



HITACHI

GE Hitachi Nuclear Energy

Richard E. Kingston
Vice President, ESBWR Licensing

PO Box 780 M/C A-65
Wilmington, NC 28402-0780
USA

T 910 675 6192
F 910 362 6192
rick.kingston@ge.com

Proprietary Notice

This letter forwards proprietary information in accordance with 10 CFR 2.390. Upon the removal of Enclosure 2, the balance of this letter may be considered non-proprietary.

MFN 09-310

Docket No. 52-010

May 14, 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 18.11-29 S03

The purpose of this letter is to submit the GE Hitachi Nuclear Energy (GEH) response to portion of the U.S. Nuclear Regulatory Commission (NRC) Request for Additional Information (RAI) NRC letter No. 310, dated February 26, 2009 (Reference 1). Verified LTR changes associated with this RAI response are identified in the enclosed markups by enclosing the text within a black box.

Enclosure 1 provides the GEH response to the subject RAI as requested in Reference 1. Enclosures 2 and 3 provide the associated document markups.

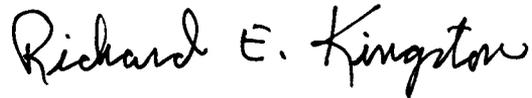
Enclosure 2 contains GE Hitachi Nuclear Energy (GEH) proprietary information as defined by 10 CFR 2.390. GEH customarily maintains this information in confidence and withholds it from public disclosure. A non-proprietary version is provided in Enclosure 3.

The affidavit contained in Enclosure 4 identifies that the information contained in Enclosure 2 has been handled and classified as proprietary to GEH. GEH hereby requests that the information of Enclosure 2 be withheld from public disclosure in accordance with the provisions of 10 CFR 2.390 and 9.17.

DOES
NRO

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

Sincerely,



Richard E. Kingston
Vice President, ESBWR Licensing

References:

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

Enclosures:

1. MFN 09-310 - 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 18.11-29 S03
2. MFN 09-310 - Markups for 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 18.11-29 S03 – Proprietary Version
3. MFN 09-310 – Markups for 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 18.11-29 S03 – Non-Proprietary Version
4. Affidavit – David H. Hinds, dated May 14, 2009

cc: AE Cabbage USNRC (with enclosure)
 RG Head GEH/Wilmington (with enclosure)
 DH Hinds GEH/Wilmington (with enclosure)

eDRF Section 0000-0100-5580 (RAI 18.11-29 S03)

Enclosure 1

MFN 09-310

**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 18.11-29 S03**

NRC RAI 18.11-29 S03

The approach to data analysis and interpretation is described in NEDE-33276P (Rev 2), Section 5.4.7. Based on the review of this material, several follow-up questions were identified:

A. Some of the performance measures described in NEDE-33276P (Rev. 2), Section 5.4.4 are to be used to directly validate or fail the design. Others are used to provide a richer context within which to interpret the findings. Specifically, which measures fall into the first category?

B. For many of the measures, the NEDE-33276P (Rev 2) states that quantitative analysis will be performed. Precisely what type of analysis will be performed and how will it be determined whether the design is validated or not.

C. For task level measures, the analysis compares TA results to performance during observed integrated system validation scenarios. Shouldn't observed performance be compared with the acceptance criteria? Please clarify specifically what this means.

D. Reference is made to the use of margins of error (p.77). Will this be factored into the assessment of whether the design meets the acceptance criteria?

GEH Response

A. Which performance measures directly validate or fail the design (Decisive) and which provide context to interpret the findings (Supplemental)?

The intent of section 5.4.4 is to distinguish two types of measures: (a) Decisive (pass-fail) and (b) supplemental. The current wording of the section is not clear to this distinction, and will be revised as described in Attachment A.

In addition to the changes to section 5.4.4, section 5.4.3.7 was revised to establish the acceptance criteria for the HRA/PRA decisive performance measure. This is depicted in Attachment A.

B. What type of quantitative analysis will be performed on performance measures? How will the quantitative analysis be used to validate the design?

Section 5.4.7 makes multiple references to quantitative and qualitative analysis.

The type of quantitative analysis is simple comparison of a measured quantity to a derived criterion value. The term was used to distinguish this from a qualitative analysis

that depends on the subjective judgment of test personnel or participants. GEH agrees that better description of how performance measures validate the design is needed.

The following changes to NEDO/NEDE 33276P clarify the performance measures and acceptance criteria.

The individual sections 5.4.4.2, 5.4.4.2.2, 5.4.4.3, and 5.4.4.3.2 describing performance measures are revised to clarify the performance measure, acceptance criteria, and how the criteria are applied. This is depicted in Attachment B.

For clarification, the term quantitative and qualitative analysis in section 5.4.7 will be replaced with a phrase that references or describes the criteria. The resulting changes are provided in Attachment B.

C. Clarify what is meant by comparing TA results to performance rather than comparing performance to acceptance criteria.

Paragraph 5.4.7 states that the data analysis and interpretation of the task level performance measures uses *the TA results as compared to performance* during observed integrated system validation scenarios.

Literally this is what the analysis will do. As described paragraph 5.4.4.3 of the NEDO/NEDE 33276P, the TA results are the basis for the Task level criteria.

Thus, for critical tasks in the scenario, test personnel will confirm the sequence of component manipulation as described in the task analysis with the actual component sequence observed.

To avoid confusion, paragraph 5.4.7 will be revised as described in Attachment C to clarify the Task level data analysis.

D. Will a margin of error be factored into the assessment of whether the design meets the acceptance criteria?

There is no margin of error factored into the assessment of whether the design meets the acceptance criteria. The criteria for the plant level acceptable performance (see section 5.4.4 Performance Measures) is based on what is required to achieve the goals of the scenario and is the same for the real world and the test environment since the goals are based on real world constraints.

However, marginal task performance is always assessed. The third decisive criteria category, Personnel task, in addition to a passing and failing level, contains an assessment level where acceptable test performance is achieved, but personnel task issues are observed. With an intermediate score on the Personnel Task Assessment (see section 5.4.4.3), as well as an identified concern on any of the supplemental performance measures that are collected (see sections 5.4.4.4 through 5.4.4.7), potential discrepancies are recorded as HEDs. Where design characteristics are contributing factors in a discrepancy, resolutions are required.

There are no DCD or LTR changes from the Part D response.

DCD Impact

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

LTR NEDE-32376P, Rev 3 will be revised as noted in the attached markup.

MFN 09-310

Enclosure 3

**Markups for Response to Portion of NRC Request for
Additional Information Letter No. 310 Related to ESBWR
Design Certification Application**

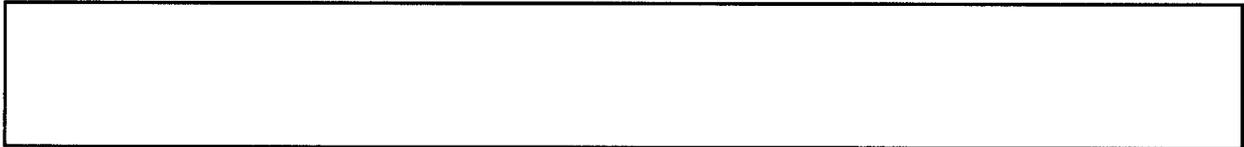
Chapter 18 - Human Factors Engineering

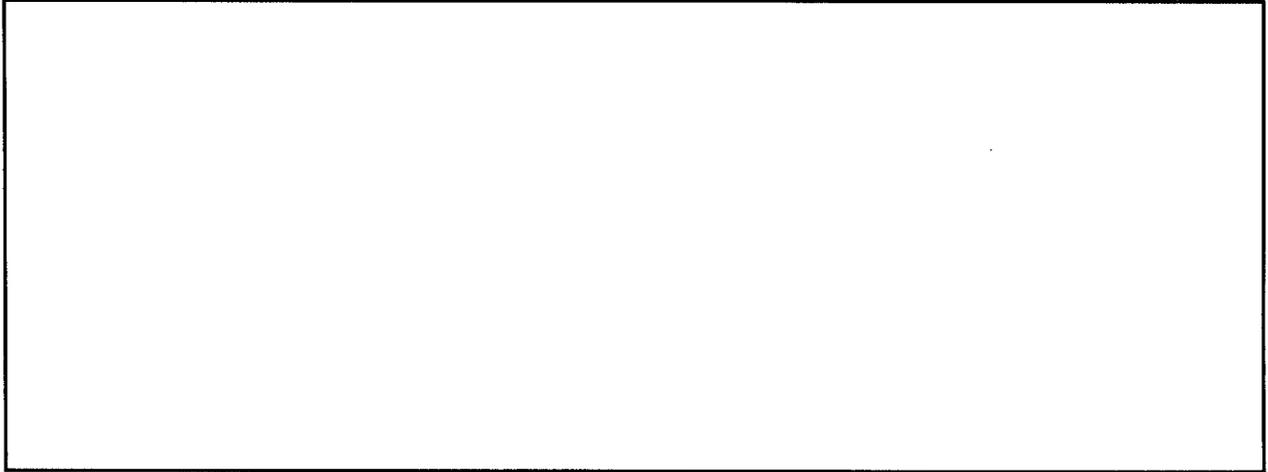
RAI Number 18.11-29 S03

Non-Proprietary Version

plant evolutions or transients, reinforce team concepts, and identify the role each individual plays within the team.

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5.4.3.13 *Staffing Objectives*

Staffing for the performance of integrated system validation testing scenarios uses licensed personnel for crewmembers or participants enrolled in training classes for the purpose of ESBWR licensing. Crews are selected to ensure that both experienced and new operators are evaluated and provide input regarding the HSI. Test participants are not allowed to act as a crewmember in a given scenario more than once.

Scenario events and tasks that result in common problems for test participants are documented as HEDs in HFEITS to track the HFE or HSI factors that are changed to resolve the problem. Tasks that result in the failure of the plant or crew to meet established acceptance criteria are also added as HEDs and tracked to resolution in HFEITS.

5.4.4 Performance Measures

A hierarchal set of performance measures are selected to assess the adequacy of the integrated system. The plant/system performance measures selected for integrated validation are selected based on the prevention or mitigation of transients and accidents, as described in DCD Tier 2, Chapter 15 - Transient Analysis. Tasks and events with high HRA/PRA risk significance are selected for measurement. Two types of performance measures are defined for the integrated system validation: (1) Decisive measures are used to pass or fail the validation test for the scenario under investigation thus confirming that the integrated elements of the design are effective in achieving the goals of the scenario, and (2) Supplemental measures are collected to provide additional information in support of validation efforts and to refine/enhance the design.

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Supplemental performance measures are developed to provide additional dimensions of information. A multidimensional approach to integrated system validation allows test personnel to view data outcomes in a richer context. This creates a greater understanding of crew performance in the varying scenario conditions, leading to more valid, well-informed conclusions and to an increased ability to diagnose and fix performance problems.

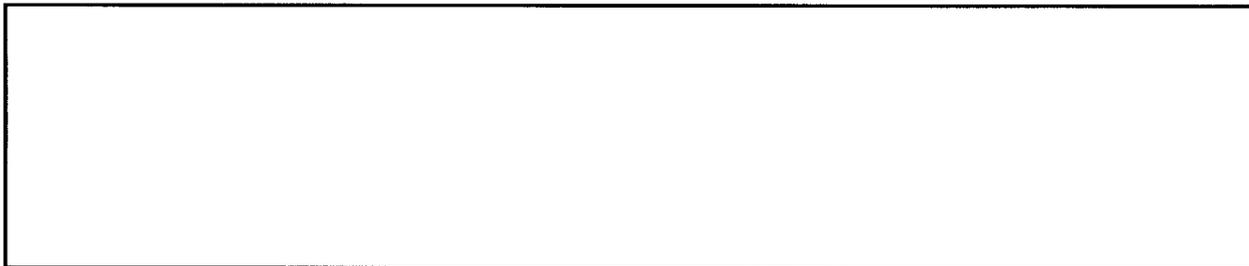
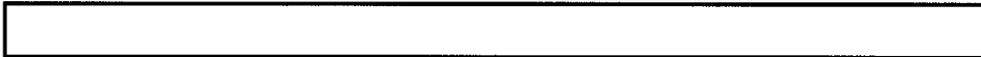
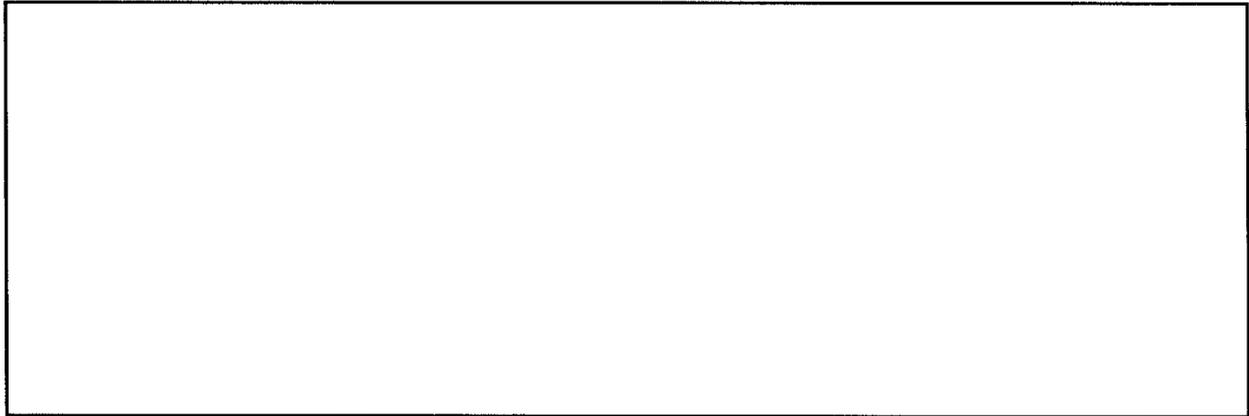
Supplemental performance measures are primarily used to provide additional information regarding the results of other performance measures. Significant problems in these areas are evaluated and addressed as well. Potential performance concerns identified in supplemental measurement areas are evaluated in the context of overall scenario performance and HEDs are written if needed. Supplemental measures include:

- Crew communication and coordination.
- Situation awareness.
- Workload (both physical and cognitive).
- Anthropometrics and physiological factors.

Satisfactory completion of integrated system validation and its associated performance measures, and criteria validates the ESBWR HSI and the context in which it is used. This includes automation, training, procedures, and staffing and qualifications.

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5.4.7 Data Analysis and Interpretation

Data analysis is conducted in accordance to the established four-tier hierarchical set of performance measures with the greatest weight placed on data coming from the highest performance measure tiers. Analysis is dependent on the type and quality of data that can be acquired. Actual data collection and analysis may be subject to variation during the course of testing.

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For each tier, it can be seen that the performance measures and their associated criteria range from pass/fail ~~quantitative analysis~~ decisive criteria at the highest significance level ([[]]) to a ~~qualitative analysis~~ at the supplemental criteria level.

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To provide additional information, timelines and movement pattern diagrams (when applicable) for each crew are constructed for each simulated scenario using video recordings and visual observation records. Test participants may provide assistance by interpreting videotaped sessions and interrelating recorded events with test data.

The resulting timelines and movement pattern diagrams are evaluated by qualified test personnel to assess the correctness, timeliness, and completeness of responses to scenarios. The information gathered from these evaluations is used to better understand the results of higher tier performance measures.

Additional information collected by test personnel observations regarding qualitative assessments of influencing factors such as lighting level, noise level, communication clarity, HSI information clarity, and other factors that influence detection, analysis, planning and implementation of actions may also be used to better understand results and data.

For performance measures used as pass/fail indicators, failed indicators must be resolved before the design can be validated. Where performance does not meet criteria for supplemental performance measures, the results are evaluated using the HED resolution process.

When making inferences from observed performance to estimated real-world performance, test personnel allow for a margin of error (some allowances are made to reflect the fact that actual performance may be slightly more variable than observed validation test performance).

Verification

Analysis inputs are verified by comparing test personnel observations to each other and by comparing personnel observations to the computer-generated event logs. Data analysis and the conclusions drawn are independently verified.

Establishing Convergent Validity

During data evaluation and analysis, convergent validity can be established by comparing data from performance measures that are intended to measure the same or closely related aspects of performance. For instance, SA ratings from test participants should have moderate to high association with SA ratings from test personnel. Likewise, posture data obtained from physical workload performance measures should have moderate to high association with related anthropometric data.

If instances occur in which two performance measures that are intended to measure the same thing have no apparent association, a HED is entered into the HFEITS.

Controlling Bias

ESBWR subject matter experts and human factors specialists control bias during evaluation stages of design and during validation and verification. The intent is to eliminate sources of bias. When that is not possible, sources of bias are measured, and are included as additional predictors in statistical analysis to statistically control for bias.

MFN 09-310

Enclosure 4

Affidavit

Hitachi Nuclear Energy Americas LLC

AFFIDAVIT

I, **David A. Piepmeyer**, state as follows:

- (1) I am the Senior Project Manager, ESBWR Engineering, 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 2 of GEH’s letter, MFN 09-310, 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 18.11-29 S03*, May 15, 2009. GEH text proprietary information in Enclosure 2, which is entitled “*Markups for 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 18.11-29 S03*”, is identified by a underline inside 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, Critical Mass Energy Project v. Nuclear Regulatory Commission, 975F2d871 (DC Cir. 1992), and Public Citizen Health Research Group v. FDA, 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 15th day of May, 2009.



David A. Piepmeyer
Hitachi Nuclear Energy Americas LLC