

December 14, 2007

Mr. Robert E. Brown
Senior Vice President, Regulatory Affairs
GE-Hitachi Nuclear Energy Americas, LLC
3901 Castle Hayne Rd MC A-45
Wilmington NC 28401

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION LETTER NO. 125 RELATED TO
ESBWR DESIGN CERTIFICATION APPLICATION

Dear Mr. Brown:

By letter dated August 24, 2005, GE-Hitachi Nuclear Energy Americas, LLC (GEH) submitted an application for final design approval and standard design certification of the economic simplified boiling water reactor (ESBWR) standard plant design pursuant to 10 CFR Part 52. The Nuclear Regulatory Commission (NRC) staff is performing a detailed review of this application to enable the staff to reach a conclusion on the safety of the proposed design.

The NRC staff has identified that additional information is needed to continue portions of the review. The staff's request for additional information (RAI) is contained in the enclosure to this letter.

To support the review schedule, you are requested to provide the requested additional information within 45 days of the date of this letter.

If you have any questions or comments concerning this matter, you may contact me at 301-415-3179 or ixb3@nrc.gov or you may contact Amy Cubbage at (301) 415-2875 or aec@nrc.gov.

Sincerely,

/RA/

Ilka Berrios, Project Manager
ESBWR/ABWR Projects Branch 1
Division of New Reactor Licensing
Office of New Reactors

Docket No. 52-010

Enclosure: Request for Additional Information

cc: See next page

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ESBWR DESIGN CERTIFICATION APPLICATION

Dear Mr. Brown:

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**Request for Additional Information (RAI)
ESBWR Design Control Document (DCD)
Chapter 18 “Human Factors Engineering”**

RAI Number	Reviewer	Question Summary	Full Text
18.2-10 S02	Bongarra J	Clarify if the documents addressing general process management tools will be submitted as part of the design certification.	<p>GEH’s response to RAI 18.2-10 does not adequately address the staff’s question. GEH has not provided any detail or referenced specific items.</p> <p>NEDO-33217, Rev. 3, Section 3.1.4.2, #6 of the implementation plan identified process management tools and indicates that these are discussed in Section 4 of the document describing the technical program. However, in MFN 07-428, GEH indicated to the staff that they plan to significantly revise the section of the plan addressing the technical program. GEH provided a markup of the plan’s table of contents providing a high-level overview of the changes planned. Please submit Rev. 4 of the plan incorporating these changes.</p>
18.2-18	Bongarra J	Identification of Detailed Implementation Plans.	<p>Review Based on NEDO-33217P, Rev. 3:</p> <p>In MFN 07-428, GEH indicated to the staff that they plan to significantly revise the section of the plan addressing the technical program. GEH provided a markup of the plan’s table of contents providing a high-level overview of the changes planned. These changes will be implemented in Rev. 4 of the plan which has not yet been submitted for staff review. Thus, this criterion will be reviewed upon receipt of the revised plan. The revised plan should reference each of the Human Factors Engineering (HFE) activity detailed implementation plans for detailed methodology descriptions.</p>
18.2.19	Bongarra J	Identification of Tier 2* information.	<p>The staff has determined that the material contained in NEDO-33217, Rev 3 and in the detailed implementation plans for the HFE activities reviewed in Sections 18.3 through 18.13 provide the basis for the staff’s safety determination. This NEDO and the implementation plans should be identified as Tier 2* in the DCD.</p>

RAI Number	Reviewer	Question Summary	Full Text
RAI 18.4-16 S02	Bongarra J	Parts of the original RAI are still open.	<p>The staff asked for additional information in RAI 18.4-16. Some parts were addressed, but the following parts of the original RAI are still open:</p> <p>(b) This is a follow-up to RAI 18.4-16. This section contains many criteria for allocating functions. Most are stated at a very general level. Are more specific criteria available for analysts to use as part of the decision making process?</p> <p>(f) This is a follow-up to RAI 18.4-16. For non-safety functions for which configuration change is required during normal or emergency operations, the methodology assumes the function will be handled by the Plant Automation System (see Figure 3). It would seem that the same set of human performance considerations should be made here as for safety functions. Please clarify the rationale for using the Plant Automation System as this is not clearly presented in NEDO-33220, Rev 1.</p>
RAI 18.4-21 S01	Bongarra J	Clarify the role of NEDO-33220.	Please clarify the role of NEDO-33220, Rev 1, Appendix A. For example, how does the analyst use HRA significance to conclude that automation is desirable? There is some guidance for several human performance considerations (from NUREG/CR-2623) in Appendix A of NEDO-33220, Rev 1, but the appendix is not referenced in the FRA Implementation Plan and the list of considerations in the Appendix is not the same as those presented in the Implementation Plan description.
RAI 18.4-25 S01	Bongarra J	Clarify and update DCD Section 18.4.2.	The content of 18.4.2 is not consistent with NEDO-33220, Rev 1. Please clarify and update DCD Section 18.4.2.

RAI Number	Reviewer	Question Summary	Full Text
RAI 18.7-7 S02	Bongarra J	Parts of the original RAI are still open.	<p>The staff asked for additional information in RAI 18.7-7 regarding the PRA/HRA which was addressed; however, the following parts of the original RAI are still open:</p> <p>2. Table 19.1-3, Importance Analysis Results, is not discussed or explained in the text of Ch. 19. Col. 2 of the Table gives the basis for inclusion of items in the Table as RAW, FV, and CCF, but does not list values or selection criteria. Rev. 2 of Plan gives acceptance criteria as FV greater than 0.1 and RAW of 2.0 for both CDF and LERF. However, these criteria are not specifically linked to the RI HAs. This should be clarified.</p> <p>8. The row for Human Actions in Table 19.2-1 states that “No operator actions are required for safety function success in the ESBWR for the first 72 hours of an event.” This is a deterministic statement. What does the PRA analysis show? Are the important HAs, as identified in the PRA, from the pre-72 hour regime? This RAI was not satisfactorily answered. Please provide a response.</p> <p>9. For Item 2b in Table 19.2-3 (spurious actuation of GDCS deluge to containment) was an error of commission modeled in the PRA? The Roadmap answer provided a discussion of the EOC method used for the HRA but didn’t answer the specific question related to Item 2b.</p>
RAI 18.7-8 S 02	Bongarra J	Provide the IMs and the criteria to be used for determining the risk important HAs.	<p>NEDO-33267, Section 4, states that, "These analyses will use a variety of importance measures and HRA sensitivity analyses assumptions to ensure that risk important actions are not overlooked." However, the particular importance measures to be used and the acceptance criteria (or cutoff values), for determining which human actions (HAs) are risk important, are not given in the report. It is noted that cutoff values, using the risk achievement worth (RAW) and Fussell-Vesely (FV) importance measures (IMs), are specified in DCD Tier 2, Section 19.5.2 for important SSCs. Please provide the IMs and the criteria to be used for determining the risk important HAs. Rev. 2 of the Plan (33267) cites a RAW value of > 2.0 and a FV of > 0.1 in Section 3.2.1. Clarify that these are the criteria for selection of the R-I HAs that will be addressed in the HFE Program.</p>

RAI Number	Reviewer	Question Summary	Full Text
RAI 18.7-9 S03	Bongarra J	Clarify why NEDO-33267 does not specifically commit to use all of these analyses in determining the risk important HAs.	The ESBWR PRA, as submitted, includes both Level 1 and Level 2 analyses and both internal and external events analyses. Clarify why NEDO-33267 does not specifically commit to use all of these analyses in determining the risk important HAs. The RAI response dated 10/1/2007 states that the following bullet will be added to Section 1.2, Scope of NEDO-33267 "Using both the ESBWR PRA level 1 and level 2 analyses and both internal and external events analysis to determine the risk important HAs. The approach for determining risk importance of human actions is described in section 3.2.1." Also, the DCD, Chapter 18.7.2 states that the process for determining the risk-important HAs includes the use of level 1, level 2, internal and external events, and the low power and shutdown PRA. This is acceptable, but the Plan should be revised per the RAI and should be clear on how all of these portions of the PRA will be used to compute the actual list of R-I HAs.
18.11-7 S01	Bongarra J	Criteria for task support verification	In the original RAI, the staff requested clarification as to what criteria were to be used in task support verification. GEH's response referred to their response to RAI 18.11-5. The staff followed up indicating that RAI response addresses the criteria for selecting tasks. This original RAI requested clarification of the criteria to be used to evaluate the Human-Systems Interfaces (HSIs) that support tasks. However, the material is unchanged in NEDO-33226, Rev. 1. Thus the RAI remains open. Please provide such clarification.
18.11-8 S01	Bongarra J	Task support verification methodology	Follow-up RAI based on NEDO-33226, Rev. 1: In the original RAI, the staff requested clarification as to which organization(s) are responsible for task support verification and why the evaluation appears limited to drawings and computer-generated displays. GEH's response referred to their response to RAI 18.11-2 and 18.11-5. The staff followed up indicating that those RAI responses do not pertain to this question. However, the material is unchanged in NEDO-33226, Rev. 1.

RAI Number	Reviewer	Question Summary	Full Text
18.11-13 S01	Bongarra J	HFE design verification methodology	<p>In the original RAI, the staff requested clarification of various aspects of HFE Design verification in NEDO-33226. GEH's responses and changes in Rev. 1 to items B and D were acceptable. The following questions remain:</p> <p>Regarding A. Section 4.3.4.1 discusses HFE design verification for panel anthropometrics. Rather than discussing the comparison of panel characteristics to HFE guidelines, the section discusses the validation of operator actions. Thus it is unclear how the verification will be performed.</p> <p>Regarding C. Section 4.3.4.3 discusses HFE design verification for HSI components. Rather than discussing the comparison of HSI characteristics to HFE guidelines, the section discusses verification criteria such as ease of monitoring and usability. Thus it is unclear how the verification will be performed. Thus, the RAI remains open.</p>
18.11-19 S01	Bongarra J	Simulation of remote actions	<p>Section 4.3.4.1 of NEDO-33226, Rev. 1, indicates that actions at local system control stations are evaluated using drawings or mockup panels, but no information as to what evaluations are performed or how the actions will be analyzed. This statement is in the HFE Design Verification section rather than an Integrated System Validation section. Beyond this statement, no information about the treatment of local actions is provided. Please provide information as to how these actions will be modeled and evaluated for validation.</p>
18.11-21 S01	Bongarra J	Participants and Validation Tests	<p>NEDO-33276, Rev 1, Section 4.4.3 generally discusses participants in validation exercises. However, several aspects of participant selections are not identified in the plan:</p> <ul style="list-style-type: none"> • how the sample of participants will account for human variability • how minimum and normal crew configurations will be assembled and what they will consist of • how sampling bias will be prevented <p>NEDO-33276 should be revised to provide the information or indicate that the detailed V&V implementation plan will address these participant sampling considerations.</p>

RAI Number	Reviewer	Question Summary	Full Text
18.11-23 S01	Bongarra J	Measurement characteristics	In the original RAI, the staff requested information on measurement characteristics. GEH's response to the RAI indicated that the level of detail in the implementation plan was not intended to discuss measurement characteristics. Such details can be provided at a later date (consistent with a programmatic level of review). However, NEDO-33276, Rev. 1, does not provide a commitment to address measurement characteristics in a detailed verification and validation (V&V) plan. Thus this RAI remains open.
18.11-24 S01	Bongarra J	Selection of performance measures	In the original RAI, the staff requested information on the selection of performance measures. GEH's response to the RAI and revision to NEDO-33276 provided some clarification of how automation will be addressed. While the details of performance measurement selection can be provided at a later date (consistent with a programmatic level of review now), NEDO-33276, Rev. 1, does not provide a clear picture of the range of measures to be used. Please provide additional clarification.
18.11-25 S01	Bongarra J	Clarify procedures and displays aspects of automation	GEH's response to the RAI and NEDO-33276, Rev. 1, provided some clarification of how automation will be addressed, but the procedures and displays aspects of this RAI were not clarified. Please provide additional clarification.
18.11-26 S01	Bongarra J	Performance criteria	In the original RAI, the staff requested specific acceptance criteria for performance measures. GEH's response to the RAI and the NEDO-33276, Rev. 1, provided high-level clarification for the example mentioned in the RAI, but it did not address the other measures. While detailed criteria can be provided with the detailed V&V plan, high level criteria, such as that given in GEH's response to the example section, should be included in the high-level plan.
18.11-28 S01	Bongarra J	Duplication of scenarios	GEH has not addressed the staff's concern regarding scenario reuse. Further, Section 4.4.9.1, of NEDO-33226, Rev. 1, discusses the presentation of scenarios to crews, but does not address how scenarios will be assigned to crews or scenario sequencing. Please provide a high-level discussion of scenario sequencing and address the staff's concern about scenario reuse.

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18.11-29 S01	Bongarra J	Data analysis	<p>In the original RAI, the staff requested information on GEH's approach to data analysis. In GEH's response to the RAI, new wording was proposed, and that wording has been included in Section 4.4.8 of NEDO-33226, Rev. 1; however, the staff's concern was not addressed.</p> <p>GEH's response states that:</p> <p style="padding-left: 40px;">The methods for analyzing the simulation results will draw from experience in EPRI OER program as summarized in EPRI NP-6560L, which provides estimates of the median response time and the standard deviation associated with different types of cue response as measures of consistency between crews and individuals. Acceptability of the MMIS clarity is that standard deviation falls within the ranges of responses demonstrated in existing plant simulations for multiple crews. For larger deviations between crews an examination of the MMIS for improvement is documented in an HED.</p> <p>This does not appear to be an appropriate means of analyzing validation data. Assuming there will sufficient data to generate reliable statistics; the analysis is based on response variability and a comparison of that variability to the range of responses demonstrated in existing plant simulations. The approach seems to focus on variability alone, and not the acceptability of performance, e.g., are required tasks performed within an acceptable time for plant safety.</p> <p>The approach to analyzing data should focus on whether observed integrated system performance (as defined by the set of performance measures selected for use in validation) is acceptable (as defined by the acceptance criteria for each of the performance measures). Please provide an explanation of the proposed approach to data analysis in light of the staff's concern.</p>

RAI Number	Reviewer	Question Summary	Full Text
18.11-32 S01	Bongarra J	HED resolution methodology	<p>Section 4.6 NEDO-33226, Rev. 1, describes the resolution process for addressing HFE issues identified in V&V. The process is depicted graphically in Figure 4. GEH's process considers the impact on human performance and risk importance of issues from both quantitative (PRA) and qualitative perspectives. Where issues are found to qualitatively impact risk, the methodology seeks to determine if they can be addressed in PRA. While the methodology appears generally complete, there are three points of clarification requested.</p> <p>A. Is there a provision for justifying a discrepancy, e.g., deviation from the style guide with justification?</p> <p>B. In Figure 4, at decision point 4, "Does Issue Meet Style Guide Requirements," actions are described for answering the question as "yes" or "no." However, for some issues meeting the style guide requirements is irrelevant. For example, an issue may be identified in integrated system validation, that a task could not be completed in time due to operator workload. In this case, the style guide requirements are not likely to be related to the issue. Instead, task reallocation to other personnel or automation may be the solution. Why is there no path to follow when the analyst concludes the issue is not related to style guide compliance?</p> <p>C. Another point of clarification relates to the final solutions identified. They appear to be overly restrictive. For example, if an issue cannot be addressed in PRA, the analyst is guided to consider changing training, procedures, or staffing/qualifications. However, as in the example above, task redesign or increased automation may be warranted. Are the proposed solutions limited to those shown in the figure?</p>
18.11-35	Bongarra J	DCD Tier 2 V&V description	<p>The material in DCD Tier 2, Section 18.11, is not completely consistent with NEDO-33276, Rev. 1. For example, the DCD discusses HED identification and resolution, while no such language is used in the NEDO. Also, the DCD does not reference the V&V implementation plan. Please update the DCD accordingly.</p>

RAI Number	Reviewer	Question Summary	Full Text
18.12-2 S01	Bongarra J	Acceptance criteria	<p>A question was raised in the original RAI concerning the acceptance criteria for final design verification. In GEH's response, they indicated the criteria are derived from the "ESBWR style guide," which is included in the "HF Guidance manual." NEDO-33278, Rev. 2, states that the criteria for final design verification will be derived from an "HSI Report." Please clarify what specific document will be used for the criteria to determine that the as-built design is acceptable.</p>
18.12-3 S01	Bongarra J	Methodology for HSI as-built verification	<p>GE's response to RAI 18.12-2 indicates that the style guide will provide acceptance criteria. The staff expects these criteria to be applied by verifying that the as-built design conforms to these criteria. The staff expected the verification to be made using the HFE Style Guide. Yet GEH's response to this RAI discusses procurement documents and the HSI Report. Please explain in more detail the HSI Report and the acceptance criteria for the final design implementation verification.</p> <p>NEDO-33278, Rev. 2, describes a final design verification methodology that appears to be based on a review of documentation rather than a review of the actual as-built design. Section 3.1.4, "General Approach" indicates that the review is conducted on documents. The individual implementation sections are all consistent with this general approach and focus on documents, not the implemented design. As per NUREG-0711, Section 12.4.6, criterion 2, it should be the design itself, as-built that is verified against the design documentation. Verifying documents with documents only establishes that the documents are in agreement, not that the controls and displays in the control room are in agreement with the design documentation. Provide justification of the proposed approach to address this concern.</p>

RAI Number	Reviewer	Question Summary	Full Text
18.12-4 S02	Bongarra J	Relative roles of the COL and GEH and as-built design verification	<p>GEH's RAI response acceptably addressed the role of the COL and GEH as part of the HFE team. However, in reviewing NEDO-33278, Rev. 2 of the plan two follow up questions were identified.</p> <p>(1) Section 1.2 of the plan describes a somewhat different organization than was identified in the RAI response. It states that the verifications are the responsibility of the COLOG. Will the COLOG be the COL license applicant?</p> <p>(2) Section 1.2 of the plan indicates that the verifications described for the plan "apply to the initial COL plants associated with the ESBWR design effort." The staff's position is that "as-built" verifications are needed for every new plant construction. Please explain why only the initial plants will be verified.</p>
18.12-7	Bongarra J	DCD Tier 2 description	<p>Design implementation activities are described in DCD Tier 2, Section 18.12. The Tier 2 description is not fully consistent with NEDO-33278, Rev 2, and should be revised. Note that the resolution of other remaining open 18.12 RAIs may necessitate additional revisions to the DCD.</p>

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