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M230088

June 22, 2023

Docket No: 99901376

Ms. Kerri Kavanagh  
US Nuclear Regulatory Commission  
Quality Assurance and Vendor Inspection Branch  
Division of Reactor Oversight  
Office of Nuclear Reactor Regulation  
US Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

Subject: Reply to a Notice of Nonconformance

References: 1) NRC Inspection Report No 99901376/2023-201  
2) Response Extension Acceptance Letter for Vendor Inspection at GNF-A  
(ML23160A199)

Dear Ms. Kavanagh,

By letter dated May 9, 2023, Global Nuclear Fuels – Americas, LLC (GNF-A) received NRC Inspection Report No. 99901376/2023-201 containing two (2) nonconformances designated 99901376/2023-201-01 and 99901376/2023-201-02. As stated in that report, the NRC inspection team determined that GNF-A was not fully implementing its QA program in the areas of inspections and audits.

The enclosures to this letter, detail the GEH/GNF-A investigation to identify the reason for the noncompliance, corrective actions taken and corrective actions planned to prevent reoccurrence.

Sincerely,

*Michelle P. Catts*

Michelle P. Catts  
Sr. VP, Nuclear Programs

Enclosures:

1. Detailed Response to Inspection Report Nonconformance 99901376/2023-201-01
2. Detailed Response to Inspection Report Nonconformance 99901376/2023-201-02

cc: Keim, Andrea, USNRC  
Griffin, Stanley, GEH  
Murray, Scott, GEH  
Neely, Brian, GNF-A  
Huth, Ryan, GNF-A

**Detailed Response to Inspection Report Nonconformance  
99901376/2023-201-01**

On May 9, 2023, GE Hitachi Nuclear Energy (GEH) received Nuclear Regulatory Commission (NRC) Inspection Report 99901376/2023-201, Notice of Nonconformance 99901376/2023-201-01 stemming from the NRC inspection of Global Nuclear Fuel – Americas (GNF-A) conducted March 20 through 24, 2023. The nonconformance is stated as follows:

*Criterion X, "Inspection," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "inspections shall be performed by individuals other than those who performed the activity being inspected."*

*Requirement 10, "Inspection," of NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," states, in part, that, "characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected."*

*Section 10.1 of GNF-A NEDO-11209-A, "GE Hitachi Nuclear Energy Quality Assurance Program Description," Revision 17, states that "inspections are performed by independent personnel who have not performed the work and do not report to the supervisors responsible for the work being inspected."*

*Contrary to the above, from March 1, 2021, through August 1, 2022, GNF-A failed to ensure that inspections were performed by individuals who do not report to the supervisors responsible for the work being inspected. Specifically, GNF-A changed CAA Temporary Operating Procedure, TOP-50075, Revisions 0 and 1, "QATS Bundle-Rods Table Inspections," which removed the requirement for Quality Inspectors to perform quality inspection activities, such as confirming the proper orientation of the water rod. This resulted in the inspection of the water rod's proper orientation by shop operations personnel who shared the same first line supervisor and contributed to several water control rods having an incorrect orientation that were not identified by the shop operations personnel.*

The nonconformance 99901376/2023-201-01 was related to inspection and a change made to in-process inspection responsibilities that did not meet the requirements of NEDO-11209-A, "GEH Quality Assurance Program Description" (QAPD), Revision 17, and contributed to two (2) instances of water rods having an incorrect orientation that were not identified by shop personnel performing an in-process check.

**The reason for this nonconformance** was implementation in March, 2021 of Quality at the Source (QATS) 1-over-1 operator check without an additional independent inspection by Quality personnel for the proper water rod orientation. All other in-process checks performed by the operators (i.e. QATS) were already being verified at final inspection by independent Quality personnel. While the implementation of QATS meets the requirements of 10 CFR 50 Appendix B, Criteria X and ASME NQA-1-2015 Requirement 10, Paragraph 100, as the second operator did not perform or supervise the work, it did not meet the more restrictive requirement of NEDO-11209-A, 10.1 which prohibits inspection by individuals who "report to the supervisors responsible for the work being inspected."

**The corrective actions that have been taken and results achieved:**

As part of the Root Cause Analysis, GNF-A extent of condition investigation of other QATS checks at the bundle assembly table did not identify any other occurrences of inspections lacking the independence required by NEDO-11209-A, 10.1.

Quality Control Inspection Instruction (QCII) 5.2.8, "Fuel Bundle Final Inspection," Rev. 103, was revised on August 5, 2022, to add verification of the proper orientation of the GNF-3 tabbed water rod by an independent Quality personnel as a part of final inspection. All other in-process checks performed by the operators were already being verified at final inspection by independent Quality personnel.

From September 9, 2022, thru April 2023, independent Quality personnel also performed the in-process check of the water rod orientation at the bundle build table to meet the requirement of NEDO-11209-A Section 10.1.

Additionally, an engineered mechanical inspection device to verify proper water rod orientation has been implemented.

As of April 17, 2023, QATS has been removed from the bundle build table and all in-process inspections are performed by independent Quality personnel in accordance with NEDO-11209-A, Section 10.1.

No mis-oriented water rods have been identified by final inspection or mechanical inspection since implementing these changes beginning September 9, 2022.

Work Instruction WI-16-106-06, revision 3.0, "Change Management – Failure Modes and Effects Analysis was issued May 26, 2023" which added Process Failure Modes and Effects Analysis (PFMEA) to enhance the evaluation of changes in the manufacturing process that could impact product quality, including human performance errors.

With these actions, specifically the implementation of water rod orientation verification at the in-process and final inspection by independent Quality personnel, GNF-A considers the noted nonconformance to be resolved.

**Detailed Response to Inspection Report Nonconformance  
99901376/2023-201-02**

On May 9, 2023, GE Hitachi Nuclear Energy (GEH) received Nuclear Regulatory Commission (NRC) Inspection Report 99901376/2023-201, Notice of Nonconformance 99901376/2023-201-02 stemming from the NRC inspection of Global Nuclear Fuel – Americas (GNF-A) conducted March 20 through 24, 2023. The nonconformance is stated as follows:

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

*NEDO-11209-A, Revision 17, Section 18.1.1 states, “The GE Hitachi Nuclear Energy (GEH) audit program is designed to verify compliance to quality assurance program requirements, to verify that performance criteria are met, to determine the effectiveness of the program, and to provide a comprehensive independent evaluation of activities and procedures.”*

*NEDO-11209-A, Revision 17, Section 18.3.1.2 identifies requirements for internal audits scheduling in which the audit intervals are dependent upon whether the activities are for a licensed facility. Specifically, Section 18.3.1.2.b states “all applicable quality assurance program elements for each functional area shall be audited within a period of two years...the period may be extended one year at a time...based on the results of an annual evaluation...” Section 18.3.1.2.c states, “activities not related to a licensed facility or other support activities – All applicable quality assurance program elements shall be audited at least once each year...This interval may be extended up to two years based on the results of an annual evaluation and objective evidence that the activities are being satisfactorily accomplished in accordance with the applicable quality assurance program elements.”*

*CP-18-100, Revision 11.0, “Quality Assurance Internal Audit,” defines the Internal Quality Assurance Program requirements for audits performed at and by GNF-A. Section 4.1.2 of CP-18-100 states, “Ensure that the organization’s QA program is audited at least every two (2) years for the applicable 18 Criteria of 10 CFR 50 Appendix B...” Section 4.1.6.3 of CP-18-100 requires scheduling of supplement audits, “when it is suspected that the quality of an item is in jeopardy due to deficiencies in the QA program.*

*Contrary to the above, GNF-A failed to implement a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.*

*Specifically,*

- *GNF-A did not adequately translate the requirement (i.e., the audit interval requirements and performance of an annual evaluation when the internal audit interval is extended beyond the specified time period) in Sections 18.3.1.2.b and c of NEDO-11209-A into its internal audit procedure CP-18-100. As a result, GNF-A did not perform an annual evaluation of its Fuel Manufacturing Organization (FMO) – Bundle Assembly when an internal audit of FMO – Bundle Assembly was not performed in 2022.*
- *GNF-A did not conduct supplemental audits of FMO – Bundle Assembly, as required by Section 4.1.6.3 of CP-18-100, when conditions indicate that the quality of an item is in jeopardy due to deficiencies in the QA program. Specifically, Condition Report (CR) 38307 was initiated in November 2021, and CRs 38729 and 38740 were initiated in February 2022, documenting issues identified that were attributed to human*

*performance issues within FMO that created conditions adverse to quality. However, GNF-A did not schedule a supplement audit of FMO and as a result, deficiencies in inspections during the bundle manufacturing process rendered the quality of assembled fuel bundles to be unacceptable or indeterminate after delivery of the product to NRC Licensees.*

**The reason for the first bullet of this nonconformance related to audit frequency** was an incorrect understanding and application of audit frequency requirements described in “GEH Quality Assurance Program Description” (QAPD), NEDO-11209-A, Revision 17, Section 18.3.1.2.

Revision 15 of NEDO-11209-A (issued May 22, 2020) implemented the 2008 edition of ASME NQA-1 with 2009 Addenda. NEDO-11209-A, Revision 15, 18.3.1.3 stated, *“Once activities have been established, internal audits are conducted to ensure all GEH Quality Assurance Program elements are evaluated for each functional area within a period of two years.”*

Under this requirement GEH/GNF-A assessed all functional areas within a period of two (2) years. The practice was to assess the pellet manufacturing areas of Fuel Manufacturing Operations (FMO) in one year and the Bundle Assembly area on the alternate year. Fuel Components Operations (FCO) was assessed on a 2-year frequency.

NEDO-11209-A, Revision 16, issued 12/23/2020, implemented the 2015 edition of ASME NQA-1, and the audit frequency requirements of 18.3.1.2, as described in the Nonconformance, were introduced based on NQA-1-2015 Requirement 18, Paragraph 201. NEDO-11209-A, Revision 17, issued 12/8/2022 maintained the Revision 16 requirements in 18.3.1.2.

As a NRC licensed facility, GEH/GNF-A considered the audit frequency for GNF-A manufacturing operations fell under Section 18.3.1.2.b which states *“After placing a licensed facility into operation - All applicable quality assurance program elements for each functional area shall be audited within a period of two years.”* and therefore, continued the previous practice of assessing all functional areas within a period of two (2) years, at minimum. Additionally, it was deemed that CP-18-100, “Quality Assurance Internal Audit Requirements”, was adequate and no revision was made to change the requirement of Section 4.1.2 which states, *“Ensure that the organization’s QA program is audited at least every two (2) years for the applicable 18 Criteria of 10 CFR 50 Appendix B”.*

The NRC inspection team concluded that the GNF-A facility is licensed under 10 CFR 70 and that the manufacturing of components for installation in a nuclear power plant under 10 CFR 50 Appendix B fall under NEDO-11209-A, Section 18.3.1.2.c which states, *“Activities not related to a licensed facility or other support activities - All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter. This interval may be extended up to two years based on the results of an annual evaluation and objective evidence that the activities are being satisfactorily accomplished in accordance with the applicable quality assurance program elements.”*

GEH/GNF-A does implement a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine effectiveness of the program; however, an annual evaluation was not performed for areas audited on a two (2) year frequency as required in NEDO-11209-A, 18.3.1.2.c.

**The corrective actions that have been taken and results achieved:**

CP-18-100, revision 12.0, was issued May 18, 2023, which implemented the requirements of NEDO-11209-A Section 18.3.1.2.c. Specifically, CP-18-100, 4.1.2 states *“Ensure that the organization’s QA program is audited at least once each year or at least once during the life of the activity, whichever is shorter. This interval may be extended up to two years based on the results of an annual evaluation and objective evidence that the activities are being satisfactorily accomplished in accordance with the applicable quality assurance program elements.”*

Additionally, GEH/GNF-A does perform an annual evaluation of GNF-A Operations as part of the annual Management Review described in CP-16-107, Revision 6.0, “Status and Adequacy Report”, which reviews operational performance including First Pass Yield (FPY), Cost of Quality (COQ), Escaping Defects, and initiation and responsiveness to Condition Reports (CR). This annual evaluation is based on data for the calendar year and provides input to the audit scheduling process.

**The corrective actions that will be taken to avoid further noncompliance:**

Full audits in accordance with CP-18-100 of FMO bundle assembly and FCO operations are scheduled in July 2023. The final reports for these audits are expected to be issued by August 31, 2023.

GEH is developing an annual evaluation process and supporting documents (to supplement the annual Status and Adequacy Report) to extend audit frequency to 2 years as described in CP-18-100. The evaluation process will include identification of organization and process changes, nonconformances, assessment/surveillance results by external agencies, and CRs generated. The evaluation process to extend audit frequency to 2 years is expected to be implemented by July 31, 2023.

This evaluation process to extend audit frequency will be applied to FMO pellet manufacturing areas which was last audited in May 2022. This evaluation is expected to be completed by August 31, 2023.

**In regard to the second bullet of this nonconformance related to the need for a supplemental audit,** GEH/GNF-A disagrees that a nonconformance exists. GEH/GNF-A Nonconformance Assessments performed at the time the CR were initiated concluded that human performance errors occurred but did not identify a potentially unifying trend indicative of a QA Program deficiency that would jeopardize product quality and prompt a supplemental audit. Hence, GEH/GNF-A does not believe that the entering condition for consideration of supplemental audit under CP-18-100, Revision 11.0, was reached.

Following the Nonconformance Assessments (NCA), GEH/GNF-A considered the already scheduled 2023 audit of FMO Bundle Assembly adequate to assess the issues identified by the cited Condition Reports (CR) which did not identify a unifying trend and implemented appropriate corrective and preventive actions.

GEH/GNF-A has a robust Corrective Action Program. The CRs cited by the NRC inspection team identified human performance issues; however CR 38307 identified improvements to Operating Procedures and training was provided to review the errors that occurred. CR 38740 and CR 38729 are related to the same issue and the customer concern regarding the use of “workarounds” and procedure adherence. The Nonconformance Assessment (NCA) performed 57 surveys, 76 observations, and multiple interviews. The NCA did not identify widespread use of workarounds, identified only 1 observation of use of an unauthorized tool, and identified cases of non-verbatim procedure use and adherence which did not have an adverse effect on product quality. As result a stop work/stand down was conducted to reinforce procedure adherence and share observed errors, additional training was provided, and additional observations were scheduled in the GNF-A observation program. Neither CR identified a unifying trend but did identify specific opportunities to implement preventive measures by reviewing the errors that occurred. None of the observed conditions cited in these CRs resulted in unacceptable or indeterminate product being delivered to GNF-A customers. GEH/GNF-A did not deem these conditions as attaining the threshold that “the quality of an item is in jeopardy due to deficiencies in the QA program” since the conditions were properly identified through the inspection process.

The incorrect water rod orientation issue was documented in CR 40108 (initiated July 27, 2022). Several corrective actions were implemented as discussed in the response to nonconformance 99901376/2023-201-01 resulting in no mis-oriented rods since September 9, 2022. A formal Root Cause Analysis (RCA) was performed and report issued October 25, 2022. Several corrective and preventive actions were identified and are in various stages of completion. GEH/GNF-A wanted to allow time to implement these actions prior to a full audit; therefore the scheduled audit for 2023 was deemed appropriate to assess these areas of concern and a supplemental audit was not needed.

**The corrective actions that have will be taken to avoid further noncompliance:**

While GEH/GNF-A does not believe a nonconformance occurred, it has nonetheless taken the following actions that addressed the audit process

GEH/GNF-A identified an opportunity to improve CP-18-100, Section 4.1.6.3, to provide additional guidance to reduce subjectivity in the determination that a supplemental audit should

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be conducted. This additional guidance will be documented in the appropriate procedure or job aid and is expected to be implemented by July 31, 2023.

Full audits in accordance with CP-18-100 of FMO bundle assembly and FCO operations are scheduled in July 2023. The final reports for these audits are expected to be issued by August 31, 2023.

With the described actions above, GEH/GNF-A considers the noted nonconformance to be adequately addressed.