

March 13, 2009

Mr. Richard Wittmeier
GE Hitachi Nuclear Energy
3901 Castle Hayne Road
Wilmington, NC

SUBJECT: NRC INSPECTION REPORT NO. 99900003/2009-201, NOTICE OF VIOLATION
AND NOTICE OF NONCONFORMANCE

Dear Mr. Wittmeier

From January 27 to 30, 2009, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the GE Hitachi Nuclear Energy (GEH) facility in Wilmington, North Carolina. The enclosed report presents the results of this inspection.

This was a limited scope inspection, which focused on assessing your compliance with the provisions of Part 21 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 21) "Reporting of Defects and Noncompliance," and selected portions of Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because NRC inspectors identified that GEH failed to meet the requirements set forth in 10 CFR Part 21 for procedures to ensure effective evaluation of deviations associated with substantial safety hazards within 60 days of discovery.

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.

During this inspection, NRC inspectors also found that implementation of your QA program failed to meet certain NRC requirements contractually imposed on you by your customers. The NRC inspectors noted a deficiency for inadequate documentation of the commercial-grade dedication process. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter.

Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance.

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/

Patrick L. Hiland
Division Director
Division of Engineering
Office of Nuclear Reactor Regulation

Docket No.: 99900003

Enclosures: 1. Notice of Violation
 2. Notice of Nonconformance
 3. Inspection Report 99900003/2009-201

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/

Patrick L. Hiland
 Division Director
 Division of Engineering
 Office of Nuclear Reactor Regulation

Docket No.: 99900003

Enclosures: 1. Notice of Violation
 2. Notice of Nonconformance
 3. Inspection Report 99900003/2009-201

DISTRIBUTION:

RidsNroDcipCqvb
 RidsNroDcipCqvp
 KKavanagh

ADAMS Accession No.: ML090720041

| OFFICE | EQVB/DE/NRR | EQVB/DE/NRR | EQVB/DE/NRR | BC: EQVB/DE/NRR | D:DE/NRR |
|--------|--------------|-----------------------|--------------------|-----------------|--------------|
| NAME | VHall | AArmstrong V.Hall for | PPrescott by phone | DThatcher | PHiland |
| DATE | 03/ 13 /2009 | 03/ 13 /2009 | 03/ 13 /2009 | 03/ 13 /2009 | 03/ 13 /2009 |

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

GE Hitachi Nuclear Energy
3901 Castle Hayne Road
Wilmington, NC

Docket Number 99900003
Inspection Report No. 99900003/2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted January 27 - 30, 2009, of activities performed at GE Hitachi Nuclear Energy (GEH), a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violations is listed below:

10 CFR Part 21, Section 21.21(a)(1), "Notification of failure to comply or existence of a defect and its evaluation," requires in part that, "Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected."

Contrary to the above, as of January 30, 2009:

GEH's 10 CFR Part 21 implementing procedure, Policies and Procedures (P&P) 70-42, "Reporting of Defects and Nonconformance under 10 CFR Part 21," dated January 22, 2009, was not an appropriate procedure to ensure evaluation of deviations and failures to comply associated with substantial safety hazards within 60 days of discovery. As a result, GEH failed to perform timely evaluations for the following deviations:

1. GEH Corrective Action Request (CAR) #45083 was initiated on April 4, 2008, regarding a configuration change affecting historical seismic qualifications of Robert Shaw safety-related pressure gauges for hydraulic control units. Completion of CAR #45083 on April 4, 2008, first identified the existence of a deviation. GEH completed its evaluation of this deviation in Potentially Reportable Condition (PRC) 08-12 on June 11, 2008, 68 days after discovery.
2. GEH CAR #45670 was initiated on June 25, 2008, regarding GEH's dedication of Model 86C temperature switches supplied by Ametek Panalarm. GEH discovered that the accuracy test data sheets for the switches were not verified by a survey. Completion of CAR #45670 on July 15, 2008 first identified the existence of a deviation. GEH completed its evaluation of this deviation in PRC 08-24 on September 18, 2008, 85 days after discovery.

This issue has been identified as Violation 99900003/2009-201-01.

This is a Severity Level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2. 201, "Notice of Violation," you are required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555-0001, with a copy to the Director, Division of Engineering, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice

ENCLOSURE 1

of Violation" 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 further 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.

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 Agency-wide Documents Access and Management 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 13th day of March 2009.

NOTICE OF NONCONFORMANCE

GE Hitachi Nuclear Energy
3901 Castle Hayne Road
Wilmington, NC

Docket Number 99900003
Inspection Report No. 99900003/2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted January 27 - 30, 2009, of activities performed at GE Hitachi Nuclear Energy (GEH), certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon GEH by NRC licensees.

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states in that "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

Chapter 5, "Instructions, Procedures, and Drawings," of GEH Quality Assurance Program Description NEDO-11-209-04A, Revision 8, dated March 31, 1989, states in part that, "activities affecting quality, including methods of complying with 10CFR50, Appendix B, are delineated, accomplished, and controlled by such documents as policies, procedures, operating instructions, design specifications, shop drawings, planning sheets, test and inspection procedures, and standing instructions."

Contrary to the above, as of January 30, 2009:

GEH failed to adequately document the engineering justification used to dedicate commercial-grade items. Two examples of inadequate documentation were:

1. GEH's dedication specifications and associated documents failed to provide an adequate link to original environmental and seismic qualifications.
2. GEH failed to adequately document its process for taking credit for Underwriters Laboratory (UL) certifications to verify material as part of the dedication process.

This issue has been identified as Nonconformance 99900003/2009-201-02.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Director, Division of Engineering, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid non-compliances; and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

ENCLOSURE 2

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.

Dated this 13th day of March 2009.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF ENGINEERING
VENDOR INSPECTION REPORT

Docket No.: 99900003

Report No.: 99900003/2009-201

Vendor: GE Hitachi Nuclear Energy (GEH)
3901 Castle Hayne Road
Wilmington, NC

Vendor Contact: Russell Bastyr
Nuclear Quality Assurance Manager
Phone: (910)547-2649
Russell.Bastyr@ge.com

Nuclear Industry: GEH is a Nuclear Steam Supply Systems (NSSS) supplier to commercial nuclear power industry. The GEH facility in Wilmington, NC provides commercially dedicated basic components to its utility customers.

Inspection Dates: January 27 – January 30, 2009

Inspection Team Leader: Victor Hall, DE/NRR

Inspectors: Paul Prescott, DE/NRR
Aaron Armstrong, DE/NRR

Approved by: Dale Thatcher, Chief
Quality & Vendor Branch
Division of Engineering
Office of Nuclear Reactor Regulation

EXECUTIVE SUMMARY

GE Hitachi Nuclear Energy
99900003/2009-201

The purpose of this inspection was to review selected portions of GE Hitachi Nuclear Energy's (GEH's) quality assurance (QA) and 10 CFR Part 21 (Part 21) programs. The inspectors focused on GEH's activities in the area of commercial-grade dedication (CGD) of replacement parts to NRC-licensed facilities. The inspection was conducted at GEH's facility in Wilmington, North Carolina.

The NRC inspection bases were:

- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations*; and
- 10 CFR Part 21, "Reporting of Defects and Noncompliance."

There were no open items from the previous inspection report 99900003/1999-202 of GEH's facility in Wilmington, North Carolina.

The results of the latest inspection are summarized below.

10 CFR Part 21 Program

The inspectors identified one violation of Part 21 with two examples. Violation 99900003/2009-2009-201-01 was cited for failure to adequately prescribe the process to perform an evaluation within 60 days as specified in Part 21. With the exception of the violation noted above, the inspectors concluded that GEH's Part 21 program was consistent with the regulatory requirements.

Corrective Action

Based on the review of GEH's corrective action process, implementing procedure, and a sample of Corrective Action Requests (CARs), the inspectors determined that GEH's process met the requirements of Criterion XVI of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Commercial-Grade Dedication

The inspectors identified two examples of a nonconformance to 10 CFR Part 50, Appendix B. Nonconformance 99900003/2009-201-02 was cited for inadequate documentation of the commercial-grade dedication process. This included lack of documentation for links to environmental and seismic qualification, and for justification for taking credit for Underwriters Laboratory certification.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The inspectors reviewed GEH's procedures that govern the Part 21 program to determine compliance with the regulations. Specifically, the inspectors reviewed Policies and Procedures (P&P) 70-42, "Reporting of Defects and Nonconformance under 10 CFR Part 21," dated January 22, 2009, and P&P 70-11, "Quality Policy and Quality System Requirements," dated May 21, 2008.

In addition, the inspectors reviewed a sample of GEH's Part 21 evaluations from the past two years to verify compliance with Part 21 requirements.

Finally, the inspectors reviewed a sample of GEH's purchase orders from the last two years to determine whether GEH properly specified the applicability of Part 21 in procurement documents for safety-related parts and services from sub-suppliers.

b. Observations and Findings

The inspectors noted that GEH's Part 21 program is governed by P&P 70-42. The inspectors noted that GEH employed a two-step process for the identification and resolution of Part 21 issues. GEH defined the first step: Potential Safety Concern (PSC) as a condition that GEH personnel identify that may represent a deviation or failure to comply. GEH defined the second step: Potentially Reportable Condition (PRC) as a condition that raises a question regarding the possible existence of a defect or failure to comply associated with a Substantial Safety Hazard.

Section 3.2, "Assessment of a PSC" of P&P 70-42 stated that:

"Once a PSC is identified, it must be fully addressed and a conclusion drawn in accordance with the process defined herein. Ten (10) working days are provided for a PSC assessment, however, the assessment report should be forwarded to the [Safety Evaluations Program Manager] as soon as a conclusion is reached. The assessment shall conclude whether the PSC represents a deviation from technical requirements or failure to comply with any applicable NRC rule, regulation, order, or license condition. The assessment report must be either from, or approved by the Responsible Manager."

Section 3.3 "Conversion to a PRC" continued:

"Notify the [Safety Evaluations Program Manager] if the assessment performed concludes that a deviation or failure to comply has occurred. Upon receipt of this information by the [Safety Evaluations Program Manager], or expiration of ten working days, the PSC becomes a PRC. It is at this point that discovery, per 10CFR21, has occurred."

GEH defined discovery in Appendix A, "Definitions" of P&P 70-42 as "the completion of the documentation first identifying the existence of a deviation or failure to comply

potentially associated with a Substantial Safety Hazard.” The inspectors observed that this definition is consistent with the regulations. However, the inspectors determined that GEH’s procedures incorrectly describe the point of discovery. Specifically, Section 3.3 of P&P 70-42 incorrectly describes discovery as the point that a PSC becomes a PRC. The PSC and PRC processes respectively allowed for 10 business days and 60 calendar days for completion. Therefore, the inspectors determined that P&P 70-42 was not an appropriate procedure to ensure evaluation of deviations and failures to comply associated with a substantial safety hazard within 60 days of discovery.

This issue has been identified as Violation 99900003/2009-201-01. The inspectors found two examples of this violation for Part 21 evaluations over 60 days:

1. GEH Corrective Action Request (CAR) #45083 was initiated on April 4, 2008, regarding a configuration change affecting historical seismic qualifications of Robert Shaw safety-related pressure gauges for hydraulic control units. The CAR stated that:

“The configuration of safety related pressure gauges dedicated and supplied by GE has changed from that originally qualified. The pressure gauges were originally manufactured by Robert Shaw and were seismically qualified with the equipment, skid, or component they were mounted to. The qualified gauges were originally supplied by Robert Shaw as safety related, under their Appendix B program. This product line was subsequently sold to Sycon Instruments who in turn sold it to CSI Instruments. Both suppliers did not have an Appendix B program. They were qualified by GE as commercial grade suppliers. This allowed GE to complete the qualification through the dedication process and supply them as Nuclear Safety Related spares to the Nuclear Industry. The GE dedication specifications allowed the vendors to certify ‘No design change made’ as a means of controlling configuration of the instrument. This method was relied upon to maintain linkage to the original qualified design. Purchase orders reviewed to date all used the vendor certification method.

On 4/3/08, Engineering compared an original HCU Robert Shaw gauge (131C9198P003) to a batch recently received from CSI(DD213A8544P029). The differences included:

1. The casing materials were different.
2. The overall gauge weights were different.
3. The fitting for the bourdon tube had changed.
4. The bourdon tube configuration had significantly changed.

Engineering could not identify any documentation which acknowledged these changes. The most significant change from a seismic analysis standpoint is the change in bourdon tube configuration. The current manufacturer is Jaguar Instruments who bought the product line from CSI. The manager of Jaguar indicated he was employed by CSI since the early 1990’s. He recalled the bourdon tube change was made about the same time he joined CSI. The scope of the bourdon tube change was limited to pressure gauges with ranges equal to or greater than 1000 psi.

GE has sold pressure gauges in that category as Safety Related replacements.”

The inspectors determined that the completion of CAR #45083 first identified the existence of a deviation. The CAR was forwarded to the GEH process owner for Part 21 in an e-mail dated April 4, 2008. As a result, GEH initiated PSC 0811 on April 7, 2008. The inspectors noted that the PSC did not contain additional information regarding the issue. On April 17, 2008, GEH opened PRC 08-12, to follow-up on PSC 0811. The inspectors noted that no additional information was provided to initiate the transfer to the PRC process. GEH converted the PSC to a PRC within 10 business days, as required by P&P 70-42.

GEH closed PRC 08-12 on June 11, 2008, 68 days after discovery, and initiation of the CAR. The inspectors verified that PRC 08-12 provided a Part 21 evaluation which concluded that the deviation identified in CAR #45083 could not create a substantial hazard, and was therefore not a defect, reportable under Part 21. However, the inspectors noted that GEH did not complete its evaluation within 60 days of discovery. This issue has been identified as one example of Violation 99900003/2009-201-01.

2. GEH CAR #45670 was initiated on June 25, 2008, regarding GEH's dedication of Model 86C temperature switches supplied by Ametek Panalarm. GEH discovered that the accuracy test data sheets for the switches were not verified by survey. The CAR stated that:

“During GEH Internal Audit conducted June 9 through June 13, 2008, (Audit no. NSQ-2008-04) the following was identified.
[Dedication specification] 164C5687PXXX requires a certificate of conformance from a supplier. Contrary to [Engineering Operating Procedure] EOP 65-2.20 and EOP 45-1.00, component/parts were ordered from a supplier (Ametek-Panalarm) on [purchase order] 431008648, which has not been audited and does not have a QA program.”

The inspectors determined that the completion of CAR #45670 first identified the existence of a deviation. The CAR was forwarded to the GEH process owner for Part 21 in an e-mail dated July 15, 2008. As a result, GEH initiated PSC 0820 on July 15, 2008. The inspectors noted that the PSC did not contain additional information regarding the issue. On July 29, 2008, GEH opened PRC 08-24, to follow-up on PSC 0820. The inspectors noted that no additional information was provided to initiate the transfer to the PRC process. GEH converted the PSC to a PRC within 10 business days, as required by P&P 70-42.

GEH closed PRC 08-24 on September 18, 2008, 85 days after discovery, and initiation of the CAR. The inspectors verified that PRC 08-24 provided a Part 21 evaluation which concluded that the deviation identified in CAR #45670 could not create a substantial hazard, and was therefore not a defect, reportable under Part 21. However, the inspectors noted that GEH did not complete its evaluation within 60 days of discovery. This issue has been identified as a second example of Violation 99900003/2009-201-01.

The inspectors did not identify any Part 21 evaluations that did not adequately address identified deviations.

In the sample reviewed, the inspectors found that GEH properly specified the applicability of Part 21 in procurement documents for safety-related parts and services from sub-suppliers.

c. Conclusions

The inspectors identified one violation of Part 21 with two examples. Violation 99900003/2009-2009-201-01 was cited for failure to adequately prescribe the process to perform an evaluation within 60 days as specified in Part 21. With the exception of the violation noted above, the inspectors concluded that GEH's Part 21 program was consistent with the regulatory requirements.

2. Corrective Action

a. Inspection Scope

The inspectors reviewed the procedure governing the implementation of GEH's corrective action program to ensure the procedure provided adequate guidance consistent with the requirements of Appendix B to 10 CFR Part 50 and Part 21. The inspectors also reviewed a sample of CARs to assess GEH's implementation of the corrective action program. Specifically, the inspectors focused on CARs generated from the recent Nuclear Procurement Issues Committee (NUPIC) audit and CARs related to commercial-grade dedication issues.

b. Observations and Findings

The inspectors noted that GEH Common Procedure (CP)-16-01, Revision 4, "Corrective Action Process," dated January 19, 2009, established the process for identifying, recording and correcting conditions adverse to quality, and defined the requirements and responsibilities for assessing enhancements and recommendations. This procedure detailed the process of identifying and documenting apparent conditions adverse to quality under the scope of GEH's quality program, investigating and correcting those adverse conditions, and closing CARs upon completion of corrective action.

The inspectors noted that CP-16-01 was a complete revision of Engineering Operating Procedure (EOP) 75-3.00, Revision 17, "Corrective Action," dated October 30, 2008. GEH re-issued CP-16-01 to identify personnel responsibilities and how to address potential Part 21 issues.

GEH's CAR document was used to identify an issue, report measures and actions taken to evaluate and resolve apparent conditions adverse to quality, and track required actions through completion. The CAR process included, but was not limited to description of the issue, the owner of the CAR, investigation and evaluation documentation results, and prescribed actions to be taken.

The inspectors reviewed a sample of CARs. No findings of significance were identified.

c. Conclusion

Based on the review of GEH's corrective action process, implementing procedure, and a sample of CARs, the inspectors determined that GEH's process met the requirements of Criterion XVI of Appendix B to 10 CFR Part 50. No findings of significance were identified.

3. Commercial-Grade Dedication

a. Inspection Scope

The inspectors reviewed GEH's process for commercial-grade dedication activities. This assessment included a review of the procedures governing the implementation of commercial-grade dedication activities, interviews with GEH personnel, a tour of GEH's dedication facilities, and a review of a sample of completed commercial-grade dedication packages. The inspectors also reviewed GEH's overarching Quality Assurance Program Description NEDO-11-209-04A, Revision 8, dated March 31, 1989.

The inspectors sampled two dedication packages for Molded Case Circuit Breakers (MCCBs) and one dedication package for a Control Power Transformer to determine whether GEH was implementing an adequate dedication program. The packages reviewed were associated with five completed safety-related purchase orders from Salem and Hope Creek Nuclear Power Plants; four for MCCBs, and one for the Transformer. The inspectors also reviewed the Design Record Files (DRFs) for the purchase orders to determine whether environmental and seismic qualifications were properly addressed.

b. Observations and Findings

The inspectors verified that GEH established adequate controls for performing technical evaluations of items. The inspectors noted that GEH's dedication process was governed by EOP 65-2.20, "Customer P.O Technical Evaluation and Dedication of Commercial Grade Items," Revision 20, dated December 12, 2008. EOP 65-2.20 established the requirements and responsibilities for dedicating commercial-grade items procured for use in safety-related applications. A separate EOP was established for dedication of commercial-grade software.

Appendix D "Qualification Assurance for Dedicated Parts," of EOP 65-2.20 stated in part that:

"The Responsible Engineer will provide reasonable assurance that the qualification requirements are maintained for the part being provided if seismic and/or environmental qualification is required either by the Purchase Order, the Selected Item Drawing or the Dedication Specification."

The inspectors determined that GEH failed to document the above requirements in its dedication process in all of the dedication packages reviewed, which included:

- Dedication Specification DD213A9893PXXX, Revision 9, dated October 27, 2005, for TEC Type Magnetic Break MCCBs, commercially manufactured by GE Consumer and Industrial (GE C&I).

- Dedication Specification DD213A9893P010, Revision 0, dated October 24, 2008, for TEC36003 Magnetic Break MCCBs, commercially manufactured by GE C&I.
- Dedication Specification Q9T58K0048G05, Revision 2, dated June 25, 2008, for a Control Power Transformer, commercially manufactured by GE C&I. The fuse-holder for this transformer is manufactured by Ferraz Shawmut, and supplied by GE C&I.

Specifically, the inspectors noted two examples of not adequately documenting the engineering justification used for verification of critical characteristics: 1) GEH failed to provide an adequate link to original environmental and seismic qualifications; 2) GEH failed to adequately document its process for taking credit for Underwriters Laboratory (UL) certifications to verify material as part of the dedication process.

Regarding environmental and seismic qualifications, the inspectors noted that GEH included equipment qualification in its dedication process. For example, the dedication specifications for MCCBs noted above included critical characteristics to justify product qualifications. The MCCBs were provided with Product Quality Certifications stating that they were qualified per:

1. GE Qualification Test Report 70ICS100, dated August 21, 1970;
2. Institute of Electrical and Electronics Engineers (IEEE) standard IEEE-323-1974 "IEEE Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations," and;
3. IEEE 344-1975 "IEEE Recommended Practices for Seismic Qualification of Class 1E Equipment for Nuclear Power Generating Stations."

The inspectors noted that the dedication specifications provided a "Justifications" section with a "Link to Tested Part," column regarding qualification. For the MCCBs, this section stated:

"Changes in documentation revision levels from that of qualified components are evaluated and recorded. The qualification of critical components is documented in DRF A12-00123-01 (1) and eDRF 0000-0033-9461."

GEH performed testing and analyses to qualify entire product assemblies, which included the sub-components. For example, the MCCBs and transformers were parts of a motor control center which was originally qualified in the 1970's. The DRFs provided historic information on the original assembly that was qualified. The inspectors noted that the DRFs are intended to provide reference material to link the original equipment qualifications of the qualified assembly to the parts being supplied. However, the inspectors determined that the dedication specifications and the DRFs did not provide adequate documentation of a link from the originally qualified assemblies to the dedicated items.

This issue has been identified as one example of Nonconformance 99900003/2009-201-02.

Regarding UL certifications, the inspectors noted that the dedication specifications above listed material as a critical characteristic. Verification of material was listed as Method 1 with the action to “confirm that the UL label/mark is attached to the circuit breaker.”

The inspectors noted that taking credit for UL listings may be acceptable per the guidance in Appendix E “Use of National Codes and Standards,” in the Electric Power Research Institute Report (EPRI) EPRI NP-5652 “Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07).” The EPRI guidance states:

“If the national code or standard includes some independent product endorsements based on qualification testing or periodic testing of selected critical characteristics, then credit can be taken for those critical characteristics being verified.”

However, EPRI NP-5652 further states that taking credit for a product manufactured to a national code or standard must be investigated on a case-by-case basis. The NRC conditionally endorsed the guidelines in EPRI NP-5652 in Generic Letter 89-02 “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” for evaluating commercial-grade products for suitability for use in safety-related applications. The staff guidance does not recognize the use of national codes or standards as a stand-alone method for acceptance of critical characteristics.

Based upon documents reviewed, and discussions with GEH staff during the inspection, the inspectors concluded that GEH failed to properly implement the guidance in EPRI NP-5652. Specifically, GEH failed to adequately document its process for taking credit for UL certifications.

This issue has been identified as a second example of Nonconformance 99900003/2009-201-02.

c. Conclusion

The inspectors identified two examples of a nonconformance to 10 CFR Part 50, Appendix B. Nonconformance 99900003/2009-201-02 was cited for inadequate documentation of the commercial-grade dedication process. This included lack of documentation for links to environmental and seismic qualification, and for justification for taking credit for UL certification.

5. Exit Meeting

On January 30, 2009, the inspectors presented the inspection scope and findings during an exit meeting with GEH Senior Vice President, Richard Wittmeier, and other GEH personnel.

ATTACHMENT

1. PERSONS CONTACTED

R. Wittmeier Senior Vice President, GEH
R. Bastyr, Quality Assurance Manager, Nuclear Parts, GEH
C. Alonso, Sourcing Quality Leader, GEH
M. Cavanaugh, Sourcing Manager, Services, GEH
T. Coury, Component Engineering Manager, GEH
R. Deuvall, Technical Project Engineer, Parts, GEH
M. Elliott, Engineering Quality Manager, GEH
M. Gerdes, Support Services Quality Leader, GEH
M. Harrington, GM Sourcing, GEH
C. Konicki, Quality Leader, GEH
M. LeBlanc, Quality Control Engineer, GEH
S. Mindel, QA Engineer, GEH
M. Moore, Project Manager, Nuclear Parts, GEH
R. Mortenson, OTR Part Manager, GEH
P. Nichols, Systems Engineering Manager, GEH
B. Pagans, Quality Control Engineer, Nuclear, GEH
A. Peklaris, Senior Quality Engineer, Nuclear Services Quality, GEH
D. Porter, Safety Evaluation Program Manager, GEH
J. Post, Document Systems Manager, GEH
G. Pratt, Project Manager, Nuclear Parts, GEH
P. Rogers, Sourcing, GEH
J. Stallings, Quality Leader, Nuclear Services, GEH
J. Stark, Sourcing, GEH
S. Swain, Principal Engineer, Services Engineer, GEH
K. Walsh, Senior Vice President – Services, GEH
G. Watford, GM Services Engineering, GEH
P. Wells, Vice President, Nuclear Parts, GEH

2. INSPECTION PROCEDURES USED

IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance"
IP 38703, "Commercial Grade Dedication"
IP 43004, "Inspection of Commercial-Grade Dedication Programs"

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

There were no open items from the previous inspection report, 99900003/1999-202 of GEH's facility in Wilmington, North Carolina.

| <u>Item Number</u> | <u>Status</u> | <u>Type</u> | <u>Description</u> |
|----------------------|---------------|-------------|--------------------|
| 99900003/2009-201-01 | Opened | NOV | 21.21 Timeliness |
| 99900003/2009-201-02 | Opened | NON | Criterion V |

4. LIST OF ACRONYMS USED

| | |
|--------|--------------------------------------|
| CAR | Corrective Action Request |
| CFR | Code of Federal Regulations |
| CGD | Commercial-Grade Dedication |
| CP | Common Procedure |
| DE | Division of Engineering |
| DRF | Design Record File |
| EQVB | Quality and Vendor Branch |
| EOP | Engineering Operating Procedure |
| GEH | GE Hitachi Nuclear Energy |
| GE C&I | GE Consumer and Industrial |
| IP | Inspection Procedure |
| MCCB | Molded Case Circuit Breaker |
| NON | Notice of Nonconformance |
| NC | North Carolina |
| NRC | Nuclear Regulatory Commission |
| NRR | Office of Nuclear Reactor Regulation |
| NUPIC | Nuclear Procurement Issues Committee |
| P&P | Policies and Procedures |
| PRC | Potentially Reportable Condition |
| PSC | Potential Safety Concern |
| QA | Quality Assurance |
| UL | Underwriters Laboratory |