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Proprietary Notice

This letter forwards proprietary information in accordance with 10 CFR 2.390. Upon the removal of Enclosure 1, the balance of this letter may be considered non-proprietary.

MFN 09-223

GE Hitachi Nuclear Energy

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Docket No. 52-010

April 9, 2009

U.S. Nuclear Regulatory Commission **Document Control Desk** Washington, D.C. 20555-0001

Subject: Submittal of Response to Portion of NRC Request for Additional Information Letter No. 310 Related to ESBWR Design Certification **Application Chapter 18 - Human Factors Engineering - RAI Number** 18.2-10 S04.

The purpose of this letter is to submit the GE Hitachi Nuclear Energy (GEH) responses to the U.S. Nuclear Regulatory Commission (NRC) Request for Additional Information (RAIs) sent by NRC letter No. 310, dated February 26, 2009 (Reference 1),

RAI 18.2-10 S04 was requested by Reference 1, and was preceded by responses in References 2, 3, 4, and 5 as requested by References 6, 7, 8, and 9, respectively.

Enclosure 1 contains GE Hitachi Nuclear Energy (GEH) proprietary information as defined by 10 CFR 2.390. GEH customarily maintains this information in confidence and withholds it from public disclosure. A non-proprietary version is provided in Enclosure 2.

The affidavit contained in Enclosure 3 identifies that the information contained in Enclosure 1 has been handled and classified as proprietary to GEH. GEH hereby requests that the information of Enclosure 1 be withheld from public disclosure in accordance with the provisions of 10 CFR 2.390 and 9.17.

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If you have any questions or require additional information, please contact me.

Sincerely,

Richard E. Kingston

Richard E. Kingston Vice President, ESBWR Licensing

References:

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- 1. MFN 09-151 Letter from U.S. Nuclear Regulatory Commission to Robert E. Brown, *Request For Additional Information Letter No. 310 Related To ESBWR Design Certification Application, dated February 26, 2009*
- MFN 08-647 Submittal of Response to Portion of NRC Request for Additional Information Letter No. 211 Related to ESBWR Design Certification Application Chapter 18 - Human Factors Engineering - RAI Number 18.2-10 S03 and 18.4-16 S03, dated October 10, 2008
- MFN 08-088 Response to Portion of NRC Request for Additional Information Letter Nos. 125 and 135 Related to ESBWR Design Certification Application – Human Factors Engineering - RAI Numbers 18.2-10 S02, 18.2-18, 18.6-13, 18.11-8 S01, 18.11-13 S01, 18.11-25 S01, 18.11-28 S01, 18.11-35, 18.11-37, 18.12-4 S02, and 18.12-7, dated March 8, 2008
- 4. MFN 07-334 Submittal of "ESBWR DCD Chapter 18, Human Factors Engineering - RAI to DCD Roadmap Document", dated June 27, 2007
- MFN 06-163, Response NRC Request for Additional Information Letter No. 28 – Human Factors Engineering – RAI Numbers 18.2-1 through 18.2-17, dated June 16, 2006
- 6. MFN 08-502 Letter from U.S. Nuclear Regulatory Commission to Robert E. Brown, *Request For Additional Information Letter No. 211 Related To ESBWR Design Certification Application, dated June 3, 2008*
- MFN 07-702 Letter from U.S. Nuclear Regulatory Commission to Robert E. Brown, GEH, Request For Additional Information Letter No. 125 Related To ESBWR Design Certification Application, dated December 14, 2007
- 8. Email from AE Cubbage to DL Lewis List of Chapter 18 RAIs for Roadmap Request, dated 5/18/07
- 9. MFN 06-150 Letter from U.S. Nuclear Regulatory Commission to David Hinds, GE, *Request For Additional Information Letter No. 28 Related To ESBWR Design Certification Application*, dated May 9, 2006

Enclosures:

- MFN 09-223 Response to Portion of NRC Request for Additional Information Letter No. 310 Related to ESBWR Design Certification Application Human Factors Engineering - Response to NRC RAI 18.2-10 S04 – Proprietary Version
- MFN 09-223 Response to Portion of NRC Request for Additional Information Letter No. 310 Related to ESBWR Design Certification Application Human Factors Engineering - Response to NRC RAIs 18.2-10 S04 – Non-Proprietary Version
- 3. Affidavit David A. Piepmeyer, dated April 9, 2009
- cc: AE Cubbage USNRC (with enclosure) JG Head GEH/Wilmington (with enclosures) DH Hinds GEH/Wilmington (with enclosures) RM Wachowiak GEH/Wilmington (with enclosures) RE Kingston GEH/Wilmington (with enclosures)

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Enclosure 2

MFN 09-223

Response to Portion of NRC Request for Additional Information Letter No. 310 Related to ESBWR Design Certification Application Human Factors Engineering RAI Number 18.2-10 S04 Non-Proprietary Version

NRC RAI 18.2-10 S04

For RAI 18.2-10 S03, related to the Human Factors Engineering (HFE) Program Review Element, HFE Process and Procedures Review Criteria, Criterion 2 (NUREG-0711 Section 2.4.3), GEH provided acceptable additional information in the response, but did not incorporate the information into the DCD. However, when an RAI response contains direction on how work will be done, then that information needs to be included in the DCD (or a document incorporated by reference). Therefore, the staff requests that GEH incorporate the information contained in the MFN into an appropriate source document. One acceptable way to accomplish this expeditiously is to incorporate the information verbatim from the RAI response as an appendix in the HFE Program implementation plan.

GEH Response

Appendix E to NEDE/NEDO 33217P (Attachment 1 to this RAI response) incorporates the content of the RAI 18.2-10 S03 response needed to support the HFE Process and Procedures Review Criteria, Criterion 2 (NUREG-0711 Section 2.4.3). The following is a summary of the changes to Appendix E from the RAI 18.2-10 S03 response:

- Supporting materials (e.g., EOP abstracts and excerpts) to the Human Factors Project Management work instruction are omitted. This includes Attachments 1, 4, 5, 6, and 7 to the supplement 3 RAI response.
- □ RAI 18.2-10 S03 introductory statements are omitted.
- Format is modified to be consistent with the LTR Appendix format.
- Prerequisites section from RAI 18.2-10 S03 response (i.e., work instructions prepared and approved and qualifications list established and maintained) is omitted.
- □ The role of "HF" not defined in the process is replaced with "QP".
- The term "HF PM work instruction" is replaced with "HFE PM process" since this is not the work instruction document. Also the term "instructions" is replaced with "planning tasks", "planning documentation", or an equivalent phrase.
- References to specific GEH EOPs and engineering documents are replaced with the term "applicable GEH engineering procedures".
- The Project Work Plan form (Attachment 2 to RAI 18.2-10 S03) is replaced with the list of data entry elements that comprise the form. The support planning form (Attachment 3 to RAI 18.2-10 S03) is omitted. This information is included in the Project Work Plan form element entitled "Organizational or personnel support needs".

- The specified period of status update (i.e., weekly) is replaced with the phrase "on a schedule to support the program reviews by the Engineering Manager or as otherwise identified in the Project Work Plan".
- Reference to the ESBWR LTR Writer's Guide is replaced with "applicable GEH Writer's Guide".
- Reference to the group organization responsible for HF activities, "HFE/Operations", is replaced with "HFE project activities" or "HFE team".
- The initial paragraph under "Roles and Personnel Qualifications" is modified to clarify that one team member may perform multiple roles/disciplines.
- □ Specific review metrics for Task schedule and Milestones are omitted.

Attachment 2 revises NEDO/NEDE 33217P section 3.1.4.2, **Process Management Tools**, to refer to Appendix E.

DCD Impact

No DCD changes will be made in response to this RAI.

LTR NEDE-33217P, Rev 4 will be revised as noted in the attached markup.

RAI Attachments

9 Pages

NEDO-33217, Rev. 5

A project work instruction is developed to further define project scope, activities and deliverables for each implementation plan listed in Subsection 2.1.2. The project work instruction is updated as changes occur in the work scope, design inputs, and outputs.

Specific project controls for the management of the software process are described in the Software Management Program Manual [2.1.2(13)] and requirements and procedures for the quality assurance of the software development process are described in the Software Quality Assurance Program Manual [2.1.2(14)].

Process Management Tools - Tools and techniques (Ex: review forms) to be utilized by the team to verify application of SPE/HFE efforts are <u>described in Appendix Eidentified in the HFE</u> and software implementation plans listed in Subsection 2.1.2, or in their respective work instructions.

Integration of HFE and Other Plant Design Activities - The integration of design activities is established in the ESBWR Project Management Manual [2.1.1(5)], GEH Project QA Plan [2.1.1(1)] and herein.

Specific design inputs are described in the individual activity plans listed in Subsection 2.1.2. Figure 3.1.4-2, Process Feedback and Issues Disposition, depicts a process for identifying, documenting, and communicating general (out of process) issues encountered in design activities.

A summary of the HFE integration into the ESBWR design process is provided in Subsection 3.2.4.2.

APPENDIX E HFE PROJECT MANAGEMENT PROCESS

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<u>1E. PURPOSE</u>

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2E. ROLES AND PERSONNEL QUALIFICATIONS

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Man-Machine Interface System Implementation Plan

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3E. SPECIAL TOOLS AND EQUIPMENT

4E. PROCESS DESCRIPTION

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Man-Machine Interface System Implementation Plan

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Man-Machine Interface System Implementation Plan

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MFN 09-223

Enclosure 3

Affidavit

GE-Hitachi Nuclear Energy Americas LLC

AFFIDAVIT

I, David A. Piepmeyer, state as follows:

- (1) I am Senior Project Manager, ESBWR Certification, GE-Hitachi Nuclear Energy Americas LLC ("GEH"). I 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's letter, MFN 90-223, Richard E Kingston to Nuclear Regulatory Commission, entitled Submittal of Response to Portion of NRC Request for Additional Information Letter No. 310 Related to ESBWR Design Certification Application Chapter 18 Human Factors Engineering RAI Number 182-10 S04, April 9, 2009. GEH text proprietary information in Enclosure 1, which is entitled "Response to Portion of NRC Request for Additional Information Letter No. 310 Related to ESBWR Design Certification Application of NRC Request for Additional Information Letter No. 310 Related to ESBWR Design Certification Application Human Factors Engineering Response to NRC RAIs 18.x-xx", is identified double square brackets [[This sentence is an example.^{3}]]. Figures and large equation objects containing GEH proprietary information are identified with double square brackets before and after the object. In each case, the superscript notation ^{3} refers to Paragraph (3) of this affidavit, which 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 qualify under the narrower definition of "trade secret", within the meanings assigned to those terms for purposes of FOIA Exemption 4 in, respectively, <u>Critical Mass Energy Project v. Nuclear Regulatory Commission</u>, 975F2d871 (DC Cir. 1992), and <u>Public Citizen Health Research Group v. FDA</u>, 704F2d1280 (DC Cir. 1983).
- (4) Some examples of categories of information which 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 other companies;
 - b. Information which, if used by a competitor, would reduce his expenditure of resources or improve his competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product;
 - c. Information which reveals aspects of past, present, or future GEH customer-funded development plans and programs, resulting in potential products to GEH;

d. Information which discloses 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 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, no public disclosure has been made, and it is not available in public sources. All disclosures to third parties, including any required transmittals to NRC, have been made, or must be made, pursuant to regulatory provisions or proprietary agreements which provide for maintenance of the information in confidence. Its initial designation as proprietary information, and the subsequent steps taken to prevent its unauthorized disclosure, are as set forth in paragraphs (6) and (7) following.
- (6) Initial approval of proprietary treatment of a document is made by the manager of the originating component, the person most likely to be acquainted with the value and sensitivity of the information in relation to industry knowledge, or subject to the terms under which it was licensed to GEH. Access to such documents within GEH is limited on a "need to know" basis.
- (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 agreements.
 - (8) The information identified in paragraph (2) above is classified as proprietary because it identifies details of GEH ESBWR methods, techniques, information, procedures, and assumptions related to the application of human factors engineering to the GEH ESBWR.

The development of the evaluation process along with the interpretation and application of the analytical results is derived from the extensive experience database that constitutes a major GEH asset.

(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 affidavit and the matters stated therein are true and correct to the best of my knowledge, information, and belief.

Executed on this 9th day of April, 2009.

David A. Piepmeyer GE-Hitachi Nuclear Energy Americas LLC