-201-06, dated April 23, 2009, GEH stated that P&P 70-14 failed to establish the methodology to specify the audit criteria specific to the type of software being audited, and committed to revise P&P 70-14 to expand guidance on requirements for documenting objective evidence in

audit checklists during audit performance. GEH also stated that P&P 70-14 would be revised to establish the methodology to specify the audit criteria specific to the type of software being audited and that full compliance would be completed by May 29, 2009. However, the GEH response letter did not document a CAR to track this issue.

The NRC inspection team reviewed GEH P&P 70-14 and found that the procedure had not been updated to expand guidance on requirements for documenting objective evidence in audit checklists during audit performance, or to enhance the audit methodology to specify the audit criteria specific to the type of software being evaluated.

Based on the above, the NRC inspection team found that GEH corrective actions had not been completed to resolve NOV 05200010/2008-201-06. GEH initiated CAR #58386 to update GEH P&P 70-14, other GEH QA computer software procedures, and the GEH internal audit checklist to cover audit guidance for all of the different types of GEH computer software. Based on this finding and on-going corrective actions initiated by GEH to address the concerns, the NRC inspection team closed NOV 05200010/2008-201-06 and identified violation 05200010/2012-201-03 to document GEH's failure to implement adequate corrective actions.

c. Conclusions

The NRC inspection team concluded that GEH's program requirements for corrective actions are consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of CARs reviewed, the NRC inspection team determined that GEH's Quality Assurance Program Description (QAPD) and associated corrective action procedures were being effectively implemented with two exceptions.

The NRC inspection team identified violation 05200010/2012-201-02 associated with GEH's failure to evaluate properly a potentially SCAQ. Specifically, GEH did not provide an adequate evaluation of potential issues resulting from partial joint penetration welds in [[]] steam dryers described in PRC 11-71, which could cause a SCAQ from generation of loose parts.

The NRC inspection team identified violation 05200010-2012-201-03 for GEH's failure to implement corrective actions related to NOV 05200010/2008-201-06 to expand guidance on requirements for documenting objective evidence in audit checklists during audit performance, and to enhance the audit methodology to specify the audit criteria specific to the type of software being evaluated.

4. Audits

a. Inspection Scope

The NRC inspection team reviewed GEH's policies and procedures governing the implementation of its audit programs to assess GEH's compliance with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The NRC inspection team

reviewed annual audit plans and internal audit reports from the last 3 years. The NRC inspection team focused its review on GEH internal and external audits.

Within the scope of this area of the inspection, the NRC inspection team reviewed audit procedures and records as noted in Section 5 of this report. The NRC inspection team also conducted interviews of GEH and ENSA staff as noted in Section 6.

b. Observations and Findings

b.1 GEH Internal Audits

GEH uses a two-tier audit system, in which GEH NQA provides independent auditing as well as internal audits of GNF and GE Hitachi Laser enrichment (GLE) QA activities. The NRC inspection team reviewed and verified that GEH/GNF/GLE P&P 70-14, "Quality Assurance Audit Requirements," is used to implement GEH NQA internal audit plans and reports to verify that GEH's program requirements were consistent with the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. P&P 70-14 requires annual audit plans to be prepared to ensure that a representative sample of GEH's quality system elements and all 18 criteria of Appendix B to 10 CFR Part 50 are audited.

b.2 External Audits

The NRC inspection team also requested the status of CARs created from external audits of GEH. GEH provided the inspection team with Ameren UE (AUE) QA external audit report No. VA10-006 conducted in August 2010. Based on this external audit, GEH entered 19 CARs into the CAP and all of these CARs were resolved. GEH also provided the inspection team with the results of two ASME external audits and one Nuclear Utility Procurement Committee (NUPIC) audit, conducted by Detroit Edison, in 2011. The four external audits generated a total of 29 CARs.

GEH also provided the NRC inspection team with objective evidence that 27 of 29 CARs from 4 external audits of GEH were resolved. GEH management also stated that external audits are used to gauge GEH performance related to audits and corrective actions are taken to improve future performance. The inspection team found that GEH adequately implemented corrective actions from external audits.

c. Conclusions

The NRC inspection team concluded through a review of (1) GNF and GEH NQA internal audit plans and reports; and (2) three external audit reports of GEH and GEH corrective actions taken from findings in these audits, that GEH's QA program requirements are consistent with the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50.

d. Entrance and Exit Meetings

On April 16, 2012, the NRC inspection team presented the scope of the inspection in an entrance meeting with GEH's Senior Vice President for Domestic Nuclear Power Plants, Brian Johnson, and other GEH personnel. On April 20, 2012, the NRC inspection team

presented the results of the inspection during an exit meeting with Brian Johnson and other GEH personnel.

On May 1, 2012, during a phone call with GEH staff, the NRC inspection team discussed the finding related to the failure to adequately implement the CAP with regard to resolving the previous inspection report finding in NOV 05200010/2008-201-06.

5. DOCUMENTS REVIEWED

- GEH Quality Assurance (QA) Topical Report, NEDO-11209-04A, "GE Hitachi Nuclear Energy [GENE] Quality Assurance Program Description," Revision 9, dated August 2011
- GEH Licensing Topical Report NEDO-33260, Revision 6, "Quality Assurance Requirements for Suppliers of Equipment and Services to the ESBWR Project," dated January 2012
- GEH LTRs NEDO-33337, "ESBWR Initial Core Transient and Accident Analyses"
- NEDO-33338, "ESBWR Feedwater Temperature Operating Domain Transient and Accident Analyses"
- GEH Design Specification 26A7032, Revision 4, "Fuel Storage Rack Design Specification," dated February 24, 2010
- GEH Engineering Operating Procedure EOP 45-4.00, Revision 22, "Supplier Submitted Supporting Documents," dated December 30, 2011
- GEH Focused Self-Assessment Plan Eng 2012-04, Assessment Dates March 29, 2012 to June 29, 2012
- GEH Licensing Topical Report NEDC-33374P-A, Revision 4, "Safety Analysis Report for Fuel Storage Racks Criticality Analysis for ESBWR Plants," dated September 2010
- GEH Licensing Topical Report NEDO-33260, Revision 6, "Quality Assurance Requirements for Suppliers of Equipment and Services to the ESBWR Project," dated January 2012
- GEH Licensing Topical Report NEDO-33373-A, Revision 5, "Dynamic, Load-Drop and Thermal-Hydraulic Analyses for ESBWR Fuel Racks," dated October 2010
- GEH NEO-866, Forms for Review/Acceptance of Purchased Design Service Documents for PO 437001935, Design Analyses for ESBWR Fuel Storage Racks, dated December 14, 2009; March 16, 2010; and January 23, 2012
- GEH New Units Engineering Process Instruction NUPI-030-05, Revision 3.1, "Engineering Design Change Control," dated November 30, 2011
- GEH Policy and Procedure P&P 70-6, Revision 0, "Digital Computer Software Classifications and Quality Requirements," dated August 2, 2011

- GEH Policy and Procedure P&P 70-11, Revision 18, “Quality System Requirements,” dated February 23, 2012
- GEH Policy and Procedure P&P 70-14, Revision 17, “Quality Assurance Audit Requirements,” dated December 15, 2011
- GEH Policy and Procedure P&P 70-30, Revision 6, “Personnel Proficiency in Quality Related Activities.” dated July 5, 2011
- GEH Policy and Procedure P&P 70-42, Revision 14, January 24, 2012, “Reporting of Defects and Noncompliance Under 10CFR Part 21,” dated January 24, 2012
- GEH Potential Safety Concern #11-07
- GEH Potential Report #07-06, #11-04, #11-20, #11-26, #11-71, #12-0312-06, #12-13, #12-20, #12-21
- GEH Policy and Procedure P&P 70-60, Revision 2, “Worker Concerns Program,” dated February 28, 2011
- GEH P&P 70-14, “Nuclear Energy Quality Assurance Audit Requirements,” Revision 17, dated December 15, 2011.
- GEH Common Procedure CP-03-04, Revision 7, “Technical Reviews,” dated February 1, 2011
- GEH Common Procedure CP-03-09, Revision 5, “Independent Design Verification,” dated April 19, 2011
- GEH Common Procedure CP-04-107, Revision 4.1, “Order Placement,” dated April 12, 2012
- GEH Common Procedure CP-07-103, Revision 5.1, “Inspection Requirements for Procured Items,” dated November 17, 2011
- GEH Common Procedure CP-23-01, Revision 11, “Engineering Computer Programs,” dated January 19, 2012
- GEH Common Procedure CP-16-01, Revision 14, “Corrective Action Process,” dated February 2, 2012
- CP-06-208, “NPP Project Documents–Document Control,” Revision 1, dated June 22, 2011
- GEH Common Procedure CP-03-106, Revision 1, “Change Management Process,” dated November 17, 2011
- GEH Common Procedure CP-19-102, Revision 1, “Nuclear Customer Issue Resolution,” dated September 22, 2011

- GEH Common Procedure CP-15-101, Revision 2, “Control and Disposition of Supplier Provided Non-Conforming Material,” dated November 16, 2011
- GEH Common Procedure CP-27-107, Revision 0, “Incident Classification and Investigation,” dated March 1, 2012
- GEH Engineering Operating Procedure EOP 42-8.00, Revision 18, “Document Initiation or Change by ERM/ECN,” dated November 1, 2011
- GEH Engineering Operating Procedure EOP 55-2.00, Revision 12, “Engineering Change Control,” dated March 7, 2012
- GEH Work Instruction WI-03-113-05, Revision 0, “PRA Model Maintenance and Update,” dated October 31, 2011
- GEH Work Instruction WI-06-118-05, Revision 1.1, “NPP Licensing Document Error Resolution,” dated January 9, 2012
- GEH FMO Maintenance OP #2300.00, Revision 5, “Work Order Administration,” dated October 11, 2011
- GEH New Units Engineering Process Instruction NUPI-030-0, Revision 3.1, “Engineering Design Change Control,” November 30, 2011
- GEH Engineering 2011 Quality Status and Adequacy Report, dated November 1, 2011
- Engineer Change Authorization ECA #SR3-1-ECA-0121, #SR3-1-ECA-0090
- GEH Potential Safety Concern #11-07
- GEH Common Procedure Work Instruction WI-03-009-01, Revision 0, “Documentation and Verification of Unapproved Software,” dated December 8, 2010
- GEH Potentially Reportable Condition PRC 11-71 Evaluation, Steam Dryer Partial Penetration Welds—[[]], dated January 26, 2012
- GEH Release Report for Design Review of MCNP-05P, dated November 14, 2007
- GEH Standard Purchase Order 437001935, Revision 3, “Design and Analysis of ESBWR FSRs,” dated January 7, 2011
- GEH Attachment T for ET-000756, Revision 3
- GEH Supplier Audit Report No. ENSA-2011-01 (June 6–10, 2011) “Audit Checklist,” dated July 8, 2011
- GEH Work Instruction WI-04-107-01. Revision 1, “Item Master File–Item Create Instructions,” dated April 5, 2011

- GEH Work Instruction WI-04-107-08, Revision 0, “GEH Attachment T Preparation Instruction,” dated May 17, 2011
- GEH Work Instruction WI-06-118-05, Revision 1.1, “NPP Licensing Documents Error Resolution,” dated January 9, 2012
- GEH Engineering Operating Procedure (EOP) 30-5.00, “Supplier Design Services Document Review,” Revision 14, dated March 29, 2011.
- GEH Form NEO-866, “Review/Acceptance of Purchased Design Service Documents,” dated March 2007
- ESI 30-01, “Alternate Calculations for Verification of Non-Level-2 Computer Code Calculations”
- GEH CP Work Instruction (WI)-03-009-01, “Documentation and Verification of Unapproved Software,” dated December 8, 2010
- GEH CP 03-09, “Independent Design Verification,” Revision 5, dated April 9, 2011
- GEH CP-23-11, “Engineering Computer Programs,” Revision 11, dated January 19, 2012
-
- GEH WI-06-118-05, “NPP Licensing Documents Error Resolution,” Revision 1, dated July 22, 2011
- GEH P&P 70-14, “Nuclear Energy Quality Assurance Audit Requirements,” dated December 15, 2011.
- GEH CP-18-02, “Supplier Audits and Commercial Grade Surveys,” Revision 5, dated December 9, 2011
- GEH CP-07-02, “Supplier Approval,” Revision 16, dated February 8, 2012
- GEH CP-16-0-04, Priority Level Decision Tree, Revision 3, dated April 8, 2011
- GEH CP-19-01, “Deviations,”
- GEH Nuclear Quality Assurance/Audits, 2009 GEH Audit Planning and Scheduling, dated January 29, 2009
- GEH Nuclear Quality Assurance/Audits, 2010 GEH Audit Planning and Scheduling, dated February 1, 2010
- GEH Nuclear Quality Assurance/Audits, 2011 GEH Audit Planning and Scheduling, dated January 17, 2011
- GEH Nuclear Quality Assurance/Audits, 2012 GEH Audit Planning and Scheduling, dated March 23, 2012

- NRC Final Safety Evaluation (September 21, 2010) for GE Hitachi Nuclear Energy L Licensing Topical Report NEDO-33374, Revision 3, "Safety Analysis Report for Fuel Storage Racks Criticality Analysis for ESBWR Plants" (ADAMS Accession No. ML102430580)
- NRC Final Safety Evaluation, for GE Hitachi Nuclear Energy L Licensing Topical Report NEDO-33373, Revision 5, "Dynamic, Load-Drop and Thermal-Hydraulic Analyses for ESBWR Fuel Racks," dated October 20, 2010 (ADAMS Accession No. ML102700448)
- Principia Report No. 764, Revision 2, "Effects of Postulated Impacts on the ESBWR Fuel Racks," dated September 18, 2008
- GEH Quality Assurance (QA) Topical Report, NEDO-11209-04A, "GE Nuclear Energy [GENE] Quality Assurance Program Description," Revision 9, dated August 2011
- GEH/GNF/GLE P&P 70-14, Revision 17, "Nuclear Energy Quality Assurance Audit Requirements," dated December 15, 2011
- GEH Policies and Procedures (P&Ps) 70-30, Revision 6, "Personnel Proficiency in Quality Related Activities," dated July 5, 2011
- GEH/GNF/GLE P&P 70-6, Revision 0, "Digital Computer Software Classifications and Quality Requirements" dated August 2, 2011
- GEH Common Procedure (CP)-16-01, Revision 13, "Corrective Action Process," dated November 18, 2011
- GEH CP-18-02, Revision 5, "Supplier Audits and Commercial Grade Surveys," dated December 9, 2011
- GEH CP-23-300, Revision 0, "Digital I&C System Life Cycle Development Program," dated December 9, 2011
- GEH CP-07-02, Revision 16, "Supplier Approval," dated February 8, 2012
- GEH Engineering Operating Procedure (EOP) 75-6.00, "Quality Assurance Records," dated November 18, 2011
- GEH Nuclear Quality Assurance/Audits, 2009 GEH Audit Planning and Scheduling, dated January 29, 2009
- GEH Nuclear Quality Assurance/Audits, 2010 GEH Audit Planning and Scheduling, dated February 1, 2010
- GEH Nuclear Quality Assurance/Audits, 2011 GEH Audit Planning and Scheduling, dated January 17, 2011
- GEH Nuclear Quality Assurance/Audits, 2012 GEH Audit Planning and Scheduling, dated March 23, 2012

- GEH Letter GEH NQA Director Letter, Mr. Russell Bastyr to Mr. Earl Mayhorn, Ameren UE, dated October 22, 2010
- GEH NQA Internal Audit–NQA-2009-10, Software Control Safety, dated October 27, 2010
- GEH NQA Internal Audit–NQA-2010-13, Software Controls, dated May 11, 2011
- GEH NQA Internal Audit–NQA-2011-02, Service I&C Engineering, dated January 16, 2012
- AmerenUE (AUE) Audit Report No. VAQ10-006, dated September 26, 2010
- GEH Response to AUE External Audit VAQ10-006, dated October 22, 2010
- GEH Response to AUE External Audit VAQ10-006, dated January 26, 2011
- GEH Response Letter to NRC Notices of Violations in Inspection Report 05200010/2008-201, dated April 23, 2009
- ENSA Audit Report AR-24/09 of CTC, Revision 0, dated September 17, 2009
- ENSA Audit Report No. AR-33/09 of Principia, Revision 0, dated October 19, 2009
- ENSA Certificate of Verification/Validation of ANSYS Version 10.0 A1, dated March 6, 2009
- ENSA General Procedure GP 05.09, Revision 10, “Validation and Verification of the Design & Analysis Computer Programmes,” dated September 22, 2010
- ENSA General Procedure GP 08.03, Revision 16, “Suppliers Audits,” dated June 29, 2011
- Detroit Edison External Audit Report, dated April 2011
- ASME External Audit Report, dated February 2011
- ASME External Audit Report, dated November 2011
- Nuclear Industry Assessment Committee (NIAC) Audit Checklist for Computer Software
- BWR Vessel and Internals Project (BWRVIP) Report BWRVIP-06-A, “Safety Assessment of BWR Reactor Internals,” March 2002, and the corresponding NRC safety evaluation report (SER) dated February 17, 2011
- GEH Corrective Action Request (CAR) #47253, #47149, #47152, #47962, #48167, #47268, #47586, #48068, #48211, #48406, #48563, #48691, #48873, #49144, #49259, #49341, #49411, #49722, #49856, #49980, #50014, #50550, #50575, #50717, #50964,

#51243, #51573, #51850, #52126, #52149, #52453, #52453, #52650, #52698, #52072,
#52981, #53139, #53140, #53558, #53646, #54217, #54220, #54257, #54634, #54710,
#54798, #55126, #55530, #55531, #55532, #55533, #55534, #55535, #55374, #55428,
#55957, #56510, #56628, #56706, #57110, #57169, #57240, #57464, #57467, #57771,
#58176, #58204, #58386, #58408, #58409

ATTACHMENT

6. PERSONS CONTACTED

NAME	COMPANY	TITLE	ENTRANCE	EXIT	INTERVIEWED
M. Elliott	GEH	Quality Assurance	√	√ X	√
J. Stallings	GEH	Quality Assurance	√	√ X	√
R. Bastyr	GEH	Nuclear Quality Assurance Manager	√	√	√
P. Campbell	GEH	Vice President, Washington Regulatory Affairs	√	√	√
P. Yandow	GEH	Regulatory Affairs	√	√ X	√
T. Enfinger	GEH	Regulatory Affairs	√	√ X	√
J. Head	GEH	Senior Vice President–Regulatory Affairs		√	
B. Johnson	GEH	Vice President–NPP Domestic Plants	√	√ X	√
S. Hamilton	GEH	Senior Vice President–Quality		X	
D. Davenport	GEH	Senior Engineer	√	√ X	
C. Alonso	GEH	Sourcing Quality Leader	√	√	√
J. McLamb	GEH	Project Manager	√	√	√
C. Bystry	GEH	Nuclear Specialist			√
J. Atento	GEH	Quality Assurance	√		√
B. Buckley	GEH	Senior Software Engineer		√ X	√
J. Fawks	GEH	Software Engineering Manager	√	√ X	√
B. Moore	GEH	Methods & Software Development Leader	√	√	
W. Metwally	GNF	Methods & Software Development Engineer			√
R. Stachowski	GNF	Chief Consulting Engineer	√	X	√
W. Marquino	GEH	Senior Engineer	√	√	√
M. Colby	GEH	NPE–Engineering Manager	√	X	
I. Nir	GEH	NPE–Engineering/Technology Program Leader			√
J. Hannah	GNF	Methods & Software Development Engineer	√	√	√
P. Ragan	GEH	Senior Engineer	√		
G. Huff	GEH	Software Engineer	√	√	

NAME	COMPANY	TITLE	ENTRANCE	EXIT	INTERVIEWED
A. Murray	GEH	Quality Program Manager	√	√	√
R. Harrington	GEH	Engineering Manager	√		√
J. Deaver	GEH	Engineering Manager	√	√ X	√
S. Butler	GEH	I&C Manager	√	√	
B. Copsey	GEH	Excellence Plan Leader	√	√ X	
J. Post	GEH	Engineering Manager	√	√	
K. Milchuck	GEH	Senior Administrative Assistant		√ X	√
M. Gerdes	GEH	Quality Leader		X	
M. Branch	GEH	Senior Engineer			√
Z. Chen	GEH	Senior Mechanical Engineer			√
P. Dey	GEH	Lead Engineer (Technologist)			√
A. Fernandez	GEH	Compliance Leader & Regulatory Counsel (Ombudsperson)			√
A. Meyers	GEH	Mechanical Analysis Vibrations & Seismic Manager			√
D. Park	GEH	Plant Analysis/Mechanical Analysis Engineer			√
J. Blum	GEH	Plant Analysis Engineer			√
G. Seeman	GEH	PRA Engineer			√
J. Shah	GEH	Stress Analysis Engineer			√
K. Williams	GEH	Worker Concern Program Manager			√
Z. Wang	GEH	Senior FE Analysis			√
W. Ren	GEH	Structural Analysis Engineer			√
D. Porter	GEH	10 CFR Part 21 Compliance Leader	√	√ X	√
S. Bowman	GEH	Engineering Manager			√
D. Otamondi	ENSA	Quality Assurance Engineer		√	√
L. Costos	ENSA	Engineer		√	√
T. Kendzia	NRC	Reactor Operations Engineer	√	√	
F. Talbot	NRC	Reactor Operations Engineer	√	√	

NAME	COMPANY	TITLE	ENTRANCE	EXIT	INTERVIEWED
G. Galletti	NRC	Senior Reactor Operations Engineer	√	√ X	
A. Allan	NRC	NRC Region II Inspector	√	√	
T. Scarbrough	NRC	NRC Technical Specialist– Mechanical Engineer	√	√	

NOTE: X - denotes attendance on the re-exit conference call May 1, 2012.

7. INSPECTION PROCEDURES USED

Inspection Procedure 35017, “Quality Assurance Implementation Inspection”

Inspection Procedure 43002, “Routine Inspections of Nuclear Vendors”

8. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
05200010/2008-201-01	Closed	NOV	Part 21.21(a)(1)
05200010/2008-201-02	Closed	NOV	Criterion III
05200010/2008-201-03	Closed	NOV	Criterion XVI
05200010/2008-201-04	Closed	NOV	Criterion XVI
05200010/2008-201-05	Closed	NOV	Criterion XVIII
05200010/2008-201-06	Closed	NOV	Criterion XVIII
05200010/2009-201-01	Closed	NOV	Criterion II
05200010/2009-201-02	Closed	NOV	Criterion XVI
05200010/2009-201-03	Closed	NOV	Criterion III
05200010/2012-201-01	Open	NOV	Criterion III
05200010/2012-201-02	Open	NOV	Criterion XVI
05200010/2012-201-03	Open	NOV	Criterion XVI

9. LIST OF ACRONYMS USED

AUE	AmerenUE
ANSI/ANS	American National Standards Institute/American Nuclear Society
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
CAR	Corrective Action Request
CFR	Code of Federal Regulation
CP	Common Procedure
DCD	Design Control Document
DRF	Design Record File
ENSA	Equipos Nucleares SA
EOP	Engineering Operating Procedure
GEH	General Electric-Hitachi
LTR	Licensing Topical Report
NQA	Nuclear Quality Assurance

P&P	Policy and Procedure
PRC	Potentially Reportable Condition
PSC	Potential Safety Concern
QA	Quality Assurance
QAPD	Quality Assurance Program Description
SOW	Statement of Work