January 20, 2011

John Stallings
GE Hitachi Nuclear Energy
3901 Castle Hayne Road
Wilmington, NC 28429

SUBJECT: NRC INSPECTION REPORT NO. 99900003/2010-201 AND NOTICE OF NONCONFORMANCE

Dear Mr. Stallings:

From December 7 to December 10, 2010, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the GE Hitachi Nuclear Energy (GEH) facility in Wilmington, North Carolina. 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." The enclosed report presents the results of this inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

During this inspection, NRC inspectors found that implementation of your QA program failed to meet certain NRC requirements contractually imposed on you by your customers. The NRC inspectors noted three deficiencies for: (1) lack of procedural guidance to ensure initiation of the corrective action procedure, (2) failure to do a technical evaluation for the selection of critical characteristics when performing commercial-grade dedication of electronics, and (3) an inadequate procedure that allowed the use of international supplier calibration services without a survey. 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 Nonconformance
2. Inspection Report 99900003/2010-201

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 Nonconformance
2. Inspection Report 99900003/2010-201

DISTRIBUTION:
RidsNroDcipCqvb
RidsNroDcipCqvp
KKavanagh
Russel.Bastyr@ge.com
Nick Hilton

ADAMS Accession No.: ML110130302

OFFICE	EQVB/DE/NRR	CQVB/DCIP/NRO	EQVB/DE/NRR	CIB1/DE/NRO
NAME	AArmstrong	VHall	JOrtega	MMagyar
DATE	1/13/2011	1/12/2011	1/13/2011	1/12 /2011
OFFICE	EQVB/DE/NRR	BC:EQVB/DE/NRR	DD:DE/NRR	
NAME	PPrescott	MMurphy	PHiland	
DATE	1/13/2011	1/18/2011	1/12 /2011	

OFFICIAL RECORD COPY

NOTICE OF NONCONFORMANCE

GE Hitachi Nuclear Energy
3901 Castle Hayne Road
Wilmington, NC 28429
Docket Number 99900003

Inspection Report 99900003/2010-201
Docket No. 99900003

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted December 7 to December 10, 2010, of activities performed at GE Hitachi (GEH) Nuclear Energy, certain activities were not conducted in accordance with NRC requirements, which were contractually imposed upon GEH by NRC licensees.

A. Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states 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 Nuclear Energy Quality Assurance Program Description NEDO-11209-04A, Revision 8, dated March 31, 1989, states in part that, "activities affecting quality, including methods of complying with 10 CFR 50, 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."

GEH's Procedural Requirements and Responsibilities (PR&R) 15, "Nonconforming Materials, Parts, or Components," dated January 8, 2008, states in part that, "This procedure gives the requirements for the identification, documentation, segregation, disposition, and necessary notifications concerning nonconforming material."

GEH's Procedural Responsibilities and Instructions (PRI) 15-5, "Service Component Operation (SCO) Nonconforming Material Control," dated July 27, 2010, is the instruction that described the implementation of nonconforming material contained in PR&R 15. PRI 15-5, Section 4.6.3, states in part that, "if timeliness or effectiveness of other corrective actions creates potential for significant adverse effects on product quality or amount of rework, repair, or scrap, initiate a Corrective Action Request (CAR) per CP-16-01."

Contrary to the above, as of December 10, 2010:

GEH's PRI 15-5 failed to prescribe appropriate quantitative or qualitative acceptance criteria for determining that activities important to safety have been satisfactorily accomplished. Specifically, PRI 15-5 lacked any threshold to initiate the corrective

action procedure for nonconforming design issues. This issue has been identified as Nonconformance 99900003/2010-201-01.

B. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, states in part that, "Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components." Additionally, Criterion III states in part that, "The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculation methods, or by the performance of a suitable testing program."

Chapter 3, "Design Control," of GEH Nuclear Energy Quality Assurance Program Description NEDO-11209-04A, Revision 8, dated March 31, 1989, states in part that, "Design verification is a process for independent review of designs against design requirements to confirm that the designer's methods and conclusions are consistent with the requirements, and that the resulting design is adequate for its specified purpose. Product designs and each application thereof are verified, consistent with contract requirements."

Contrary to the above, as of December 10, 2010:

GEH failed to verify the adequacy of design when performing commercial-grade dedication of electronics. Specifically, GEH's dedication process did not ensure that a technical evaluation was performed for the selection of critical characteristics to provide a link to original environmental and seismic qualifications.

This issue has been identified as Nonconformance 99900003/2010-201-02.

C. Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states 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. The instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

Criterion VII, "Control of Purchased Material, Equipment, and Services," states in part that, "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery."

Chapter 7, "Control of Purchased Material, Equipment and Services," of GEH Nuclear Energy Quality Assurance Program Description NEDO-11209-04A, Revision 8, dated March 31, 1989, states in part that, "measures for evaluation, certification, or

qualification, and selection of procurement sources by engineering and QA personnel include the use of historical quality performance data, source surveys (including a review of the supplier's QA Program), or source qualification programs."

GEH Policies and Procedures (P&P) 70-14, "Quality Assurance Audit Requirements," dated July 29, 2010, states in part that, "Supplier audits [surveys] of commercial grade calibration suppliers is not required for GEH/GNF/GLE or GEH/GNF/GLE suppliers if the calibration supplier has been assessed and certified by the following accreditation bodies:

- NVLAP [National Voluntary Laboratory Accreditation Program]
- A2LA [The American Association for Laboratory Accreditation]
- ACLASS Accreditation Services [ACLASS]
- Laboratory Accreditation Bureau [LAB]
- International Accreditation Services, Inc. [IAS]

For international suppliers, calibration services purchased from international calibrations suppliers accredited by ILAC [International Laboratory Accreditation Cooperation] are considered to have an equivalent accreditation to NVLAP and A2LA per the ILAC Mutual Recognition Agreement."

Contrary to the above, as of December 10, 2010:

GEH failed to prescribe instructions appropriate to the circumstances. Specifically, P&P 70-14 did not prescribe measures to perform a survey of international calibration services suppliers.

This issue has been identified as Nonconformance 99900003/2010-201-03.

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.

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 20th day of January 2011.

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

Docket No.:	99900003
Report No.:	99900003/2010-201
Vendor:	GE Hitachi Nuclear Energy 3901 Castle Hayne Road Wilmington, NC 28429
Vendor Contact:	Russell Bastyr, Nuclear Quality Assurance Manager Phone: (910) 547-2649 Russell.Bastyr@ge.com
Nuclear Industry Activity:	GE Hitachi Nuclear Energy is a Nuclear Steam Supply Systems (NSSS) supplier to the commercial nuclear power industry. The GEH facility in Wilmington, NC provides commercially dedicated basic components to its utility customers.
Inspection Dates:	December 7 – December 10, 2010
Inspection Team Leader:	Paul Prescott, EQVB/DE/NRR
Inspectors:	Jonathan Ortega-Luciano, EQVB/DE/NRR Aaron Armstrong, EQVB/DE/NRR Victor Hall, CQVB/DCIP/NRO Michael Magyar, CIB1/DE/NRO
Approved by:	Martin C. Murphy, Branch Chief Quality & Vendor Branch Division of Engineering Office of Nuclear Reactor Regulation

ENCLOSURE 2

EXECUTIVE SUMMARY

GE Hitachi Nuclear Energy
99900003/2010-201

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 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 99900003/2009-201 of GEH's facility in Wilmington, North Carolina. The results of this inspection are summarized below.

10 CFR Part 21 Program

Based on the review of GEH's 10 CFR Part 21 program, implementing procedures, and a sample of Part 21 evaluations, the inspectors determined that GEH's process met the requirements 10 CFR Part 21. No findings of significance were identified.

Corrective Action

The inspectors identified Nonconformance 99900003/2010-201-01 for failure to prescribe appropriate quantitative or qualitative acceptance criteria to initiate the corrective action process. With the exception of the Nonconformance noted above, the inspectors concluded that GEH's corrective action and nonconformance processes met the requirements of Criterion XVI of Appendix B to 10 CFR Part 50.

Commercial-Grade Dedication

The inspectors identified Nonconformance 99900003/2010-201-02 for failure to verify the adequacy of design when performing commercial-grade dedication of electronics. With the exception of the Nonconformance noted above, the inspectors concluded that GEH's commercial-grade dedication requirements and implementation were consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50.

Audits

The inspectors identified Nonconformance 99900003/2010-201-03 for failure to have an appropriate procedure to ensure appropriate control of procurements activities for determining that an important activity (e.g., performing a survey of international calibration suppliers) was satisfactorily accomplished. With the exception of the Nonconformance noted above, theinspectors concluded that GEH's internal and external audit program requirements and implementation were consistent with the regulatory requirements of Criterion VII and XVIII of Appendix B to 10 CFR Part 50.

REPORT DETAILS

1. 10 CFR Part 21 Program

   a. Inspection Scope

   The inspectors reviewed NEDO-11209-04A, "GE Nuclear Energy Quality Assurance Program Description," dated March 31, 1989, and procedures that governed the Part 21 program to determine compliance with 10 CFR Part 21. Specifically, the inspectors focused on implementing Policies and Procedures (P&P) 70-42, "Reporting of Defects and Nonconformance under 10 CFR Part 21," dated December 2, 2010, and GEH's Common Procedure (CP) 16-01, "Corrective Action Process," dated October 18, 2010.

   In addition, the inspectors evaluated Potentially Reportable Conditions (PRCs) and Corrective Action Requests (CARs) from the past year to verify compliance with Part 21 requirements. The following PRCs and associated CARs were reviewed:

   - PRC# 10-33 / CAR-51394, "During final inspection of Bundle JY542, a Bent Flow Tab was Found at the A1 Corner Location of the Space," dated April 15, 2010
   - PRC# 10-10 / CAR-50500, "Potential Defective Material - Diaphragm 2 PLY Dacron Fabric P/N Q25471-A2," dated January 22, 2010
   - PRC# 10-76 / CAR-52969, "EGR that Plant Hatch tried to Install on Unit 1 and Functional Test after Installation Revealed Polarity of EGR was Reversed," dated October 07, 2010
   - PRC# 10-65 / CAR-52532, "Cracks Indication have been Observed on Four Irradiated Marathon Control Rods during End of Life Inspection," dated August 24, 2010

   b. Observations and Findings

   The inspectors noted that GEH's Part 21 program was governed by P&P 70-42, which was a two-step process for the identification and resolution of Part 21 issues. GEH's first step was Potential Safety Concerns (PSCs), where GEH's personnel identified potential deviations or failure to comply. The second step of the process were PRCs, in which GEH personnel identified the possibility of the existence of a defect or failure to comply that could create a substantial safety hazard. P&P 70-42 described the implementation of requirements contained within NEDO-11209-04A.

   Once a PSCs was initiated, they were required to be fully addressed and conclusions drawn in accordance with the process defined in P&P 70-42. A maximum of 14 calendar days was provided for PSC assessment. Assessment reports were then forwarded to the Safety Evaluation Program Manager (SEPM) as soon as conclusions were reached. The assessment concluded whether the PSC represented a departure from technical requirements or failure to comply with any applicable NRC rule, regulation, order, or license condition. The responsible manager was required to originate, or approve the

assessment report. No formal assessment reports were required if the PSC was converted to a PRC.

The responsible manager, or delegate, notified the SEPM if the evaluation concluded that a deviation or failure to comply existed. The SEPM may also be requested to convert a PSC to PRC. The inspectors noted that upon receipt of this information, or expiration of the 14-day period, the PSC then became a PRC. Once a PRC was issued it was fully addressed and a conclusion drawn within 60 calendar days from the date of discovery. These 60 calendar days included any time spent in the PSC assessment step. GEH's Part 21 process was modified to include the time for the PSC assessment into the 60 calendar days. GEH explained that this process was changed as a response to a corrective action requests, issued following the NRC's previous inspection.

No findings of significance were identified.

c. Conclusions

Based on the review of GEH's 10 CFR Part 21 program, implementing procedures, and a sample of Part 21 evaluations, the inspectors determined that GEH's process met the requirements 10 CFR Part 21.

2. Corrective Action

a. Inspection Scope

The inspectors reviewed NEDO-11209-04A and procedures governing the implementation of GEH's corrective action program to ensure that GEH provided adequate guidance consistent with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21. Specifically, the inspectors focused on CP-16-01 and reviewed the four CARs associated with the PRCs that were detailed in Section 1.a. of this inspection report to assess GEH's implementation of the corrective action program.

Additionally, the inspectors reviewed GEH's Quality Inspection Standard (QAS) 0203A, "Electronic Inspection Report (IR)-SC," dated November 19, 2004, GEH's Procedural Requirements and Responsibilities (PR&R 15) "Nonconforming Materials, Parts, or Components," dated January 8, 2008, and Procedural Responsibilities and Instructions (PRI) 15-5, "Service Component Operation (SCO) Nonconforming Material Control," dated July 27, 2010.

b. Observations and Findings

The inspectors noted that CP-16-01 described the implementation of requirements contained within NEDO-11209-04A, and applied to all CARs initiated internally from customers and audits. CP-16-01 defined the CAR priority levels as the following: A. Significant Condition Adverse to Quality (SCAQ), B. Condition Adverse to Quality (CAQ), C. Broke/Fix, and D. Recommendation/Enhancement. The procedure applied to GEH, GNF, and GLE and covered the activities for documenting, evaluating, and reporting conditions adverse to quality as required by Appendix B to 10 CFR Part 50. The

inspectors noted that CP-16-01 implemented the corrective actions required by P&P 70-14, "Quality Assurance Audit Requirements," dated July 29, 2010, and allowed for the initiation of Part 21 evaluations per P&P 70-42.
The inspectors noted that PR&R 15 stated in part that, "lower tier instructions may be developed by designated functions process where 'how-to' details are needed (for clarification and consistency) for the deliverables described it in the PR&Rs."

GEH's PRI 15-5 provided detailed guidance on addressing nonconforming products and rework routines associated with design issues. This procedure covered the identification of nonconforming products, supplier in process nonconforming products, scrap items, and non-supplier in process nonconforming products. The procedure also established the routines for pre-approved rework planning, new rework planning, Material Review Board repair plans, and Returned Material Authorization.

Section 4.6.3, "Corrective Action," of PRI 15-5 stated in part that, "If timeliness or effectiveness of other corrective actions creates potential for significant adverse effects on product quality or amount of rework, repair, or scrap, initiate a corrective action request per CP-16-01." According to GEH personnel, CARs were issued at the discretion of the Service Component Operation (SCO) personnel. The inspectors determined that PRI 15-5 did not provide appropriate procedural guidance for the quantitative or qualitative acceptance criteria to initiate the corrective action process. Specifically, GEH's PRI 15-5 lacked any threshold to initiate CP-16-01 for nonconforming design issues. This issue was identified as Nonconformance 99900003/2010-201-01. Despite the procedural deficiency, the inspectors did not identify any examples of missed evaluations by GEH's corrective action process.

c. Conclusion

The inspectors identified Nonconformance 99900003/2010-201-01 for failure to prescribe appropriate quantitative or qualitative acceptance criteria to initiate the corrective action process. With the exception of the Nonconformance noted above, the inspectors concluded that GEH's corrective action and nonconformance process met the requirements of Criterion XVI of Appendix B to 10 CFR Part 50.

3. Commercial-Grade Dedication Process

a. Inspection Scope

The inspectors reviewed GEH's NEDO-11209-04A, Engineering Operating Procedure (EOP) 65-2.20, "Customer P.O. Technical Evaluation and Dedication of Commercial Grade Items," dated September 25, 2009, and the implementation process for commercial-grade dedication activities. The inspectors also reviewed the procedures governing commercial-grade dedication activities, interviewed GEH's personnel, observed ongoing activities at the facility, and the implementation process for commercial-grade dedication activities.The inspectors reviewed a sample of 15 dedication packages to determine whether GEH was implementing an adequate dedication program. Specifically, the inspectors selected dedication packages from GEH's Electrical, Mechanical, and Electronics product lines.

b. Observations and Findings

The inspectors noted that GEH's dedication process was governed by EOP 65-2.20. This procedure established the requirements and responsibilities for dedicating commercial-grade items procured for use in safety-related applications. The inspectors noted that EOP 65-2.20 provided the requirements and responsibilities for dedication commercial-grade items procured for use in safety-related applications in licensed nuclear facilities. The EOP described diverse methods for dedication as detailed below. It also stated that is was not intended for dedication of commercial-grade software.

The inspectors noted that for electrical and mechanical components, GEH implemented a Technical Evaluation/Dedication (TED) Database as described in EOP 65-2.20. GEH explained that this process was developed as a response to a corrective action request, issued following the NRC's previous inspection. The inspectors noted that the new database allowed GEH engineers to methodically identify safety function and select critical characteristics for its dedication packages. The TED database included a technical evaluation of the linkage to qualification test reports when applicable. For example, GEH dedicated commercial relays that had been part of assemblies previously tested for seismic and environmental qualification. The TED database noted what critical characteristics, such as dimensions and materials of specific moving parts, required verification to provide a link to the original qualification. The inspectors also noted that the TED database provided justification for the use of sampling, and included a section for the evaluation of operating experience. The inspectors did not identify any issues with GEH's dedication practices when the TED database was implemented.

For the dedication of electronic components, the inspectors noted that GEH applied an older dedication methodology. The inspectors noted one deficient example for dedication of Sales Order 1003419, for an inverter shipped to First Energy Corporation for Perry Nuclear Power Plant. The Certificate of Conformance stated that the inverter was qualified per IEEE-344-1975, "Recommended Practice for Seismic Qualification of Class 1E Equipment for Nuclear Power Generating Stations." The corresponding Dedication Package DA265A1845, dated March 24, 2010, also listed this industry standard as a requirement. However, the inspectors determined that GEH's dedication process failed to provide objective evidence that this inverter satisfied the requirements of IEEE-344-1795. The inspectors determined that GEH's methodology for the dedication of electronics failed to verify the adequacy of design. Specifically, GEH's dedication process did not ensure that a technical evaluation was performed for the selection of critical characteristics to provide a link to original environmental and seismic qualifications. The inspectors identified this issue as nonconformance 99900003/2010-201-02.

During the observation of dedication activities at the GEH facility, the inspectors noted that GEH verified critical characteristics in accordance with written instructions, procedures, and drawings. The inspectors also noted that these activities were performed by qualified personnel using calibrated equipment. The inspectors did not identify any issues with GEH's activities related to the verification of critical characteristics.

c. Conclusion

The inspectors identified Nonconformance 99900003/2010-201-02 for failure to verify the adequacy of design when performing commercial-grade dedication of electronics. With the exception of the Nonconformance noted above, the inspectors concluded that GEH's commercial-grade dedication requirements and implementation were consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50.

4. Audits

a. Inspection Scope

The inspectors reviewed Section 18, "Audits," of NEDO-11209-04A and the implementing procedures that governed the process for internal and external audits. The inspectors reviewed a sample of external audit reports performed to support the dedication packages noted above to ensure that identified critical characteristics were addressed. The inspectors reviewed the most recent internal audit to verify adequate implementation of corrective actions for findings identified during the audit.

The following external audit/survey reports were reviewed:

- Robertshaw Industrial Product Division of Maryville, TN: Robertshaw supplies scram valves and associated replacement parts. The survey was performed November 19-20, 2009
- National Technical Systems Corporation (NTS) of Acton, MS: NTS supplies testing and equipment qualification services. The audit was performed November 19-20, 2008
- Magnetrol International, Inc. of Downers Grove, IL: Magnetrol supplies liquid level switches and associated replacement parts. The survey was performed August 14-15, 2008
- Rexal of Swedesboro, NJ: Rexal supplies breaker piece parts for GEH breakers. The survey was performed April 29, 2008

b. Observations and Findings

b1. External Audits/Surveys

The inspectors noted that GEH's P&P 70-14 and CP 18-02, "Supplier Audits and Commercial Grade Surveys," dated October 26, 2009, described the process for conducting periodic audits or commercial-grade surveys of suppliers to evaluate the effectiveness of their quality program, and of their ability to supply materials in accordance with identified critical characteristic attributes. The inspectors focused their evaluation on the surveys conducted in support of the dedication packages, detailed in Section 3 of this inspection report. The surveys were conducted by either a third party or

GEH. Most of the surveys were performed using the Nuclear Industry Assessment Committee (NIAC) checklist.

The inspectors noted that some of the surveys had been conducted as audits. The critical characteristics that the vendor's programmatic controls were to be verified had not been clearly identified. The most recent Nuclear Procurement Issues Committee (NUPIC) audit had also identified this issue. GEH had issued CAR No. 52558 to document this issue. An extent of condition was performed on current reports that identified the suppliers for which a survey, Method 2 of EPRI NP- 5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)," was credited. A review of those suppliers' reports was performed to ensure that the necessary programmatic controls were in place for the identified critical characteristics that GEH was trying to credit for the dedication process. The inspectors reviewed the technical justifications provided in the CAR that addressed the initial Method 2 discrepancies and the other associated corrective actions to prevent recurrence of the issue. No further concerns were identified.

The inspectors noted in P&P 70-14, that GEH had implemented a QA program alternative for acceptance of accreditation of commercial-grade calibration services by a nationally-recognized accrediting body, using procedures consistent with international standards and guidelines, specifically those found in the American National Standards Institute/International Standardization Organization/International Electrotechnical Commission (ANSI/ISO/IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." The NRC had approved the alternative in a safety evaluation (ADAMS Accession No. ML052710224). The alternative allowed the accreditation process to be credited in lieu of a supplier commercial-survey. Additional stipulations were provided to be met in order to comply with the staff's safety evaluation. One stipulation was that the safety evaluation was limited to only nationally-recognized accrediting bodies; therefore, only domestic calibration suppliers would be acceptable for use. However, P&P 70-14 also allowed for the use of international calibration suppliers. The inspectors identified that GEH's acceptance of the use of international calibration suppliers did not meet the intent for acceptable use of the alternative approved in the safety evaluation. Therefore, the inspectors found that P&P 70-14 was inappropriate for control of procurement activites (e.g., performing a survey of international calibration suppliers) was satisfactorily accomplished. This issue was identified as Nonconformance 999000033/2010-201-03.

b2. Internal Audits

The inspectors noted that GEH's latest internal audit report, NSQ-2010-03 reviewed the technical adequacy and implementation of applicable procedures for selected projects in the Services Business. The Services group included Parts, Field Services, Reactor Services, and Performance Services. The inspectors noted that GEH did not perform, as part of this internal audit, a review of implementation of internal audits. This audit was conducted by auditors outside of the organization, in order to provide an independent review. The inspectors noted that Audit Report NQA-2009 documented the review of internal audits. The audit was conducted by qualified auditors and performed in accordance with the NIAC checklist. NSQ-2010-03 addressed the other 17 criteria of

Appendix B to 10 CFR Part 50 and was performed by qualified auditors with the NUPIC checklist. Audit report findings and observations had corresponding CARs generated, which documented the issue and associated corrective actions. The inspectors verified that the corrective active were implemented and appeared adequate.

No findings of significance were noted related to internal audits.

c. Conclusion

The inspectors identified Nonconformance 99900003/2010-201-03 for failure to have an appropriate procedure for determining that an important activity (e.g., performing a survey of international calibration suppliers) was satisfactorily accomplished. With the exception of the Nonconformance noted above, the inspectors concluded that GEH's audit program requirements and implementation were consistent with the regulatory requirements of Criterion VII and XVIII of Appendix B to 10 CFR Part 50.

5. Exit Meeting

On December 10, 2010, the inspectors presented the inspection scope and findings during an exit meeting with Mr. John Stallings, Acting Nuclear Quality Leader, and GEH personnel.

ATTACHMENT

1. PERSONS CONTACTED

J. Stallings, Quality Leader, Nuclear Services, GEH
R. Bastyr, Quality Assurance Manager, Nuclear Parts, GEH
C. Akiri, GM Parts Services, GEH
C. Alonso, Sourcing Quality Leader, GEH
M. Badewitz, System Engineer, Electrical Comp Tech Lead, GEH
T. Coury, Component Engineering Manager, GEH
R. Deuvall, Technical Project Engineer, Parts, GEH
J. Dwertman, Manager, Systems Engineering, GEH
M. Elliott, Engineering Quality Manager, GEH
B. Ernes, Manager, Engineering Ops & Quality, GEH
M. Gerdes, Support Services, GEH
S. Griffin, Sourcing Quality Engineer, GEH
S. Gowdy, PM Regulatory affairs, GEH
J. Head, GM Regulatory affairs, GEH
T. Jordu, NQA, GEH
K. Lagasse, GM Services, GEH
R. Mortensen, Parts Ordering Manager, GEH
P. Nichols, Systems Engineering Manager, GEH
A. Peklaris, Sourcing Quality Engineer, GEH
D. Porter, Safety Evaluation Program Manager, GEH
J. Schwan, Component Engineering, GEH
S. Swain, Principal Engineer, GEH
G. Watford, Services Engineering, GEH
M. White, Customer Service Manager 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

The NRC conducted its previous inspection of GEH’s facility in Wilmington, North Carolina on January 27, 2009. There were no remaining open items from that inspection.

Item Number	Status	Type	Description
99900003/2010-201-01	Opened	NON	Criterion V
99900003/2010-201-02	Opened	NON	Criterion III
99900003/2010-201-03	Opened	NON	Criteria V & VII

4. LIST OF ACRONYMS USED

A2LA	The American Association for Laboratory Accreditation
ACLASS	Accreditation Services
CAR	Corrective Action Request
CP	Common Procedure
CQVB	Quality and Vendor Branch 2
DCIP	Division of Construction and Inspection Programs
DE	Division of Engineering
EQVB	Quality and Vendor Branch
GEH	GE Hitachi Nuclear Energy
GLE	Global Laser Enrichment
GNF	Global Nuclear Fuel
IAS	International Accreditation Services, Inc.
IP	Inspection Procedure
IR	Electronic Inspection Report
LAB	Laboratory Accreditation Bureau
NIAC	Nuclear Industry Assessment Committee
NON	Notice of Nonconformance
NRC	Nuclear Regulatory Commission
NRO	Office of New Reactors
NRR	Office of Nuclear Reactor Regulation
NUPIC	Nuclear Procurement Issues Committee
NVLAP	National Voluntary Laboratory Accreditation Program
P&P	Policies and Procedures
PRC	Potentially Reportable Condition
PSC	Potential Safety Concern
QA	Quality Assurance
SCAQ	Significant Condition Adverse to Quality
SCO	Service Component Operation
SEPM	Safety Evaluation Program Manager
TED	Technical Evaluation/Dedication