ENCLOSURE 2

M180080

Detailed Response to Inspection Report Nonconformance 99901376/2018-201-01

Non-Proprietary Information – Class I (Public)

IMPORTANT NOTICE

This is a non-proprietary version of Enclosure 1, from which the proprietary information has been removed. Portions of the enclosure that have been removed are indicated by an open and closed bracket as shown here [[ ]].

Detailed Response to Inspection Report Nonconformance 99901376/2018-201-01

On April 4, 2018, GE Hitachi Nuclear Energy (GEH) received Nuclear Regulatory Commission (NRC) Inspection Report No. 99901376/2018-201, Notice of Nonconformance stemming from the NRC inspection of Global Nuclear Fuel – Americas (GNF-A) conducted the week of February 26. The nonconformance is stated as follows:

> *Criterion XVI "Corrective Action," 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 "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected."*
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> *Contrary to the above, as of March 2, 2018, GNF-A failed to assure that conditions adverse to quality were effectively identified and corrected. Specifically, in December of 2016, GNF-A initiated a condition report (CR) to address a significant number of gages (as determined by the gage lab supervisor) that were past their calibration due date and were still on the manufacturing floor. Subsequently, in March of 2017, GNF-A initiated another CR to address a significant number of gages that were past their calibration due date and were also still on the manufacturing floor. Then, during the review of GNF-A's calibration program, the NRC inspection team identified that a large number of gages were past their calibration due date and were still on the manufacturing floor.*

Due to the division of programmatic responsibilities associated with the joint venture structure, GEH and GNF-A offer the following evidence in response to this nonconformance:

GEH controls the gage calibration program used across GEH and GNF-A. At any given time, GEH/GNF-A has roughly 3000 gages issued across 28 different areas and locations. Under GEH/GNF-A processes and contract requirements, personnel are responsible, at the time of use of a gage, to ensure that it is currently within its calibration interval. Upon expiration of the calibration, personnel are not timely in returning the gage to the Gage Lab. GEH/GNF-A identified an adverse trend in untimely return of gages for calibration in November 2015. This issue had been identified through internal audits and condition reports. Condition report (CR) 17312 was initiated on November 10, 2015 to address the adverse trend and a Non-conformance Assessment (NCA) was performed. As-found conditions of delinquent gages were determined to have no impact on the safety and quality of accepted and released product.

The CR 17312 NCA identified several gaps in the gage processing system, including an inefficient return process, delays in updating gage status in the calibration laboratory, and lack of adequate visibility of gage status to gage users and their managers. Several corrective actions to prevent recurrence were identified and implemented including:

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All preventive actions documented in the CR 17312 NCA, including launch of the new dashboard, were completed in December of 2016.

Note that the NRC Inspection Report No. 99901376/2018-201 states that GNF-A failed to recognize and correct the deficiency in the calibration program that would alert Area Owners responsible for gages to instruments going past their calibration due dates. In fact, the program improvements do alert Area Managers daily to instruments going past their calibration due dates. The issue is that alerted staff did not take appropriate or timely actions based upon that notification. Due to the late identification of this issue during the inspection, NRC inspection staff did not have sufficient time to evaluate the current GEH/GNF-A notification process.

An additional trend condition report (CR) 19894 was initiated in July of 2016 while transitioning to the new process. This condition report was the result of several condition reports written on incorrect gage status updates in Oracle™. This condition report included an NCA that identified additional changes to the Gage Dashboard report for which software updates/corrections were subsequently implemented. All preventive actions documented in CR 19894 were completed in April 2017. Once again, no safety implications were identified by the CR 19894 NCA.

GEH/GNF-A initiated condition reports 23261 and 25109 in December 2016 and March 2017 to address increases in delinquent gages to ensure proper transition to the new Gage Dashboard.

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GEH/GNF-A has subsequently documented this increase in condition report 28026, and completed a NCA of the delinquent gage issue. The NCA identified the following Causal Factors:

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GEH/GNF-A made improvements to its calibration program workflow on March 10, 2018 to assist Area Owners in meeting their responsibilities. The workflow was revised to provide for notification of the GEH Gage Lab when remote sites send gages out for calibration.

GEH/GNF-A is taking the following additional corrective actions to address the delinquent gage issue:

- Create and implement a plan to send out for calibration, existing delinquent gages from the supplier who uses GEH/GNF-A gages, and from the San Jose facility. This action will be completed by May 30, 2018.

- Provide coaching to Area Owners responsible for gages, and their managers, on the importance of returning gages for calibration, including preventing use of expired gages and determining as found conditions. This action will be completed by May 30, 2018.
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]] This action will be implemented by May 30, 2018.

GEH/GNF-A is taking the following actions to prevent recurrence of this issue:

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]] Track return of all gages from the San Jose laboratory to Wilmington and assign them to local Area Owners. This action will be completed by September 28, 2018.
- Develop and implement a plan for more efficiently and effectively controlling calibration of GEH/GNF-A gages used by the GEH/GNF-A supplier. This action will be completed by June 29, 2018.
- Evaluate opportunities to transfer responsibility for GEH/GNF-A gages used by the GEH/GNF-A supplier to the supplier themselves except for special GEH/GNF-A fixtures. This action will be completed by July 31, 2018.

GEH/GNF-A believes that these preventive actions will significantly reduce the number and risk of delinquent gages. A review of delinquent gage data on April 8, 2018 finds that the number of delinquent gages would drop to twelve with an average delinquency of 2.2 weeks. GEH/GNF-A has conducted an extent of condition review of this non-conformance. The review time frame was bounded by the implementation of calibration program changes in January 2017. GEH/GNF-A reviewed all out-of-tolerance gage reports from January 1, 2017 to-date to determine if any as found out-of-tolerance condition had an impact on accepted or released product. There were no instances of as found out-of-tolerance conditions having impact on accepted or released product.

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As documented in Nuclear Regulatory Commission (NRC) Inspection Report No. 99901376/2018-201, the GNF-A Corrective Action Program is effective to timely document conditions adverse to quality and to prevent recurrence as demonstrated by use of trend condition reports.

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The number of trending condition reports per year varies, but provides evidence that GEH/GNF-A look for adverse trends in the Corrective Action Program, and issue trending condition reports to address them.

In conclusion, the GEH/GNF-A Corrective Action Program, including use of trend data, has made significant improvements in the gage control program since 2015, with similar successes in other areas. GEH/GNF-A believes this indicates that the Corrective Action Program is driving continuous improvement, as intended. Recent upsets with timely return of gages for calibration, due primarily to performance of remote sites and suppliers, is an indication of further needed improvement in the gage control program. The identified corrective and preventive actions presented will address those issues.

GE-Hitachi Nuclear Energy Americas LLC

AFFIDAVIT

I, Jerald G. Head, state as follows:

(1) I am the Senior VP, Regulatory Affairs, of GE-Hitachi Nuclear Energy Americas LLC (GEH), and have been delegated the function of reviewing the information described in paragraph (2) which is sought to be withheld, and have been authorized to apply for its withholding.

(2) The information sought to be withheld is contained in Enclosure 1 of GEH letter M180080, Jerald G. Head (GEH) to Document Control Desk (USNRC), "Reply to a Notice of Nonconformance," April 27, 2018. The proprietary information in Enclosure 1, which is entitled "Detailed Response to Inspection Report Nonconformance 99901376/2018-201-01", is identified by a dotted underline inside double square brackets. [[This sentence is an example.{3}]] Figures and large objects containing GEH proprietary information are identified with double square brackets before and after the object. In all cases, the superscript notation {3} refers to Paragraph (3) of this affidavit that provides the basis for the proprietary determination.

(3) In making this application for withholding of proprietary information of which it is the owner or licensee, GEH relies upon the exemption from disclosure set forth in the Freedom of Information Act (FOIA), 5 USC Sec. 552(b)(4), and the Trade Secrets Act, 18 USC Sec. 1905, and NRC regulations 10 CFR 9.17(a)(4), and 2.390(a)(4) for trade secrets (Exemption 4). The material for which exemption from disclosure is here sought also qualifies under the narrower definition of trade secret, within the meanings assigned to those terms for purposes of FOIA Exemption 4 in, respectively, Critical Mass Energy Project v. Nuclear Regulatory Commission, 975 F2d 871 (DC Cir. 1992), and Public Citizen Health Research Group v. FDA, 704 F2d 1280 (DC Cir. 1983).

(4) Some examples of categories of information that fit into the definition of proprietary information are:

a. Information that discloses a process, method, or apparatus, including supporting data and analyses, where prevention of its use by GEH's competitors without license from GEH constitutes a competitive economic advantage over GEH and/or other companies.

b. Information that, if used by a competitor, would reduce their expenditure of resources or improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.

c. Information that reveals aspects of past, present, or future GEH customer-funded development plans and programs, that may include potential products of GEH.

d. Information that discloses trade secret and/or potentially patentable subject matter for which it may be desirable to obtain patent protection.

The information sought to be withheld is considered to be proprietary for the reasons set forth in paragraphs (4)a. and (4)b above.

(5) To address 10 CFR 2.390(b)(4), the information sought to be withheld is being submitted to the NRC in confidence. The information is of a sort customarily held in confidence by GEH, and is in fact so held. The information sought to be withheld has, to the best of my knowledge and belief, consistently been held in confidence by GEH, not been disclosed publicly, and not been made available in public sources. All disclosures to third parties, including any required transmittals to the NRC, have been made, or must be made, pursuant to regulatory provisions or proprietary and/or confidentiality agreements that provide for maintaining the information in confidence. The initial designation of this information as proprietary information, and the subsequent steps taken to prevent its unauthorized disclosure are as set forth in the following paragraphs (6) and (7).

(6) Initial approval of proprietary treatment of a document is made by the manager of the originating component, who is the person most likely to be acquainted with the value and sensitivity of the information in relation to industry knowledge, or who is the person most likely to be subject to the terms under which it was licensed to GEH.

(7) The procedure for approval of external release of such a document typically requires review by the staff manager, project manager, principal scientist, or other equivalent authority for technical content, competitive effect, and determination of the accuracy of the proprietary designation. Disclosures outside GEH are limited to regulatory bodies, customers, and potential customers, and their agents, suppliers, and licensees, and others with a legitimate need for the information, and then only in accordance with appropriate regulatory provisions or proprietary and/or confidentiality agreements.

(8) The information identified in paragraph (2) above is classified as proprietary because it contains detailed descriptions of internal procedures and processes as well as the concise results of corrective action program assessments, evaluations, and future business plans.

(9) Public disclosure of the information sought to be withheld is likely to cause substantial harm to GEH's competitive position and foreclose or reduce the availability of profit-making opportunities. The information is part of GEH's comprehensive BWR safety and technology base, and its commercial value extends beyond the original development cost. The value of the technology base goes beyond the extensive physical database and analytical methodology and includes development of the expertise to determine and apply the appropriate evaluation process. In addition, the technology base includes the value derived from providing analyses done with NRC-approved methods.

The research, development, engineering, analytical and NRC review costs comprise a substantial investment of time and money by GEH. The precise value of the expertise to devise an evaluation process and apply the correct analytical methodology is difficult to quantify, but it clearly is substantial. GEH's competitive advantage will be lost if its competitors are able to use the results of the GEH experience to normalize or verify their own

process or if they are able to claim an equivalent understanding by demonstrating that they can arrive at the same or similar conclusions.

The value of this information to GEH would be lost if the information were disclosed to the public. Making such information available to competitors without their having been required to undertake a similar expenditure of resources would unfairly provide competitors with a windfall, and deprive GEH of the opportunity to exercise its competitive advantage to seek an adequate return on its large investment in developing and obtaining these very valuable analytical tools.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 27th day of April 2018.

Jerald G. Head
Sr. VP, Regulatory Affairs
GE-Hitachi Nuclear Energy Americas, LLC
3901 Castle Hayne Road
Wilmington, NC 28401
Jerald.head@ge.com