



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 4, 2019

Ms. Michelle Catts, Sr. Vice President
Regulatory Affairs
3901 Castle Hayne Road
Wilmington, NC 28429

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF
GE HITACHI NUCLEAR ENERGY, NO. 99900003/2019-201

Dear Ms. Catts:

On September 16-19, 2019, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the GE Hitachi Nuclear Energy (GEH) facility in Wilmington, NC. This limited-scope routine inspection assessed GEH's compliance with provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." This inspection also verified GEH's compliance with the requirements of 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements," 10 CFR 73.22, "Protection of Safeguards Information: Specific Requirements," and the Commission Order No. EA-07-231, "Order Imposing Safeguards Information Protection Requirements and Fingerprinting and Criminal History Records Check Requirements for Access to Safeguards Information," for handling Safeguards Information (SGI) related to new reactor designs.

This technically-focused inspection specifically evaluated GEH's implementation of the quality activities associated with the treatment of safety-related products and services supplied to the domestic nuclear power industry and the SGI program to determine its effectiveness in protecting SGI. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC endorsement of GEH's overall quality assurance (QA), 10 CFR Part 21 or SGI programs.

Based on the results of this inspection, the NRC inspection team found the implementation of your QA program and the implementation of your SGI program met the applicable requirements. No findings of significance were identified.

In accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," of the NRC's "Rules of Practice," a copy of this letter, and its enclosure(s), will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's

M. Catts

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Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions concerning this matter, please contact Ms. Andrea Keim of my staff at (301) 415-1671.

Sincerely,

Kerri A. Kavanagh, Chief **/RA/**
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

Docket No.: 99900003

EPID: I-2019-201-0063

Enclosure:
Inspection Report No. 99900003/2019-201
and Attachment

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF
GE HITACHI NUCLEAR ENERGY, REPORT NO. 99900003/2019-201
Dated: November 4, 2019, 2019

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

Docket No.: 99900003

Report No.: 99900003/2019-201

Vendor: GE Hitachi Nuclear Energy
3901 Castle Hayne Road
Wilmington, NC 28402

Vendor Contact: Ms. Carmen Alonso
Email: Carmen.Alonso@ge.com
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Nuclear Industry Activity: GE Hitachi Nuclear Energy (GEH) provides nuclear core design and fuel load pattern validation services as well as other engineering and design services for new and operating nuclear reactors. In addition, as part of its nuclear work, GEH implements a program for the management and protection of Safeguards Information.

Inspection Dates: September 16-19, 2019

Inspectors: Andrea Keim NRR/DRO/IQVB, Team Leader
Thomas Herrity NRR/DRO/IQVB
Aaron Armstrong NRR/DRO/IQVB
Jeffery Jacobson NRR/DRO/IQVB

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Reactor Regulation

Enclosure

EXECUTIVE SUMMARY

GE Hitachi Nuclear Energy
99900003/2019-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted a vendor inspection at the GE Hitachi Nuclear Energy (GEH) facility in Wilmington, NC, to verify that it had implemented an adequate quality assurance (QA) program that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." In addition, the NRC inspection team verified that GEH had implemented a program to protect Safeguards Information (SGI) in accordance with the requirements of 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements," 10 CFR 73.22, "Protection of Safeguards Information: Specific Requirements," and Commission Order No. EA-07-231, "Order Imposing Safeguards Information Protection Requirements and Fingerprinting and Criminal History Records Check Requirements for Access to Safeguards Information."

Specific activities observed by the NRC inspection team included:

- Hydraulic pressure retention test of control rod actuator assemblies
- Calibration of measuring and testing equipment (M&TE)
- Boron carbide (B4C) blending
- B4C capsule loading
- Simulation of receipt inspection for B4C material
- Condition Review Group (CGR) screening meeting

The following regulations served as the bases for the NRC inspection:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21
- 10 CFR Part 73
- 10 CFR 50.46

During this inspection, the NRC inspection team implemented Inspection Procedures (IP) 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017; IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated February 13, 2012; and IP 81811, "Protection of Safeguards Information by Design Certification Applicants and Vendors," dated September 6, 2016.

10 CFR Part 21

The NRC inspection team reviewed GEH's policies and implementing procedures that govern the implementation of its 10 CFR Part 21 program to verify compliance with the requirements of 10 CFR Part 21. The NRC inspection team: (1) evaluated the 10 CFR Part 21 postings; (2) reviewed a sample of purchase and receipt documents; (3) reviewed 10 CFR Part 21 evaluations; and (4) verified that GEH's nonconformance and corrective action programs provide a link to the 10 CFR Part 21 program. No findings of significance were identified.

Control of Measuring and Test Equipment

The NRC inspection team reviewed GEH's policies and implementing procedures that govern the control of the M&TE program to verify compliance with the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

The NRC inspection team observed that M&TE was calibrated, labeled, tagged, handled, stored, or otherwise controlled to indicate the calibration status and its traceability to nationally recognized standards. The NRC inspection team also confirmed that when M&TE is found to be out of calibration, GEH initiates a nonconformance report and performs an evaluation to determine the extent of condition. No findings of significance were identified.

Manufacturing and Control of Special Processes

The NRC inspection team reviewed GEH's policies and implementing procedures that govern the fabrication and work control processes to verify compliance with the regulatory requirements Criterion IX, "Control of Special Processes," and Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50.

The NRC team observed the hydrostatic test of non-American Society of Mechanical Engineers (ASME) pressure boundary components and B4C blend testing to verify the operators were correctly certified to conduct the tests and that they conducted the tests in accordance with established procedures. The NRC inspection team reviewed the training records to ensure that personnel conducting other special processes or operations and tests had been correctly trained and are qualified. No findings of significance were identified.

Oversight of Suppliers and Internal Audits

The NRC inspection team reviewed GEH's policies and implementing procedures that govern oversight of suppliers and the internal audit program to verify compliance with the requirements of Criterion IV, "Procurement Document Control," Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of GEH's procurement documents and internal audits. No findings of significance were identified.

Commercial Grade Dedication

The NRC inspection team reviewed GEH's policies and implementing procedures that govern the implementation of its commercial grade dedication (CGD) program to verify compliance with

the requirements of Criterion III, "Design Control," Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of GEH's CGD packages to assess the different elements of GEH's CGD program.

The NRC inspection team reviewed GEH's design control process and verified that procedures delineated design activities in a planned, controlled, and orderly manner and that procedures provided controls for design inputs, outputs, design analyses and GEH's organizational interfaces. The NRC inspection team reviewed GEH's design process to verify it permits for the selection and review for suitability the application of materials, parts, equipment and processes that are essential to the function of safety-related products. In addition, the NRC inspection team verified design inputs were correctly translated into GEH's specifications, drawings, procedures, or instructions. The NRC inspection team also verified GEH's procedures are implemented to control design changes and design changes are subject to design control measures commensurate with those applied to the original design. No findings of significance were identified.

Environmental Qualification

The NRC inspection team reviewed GEH's data associated with the qualification of certain replacement solenoid valves used in the hydraulic control units, part of the control rod drive system in boiling water reactors (BWR) reactors. The NRC inspection team reviewed the basis for the activation energy of 1.30 eV assigned to the Viton 515 AB diaphragm material and used in the thermal aging calculations. The NRC inspection team identified that the existing qualification file did not contain a sufficient basis for the activation energy chosen for the Viton 515 AB material. However, during the inspection, GEH was able to locate additional information that supported the use of the 1.30 eV activation energy. GEH issued condition report (CR) 32583 during the inspection to clarify the Environmental Qualification (EQ) file and GEH Report, NEDC-323365P, with respect to the basis for the chosen activation energy for the Viton 515 AB diaphragms. No findings of significance were identified.

Corrective Action

The NRC inspection team reviewed GEH's implementation of its policies and procedures governing corrective actions to verify compliance with the requirements of Criterion XVI, "Corrective Actions", of Appendix B to 10 CFR Part 50. The NRC inspection team verified that the procedures contained sufficient guidance for non-conforming conditions and are evaluated for Part 21 applicability.

The NRC inspection team reviewed a sample of CRs. The specific CRs reviewed are listed in Appendix to this report. The NRC inspection team also reviewed GEH's actions associated with its response to a Notice of Nonconformance (NON) contained in NRC Inspection Report 999000003/2010-201. The NRC inspection team verified that GEH had taken adequate corrective actions to NONs 999000003/2010-201-01, 02, and 03. These three NONs are now considered closed.

The NRC inspection team reviewed CR 24961, dated February 24, 2017, associated with the qualification of a low voltage circuit breaker switch that had been substituted for a previously qualified and tested part. The NRC inspection team determined that GEH lacked a sufficient basis to determine that the replacement switch would be covered by the existing qualification reports. GEH issued a CR 32661 to document the lack of a qualification basis. However, this

issue was determined by the NRC inspection team to be a minor item because, as of the date of the inspection, GEH had not shipped any of the replacement switches to any U.S. customers.

The NRC inspection team also reviewed CR 25509, dated April 28, 2017, associated with a deficiency that had been identified in GEH's loss of coolant accident (LOCA) analyses for BWR operating units. Although, GEH indicated that the issue could put the plants outside their licensing basis, GEH concluded the issue did not constitute a substantial safety hazard and was not reportable under 10 CFR Part 21. The NRC and BWR owner's group are aware of the issue.

The NRC inspection team determined that GEH's implementation of its policies and procedures associated with corrective actions met the requirements of Criterion XVI, "Corrective Actions," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Control of Safeguards Information

During this inspection, the NRC inspection team implemented IP 81811, "Protection of Safeguards Information by Design Certification Applicants and Vendors," dated September 6, 2016. In accordance with the IP, the NRC inspection team conducted the following activities:

- observed the physical security measures GEH has in place to control access to the safeguards information (SGI);
- reviewed records for receipt, retention, distribution, and destruction of SGI;
- reviewed GEH procedures for governing the handling of SGI and granting access to individuals and sub-contractor firms;
- conducted interviews with GEH staff to assess knowledge of processes and procedures;
- and reviewed personnel records for screening of information users to assess decisions granting access to individual.

The NRC inspection team concluded that GEH's SGI protection policies and implementing procedures comply with the applicable requirements of 10 CFR 73.21 and 10 CFR 73.22, and the Commission's Order No. EA-07-231, dated September 12, 2007. The NRC inspection team also verified that GEH's personnel are implementing these policies and procedures effectively. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21

a. Inspection Scope

The NRC inspection team reviewed GE Hitachi Nuclear Energy's (GEH's) policies and implementing procedures that govern the implementation of its Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," program to determine compliance with regulatory requirements. In addition, the NRC inspection team evaluated the 10 CFR Part 21 postings and a sample of GEH's purchase documents for compliance with the requirements of Section 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation," and Section 21.31, "Procurement Documents." The NRC inspection team also evaluated whether GEH's corrective action and nonconformance programs provide a link to the 10 CFR Part 21 program for evaluation and reportability, as applicable.

In addition, for a 10 CFR Part 21 evaluation performed by GEH, the NRC inspection team verified that GEH had effectively implemented the requirements for evaluating deviations and failures to comply.

The NRC inspection team discussed the 10 CFR Part 21 program with GEH's management and staff. The attachment to this inspection report lists the documents reviewed and staff interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

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

2. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed GEH's policies and implementing procedures that govern the measuring and test equipment (M&TE) program to verify compliance with the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

For a sample of M&TE, the NRC inspection team reviewed the calibration stickers and determined that the stickers documented the current calibration dates, including the calibration due date. The NRC inspection team also verified that the M&TE had been calibrated, adjusted, and maintained at prescribed intervals prior to use. The calibration records reviewed by the NRC inspection team indicated the accuracy required, calibration results, calibration dates, and the due dates for re-calibration.

The NRC inspection team reviewed equipment located in the M&TE calibration lab area, the receiving area, and the fabrication shops and observed that the M&TE was labeled, handled, and stored in a manner that indicated the calibration status of the instrument and ensured its traceability to calibration test data via the unit's unique identifier. The NRC inspection team observed that GEH's process requires its staff to follow sign-out procedures before receiving M&TE.

The NRC inspection team also discussed the M&TE program with GEH's Laboratory Technicians and the Supervisor. The attachment to this inspection report lists the documents reviewed and the staff interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that GEH established its M&TE program in accordance with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that GEH is implementing its policies and procedures associated with the M&TE program. No findings of significance were identified.

3. Control of Special Processes

a. Inspection Scope

The NRC inspection team reviewed GEH's policies and implementing procedures that govern the special processes and critical manufacturing steps to verify compliance with the requirements of Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed critical manufacturing steps to ensure proper control of items. The NRC inspection team verified that procedures have been established and implemented for the control of special processes, the procedures direct generation of inspection control documents such as travelers and checklists, the processes are carried out in accordance with established procedures, and special processes and critical manufacturing steps have been performed by qualified personnel. The NRC inspection team verified that completed special processes were appropriately documented in manufacturing step records and test reports complying with GEH's procedures and the applicable technical requirements.

The NRC inspection team discussed the special process and critical manufacturing steps with GEH's management and technical staff. The attachment to this inspection report lists the documents reviewed and the staff interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that GEH established its special process and critical manufacturing step programs in accordance with the regulatory requirements of Criterion IX of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that GEH is effectively implementing its policies and procedures associated with the special process and critical manufacturing step programs. No findings of significance were identified.

4. Oversight of Suppliers

a. Inspection Scope

The NRC inspection team reviewed GEH's policies and implementing procedures that govern the implementation of its oversight of contracted activities to verify compliance with the requirements of Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50.

Specifically, a review was performed of GEH's QA process and procedures to verify that adequate controls have been established and implemented for the control and release of procurement documents and subsequent changes. A sample of GEH's procurement documents was reviewed to ensure that controls have been properly implemented. The documentation related to purchase orders (POs) is adequately controlled and reviewed consistent with procedures and regulatory requirements.

A sample of external audits was reviewed to confirm that activities affecting quality comply with the QA program and have been implemented effectively. The NRC inspection team verified that GEH has qualified its suppliers and put them on an approved supplier list (ASL) based on source evaluation and selection. The NRC inspection team verified that triennial audits were being performed. Responsibilities and

procedures for auditing, documenting and reviewing audit results and designating management levels to review and assess audit results were established.

Additionally, the NRC inspection team evaluated GEH's annual supplier evaluations. The evaluation included a review of any associated nonconformances, condition reports (CRs) and receipt inspections from the specific supplier. The NRC inspection team ensured that the ASL reflected the supplier's current QA program and had been reviewed and accepted by GEH.

The NRC inspection team also discussed the supplier oversight program with GEH's management and technical staff. The attachment to this inspection report lists the documents reviewed and the staff interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that GEH is implementing its oversight of contracted activities in accordance with the regulatory requirements of Criterion IV and Criterion VII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that GEH is effectively implementing its policies and procedures associated with the oversight of contracted activities. No findings of significance were identified.

5. Commercial Grade Dedication

a. Inspection Scope

The NRC inspection team reviewed GEH's policies and implementing procedures that govern the implementation of its commercial-grade dedication (CGD) program to verify compliance with the requirements of Criterion III, "Design Control," Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed a sample of CGD plans, reports, associated POs, and commercial-grade surveys of several commercial suppliers on GEH's ASL to assess the different elements of the CGD program. The NRC inspection team verified that the technical evaluations documented the criteria for the identification of item functions, credible failure mechanisms/modes, selection of critical characteristics and acceptance criteria, the identification of verification methods, and justification of the sampling methodologies as applicable. Furthermore, the NRC inspection team reviewed the dedication packages, associated drawings and inspection reports to verify that the critical characteristics and acceptance methods were correctly specified, that the drawings and material specifications containing the associated acceptance criteria for each critical characteristic were referenced, and that the inspection reports adequately documented the acceptance of the critical characteristics to verify effective implementation of GEH's design control and CGD processes.

The NRC inspection team reviewed Dedication Specification 005N0454 Revision 1, for molded case type THED circuit breakers. The NRC inspection team verified the appropriateness of the specified critical characteristics and that all critical characteristics were being properly verified, including verification of circuit interrupting ratings which was done via a commercial grade survey performed by GEH of the circuit breaker manufacturer. The NRC inspection team reviewed the GEH commercial grade survey and verified the survey report appropriately contained a link to critical characteristics being credited by the survey. The NRC inspection team reviewed GEH's basis for seismic qualification including traceability back to the original qualification report (Laboratory Report 43757-1, "Seismic Simulation Test Report," dated June 26, 1978), and specific tests performed to establish similarity to the originally tested components. The NRC inspection team verified the adequacy of the original seismic qualification to ensure that there was no spurious tripping of the circuit breakers during the seismic testing.

The NRC inspection team also discussed the design control and CGD program with GEH's management and technical staff. The attachment to this inspection report lists the documents reviewed and the staff interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that GEH established its design control and CGD programs in accordance with the regulatory requirements of Criteria III, IV, and VII of Appendix B to 10 CFR Part 50. Based on the sample of documents reviewed, the NRC inspection team also determined that GEH is implementing its policies and procedures associated with its design control and CGD programs. No findings of significance were identified.

6. Environmental Qualification

a. Inspection Scope

The NRC inspection team reviewed GEH's policies and implementing procedures that govern the implementation of design control to verify compliance with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed GEH data that was associated with replacement solenoid valves being supplied to various U.S. nuclear power stations. The replacement valves are part of the hydraulic control units, which provide the motive force for inserting control rods into boiling water reactors (BWRs). The replacement valves contain Viton diaphragms of an improved material type, designed to eliminate previously reported failures of these valves. The valves are environmentally qualified by GEH to "Environmental Qualification Report for BWR Owners Group," NEDC-32365P, Addendum 4, Revision 1, dated December 2017. The NRC inspection team reviewed the basis for the activation energy of 1.3 eV assigned to the Viton 515 AB material and used in the thermal aging calculations. The NRC inspection team reviewed an associated PO from GEH to the vendor for these valves, GEH PO 431006903, Revision

8, dated 7/8/2007. The NRC inspection team also reviewed GEH Drawing 107E6022, dated 6/1/1992, of the valves, including a material list that specifically designated the Viton 515 AB material. The attachment to this inspection report lists the documents reviewed and the staff interviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team identified a minor issue with a determined qualification file that did not contain an adequate basis for the activation energy chosen for the Viton 515 AB material. During the inspection, GEH was able to locate additional information in the form of an internal letter/report, CDP96201, dated December 1, 1996, which contained data associated with testing performed to determine the activation energy of the Viton 514 ZE material (name later changed to Viton 515 AB). This additional data supported the use of the 1.30 eV activation energy based upon a 50 percent loss of tensile strength of the material which was correlated to a 5 percent loss of weight. GEH issued CR 32583 during the inspection to clarify the environmental qualification file and GEH Report, NEDC-323365P, with respect to the basis for the chosen activation energy for the Viton 515 AB diaphragms.

No findings of significance were identified.

c. Conclusion

The NRC inspection team determined that GEH's implementation of its policies and procedures associated with design control and environmental qualification met the requirements of Criterion III of Appendix B to 10 CFR Part 50. No findings of significance were identified.

7. Nonconformances and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed GEH's implementation of its policies and procedures governing nonconformances and corrective actions, in order to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Actions", of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed the current corrective actions, nonconformance and Part 21 procedures and verified they contained sufficient guidance for entering nonconforming conditions into the corrective action program as applicable, and that the nonconformance and corrective action programs provide sufficient guidance to be evaluated for Part 21 applicability.

The NRC inspection team reviewed a sample of nonconformance reports (NCRs) and CRs. The specific NCRs and CRs reviewed are listed in the Appendix to this report. The NRC inspection team also reviewed GEH's actions associated with its response to a Notice of Nonconformance contained in NRC Inspection Report 99900003/2010-201. The attachment to this inspection report lists the documents reviewed and the staff interviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team reviewed CR 24961, dated February 24, 2017, which was associated with the qualification of a low voltage circuit breaker switch that had been substituted for a previously qualified and tested part. GEH had identified that the switch substitution had been performed without completing an appropriate evaluation that considered the switch's seismic qualification. The NRC inspection team also reviewed the associated 10 CFR Part 21 evaluation contained in potentially reportable condition (PRC) 17-03 and the associated design basis record, (DBR)-0026621, Revision 1, which provided an assessment for the qualification of the replacement switch. The NRC inspection team questioned the basis contained in the DBR for concluding the replacement switch was equivalent, specifically, whether GEH could take credit for the commercial ratings (without performing any independent verification of the commercial ratings) of the switch as a means of justifying its equivalency to the previously qualified and tested switch. The NRC inspection team determined that GEH lacked sufficient basis to determine that the replacement switch would be covered by the existing qualification reports. GEH issued CR 32661 to document the lack of a qualification basis. However, this issue was determined by the NRC inspection team to be a minor issue as GEH had not shipped any of the replacement switches to any U.S. customers.

The NRC inspection team also reviewed CR 25509, dated April 28, 2017, which was associated with a deficiency that had been identified in the GEH performed loss of coolant accident (LOCA) analyses for BWRs. The deficiency concerned acoustic loads were erroneously assumed to be negligible and were unaccounted for in the recirculation line break LOCA analysis. The NRC inspection team also reviewed the associated 10 CFR Part 21 evaluation contained in PRC 17-04. The results of GEH's analysis were communicated to each of the affected BWR operating units via GEH letters SC 11-07, dated June 10, 2013 and DOC-0009-6295, dated April 25, 2018. In the letters, GEH indicated that issue could put the plants outside their licensing basis

No findings of significance were identified.

Closeout of Previous Issues

NON 99900003/2010-201-01 (closed)

This NON documented the lack of a threshold for entering issues concerning parts that do not meet design requirements into the corrective action program. The NRC inspection team verified that GEH took corrective actions to update the relevant procedure to require its staff to record the results of the Part 21 applicability review in the non-conformance disposition record. Corrective actions were also taken to add the guidance for Part 21 applicability to the non-conformance disposition procedure.

NON 99900003/2010-201-02 (closed)

This NON documented the failure to appropriately consider environmental and seismic considerations during the CGD of electronics. The NRC inspection team reviewed GEH's corrective actions associated with this NON and sampled CGD packages during the inspection that involved seismically and/or environmentally qualified components. Based upon the sample CGD packages reviewed, the NRC inspection team concluded that environmental and seismic considerations are now being assessed appropriately.

NON 99900003/2010-201-03 (closed)

This NON documented inappropriate use of the International Laboratory Accreditation Certification (ILAC) in the CGD process for commercial international calibration providers. The NRC inspection team identified that since this NON was written, the NRC has revised its guidance in this area and now allows credit to be given (in lieu of performing a commercial grade survey) for third party accreditation of international calibration service providers that have been accredited by one of the approved accrediting bodies. The NRC inspection team reviewed GEH's guidance associated with allowing such credit in DP-07-02, "Supplier Approval," Revision 32 as well as Paragraph 7.8 of NEDO-11209-A, "GEH Hitachi Nuclear Energy Quality Assurance Program Description," Revision 13 and determined that it was appropriate.

c. Conclusions

The NRC inspection team concluded that GEH adequately implemented its 10 CFR Part 21 program. The NRC inspection team also concluded that GEH adequately implemented its corrective action programs in accordance with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that GEH is implementing its policies and procedures associated with the 10 CFR Part 21 and corrective action programs. No findings of significance were identified.

7. Safeguards Information Program

a. Inspection Scope

The NRC inspection team reviewed GEH's policies and implementing procedures to verify that GEH's information protection system effectively protects Safeguards Information (SGI), as defined in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements," and 10 CFR 73.22, "Protection of Safeguards Information: Specific Requirements," and prevents unauthorized disclosure. This is inclusive of control of SGI information provided to applicants and vendors by the NRC.

The NRC inspection team (1) reviewed GEH's implementing procedures for controlling and protecting SGI; (2) interviewed GEH's SGI program personnel; (3) inspected the SGI secured location and locked SGI security containers; (4) reviewed a sample of SGI hardcopy materials for proper markings and storage; (5) verified labeling of electronic media such as SGI hard drives and laptops; and (6) reviewed a sample of logs, access lists, program self-assessments, and corrective actions. The NRC inspection team also reviewed a sample of personnel files regarding personnel conditions for access to SGI material.

The NRC inspection team also discussed the SGI program with GEH's management and technical staff. The attachment to this inspection report lists the documents reviewed and the staff interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that GEH established its SGI protection program in accordance with the applicable requirements of 10 CFR 73.21, 10 CFR 73.22, and the Commission's Order No. EA-07-231. Based on the limited sample of documents reviewed and activities observed, the NRC inspection team determined that GEH is implementing its policies and procedures associated with the SGI program in accordance with the regulatory requirements of 10 CFR 73.21 and 10 CFR 73.22. No findings of significance were identified.

8. Internal Audits

a. Inspection Scope

The NRC inspection team reviewed GEH's policies and procedures that govern internal audits to verify compliance with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of internal audit reports from 2017 through 2019. The NRC inspection team verified that internal audits were performed by qualified auditors. The NRC inspection team verified that lead auditors prepared and approved plans that identified the audit scope and checklist criteria prior to the audit. The NRC inspection team verified the internal audits contained adequate documented evidence and that audits were performed by personnel not having direct responsibilities in the areas being audited. In addition, the NRC inspection team confirmed that audit findings were dispositioned, and corrective actions were implemented to correct the issues identified. The attachment to this inspection report lists the documents reviewed and the staff interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that GEH is conducting its internal audits in accordance with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and interviews conducted, the NRC inspection team determined that GEH is adequately implementing its policies and procedures associated with internal audits. No findings of significance were identified.

8. Entrance and Exit Meetings

On September 16, 2019, the NRC inspection team discussed the scope of the inspection with Michelle Catts, Vice President, Regulatory Affairs, and other members of GEH's management and technical staff. On September 19, 2019, the NRC inspection team presented the inspection results and observations during an exit meeting with Ms. Catts, and other members of GEH's management and technical staff. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals whom the NRC inspection team interviewed.

Attachment

1. **ENTRANCE/EXIT MEETING ATTENDEES**

Name	Title	Affiliation	Entrance	Exit	Interviewed
Robert Ayer	Engineering Manager	GE Hitachi (GEH)	X	X	
Mark Elliott	Services Quality Leader	GEH	X	X	X
Carmen Alonso	Quality Oversight	GEH	X	X	X
Tammy Orr	GM NOS	GEH	X	X	
Jon Mailey	Lead Quality Engineer	GEH	X		
Paul Ragan	Sourcing	GEH	X	X*	
Anne Murray	CAP Leader	GEH	X	X	
Michelle Catts	Regulatory Affairs Manager	GEH	X	X	X
Mike Eason	Dedication Center Manager	GEH	X	X	
Mark Allison	Manager - Electrical	GEH	X*	X*	
Alex Peklaris	Manager – Document Control/Records	GEH	X*		
Dave Donovan	Tech Leader – Electrical Components	GEH	X*		
Joseph Cambell	QC Engineer	GEH	X*		
Atul Karve	Software Director	GEH	X*	X*	
Shawn McConnell	Training	GEH	X*	X*	
Bobbie Lockwood	Services Operations GM	GEH	X*	X*	

Name	Title	Affiliation	Entrance	Exit	Interviewed
Glen Waterford	Chief Engineers Office, GM	GEH		X	
Jhansi Kandasamy	Engineering, GM	GEH		X	
Mark Gordes	Quality Oversight	GEH		X	
Stanley Griffin	Quality Audit Program Leader	GEH		X	
Benjamin Graebe	Parts Project Engineer	GEH		X*	
Wade Mattox	Safeguards Information (SGI)	GEH		X*	X
Dan Papone	Chief Engineering Officer	GEH		X*	
Steve Swain	SGI	GEH			X
Marianne Stacks	Project Improvement Leader	GEH			X
Paul Arnett	Authorized Nuclear Inspector	Hartford Insurance			X
Jon Phillip	Services Leader	GEH			X
Jon Mayley	Lead QC Engineer, Acting Quality Manager	GEH			X
David Stevens	Hydro Technician	GEH			X
April Mabe	Machine Operator	GEH			X
Tommy Batten	H23 Gauge Inspector	GEH			X
Will McCormack	H23 Gauge Inspector	GEH			X
Ken Rocha	H23 Gauge Inspector	GEH			X
Brian McGuinness	SCP Safety Engineer	GEH			X
Robin Wood	SCO Supplier Quality Engineer/Program Manger Purchase Material QC	GEH			X

Name	Title	Affiliation	Entrance	Exit	Interviewed
Thomas Herrity	Inspector	NRC	X	X	
Aaron Armstrong	Inspector	NRC	X	X	
Jeff Jacobson	Inspector	NRC	X	X	
Andrea Keim	Inspector	NRC	X	X	

* Present via telephone

2. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated February 13, 2012

IP 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017

IP 81811, "Protection of Safeguards Information by Design Certification Applicants and Vendors," dated September 6, 2016

3. LIST OF ITEMS OPENED, CLOSED AND DISCUSSED

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

4. DOCUMENTS REVIEWED

Policies, Procedures, and Instructions

- NEDO-11209-A, "GE Hitachi Nuclear Energy Quality Assurance Program Description," Revision 13, dated October 16, 2017
- Common Procedure (CP)-03-100, "Design Process," Revision 5.2, dated August 1, 2019
- CP-16-108, "Corrective Action Program," Revision 12, dated May 9, 2019
- CP-06-104, "Protection of Safeguards Information," Revision 5, dated April 8, 2019
- CP-07-02, "Supplier Approval," Revision 32, dated August 20, 2019
- CP-07-03, "Supplier Selection and Management," Revision 7.3, dated November 29, 2018
- CP-07-104, "Customer Purchasing Order Technical Evaluation and Deductions of Commercial Grade Items and Services," Revision 6.3, dated July 24, 2019
- CP-07-106, "Receiving Inspections and Routines," Revision 1.1 dated October 27, 2017
- CP-12-101, "Calibration Control Program," Revision 7, dated August 19, 2019
- CP-10-105, "Inspection Requirements for Procured Items," Revision 15, dated May 25, 2018

- CP-12-102, "Calibration Program for Instrumentation and Controls," Revision 2.1, dated November 18, 2016
- CP-15-100, "Control of Nonconforming Items," Revision 3.2, dated June 22, 2017
- CP-15-101, "Control and Disposition of Supplier Provided, Nonconforming Items," Revision 14.2 dated June 14, 2019
- CP-15-103, "Control and Disposition of Nonconforming Material at the Philadelphia Service Center," Revision 6.0, dated June 24, 2019
- CP-16-108, "Corrective Action Program," Revision 12, dated May 9, 2019
- CP-18-02, "Supplier Audits and Commercial Grade Surveys," Revision 15.1, dated March 15, 2019
- CP-18-202, "Focused Self-Assessments," Revision 12, dated April 17, 2019
- WI-03-100-22, "Materials and Process Engineering Control," Revision 0.0, dated June 24, 2014
- WI-03-100-32, "Engineering tests," Revision 1.0, dated April 9, 2018
- WI-03-100-30, "Design Verification," Revision 3.3, dated December 13, 2018
- WI-07-104-02, "Dedication Specification Generation," Revision 4.0, dated January 25, 2017
- WI-10-105-01, "Receiving Inspection, Revision 8.0, dated September 11, 2019
- WI-10-105-03, "Clarification for Verification Methods Required by Dedication Specification," Revision 5.0, dated August 2, 2018
- WI-10-105-02, "Commercial Grade Dedication," Revision 7.2, dated January 21, 2019
- WI-12-101-02, "WFSC Tooling Calibration Requirements," Revision 3.0, dated April 1, 2019
- WI-15-100-01, "SCO Nonconforming Material Control," WI-15-100-01, Revision 3.1, dated May 24, 2019
- WI-15-100-03, "WFSC Nonconforming Material Control," Revision 3.0, June 14, 2019
- WI-16-108-07, "Reporting of Defects and Noncompliance Under 10 CFR Part 21," Revision 6, dated July 15, 2019
- WI-5321C, "Tube Density," Revision 19, February 13, 2019

- Quality Control Examination Instruction (QCEI), “Ultrasonic Examination Colmonoy Hard-Faced Tubular Products,” Number 604, Revision 8.0, No date
- QCEI, “Fluorescent Penetrant Test – Water Washable,” Number 665, Revision 23, dated May 16, 2018
- QCEI, “Color Penetrant Exam – Solvent Removable,” Number 676, Revision 25, dated April 28, 2016
- QCEI, “Visual Examination,” Number 685, Revision 6, dated January 22, 2013
- QCEI, “Helium Leak Detection (SCO),” Number 704, Revision 17
- QCEI, “Eddy Current Examination – Ultra Control Blade Tube-to-Tube/Tube-to-Tie rod Welds,” Number 716, Revision 5, dated May 14, 2012
- QCEI, “Eddy Current Examination Using an Array Probe – Ultra Control Blade Tube-to-Tube/Tube-to-Tie Rod Welds,” Number 718, Revision 6
- QCEI, “Eddy Current Examination – Control Blade Capsule Body Tubes,” Number 720, Revision 1
- Quality Control Test Instruction (QCTI), “Cylinder, Tube and Flange, DWG 919D258 All Groups,” Number 715, Revision 13, No date
- QCTI, “Piston Tube Assembly”, Number 716, Revision 17, no date
- “GEH Certification of Non-Destructive Testing Personnel, 386HA480,” Revision 29, dated August 15, 2019
- Welding Procedure Specification (WPS), WPS-002, Revision 01, no title or date
- WPS-003, Revision 02; WPS-004, Revision 00; WPS-005, Revision -; WPS-007, Revision 01; WPS-011, Revision 02; WPS-026, Revision 03
- XM-19, “Stress Relief, Anneal,” Revision 26, dated March 13, 2017
- G15-B-13, “Calibration of Dial and Vernier Calipers,” Revision 5.1, No date
- G15-B-01, “Calibration of Outside Micrometers,” Revision 11.0, August 25, 2018
- G15-B-13, “Calibration of Dial and Vernier Calipers,” Revision 5.5, dated March 3, 2016
- GEH-HQ-0019, Training Documents for Reporting Defects and Non-conformances based on WI-16-108-07, “Reporting Defects and Non-conformances per 10 CFR 21”
- QC-11-343A4246, “Receiving Inspections,” Revision 0; “Boron Carbide Powder (B4C),” Revision 1, dated July 18, 2019

- Product Lifecycle Management (PLM) System pages for DWG 343A4246, Revision 0, Born Carbide Powder (B4C) Revision 1, dated August 26, 2019
- A-196, "Safety Related/ASME Code Supplies – QA System Requirements," Revision 13 dated April 18, 2018

Purchase Orders

- GEH PO 431006903, Revision 8, dated July 8, 2007
- GEH PO 437111126, Revision 3, dated August 20, 2017
- GEH PO 437113444, Revision 1, dated January 8, 2018
- GEH PO 437109970, Revision 1, dated October 23, 2017
- GEH PO 437097206, Revision 3, dated June 23, 2015
- GEH PO 437113959, Revision 2, dated January 2018
- GEH PO 437119222, Revision 0, dated December 11, 2018
- PO 10560447, Revision 0, dated September 26, 2018
- PO 00680080, Revision 3, dated March 6, 2019
- PO 03061488, Revision 3, dated January 16, 2018

Design and Commercial-Grade Dedication Records

- Dedication Specification (DS) PLM #002N4631, Revision 3, dated May 22, 2019
- DS 004N441, Revision 0
- Inspection Plan for 004N441, Revision 0, dated February 6, 2018
- DS PLM 002N1727, "Spectra RMS molded case circuit breakers, oracle project number: 172901," Revision 1
- DS PLM 002N1727, "Relay 24 Vdc Hermetically Sealed," P.O. 26A8291, Revision 9, January 11, 2012
- GEH Drawing 107E6022, dated June 1, 1992
- Inspection Plan for 002N4631, Revision 3, dated May 22, 2019
- Environmental Qualification (EQ) Report DRF HAF 151, "Action Environmental Testing Test Report 17200-82N," dated February 27, 2010

- EDE-AN-2013-01, "2013 Surveillance Activity," Revision 1, dated February 10, 2010
- Qualification report HFA 006/007/012, "Type HAF100 Century service Relay," Revision 1, dated December 5, 1997
- GEH letter SC 11-07, dated June 10, 2013
- NEDC-32365P, "Environmental Qualification Report for BWR Owners Group," Addendum 4, Revision 1
- PRC 17-03 and the associated Design Basis Record, DBR-0026621, Revision 1
- PRC 17-04 and associated Part 21 evaluation
- GEH letter DOC-0009-6295, dated April 25, 2018
- Laboratory Report 43757-1, "Seismic Simulation Test Report," dated June 26, 1978
- Product Quality Certificate (PQC) 1020632 for PO 00680080, Revision 3, dated May 23, 2019
- PQC 1020375, for SNG49087-0157, Revision 1, January 11, 2019

Miscellaneous

- Part 21 Poster location spreadsheet, dated March 5, 2019
- Email, "Rollout of Revision to WI-16-107-07", July 11, 2019
- NRC letter "Request for Approval of Revision to Safeguards Information Protection Procedure to Incorporate Steps to Approve Additional Storage Facilities," dated August 27, 2009

Commercial Grade Surveys, Audit Reports and Annual Evaluations

- GEH audit JH-SGI-2017-01, dated September 11, 2017
- GEH audit SIAI-SGI-2019-01, dated January 8, 2019
- GEH Internal Audit Report Number NQA-2018-12, dated December 13, 2018
- GEH Internal Audit Report Number NQA-2017-13, dated November 21, 2017
- GEH Internal Audit Number NQA-2018-01 of Service Components Operation, dated April 10, 2018

- GEH Internal Audit Number NQA-2019-2 of Service Components Operation, dated April 24, 2019
- GEH Audit Evaluation of NIAC Audit #24065, dated April 15, 2019
- Audit Report EMORY-2018-01, dated March 3, 2018
- Audit Report UKA-2016-01, dated October 28, 2016
- Audit Report ESI-2017-12, dated January 11, 2018
- GEH Audit Evaluation of NIAC Audit 24005, dated June 19, 2019
- GEH Audit Evaluation of NIAC Audit QA-18-16-23085, dated September 4, 2018
- GEH Audit Evaluation of NIAC Audit 23019, dated November 8, 2018
- GEH Audit Evaluation of NIAC Audit 21014, dated November 15, 2016
- 2019 Supplier Audit Schedule, dated September 18, 2019
- 2019 Internal Audit Schedule, dated August 30, 2019
- 2018 Internal Audit Schedule, dated July 31, 2018
- Annual Evaluation of a metal working facility, dated April 1, 2019
- Annual Evaluation of a radiation monitoring systems facility, dated April 8, 2019
- Annual Evaluation of a valve manufacturing facility, dated October 12, 2017
- Annual Evaluation of a pressure and flow control systems facility, dated May 1, 2019
- Annual Evaluation of diesel engine facility, dated November 19, 2018
- Annual Evaluation of a testing lab, dated August 17, 2018

Qualification Records

Nonconformance Reports (NCRs)

- NCR SCO-2584NE-A1
- NCR 25548
- NCR 26281
- NCR 25772
- NCR 26260
- NCR 26281

- NCR 24746
- NCR 24733
- NCR 25835
- NCR 25837
- NCR 25839

Condition Reports (CRs) Opened During the NRC Inspection

- CR32583
- CR32661

Condition Reports Reviewed

- CR-32385
- CR-32269
- CR-31122
- CR-31399
- CR-31501
- CR-29072
- CR-26743
- CR-31673
- CR-26741
- CR-25509

5. ACRONYMS

ADAMS	Agencywide Documents Access and Management System
ASME	American Society of Mechanical Engineers
ASL	Approved Suppliers List
B4C	Boron Carbide
BWR	Boiling Water Reactor
CP	Common Procedure
CGD	Commercial Grade Dedication
CRs	Condition Reports
CRG	Condition Review Group
DBR	Design Basis Record
DS	Dedication Specification
EQ	Environmental Qualification
GEH	GE Hitachi
IP	Inspection Procedure
LOCA	Loss of Coolant Accident
M&TE	Measuring and Test Equipment
NCR	Nonconformance Report
NIAC	Nuclear Industry Assessment Committee
NRC	Nuclear Regulatory Commission
PLM	Product Lifecycle Management
POs	Purchase Orders
PQC	Product Quality Certificate
PRC	Potentially Reportable Condition

QA	Quality Assurance
QCEI	Quality Control Examination Instruction
QCTI	Quality Control Test Instruction
SGI	Safeguards Information
WI	Work Instruction
WPS	Welding Procedure Specification