

March 25, 2009

Mr. Mark Harvey
Vice President Quality
Nuclear Plant Projects
GE Hitachi Nuclear Energy
3901 Castle Hayne Road
Wilmington, NC 28401

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
05200010/2008-201, NOTICE OF VIOLATION TO GENERAL ELECTRIC-
HITACHI NUCLEAR ENERGY

Dear Mr. Harvey:

On December 15-19, 2008, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the General Electric-Hitachi (GEH) Nuclear Energy facility in Wilmington, North Carolina. 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 to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50), "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and the provisions of 10 CFR Part 21, "Reporting of Defects and Noncompliance." The inspection also focused on the development and use of GEH software codes to perform safety analyses for the ESBWR design certification. This NRC inspection report does not constitute NRC endorsement of GEH's overall quality assurance or 10 CFR Part 21 programs.

During the inspection, the NRC inspectors found that the implementation of GEH's Quality Assurance (QA) program failed to meet certain NRC requirements. Specifically, GEH's design control program failed to document the justification or rationale for the use of a particular version of a non-Level 2 code during an alternate calculation to verify original calculations and assumptions. Furthermore, the NRC inspectors identified inadequate implementation of GEH QA program requirements in the area of corrective action and internal audits. These violations to the requirements of Appendix B to 10 CFR Part 50 are cited in the enclosed Notice of Violation, and the circumstances surrounding them are described in the enclosed inspection report. Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed Notice of Violation.

In addition, based on the results of this inspection, the NRC has determined that a violation of NRC requirements occurred. Specifically, a review of GEH's 10 CFR Part 21 implementation identified that GEH failed to perform Part 21 evaluations when other GEH organization indicated that a software problem had impacted their use of the code. This violation is cited in the enclosed Notice of Violation and the circumstances surrounding it is described in detail in the subject inspection report.

M. Harvey

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You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether 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.

Sincerely,

/RA/

John A. Nakoski, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No. 05200010

Enclosures:

1. Notice of Violation
2. Inspection Report No. 05200010/2008-201

M. Harvey

- 2 -

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Sincerely,

/RA/

John A. Nakoski, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No. 05200010

Enclosures:

1. Notice of Violation
2. Inspection Report No. 05200010/2008-201

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NOTICE OF VIOLATION

GE Hitachi Nuclear Energy
3901 Castle Hayne Road
Wilmington, NC 28401

Docket Number 05200010
Inspection Report Number 2008-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted on December 15-19, 2009, at the General Electric – Hitachi (GEH) Nuclear Energy facility at Wilmington, North Carolina, the following violations of NRC requirements was identified:

- A. Section 21.21, “Notification of failure to comply or existence of a defect and its evaluation,” of Part 21 of Title 10 of the *Code of Federal Regulations*, “Reporting of Defects and Noncompliance” (10 CFR Part 21), requires, in part, that each individual, corporation, partnership, dedicating entity, or other entity subject to 10 CFR Part 21 adopt procedures to evaluate deviations and failures to comply as soon as practicable in order to identify defects and failures to comply associated with substantial safety hazards.

Section 7.7.3 of GNF CP 23-01, “Engineering Computer Programs,” Revision 1, dated February 14, 2006, states that GEH internal users of software are to document and report to GEH Computer Department any engineering computer program technical usage problems, including potential errors.

Section 7.6.2 of GNF CP 23-01, states that GEH Computer Department documents all problems in engineering computer program problem reports and transmits them to the design and development organization managers for evaluation.

Section 7.7.6 of GNF CP 23-01, states that during the evaluation process, the problem is to be evaluated for any potential reportable conditions in accordance with the requirements of GNF P&P 70-42, “Reporting of Defects and Non-Compliance under 10 CFR Part 21,” dated September 25, 2008.

Contrary to the above, as of December 19, 2008, GEH failed to perform a Part 21 evaluation when another GEH organization indicated that a software problem had impacted their use of the code. Specifically, GEH Engineering Computer Program problem report 2007-20 reported usage problems with the application of the GEXL critical quality boiling length correlation built into the TRACG code and was not adequately forwarded to GEH Nuclear Quality Assurance for Part 21 processing. As a result, GEH failed to document the evaluation of Engineering Computer Program problem report 2007-20 for potential safety concerns, and subsequent Part 21 reporting.

This issue is identified as Violation 05200010/2008-201-01.

This is a Severity Level IV violation (Supplement VII of the Enforcement Policy).

- B. Criteria III, “Design Control”, of Appendix B to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50), “Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” states, in part, that design control measures shall provide for verifying and checking the adequacy of the design by the use of alternate or simplified calculational methods.

NEDO-11209-04A, "GE Nuclear Energy Quality Assurance Program Description," Revision 8, dated March 31, 1989, states that design verification is a process for an independent review of designs against design requirements to confirm that the designer's methods and conclusions are consistent with requirements, and that the resulting design is adequate for its specified purpose.

Global Nuclear Fuel (GNF) Common Procedure (CP) 03-09, "Independent Design Verification," Revision #1, dated January 4, 2006, provides instructions for independent verification of computer software programs designed, developed, and used by GEH.

Appendix F of GNF CP 03-09 provides instructions for the use of non-Level 2 codes for alternative calculations and verifications of software code during the development of GEH software products to verify correctness of an original calculation and developer's assumptions. Appendix F of GNF CP 03-09 allows for the use of several different versions of non-Level 2 computer codes, if appropriate justification is documented.

Contrary to the above, as of December 19, 2008, GEH failed to document the justification or rationale for the use a particular version of a non-Level 2 code during alternate calculations to verify original calculations and developer's assumptions.

This issue is identified as Violation 05200010/2008-201-02.

This is a Severity Level IV violation (Supplement II of the Enforcement Policy).

- C. Criterion XVI, "Corrective Action", of Appendix B to 10 CFR Part 50 states, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

NEDO-11209-04A states that conditions adverse to quality or nonconformance such as: failures, malfunctions, deficiencies, and deviations in material and equipment are promptly identified, documented, and corrected or otherwise handled in accordance with established procedures. In addition, NEDO-11209-04A states that corrective action follow-up and closeout procedures provide for assuring that corrective action commitments are implemented in a systematic and timely manner. Furthermore, NEDO-11209-04A states that corrective action documentation and request forms or formal letters are used to document the corrective-action-related requests, responses and follow-up.

GNF CP 23-01, "Engineering Computer Programs," Revision 1, dated February 14, 2006, requires that software problems are presented as notifications to potentially affected users. Section 7.7.5 of GNF CP 23-01 requires internal software users to respond to Engineering Computer Program (ECP) problem reports within 30 days of notification.

Contrary to the above, as of December 19, 2008, of the 54 internal user responses required for the four ECP problem reports evaluated (2008-44, 2008-14, 2008-09 and 2007-42), 23 responses were received after 30 days or were not received by the GEH Computer Department.

This issue is identified as Violation 05200010/2008-201-03.

This is a Severity Level IV violation (Supplement II of the Enforcement Policy).

- D. Criterion XVI, "Corrective Action", of Appendix B to 10 CFR Part 50 states, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

NEDO-11209-04A states that conditions adverse to quality or nonconformance such as: failures, malfunctions, deficiencies, and deviations in material and equipment are promptly identified, documented, and corrected or otherwise handled in accordance with established procedures. NEDO-11209-04A also stated that procedures provide for significant conditions adverse to quality to be identified, their causes to be determined, and for corrective action to be taken.

GNF CP 23-01 provides the instructions for the GEH software Corrective Action Program (CAP) for Level 2 software codes.

GNF CP 16-01, "Corrective Action Process and Self-Assessments," Revision 3, dated March 14, 2008, provides instructions for General Electric Nuclear Energy's Corrective Action Report process that is used in many departments throughout GEH.

Appendix F of GNF CP 03-09 provides instructions for the use of non-Level 2 codes for alternative calculations and verifications of software code during the development of GEH software products to verify correctness of an original calculation and developer's assumptions.

Contrary to the above, as of December 19, 2008, GEH failed to have an adequate corrective action program for Level 1 software code errors. GEH was not able to provide the NRC Inspection Team documentation that showed where errors in Level 1 codes were processed through either the General Electric Nuclear Energy's Corrective Action Report process or the GEH software Corrective Action Program.

This issue is identified as Violation 05200010/2008-201-04.

This is a Severity Level IV violation (Supplement II of the Enforcement Policy).

- E. Criteria XVIII, "Audits", of Appendix B to 10 CFR Part 50 states, in part, that a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

NEDO-11209-04A states that a comprehensive system of planned and documented audits is carried out to verify product quality and compliance with the QA Program. NEDO 11209-04A further states that audits are conducted at scheduled intervals as documented in audit schedule planning.

NEDO-11209-04A also states GEH staff-level organizations are required to perform annual self-audits to determine the effectiveness of, and verify compliance with, assigned portions

of the QA Program. Each organization prepares plans for the conduct of internal audits prior to February 1 of each year so that during the course of each year all aspects of the QA Program are included in at least one self-audit.

Section 2.3.3 of GNF Policy and Procedures (P&P) 70-14, "GNF Quality Assurance Audit Requirements," dated November 2, 2007, requires that an annual audit plan is prepared to ensure that a representative sample of GEH's quality system elements and all 18 criteria of 10 CFR 50, Appendix B, are audited. Section 2.11.6 of GNF P&P 70-14 also requires audit records are maintained for a minimum of three years or three years from the completion date of any corrective action.

Contrary to the above, as of December 19, 2008, GEH failed to have the GEH NQA audit plans for 2006 and 2007.

This issue is identified as Violation 05200010/2008-201-05.

This is a Severity Level IV violation (Supplement II of the Enforcement Policy).

- F. Criteria XVIII, "Audits", of Appendix B to 10 CFR Part 50 states, in part, that a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibility in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited.

NEDO-11209-04A requires that QA audits be conducted using pre-established written procedures or checklists by appropriately trained personnel not having direct responsibilities in the area being audited. In addition, NEDO-11209-04A requires that audit results are documented by the auditors and transmitted for review by management having responsibility in the area audited.

Contrary to the above, as of December 19, 2008, GEH failed to include specific criteria in its checklists, and as such failed to adequately document the basis of the audit findings to support the audit conclusions. For example:

1. Engineering Computer Programs (ECPs) are audited as part of the annual Global Nuclear Fuels-America nuclear fuel design audit. This annual audit only includes a sample of the more than 100 ECPs being used by GEH for compliance with applicable policies and procedures. The checklists used for these audits only contain general information on software criteria. GEH has different requirements and governing policies for its different software types. GEH audit checklists do not specify the criteria against which the software are to be audited in order that the auditors can evaluate the compliance of the software program to GEH policies and procedures.
2. The GEH NQA audit of GNF-A (Audit Q0617, dated October 27, 2006) included an assessment of the Part 21 program and was found to be satisfactory. GEH's basis for this assessment cited P&P 70-42, "Reporting of Defects and Non-Compliance under 10 CFR Part 21, without documenting how this satisfied 10 CFR Part 21."

These issues are identified as Violation 05200010/2008-201-06.

This is a Severity Level IV violation (Supplement II of the Enforcement Policy).

Pursuant to the provisions of 10 CFR 2.201, 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 John A. Nakoski, Chief, Quality and Vendor Branch 2, 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: (1) the reason for the violation or, if contested, the basis for disputing the violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid violations; 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.

Since your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), 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. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. 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.

Dated this 25th day of March 2009.

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

VENDOR INSPECTION REPORT

Report No: 05200010/2008-201

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

Vendor Contact: Mr. Mark Harvey
Vice President Quality
Nuclear Plant Projects

Background: The U.S. Nuclear Regulatory Commission (NRC) under Title 10, Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," of the *Code of Federal Regulations* (10 CFR Part 52) is conducting a design certification review of GEH Economic Simplified Boiling Water Reactor (ESBWR). The NRC Inspection Team focused its inspection on the computer codes that GEH used to perform safety analyses for the ESBWR design

Inspection Dates: December 15-19, 2009

Inspectors:	Daniel Pasquale	NRO/DCIP/CQVB	Lead Inspector-in-training
	Michael Morgan	NRO/DCIP/CQVB	Inspector
	George Lipscomb	NRO/DCIP/CQVB	Inspector-in-training
	Bruce Bovol	NRO/DNRL/NGE1	Project Manager
	Weidong Wang	NRO/DSRA/SRSB	Technical Specialist
	Andrew Bielen	NRO/DSRA/SRSB	Technical Specialist
	Jaclyn Dorn	NRO/DSRA/SRSB	Technical Specialist
	James Gilmer	NRO/DSRA/SRSB	Technical Specialist
	Joshua Kaizer	NRR/ADES/DSS/SNP	Technical Specialist
	Jose March-Leuba	Oak Ridge National Laboratory (ORNL)	Contractor
	John A. Nakoski	NRO/DCIP/CQVB	Observer

	/RA/	3/25/2009
Approved By:	John A. Nakoski, Chief Quality & Vendor Branch 2 Division of Construction Inspection & Operational Programs Office of New Reactors	Date

EXECUTIVE SUMMARY

General Electric-Hitachi Nuclear Energy
05200010/2008-201

This inspection focused on quality activities that GEH implemented for the design, development, and use of software programs in support of the ESBWR design certification. The NRC Inspection Team verified that GEH had implemented an adequate software quality assurance (QA) program that complies with the requirements of Appendix B to 10 CFR Part 50, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." In addition, the NRC Inspection Team evaluated portions of GEH's implementation of 10 CFR Part 21, "Reporting of Defects and Noncompliance," (Part 21) for evaluating software deviations and reporting of defects that could create a substantial safety hazard. The NRC Inspection Team utilized Inspection Procedure (IP) 43003, "Reactive Vendor Inspection," and IP 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance," during the conduct of this inspection.

Prior to this inspection, three previous NRC inspections were performed, one in December 2006 (0520010/2006-202), one in April 2006 (0520010/2006-201), and one in November 2005 (0520010/2005/201). A previous NRC audit was also performed in December 2006 as part of an ESBWR design certification review. All three inspections and the audit were performed at GEH's facility in Wilmington, North Carolina.

This inspection was performed based on requests from the Office of New Reactors (NRO), Division of Safety Systems and Risk Assessment (DSRA), Nuclear Performance and Code Review Branch (SRSB) for verification of GEH's software version control and configuration management processes on software used to perform safety analyses for the ESBWR design certification.

As described below, the NRC Inspection Team concluded that certain GEH's QA policies and procedures, and the implementation of them were not in compliance with the applicable requirements of 10 CFR Part 21 and Appendix B to 10 CFR Part 50.

10 CFR Part 21

The NRC Inspection Team issued **Violation 05200010/2008-201-01** because GEH failed perform a Part 21 evaluation when another GEH organization indicated that a software problem had impacted their use of the code. Specifically, the NRC Inspection Team found that GEH Engineering Computer Program problem report 2007-20 reported technical usage problems with the application of the GEXL critical quality boiling length correlation built into the TRACG code (GEXL) and was not adequately forwarded to GEH Nuclear Quality Assurance (NQA) for Part 21 processing.

Design Control

The NRC Inspection Team issued **Violation 05200010/2008-201-02** because GEH failed to document the justification or rationale for the use a particular version of a non-Level 2 code during an alternate calculation to verify original calculations and developer's assumptions.

Corrective Actions

The NRC Inspection Team issued **Violation 05200010/2008-201-03** because Global Nuclear Fuel (GNF) Common Procedure (CP) 23-01, "Engineering Computer Programs," Revision 1, dated February 14, 2005, requires that GEH internal software users respond to Engineering Computer Problem (ECP) problem reports within 30 days, and of the 54 internal user responses required for the four ECP problem reports evaluated, 23 responses were received after 30 days or were not received by the GEH Computer Department.

In addition, the NRC Inspection Team issued **Violation 05200010/2008-201-04** because GEH failed to have an adequate corrective action program for Level 1 software code errors. GEH was not able to provide the NRC Inspection Team documentation that showed where errors in Level 1 codes were processed through either the General Electric Nuclear Energy's (GENE) Corrective Action Report (CAR) process or the GEH software Corrective Action Program (CAP).

Audits

The NRC Inspection Team issued **Violation 05200010/2008-201-05** in response to GEH's failure to have the GEH NQA audit plans for 2006 and 2007. The NRC Inspection Team noted that Section 2.3.3 of GNF Policy and Procedure (P&P) 70-14, "GNF Quality Assurance Audit Requirements," dated November 2, 2007, requires preparation of an audit plan to ensure that a representative sample of GEH's quality system elements and all 18 criteria of 10 CFR Part 50, Appendix B, are audited.

The NRC Inspection Team issued **Violation 05200010/2008-201-06** because GEH does not include specific criteria in its checklists, and as such failed to adequately document the basis of the audit findings to support the audit conclusions. For example, the NRC inspectors determined that the auditors would not be able to evaluate the effectiveness of the software program without specifying the criteria to be audited, since GEH has different requirements and governing policies for its different software types. In addition, based on the limited information included in the audit report, the NRC inspectors could not determine if the GEH NQA auditors had adequately verified that the Part 21 program was effectively implemented.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspectors reviewed GEH policies and procedures governing the Part 21 program. Specifically, the NRC inspectors assessed how those guidelines have been applied to its ECPs. The NRC inspectors focused their efforts on the GEH software CAP and how this program is initiated with an ECP problem report. The inspectors also assessed how the GEH software CAP and the associated ECP problem reports were captured by the GEH Part 21 process. Since the GEH Part 21 program was the subject of a recent NRC inspection (See Inspection Report 05200010/2006-201 ADAMS Number ML061390065), the Part 21 program as applied to other GEH organizations was not an emphasis during this inspection.

In addition, the NRC inspectors evaluated the GEH 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 inspectors reviewed the following procedures and records:

- NEDO-11209-04A, "GE Nuclear Energy [GENE] Quality Assurance Program Description," Revision 8, dated March 31, 1989.
- GEH P&P 70-42, "Reporting of Defects and Non-Compliance under 10 CFR Part 21," dated September 25, 2008.
- GNF CP 23-01, "Engineering Computer Programs," Revision 1, dated February 14, 2006.
- ECP Problem Report 2008-57, "IBNDL01A" dated November 7, 2008.
- ECP Problem Report 2007-24, "GESAM02A" dated May 8, 2007.
- ECP Problem Report 2007-20, "GEXL01A," dated April 10, 2007.

b. Observations and Findings

b.1 10 CFR Part 21 Postings

The NRC inspectors evaluated GEH's compliance with the posting requirements of 10 CFR 21.6. The NRC inspectors found that GEH had posted notices that included a copy of Section 206 of the Energy Reorganization Act of 1974, a current copy of Part 21, GEH P&P 70-42, and a memorandum that included the name and contact information for GEH's Safety Evaluation Program Manager. Nine buildings were inspected on the main GEH facility. The NRC inspectors did not identify any findings in this area.

b.2 10 CFR Part 21 Procedure

GEH P&P 70-42 outlines the procedure and responsibilities to identify, control, document, and resolve conditions used for reporting defects and noncompliance discovered at GEH. During the review of GEH P&P 70-42, the NRC inspectors found that the procedure was applicable to ECPs and contained adequate guidance to meet regulation requirements.

The NRC inspectors noted, in section 7.7.3 of GNF CP 23-01, that the GEH internal user of the software is to document and report to GEH Computer Department any ECP technical usage problems including potential errors. In accordance with section 7.6.2 of GNF CP 23-01, GEH Computer Department documents all problems in ECP problem reports and transmits them to the design and development organization managers for evaluation. The NRC inspectors further noted, in section 7.7.6 of GNF CP 23-01, that during the evaluation process, the problem is to be evaluated for any potential reportable conditions in accordance with the requirements of GNF P&P 70-42. The GEH NQA is then required to initiate, if appropriate, any Part 21 actions; i.e., the possible reporting of the defect/noncompliance.

b.3 Part 21 Implementation

The NRC inspectors found that although ECP problem reports document problem impact, the assignment of a potential safety concern classification and tracking number is based on the result of other GEH user feedback.

The NRC inspectors reviewed and verified that ECP problem reports included written documentation showing that the required potential safety concerns evaluations had been completed. The NRC inspectors noted that only a few ECP problem reports had associated potential safety concern numbers (i.e., ECP problem reports 2007-24 and 2008-57). However, the NRC inspectors further noted that the majority of the ECP problem reports did not have an assigned potential safety concern number or documentation that such a number was not needed. The NRC inspectors noted that GEH records also lacked potential safety concern evaluation documentation in cases where customer feedback indicated that the software problem had impacted their use of the code. These reports were not forwarded to the GEH NQA for Part 21 processing. As such, the NRC inspectors determined that GEH failed to document the evaluation of ECP problem reports for potential safety concerns, and subsequent Part 21 reporting. **This issue is identified as Violation 05200010/2008-201-01.**

In ensuring compliance with the reporting requirement of Part 21, the NRC inspectors requested copies of Part 21 records for all TRACG, PANAC11, and TGBLA evaluations that GEH had completed over the previous three years. The NRC inspectors found that GEH NQA had not performed Part 21 evaluations for the above requested codes.

GEH NQA personnel provided documentation for two potential reportable conditions related to other software codes for NRC inspector review. ECP problem report 2007-24 was found to be a potential reportable condition and was completed for a GESAM02A code in 2007. The potential reportable condition evaluation concluded that the condition did not warranted a Part 21 report and was therefore removed from any further Part 21 considerations. The NRC inspectors also looked at ECP Problem Report 2008-57 for an IBNDL01A code that was being processed during the inspection period. A completed evaluation was not available to the NRC inspectors at the end of the inspection period.

c. Conclusions

The NRC inspectors found that GEH's Part 21 postings met 10 CFR 21.6(a) requirements. In addition, NRC inspectors found that GEH P&P 70-42 incorporated the requirements of 10 CFR 21.21 and the requirements were applicable to the Engineering Computer Programs. However, NRC inspectors found that GEH failed to document the evaluation of ECP problem reports for potential safety concerns, and subsequently Part 21 reporting.

For instance, one of the GNF-America Method Groups indicated that ECP problem report 2007-20 has an impact on its use of the PANAC code and required further evaluation. ECP problem report 2007-20, describe a problem with GEXL that is used by the PANAC code in a subroutine that performs nuclear core heat flux calculations. **This issue is identified as Violation 05200010/2008-201-01.**

2. Design Control

a. Inspection Scope

The NRC inspectors reviewed GEH's policies and procedures governing the implementation of its design control programs to verify compliance with the QA requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. The NRC inspectors reviewed samples of three completed Software Design Descriptions (SDDs), for software designed, developed, and used by GEH in support of the ESBWR design certification.

Within the scope of this area of the inspection, the NRC inspection inspectors reviewed the following GEH procedures and records:

- NEDO-11209-04A, "GE Nuclear Energy [GENE] Quality Assurance Program Description," Revision 8, dated March 31, 1989.
- GNF CP 03-04, "Design Review," Revision 4, dated February 5, 2007.
- GNF CP 03-08, "Design Record File," Revision 1, dated May 11, 2005.
- GNF CP 03-09, "Independent Design Verification," Revision 1, dated January 4, 2006.
- GNF CP 23-01, "Engineering Computer Programs," Revision 1, dated February 14, 2005.
- GNF Procedural Requirements and Responsibilities (PR&R) Matrix 06, "Document Control," dated January 7, 2008.
- GNF PR&R Matrix 23, "GNF-A; PR&R Matrix; Software", dated January 9, 2008.
- GNF Design Review Report File 000-0066-0872, "Cell Friction Methodology Update," dated July 7, 2006.
- Software Design Description "PANAC11A Engineering Computer Program," Revision 0, dated April, 1997.
- NEDE-32176P, "Differences Between TRACG and TRAC-BF1," Revision 3, dated April 20, 2006.
- NEDE-32176P, "TRACG Model Description," Revision 3, dated April 20, 2006.
- Engineering Service Instruction 30-1.00, "Alternate Calculations for Verification of Non-Level 2 Computer Code Calculations," Revision 8.

b. Observations and Findings

b.1. Design Control

GNF CP 23-01 provides instruction for ECP design, development, use, and control. The procedure also provides direction to GEH personnel so that they can control computer programs in accordance with GENE QA program description NEDO-11209-04A. The NRC inspectors found that GNF CP 23-01 contained adequate provisions for control of design inputs, processes, outputs, and changes. The NRC inspectors also noted that: 1) design records to be retained were properly described; 2) responsibilities for program development, use, and control were adequately defined; and 3) proper organizational interfaces were described and presented

to the analytical software developers.

The NRC inspectors noted that GEH uses multiple levels to classify ECP software. GEH Computer Department codes are initially designated as Level 1 codes. These codes are to progress to Level 2 when they are approved and available for customer use. The NRC inspectors further noted that GEH uses a Level 3 designation for software codes that are historical or for software codes that are not used for design.

The NRC inspectors reviewed completed software design packages, including: 1) SDDs for PANAC11A; 2) NEDE-32176P; and 3) NEDE-32176. The NRC inspectors found that the SDDs contained the required elements as presented in GNF CP 23-01. Further, the NRC inspectors verified that software design inputs were appropriately translated into the ECP design documents. The NRC inspectors did not identify any issue in this area.

b.2. Design Verification

GNF CP 03-09 provides instructions for independent verification of computer software programs designed, developed, and used by GEH. The procedure also provides direction to GEH personnel so that they can accomplish design verification in accordance with GENE QA program description NEDO-11209-04A. The NRC inspectors found that CP 03-09 contained adequate provisions for the verification of GEH computer software programs. The NRC inspectors also noted that: 1) typical items that required design verification were appropriately listed; 2) personnel involved in such verifications were properly identified; 3) software designs were adequately and appropriately identified prior to their release to other GEH organizations; and 4) verification responsibilities of other GEH organizations, including GNF-America and GNF-Japan, were properly identified and defined.

GNF CP 03-09 states that GEH uses Level 2 and non-Level 2 codes. Level 2 codes are codes that are fully approved by GEH for design and development of software products. Non-Level 2 codes are codes that have been developed and tested, but have not been fully approved by GEH for the design and development of software products. However, Appendix F of GNF CP 03-09 provides instructions for the use of non-Level 2 codes for alternative calculations and verifications of software code during the development of GEH software products.

The NRC inspectors noted in Appendix F of GNF CP 03-09 that alternative calculations are performed to verify correctness of an original calculation and developer's assumptions. The NRC inspectors noted that Appendix F of GNF CP 03-09 allows for the use of several different versions of non-Level 2 computer codes, if appropriate justification for use of the code is documented. Such action maintains proper design control so that further verification of the design can be adequately assessed. The NRC inspectors were unable to find any documented justification or rationale for the use a particular version of a code for a specific calculation. On the final day of the inspection, GEH developed a draft GEH Nuclear Energy CAR to address this issue. At the time of the inspection, no CAR number had been assigned. **This issue is identified as Violation 05200010/2008-201-02.**

c. Conclusion

The NRC inspectors concluded that GEH's design control and verification program requirements are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. However, the NRC inspectors found that GEH failed to fully document its justification and their rationale for the selection of various versions of software for the testing of

certain computer software codes. **This issue is identified as Violation 05200010/2008-201-02.**

3. **Test Control**

a. **Inspection Scope**

The NRC inspectors reviewed GEH policies and procedures for the control of tests that are performed, in order to demonstrate that the software was appropriately tested. This evaluation was conducted to assess GEH's compliance with the requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. The NRC inspectors reviewed a sample of completed GEH design record files to ensure approved test methodologies were performed.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following GEH procedures and records:

- NEDO-11209-04A, "GE Nuclear Energy [GENE] Quality Assurance Program Description," Revision 8, dated March 31, 1989.
- GNF CP 03-09, "Independent Design Verification," Revision 1, dated January 4, 2006.
- GNF CP 23-01, "Engineering Computer Programs," Revision 1, dated February 14, 2005.
- Engineering Service Instruction 30-1.00, "Alternate Calculations for Verification of Non-Level 2 Computer Code Calculations," Revision 8.
- Engineering Service Instruction 30-1.00, Appendix A, "Spreadsheet Input Guidelines," Revision 8.
- GEH Design Record File 0000-0081-1862, "Inadvertent Isolation Condenser Initiation (IICI) Analysis for Equilibrium Core," Revision 0, dated May 20, 2008.
- GEH Design Record File 0000-0092-7948, "TRACG04P Transient Calculations to Assess Impact of Using PRIME," Revision 0, dated October 20, 2008.
- GEH Design Record File 0000-0037-3413, "TRACG Component Models and Inputs for FW Lines," Revision 2, dated December 17, 2008.
- GENE Work and Quality Plan 50-3622, "TRACG Model LTR, NEDE-32176P," Revision 3, dated October 29, 2007.

b. **Observations and Findings**

Appendix B of GNF CP 03-09 and GNF CP 23-01 provide guidance for the testing of software codes under GEH's testing program. The testing program adequately defines required testing, requirements of testing personnel, establishment of proper hardware and environmental conditions, and appropriate acceptance criteria. Based on the review of a sample of design record files, that included calculation and test descriptions, the NRC inspectors determined that the tests were accomplished in accordance with the GEH's approved procedures and guidance documents. The NRC inspectors also determined that appropriate test plans were in place for testing. The NRC inspectors did not identify any issues in this area.

c. **Conclusions**

The NRC inspectors concluded that GEH's test control program for the testing of software is consistent with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50. Based on the sample of records reviewed, the NRC inspectors also determined that GEH's associated testing procedures were effectively implemented.

4. Corrective Action

a. Inspection Scope

The NRC inspectors reviewed GEH's policies and procedures for the implementation of the corrective action program. The NRC inspectors assessed GEH's corrective action program compliance with the requirements of Appendix B to 10 CFR Part 50, Criterion XVI, "Corrective Action." The NRC inspectors focused most of their corrective action inspection efforts in review of GEH ECP problem reports relating to the TRACG, PANAC11, and TGBLA software codes. The NRC inspectors also reviewed nine 2007 and 2008 software problem reports to evaluate GNF corrective action processes.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures and records:

- NEDO-11209-04A, "GE Nuclear Energy Quality Assurance Program Description," Revision 8, dated March 31, 1989.
- PR&R 23, "Software," dated January 9, 2008.
- GEH P&P 70-42, "Reporting of Defects and Non-Compliance under 10 CFR Part 21," dated September 25, 2008.
- GNF CP 23-01, "Engineering Computer Programs," Revision 1, dated February 14, 2006.
- GNF CP 16-01, "Corrective Action Process and Self-Assessments," Revision 3, dated March 14, 2008.
- Methods and Software Development Organization Chart, dated December 2008..
- ECP Problem Report 2008-44, "PANAC11A," dated October 8, 2008.
- ECP Problem Report 2008-57, "IBNDL01A," dated November 7, 2008.
- ECP Problem Report 2008-14, "TGBLA06A," dated April 15, 2008.
- ECP Problem Report 2008-09, "TRACG04A," dated January 24, 2008.
- ECP Problem Report 2008-08, "RXNOM01A," dated January 18, 2008.
- ECP Problem Report 2008-06, "ISCOR09A," dated January 14, 2008.
- ECP Problem Report 2007-42, "PANAC11P," dated November 7, 2007.
- ECP Problem Report 2007-24, "GESAM02A," dated May 8, 2007.
- ECP Problem Report 2007-20, "GEXL01A," dated April 10, 2007.

b. Observations and Findings

The NRC inspectors noted that GEH design software has two corrective action programs. The first program is the GEH software CAP. The NRC inspectors noted that this software CAP is governed by GNF CP 23-01 and it is unique to software. The NRC inspectors also noted that within this software CAP, potential problems are noted on a software problem report. The second program used by GEH is GENE's CAR process. The NRC inspectors noted that this CAR process is governed by GNF CP 16-01 and is used in many departments throughout GEH.

The NRC inspectors found that both of the above processes feed into GEH's Part 21 program. The NRC inspectors noted that Part 21 reporting is governed by GEH P&P 70-42 and managed by GEH NQA.

GNF CP 23-01 requires that software problems are presented as notifications to potentially affected customers. GNF CP 23-01 provides the time requirements associated with addressing software problems, and in addition, provides methods for tracking their resolutions. GEH Computer Department sends ECP problem reports via email to GEH internal users, external customers, and other interested parties. The NRC noted that GNF CP 23-01 requires that GEH internal users respond to ECP problem reports within 30 days. The NRC inspectors also noted that the procedure requires tracking of the responses. The NRC inspectors further noted that there are no response requirements for external customers or other interested parties. However, GEH Computer Department tracks that those external users and other interested parties have received the ECP problem reports.

The NRC inspectors reviewed ECP problem reports for the TRACG, PANAC11, and TGBLA software codes. The NRC inspectors noted that four ECP problem reports were initiated over the last 13 months. For these four reports, 54 internal user responses were required. However, 23 were received after 30 days or were not received by the GEH Computer Department. **This issue is identified as Violation 05200010/2008-201-03.**

The NRC inspectors noted that GEH uses multiple levels to classify ECP software. The GEH Computer Department codes are initially designated as Level 1. These codes are to progress to Level 2 when they are approved and available for use. Level 2 software codes are the codes that are covered by GEH software CAP as presented in GNF CP 23-01. As allowed by Appendix F of GNF CP 03-09, the NRC inspectors found that GEH internal users used Level 1 codes for alternate design calculations. The NRC inspectors noted that GNF CP 23-01 does not provide instructions for the initiation of an ECP problem report when Level 1 codes are used.

The NRC inspectors requested documentation that would show that Level 1 software code errors were routinely processed through GENE's CAR process, as an alternative to the GEH software CAP. GEH was unable to provide the NRC inspectors with documentation that showed that errors in Level 1 codes were processed through either the GENE's CAR process or the GEH software CAP. **This issue is identified as Violation 05200010/2008-201-04.**

c. Conclusions

The NRC inspectors determined through the review of GEH's ECP problem reports that GEH is generally implementing GEH's software CAP consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. However, as identified above, the NRC inspectors found that of the 54 required internal user responses for the four ECP reports reviewed, 23 responses were received after 30 days or were not received by the GEH Computer Department. Also, the NRC inspectors determined that GEH's software CAP failed to include processing of Level 1 software code errors. These issues are identified in **Violation 05200010/2008-201-03 and Violation 05200010/2008-201-04**, respectively.

5. Audits

a. Inspection Scope

The NRC inspectors reviewed GEH's policies and procedures governing the implementation of GEH's audit programs to assess GEH's compliance with the requirements of Appendix B to 10 CFR Part 50, Criterion XVIII, "Audits". The NRC inspectors reviewed annual audit plans and internal audit reports from the last three years. The NRC inspectors focused the review in the internal audits to GEH Computer Department related to ECPs.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedure and records:

- NEDO-11209-04A, "GE Nuclear Energy Quality Assurance Program Description," Revision 8, dated March 31, 1989.
- GNF P&P 70-14, "GNF Quality Assurance Audit Requirements," dated November 2, 2007.
- GNF Quality Internal Audit Plan for 2006, Revision 0, dated January 31, 2006.
- GNF Quality Internal Audit Plan for 2007, Revision 0, dated January 24, 2007.
- GNF Quality Internal Audit Plan for 2008, Revision 1, dated January 23, 2008.
- NQA Audit Plan for 2008, Revision 1, dated June 16, 2008.
- GNF Internal Audit 2008-07 Checklist, "GNF-A Design," inspection date October 27, 2008.
- GNF Internal Audit 2007-07 Report, "GNF-A Nuclear Fuel Design".
- GNF Internal Audit 2006-06 Report, "GNF-A Nuclear Fuel Design".
- NQA Audit Q0617 Checklist, "GNF-A," dated October 27, 2006.
- NQA Audit Q0708 Checklist and Report, "GNF-J," dated June 14, 2007.
- NQA-2008-07 Audit Report, "Custom Fabrication," dated October 1, 2008.
- Nuclear Energy Corrective Action Request No. 46131, dated August 14, 2008.

b. Observations and Findings

GEH uses a two-tier audit system, where GEH NQA provides independent auditing and GNF conducts internal audits. The NRC inspectors noted that section 2.3.3 of GNF P&P 70-14 requires that an annual audit plan is 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.

The NRC inspectors also noted in section 2.11.6 of GNF P&P 70-14 that there is a requirement to retain audit records for a minimum of three years or three years from the completion date of any corrective action. The NRC inspectors requested GNF and GEH NQA annual audit plans for the last three years. GEH NQA audit plans for 2006 and 2007 were not available for review. The NRC inspectors noted that GEH NQA personnel searched their records but they could not locate the requested audit plans. **This issue is identified as a Violation 05200010/2008-201-05.**

GNF personnel indicated to the NRC inspectors that audits of ECPs software company procedure compliance is assessed as part of the annual GNF-A nuclear fuel design audit. The NRC inspectors reviewed the software portions of three GNF internal audit reports. The NRC inspectors determined that GNF samples a few individual ECPs annually from the pool of over 100 total ECPs and evaluates them for compliance with GEH policies and procedures.

Although not listed specifically as an evaluation criteria, Part 21 reporting is indirectly evaluated through the evaluation of company procedures GNF CP 23-01, PR&R 23, and GEH P&P 70-42. Corrective action reports are issued for any audit findings. Additionally, GEH NQA personnel indicated to the NRC inspectors that the last GEH NQA audit that included a review of the ECP was completed in October 2006. The inspectors reviewed the GEH NQA audit and determined that GEH NQA audits evaluate for Appendix B to 10 CFR Part 50 and 10 CFR Part 21 compliance.

During the review of the internal audit checklists, the NRC inspectors found that both GNF and GEH NQA audits contain software elements. However, the NRC inspectors noted that the checklists only contained general information on software criteria. The NRC inspectors noted that the checklists did not differentiate between engineering design, I&C, plant simulation, or machinery control software. It is important to note that GEH has different requirements and governing policies for its different software types. For example, elements of GNF CP 23-01 that apply to engineering design software would not apply to I&C software. The NRC inspectors noted that GNF and GEH NQA auditors inspected generic software requirements. The NRC inspectors found that the documentation supporting the audit of software was not sufficient to determine the effectiveness of the software program without specifying the criteria audited contrary to the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. **This issue is identified as an example of Violation 05200010/2008-201-06.**

In addition, the NRC inspectors noted during the GEH NQA Q0617 audit that an assessment of the Part 21 program was performed and found to be satisfactory. However, the NRC inspectors noted that the only basis for this assessment was citing P&P 70-42. There was no additional documentation in the audit report for this assessment. As a result of this limited information, the NRC inspectors could not determine if the GEH NQA auditors had adequately verified that the Part 21 program was effectively implemented. The NRC inspectors found the documentation of the basis for NQA auditor findings during the GEH NQA Q0617 audit did not support the audit conclusions. **This issue is identified as another example of Violation 05200010/2008-201-06.**

c. Conclusions

The NRC inspectors determined through a review of GNF and GEH NQA internal audit plans and reports that GEH's program requirements were consistent with the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. However, as identified above, GEH failed to have the GEH NQA audit plans for 2006 and 2007. Also, the NRC inspectors found that GEH does not include specific criteria in its checklists, and as such failed to adequately document the basis of the audit findings to support the audit conclusions. These issues are identified as **Violation 05200010/2008-201-05 and Violation 05200010/2008-201-06**, respectively.

6. Exit Meeting

On December 19, 2008, the inspectors and technical specialists presented the inspection scope and findings during an exit meeting with Mark Harvey, Vice President Quality, Nuclear Plant Projects, and GEH personnel.

ATTACHMENT

1. PERSONS CONTACTED

M. Harvey, Vice President Quality, Nuclear Plant Projects, GEH
J. Bowman, P.E., Vice President, Methods & software Development, GEH
A. Lingenfelter, Vice President, Fuel Engineering, GNF
R. Brown, Senior Vice President, Regulatory Affairs, GEH
J. Atento, Nuclear Plant Projects Quality, GEH
J. Fawks, Manager Software Engineering, GEH
R. Bastyr, NQA Director, GEH
R. Kingston, Manager, ESBWR Licensing, GEH
D. Hinds, Manager, New Units Engineer, GEH
W. Marquino, Manager, ESWR Systems Engineer, GEH
Y. Lee, Nuclear Plant Projects Quality, GEH
D. Rock, TH Methods Gag, GNF
J. Smith, Lead Engineer, GNF
B. Moore, Methods Manager, GNF
J. Harrison, Regulatory Affairs, Fuels, GEH
R. Stachowski, Chief, Consulting Engineer- Nuclear, GNF
M. Solmos, Safety and Performance Analysis Engineer, GEH
J. Smith, Lead Engineer/Technologist, Methods, GNF
V. Mills, Nuclear Method, GNF
C. Heck, Consulting Engineer, GEH
M. Cook, Engineer, GEH
J. Yang, Engineer, GEH
L. Heckle, Manager, Software QA, GEH
J. Anderson, Chief, Consulting Engineer, GEH
M. D. Alamgir, Acting Manager, ESBWR Safety Awareness, GEH
B. Shiralker (via telephone), Technical Expert, GEH
Y. Cheung, Principle Engineer, GEH
P. Saha, Principle Engineer, GEH
B. Aktas, Principle Engineer, GNF
J. Escaville, Plant Performance Engineer, GEH
C. Goodson, Plant Performance Engineer, GEH
J. Yang, Plant Performance Engineer, GEH
S. Moen, Project Engineer, GEH
J. Klapproth, General Manager, Engineering, GEH

2. INSPECTION PROCEDURES USED

IP 43003, "Reactive Vendor Inspection,"

IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance"

IP 43004, "Inspections of Commercial-Grade Dedication Programs."

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
05200010/2008-201-01	Open	NOV	<u>10 CFR Part 21</u> : Failure to perform Part 21 evaluation when other GEH organization indicated that a software problem had impacted their use of the code
05200010/2008-201-02	Open	NOV	<u>Design Control</u> : Failure to document the justification or rationale for the use a particular version of a non-Level 2 code during an alternate calculation to verify original calculations and developer's assumptions.
05200010/2008-201-03	Open	NOV	<u>Corrective Action</u> : Failure to get ECP problem reports responses in a timely manner.
05200010/2008-201-04	Open	NOV	<u>Corrective Action</u> : Failure to have adequate corrective action program for Level 1 software code errors.
05200010/2008-201-05	Open	NOV	<u>Audits</u> : Failure to have the GEH NQA audit plans for 2006 and 2007.
05200010/2008-201-06	Open	NOV	<u>Audits</u> : Failure to adequately document the basis of the audit findings to support the audit conclusions.