



HITACHI

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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 08-481

Docket No. 52-010

July 2, 2008

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

Subject: Response to Portion of NRC Request for Additional Information Letter No. 178 Related to ESBWR Design Certification Application – Human Factors Engineering - RAI Numbers 18.7-7 S03, 18.7-8 S03, 18.8-2 S02, 18.11-21 S02, 18.11-25 S02, 18.11-32 S02, and 18.12-4 S03

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. 178, dated May 6, 2008 (Reference 1).

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.

RAI 18.7-7 S03 was requested by Reference 1 and was previously responded to in Reference 2, as requested by Reference 3. Reference 5 requested the first supplement responded to by Reference 4. Reference 6 provided the original response, as requested by the NRC in Reference 7.

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RAI 18.7-8 S03 was requested by Reference 1 and was previously responded to in Reference 8, as requested by Reference 3. Reference 5 requested the first supplement responded to by Reference 4. Reference 6 provided the original response, as requested by the NRC in Reference 7.

RAI 18.8-2 S02 was requested by Reference 1 and was previously responded to in Reference 9, as requested by Reference 10. Reference 11 provided the original response, as requested by the NRC in Reference 12.

RAI 18.11-21 S02 was requested by Reference 1 and was previously responded to in Reference 13, as requested by Reference 3. Reference 14 provided the original response, as requested by the NRC in Reference 15.

RAIs 18.11-25 S02 was requested by Reference 1 and was previously responded to in Reference 16, as requested by Reference 3. Reference 14 provided the original response, as requested by the NRC in Reference 15. Note that RAI response 18.11-25 S02 contains proprietary information.

RAI 18.11-32 S02 was requested by Reference 1 and was previously responded to in Reference 2, as requested by Reference 3. Reference 14 provided the original response, as requested by the NRC in Reference 15.

RAIs 18.12-4 S03 was requested by Reference 1 and was previously responded to in Reference 16, as requested by Reference 3. Reference 18 requested the first supplement responded to by Reference 17. Reference 19 provided the original response, as requested by the NRC in Reference 15.

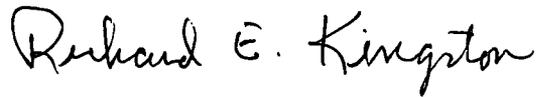
GEH responses to RAIs 18.7-7 S03, 18.7-8 S03, 18.8-2 S02, 18.11-21 S02, 18.11-25 S02, 18.11-32 S02, and 18.12-4 S03 are provided in Enclosure 1.

Also note that these RAI responses correspond to and answer seven open items listed in Reference 20. Please consider these open items to be addressed by this letter.

Verified Licensing Topical Report (LTR) changes associated with these RAI responses are identified in the enclosed LTR markups by enclosed text within a black box. The marked-up pages may contain unverified changes in addition to the verified changes resulting from these RAI responses. Other changes shown in the markup(s) may not be fully developed and approved for inclusion in the respective LTR. RAI responses for 18.7-7 S03 and 18.7-8 S03 were included in DCD Revision 5.

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

Sincerely,



Richard E. Kingston
Vice President, ESBWR Licensing

References:

1. MFN 08-460 - Letter from U.S. Nuclear Regulatory Commission to Robert E. Brown, GEH, *Request For Additional Information Letter No. 178 Related To ESBWR Design Certification Application*, dated May 6, 2008
2. MFN 08-154 - 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 18.2-19, 18.2-20, 18.4-16 S02, 18.4-21 S01, 18.4-25 S01, 18.7-7 S02, 18.11-32 S01, 18.12-2 S01, 18.12-3 S01
3. 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
4. MFN 07-334 - Submittal of “*ESBWR DCD Chapter 18, Human Factors Engineering - RAI to DCD Roadmap Document*”, dated June 27, 2007
5. Email from AE Cabbage to DL Lewis, *List of Chapter 18 RAIs for Roadmap Request*, dated May 18, 2007
6. MFN 06-403, *Response to Portion of NRC Request for Additional Information Letter No. 64 – Human Factors Engineering – RAI Numbers 18.7-1 through 18.7-15*, dated October 27, 2006
7. MFN 06-352, Letter from U.S. Nuclear Regulatory Commission to David Hinds, *Request for Additional Information Letter No. 64 Related to ESBWR Design Certification Application*, dated September 25, 2006
8. MFN 08-298, *Response to Portion of NRC Request for Additional Information Letter No. 125 Related to ESBWR Design Certification Application – Human Factors Engineering - RAI Numbers 18.7-8 S02 and 18.7-9 S03*, dated March 28, 2008
9. MFN 08-050, *Response to Portion of NRC Request for Additional Information Letter No. 119 Related to ESBWR Design Certification Application – Human Factors Engineering - RAI Numbers 18.8-2 S01, 18.8-8 S02, 18.8-16 S02, 18.8-17 S02, 18.8-18 S02, 18.8-31 S02, 18.8-32*

- S02, 18.8-33 S02, 18.8-35 S02, 18.8-41 S02, 18.8-49 S02 and 18.8-50 through 18.8-59, dated March 11, 2008*
10. MFN 07-657, *Request for Additional Information Letter No.71 Related to ESBWR Design Certification Application, dated October 10, 2007*
 11. MFN 06-443, *Response to Portion of NRC Request for Additional Information Letter No. 71 – ESBWR Human Factors Engineering NEDO-33268, Rev. 1, Human-System Interface Design Implementation Plan – RAI Numbers 18.8-1 through 18.8-49, dated November 20, 2006*
 12. MFN 06-383, *Request for Additional Information Letter No.119 Related to ESBWR Design Certification Application, dated December 5, 2007*
 13. MFN 08-281, *Response to Portion of NRC Request for Additional Information Letter Nos. 125 Related to ESBWR Design Certification Application - Human Factors Engineering - RAI Number 18.11-21 S01, dated March 26, 2008*
 14. MFN 06-446, *Response to Portion of NRC Request for Additional Information Letter No. 74 – ESBWR Human Factors Engineering NEDO-33276, Rev. 0, HFE Verification and Validation Implementation Plan – RAI Numbers 18.11-1 through 18.11-33, dated November 22, 2006*
 15. MFN 06-386, *Request for Additional Information Letter No.74 Related to ESBWR Design Certification Application, dated October 11, 2006*
 16. 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*
 17. MFN 07-499, *Response to Portion of NRC Request for Additional Information Letter No. 105 Related to ESBWR Design Certification Application - ESBWR Human Factors Engineering – RAI Numbers 18.4-1 S02, 18.4-7 S02, 18.7-9 S02, and 18.12-4 S01, dated October 1, 2007*
 18. MFN 07-460, *Request for Additional Information Letter No.105 Related to ESBWR Design Certification Application, dated August 16, 2007*
 19. MFN 06-447, *Response to Portion of NRC Request for Additional Information Letter No. 74 Related to ESBWR Design Certification Application – ESBWR Human Factors Engineering NEDO-33278, Rev. 1, ESBWR HFE Design Implementation Plan - RAI Numbers 18.12-1 through 18.12-6, dated November 18, 2006*
 20. MFN 08-194 - *Letter from U.S. Nuclear Regulatory Commission to Robert E. Brown, GEH, Economic Simplified Boiling Water Reactor (ESBWR) Chapter 18 Open Items, dated February 28, 2008*

Enclosures:

1. MFN 08-481 -Response to Portion of NRC Request for Additional Information Letter No. 125 Related to ESBWR Design Certification Application - Human Factors Engineering - RAI Numbers 18.7-7 S03, 18.7-8 S03, 18.8-2 S02, 18.11-21 S02, 18.11-25 S02, 18.11-32 S02, and 18.12-4 S03 – Proprietary Version
2. MFN 08-481 -Response to Portion of NRC Request for Additional Information Letter No. 125 Related to ESBWR Design Certification Application - Human Factors Engineering - RAI Numbers 18.7-7 S03, 18.7-8 S03, 18.8-2 S02, 18.11-21 S02, 18.11-25 S02, 18.11-32 S02, and 18.12-4 S03 – Non-Proprietary Version
3. MFN 08-481 - Affidavit

Attachment:

1. MFN 08-481, Attachment 1-Markups and Added Text for RAIs

cc: AE Cabbage USNRC (with enclosure)
RE Brown GEH/Wilmington (with enclosure)
DH Hinds GEH/Wilmington (with enclosure)
GB Stramback GEH/San Jose (with enclosure)
eDRF 0000-0085-2700

Enclosure 2

MFN 08-481

Response to Portion of NRC Request for Additional

Information Letter No. 178 Related to ESBWR

Design Certification Application

Human Factors Engineering

RAI Numbers

**18.7-7 S03, 18.7-8 S03, 18.8-2 S02, 18.11-21 S02, 18.11-25
S02, 18.11-32 S02, and 18.12-4 S03**

Non-Proprietary Version

Do Not Electronically Transmit

For historical purposes, the original text of RAIs 18.7-7, 18.7-8, 18.8-2, 18.11-21, 18.11-25, 18.11-32, and 18.12-4 and any previous supplemental text and GE/GEH responses are included preceding each supplemental response. Any original attachments or DCD mark-ups are not included to prevent confusion.

RAI Number 18.7-7

NEDO-33267 and DCD Tier 2, Chapter 18.7 state in several places that the PRA/HRA will provide a listing of potentially risk-important human interactions for use in several portions of the HFE program. The initial PRA/HRA for ESBWR has been completed and submitted to NRC along with Chapter 19 of the DCD. Therefore, sufficient information is available to develop the initial list of risk important actions using the methods discussed in this report. The PRA and DCD Chapter 19 provide very informative lists of risk important structures, systems and components (SSCs), however they note in several places that human actions are not included. It is not clear why human actions were excluded from these importance listings and are not in NEDO-33267. Please provide the initial list of risk important human actions.

GE Response

Risk important operator actions developed from the PRA rev. 1 are listed in Tier 2 Chapter 19 Rev 1, September 2006, in Table 19.2-3 on Risk Insights and Assumptions.

The use of the PRA/HRA in human factor engineering (HFE) is an iterative process, and this initial listing will be enhanced with additional actions as the design matures. For example, system level actions that are included within system level reliability models of the design level PRA do not specifically separate the automatic versus manual actions. This use of generic failure rate estimates for the structures, systems and components is adequate for estimating the overall risk in terms of the top down level 1 and 2 PRA. However, an enhanced listing of human actions requires the allocation of manual versus automated actions in each system and modeling within the PRA to expand the initial risk importance listing.

The HRA plan indicates that a process will be established to enhance this listing as an iterative tool to pass between the HFE/HRA assessments and the PRA/HRA risk evaluation. The list will be dynamic as HSI design features are established, and will be upgraded as the design details are established and modeled in the PRA. Listings of risk important actions in Table 19.2-3 will be further enhanced through implementation of the HFE HRA plan.

Reference to Table 19.2-3 in Tier 2 Chapter 19 Rev 1, September 2006 will be provided in the next revision to section 5.2 second paragraph of NEDO-33267.

“The initial baseline ESBWR PRA study which is described in the ESBWR DCD Chapter 19 will be used as the starting point for defining risk important human actions (e.g., Table 19.2-3 in Tier 2 Chapter 19 Rev. 1, September 2006).” Also the reference for chapter 19 will be updated.

DCD/LTR Impact

LTR NEDO-33267, Rev 0 will be revised as described above.

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

RAI Number 18.7-7 Supplement 1

The response refers to the updated Chap. 19, Rev. 1 and specifically Table 19.2-3. The initial list of R-I HAs, that was requested in the RAI, was not provided. The updated Chap. 19 and PRA/HRA still appear to have in HA modeling that may limit the ability to correctly identify the R-I HAs. This should be improved, as necessary, so that the R-I HAs can be identified and so that the design process can appropriately address R-I HAs. We did note that Table 18-2 of the PRA includes HAs and contains both RAW and F-V importance values. Examples of issues: 1. From the RAI response "...system-level actions that are included within system level reliability models of the design level PRA do not specifically separate the automatic versus manual actions..., an enhanced listing of human actions requires the allocation of manual versus automated actions in each system and modeling within the PRA to expand the initial risk importance listing." Without such separation, how can R-I manual actions (such as manual actuation upon automation failure) be identified. 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, CCF but does not list values or selection criteria. 3. Operator actions are not clearly identified in Table 19.1-3, for example N21, condensate and feedwater valves are listed, but it is not clear if they are auto or manually operated. 4. In justifying the less than complete status of the PRA, Section 19.2.1 states that "...many aspects of assessing human actions cannot be analyzed in absence of a physical, operating plant and operation staff." This is true but other shortcomings, as in example #1 above, do not require an operating staff to model. Section 19 overall discusses the use of PRA insights for design decisions. However, this could be compromised by the limited nature of HA modeling. For example insights related to functional allocation between operators and automation may be lost. 5. In the discussion of Significant CD sequences in Section 19.2.3.1.1, it is not always clear whether actions are automatic or performed by operators (e. g., injection with CRD pumps). 6. The RAI response referred to Table 19.2-3 for important operator actions, but that Table includes all risk insights and assumptions. Thus, it is not clear which items are the risk-important operator actions. And the dispositions for HAs in the Table would not seem to include all activities for these actions that would be called out by the implementation plan. 7. Table 19.2-3 appeared to be incomplete. For example, operator actions noted in Section 19.2.3.1.2 (Significant Large Release Sequences) related to LERF for minimizing water accumulation in lower drywell with core in vessel are not listed in Table 19.2-3. The dominant operator actions for internal shutdown fires from Sec. 18.4.3 of the ESBWR PRA are not included in the Table. 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? 9. For Item 2b in Table 19.2-3 was an error of commission modeled in the PRA?

GEH Response

Chapter 18 Roadmap Document								
RAI NO	SEC	#	NRC Supplemental	DocName/Question	Resolved	Plan	Section	Resolution Description
18.7-7	7	7	N	LTR NEDO-33267	From GE response	33267	4.2	Para change per RAI
18.7-7	7	7.0	Y	Risk-important (R-I) Human Actions (HAs)	From GE response	33267	3.2.1 4.2	The initial list of human actions with a potential for risk contribution will be in the phase 0 HRA summary report. The criteria and approach for determining risk important human actions are provided in section 3.2.1 and the process for identifying additional actions through interaction with the HFE tasks is addressed in the third paragraph of section 4.2.
	7	7.1	Y	Issue 1- manual v. auto actions	From GE response	33267	3.1, 4.2	The allocation of functions activity in the operations analysis will establish the manual actions. In the case of the ESBWR the passive features and automation of the safety-related systems virtually eliminate the need for the safety-related human actions required for design basis events (e.g., manually start a safety system). These design features reduce the CDF to a mean value much lower than the plants used as the basis for the NRC risk regions in RG 1.174. As a result the risk boundaries associated with the risk regions in RG 1.174 are far above the ESBWR baseline risk. Hence, the ESBWR basic events representing HIs do not become important contributors to plant

Chapter 18 Roadmap Document								
RAI NO	SEC	#	NRC Supplemental	DocName/Question	Resolved	Plan	Section	Resolution Description
								risk on an absolute basis.
	7	7.2	Y	Issue 2-Table 19.1-3 is not discussed and does not list values or criteria	From GE response	33267	3.2	These will be provided in the HRA initial results summary report for rev 1 of the PRA. Summary: To evaluate the risk impact of the HIs for the beyond design basis events a relative risk approach is used. First, risk sensitive actions that support ESBWR safety for beyond design basis events are identified in both the PRA and through the top down HFE operational analysis. Sensitivity analyses using the FV, RAW and RRW described above on the to basic events related to HIs human action tasks in are used to create a listing of the top risk contributors on a relative basis. This listing is generated in the PRA and is compared with the top down operational analysis to identify gaps and support requantification for the PRA. On a relative scale the HIs with a FV greater than 0.1 and RAW of 2.0 for CDF and LERF are subjected to the greatest detail in the HFE tasks, even though the absolute risk values are far below regions I and II described in NUREG-1764 (NRC, 2004).

Chapter 18 Roadmap Document								
RAI NO	SEC	#	NRC Supplemental	DocName/Question	Resolved	Plan	Section	Resolution Description
	7	7.3	Y	Issue 3-operator actions not clearly identified in Table 19.1-3	From GE response	33267	3.2 4.2	The operating assumption is that these will be automated actions with the operator in a monitoring role with manual backup in the case of automation failure. The allocation of function will complete the determination of manual actions. The approach described in issue 2 is followed for these actions
	7	7.4	Y	Issue 4-with justifying incomplete PRA status, insights related to functional allocation may be lost	From GE response	33267	Figure 3 4.2.2 4.2.3 4.2.4	The functional allocation and detailed task information from the operation analysis are key inputs to the refinement of both the HRA and the PRA. After the initial listing of risk-important human actions from the PRA (labeled PRA/HRA probabilistic importance evaluation in Fig 3), the allocation and task details are used to expand the risk important actions (HRA qualitative evaluation for HFE tasks in Fig 3). This re-analysis is used to update the HRA and PRA (iteration loop).
	7	7.5	Y	It is not clear if actions are manual or automatic in CD sequences in 19.2.3.1.1	From GE response	33267	3.2 4.2	See answer to issues 1, 3, and 4.

Chapter 18 Roadmap Document								
RAI NO	SEC	#	NRC Supplemental	DocName/Question	Resolved	Plan	Section	Resolution Description
	7	7.6	Y	It is not clear from Table 19.2-3 which items are risk-important Human Actions and it seems not to include all activities called for in the HRA implementation plan	From GE response	33267	4.2	The Risk Important actions modeled in the PRA are listed and screened in the HRA initial results summary report. From the ESBWR PRA model as described in DCD Tier 2 Chapter 19 Rev 1, September 2006, Tables 19.1-3, 19.2-1 and 19.2-3 list important components, systems functions, tasks and event initiators considered in the ESBWR PRA model and PRA models of previous BWR designs. Table 19.1-3 lists hardware elements that are important. The human interactions for these hardware elements including manual operation (if assigned in the allocation of functions), maintenance, repair, and backup to automatic functions are defined during the operational analysis by the HFE team. These results are then employed as described in item 18.7-7(4).
	7	7.7	Y	Table 19.2-3 incomplete	From GE response	33267	4.2	The human actions in these events will be identified in the operations analysis. See response to 18.7-7(4).

Chapter 18 Roadmap Document								
RAI NO	SEC	#	NRC Supplemental	DocName/Question	Resolved	Plan	Section	Resolution Description
	7	7.8	Y	No operator actions for first 72 hrs - Is this from PRA? Are human actions in PRA from the pre-72 hrs	From GE response	33267	4.2	The initial baseline ESBWR PRA study is used as the starting point for defining risk-important HA tasks. The ESBWR design objective is to avoid the need for operator actions for the first 72 hours following an initiating event for the design basis events. The types of human actions from the initial PRA are actions such as misposition valve (either latent Type A, or commission type C). These are addressed in initial HRA and are described in the HRA results summary report. The operations analysis will identify and analyze human actions supporting these events. See response for 18.7-7(4).
	7	7.9	Y	Was error of commission modeled in PRA?	From GE response	33267	3.2.3	Errors of commission are addressed as follows: The Risk Important actions modeled in the PRA, are compared with other PRA studies and with important OER events. Data from the OER provide error modes, including potential examples of errors of commission (EOC). The results are listed and screened in the HRA and documented in the HRA results summary report. Errors of commission from the initial results include premature depressurization.

RAI Number 18.7-7 Supplement 2

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:

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.

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.

9. For Item 2b in Table 19.2-3 (spurious actuation of GDACS 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.

GEH Response

Table 19.1-3 was removed from the DCD in revision 4 with the pertinent information restructured in Tables 19.2-2 and 19.2-3.

Also, the PRA referenced in Chapter 19 DCD revision 4 demonstrated that no accidents generated early health effects as considered for a large early release frequency (LERF), thus the PRA team uses the term large release frequency (LRF) to address accident sequences that result in containment releases. For this reason the calculation for LRF is used for measuring the importance of human action instead of the calculation for LERF. The PRA/HRA models will continue to search for LERF sequences.

Comment 2 Discussion

Both quantitative and qualitative tools are used by GEH to develop risk insights for the ESBWR. The risk insights are based on the use of the importance measures Risk Achievement Worth (RAW) and Fussell Vesely (FV) to measure the risk importance of basic events and common cause failures that contribute to the CDF for level 1 and LRF for level 2, internal and external events, and other special PRA models. The risk summary information and insights in DCD Chapter 19 rev 2 were significantly revised with additional information added based on results from Rev. 2 of NEDO-33201 PRA Model which accounted for greater understanding of the design features and operator interface design. The ESBWR PRA defines potentially risk-significant structure, system

or component (SSC) and HI events and information using conservative thresholds such as FV greater than 0.01, and a RAW greater than 5.0 for individual basic events and a RAW greater than 50.0 for common cause failures. The resulting listings of SSCs and HIs in NEDO-33201 Rev 2 section 18 are used to generate the risk insights that are qualitatively provided in Table 19.2-3. Some of the insights from the predecessor PRA models have been addressed through design changes and no longer appear, because the risk values are well below the quantitative PRA risk importance identification values. The HFE design examines all human interactions (HIs) required for each system and mode of operation during the operational assessment, task analysis and HRA. Many of these actions are addressed implicitly in the PRA at a functional level until specifically identified as an automatic system or operator control action as determined in the operational assessment. Once incorporated in the PRA models, any potentially risk important human actions are examined and are kept below the threshold risk measures for FV of 0.1 and for RAW of 2.0 through verification that the design clearly provides the means to identify, plan, and carry out the action within the required timing.

In summary:

The ESBWR PRA defines potentially risk-significant SSC and HI events and information that contribute to CDF and LRF using conservative thresholds such as FV greater than 0.01, and a RAW greater than 5.0 for individual basic events and a RAW greater than 50.0 for common cause failure events. The goal of the HRA and HFE operational analysis in DCD Chapter 18 is to verify that the means are provided in the plant design to keep the quantitative risk importance of all potentially risk important human interactions modeled in the PRA below a FV value of 0.1 and RAW of 2.0. The goals are met by ensuring that information for identifying, planning and implementing the needed action within the time permitted is provided in the design or by providing automated support to carry out the needed action. For example, the operator can identify the need for manual actions through the HSI plan through procedures and training and implement with tools as needed.

The revised approach is added to NEDO-33267, section 3.2.1 as provided in the attached markup. The quantitative thresholds for evaluating the risk importance of human actions are added to DCD Tier 2, Section 19.2.2.1 as noted in the attached markup.

Comment 8 Discussion

The deterministic statement in DCD Revision 4, September 2007, Tier 2, “No operator actions are required for safety function success in the ESBWR for the first 72 hours of an event,” relates to the design goal of providing passive cooling and automatic systems for responding to the DCD Chapter 15 design basis events. These design basis events provide the means for sizing the systems to respond to an initiating event and a single failure except for special initiators such as fire, which go beyond single failures.

The role of the licensed operators in the ESBWR is to be in control of the plant via monitoring with the potential to override the automatic responses to obtain a better path to shutdown, restart, plant operating points and protection of safety barriers than provided

by the automatic system; or as backup to automated system failures that might occur as a result of multiple and common cause failures. Thus, in considering multiple failures in many sequences that go beyond the design basis events, the PRA treats many operator actions combined with failures of the automatic control and protection systems as a basic event. If the sequence becomes important, then the details of the operator interaction during the sequence is explicitly defined and is further evaluated by human factors engineering if identified as risk important. Such specific operator actions occur near the recognition of additional failures and are clearly within the 72-hour regime.

Therefore, by design, operator actions are not required for any safety function success in the ESBWR for the first 72 hours of an event as long as the plant is operated within its design basis. Many important actions can be actuated or inhibited either manually or automatically. Example manual actions in predecessor plants that have automatic initiation in the ESBWR include reactor vessel depressurization, ADS inhibit, actuation of standby liquid control, and equipment alignments for reactor core and suppression pool cooling.

The PRA also addresses cases where the plant is outside the design basis due to hypothetical event sequences that involve multiple failures. In cases where the automatic systems fail, the operators can switch from their normal monitoring functions, to actively control systems that are needed for safe operation of the plant at any time. For rare events in the ESBWR, such as automatic control failures, the operators provide the back up to selected automatic functions. In this way the operator actions can provide another path to shutdown, cooldown, managing the operating point or providing barrier protection than would normally be achieved with reliance only on the automated systems. This use of operators (i.e. manual recovery actions) provides an additional reduction in the frequency of the hypothetical core damage sequences.

The human action section right hand column in Table 19.2-1 will be revised as noted in the attached markup.

Comment 9 Discussion

Table 19.2-3 was revised with additional information added based on results from Rev. 2 of NEDO-33201 PRA Model. The question of explicitly modeling errors of commission (EOC) in the PRA has been replaced with an identification of possible situations, making an assumption for the PRA with regard to the impact and providing the information to human factors engineering for operational assessment including detailed task analysis and identification of HSI features, procedures and training to minimize the potential for an EOC. The results of these HFE/HRA evaluations are returned to the PRA for adjustment of the assumptions. There is no need to adjust format for Table 19.2-3, but the content is updated as the HFE results are completed and human interface systems are developed and tested.

There are no document revisions as a result of this comment response.

DCD Impact

DCD Tier 2, Subsection 19.2.2.1 will be revised as noted in the attached markup (see Attachment).

DCD Tier 2, Table 19.2-1 will be revised as noted in the attached markup (see Attachment).

NEDO-33267 Section 3.2.1.1 will be revised as noted in the attached markup (see Attachment).

RAI Number 18.7-7 Supplement 3

The RAI response includes markups to NEDO-33267 that provide additional detail on the probabilistic risk assessment/human reliability analysis (PRA/HRA). There are some aspects of the RAI response that need additional clarification.

- The question regarding Table 19.1-3 was answered by deleting the Table and moving information into Tables 19.2-2 and -3. But the same problems remain. The tables are not adequately explained in the text. It is not clear how the items were selected for the tables. What are the criteria and thresholds? Are the human interactions (HIs) in the table risk-important? Are they the only risk-important HIs?*
- In the RAI response to Comment 2 on p. 20, explain what was meant by “the quantitative PRA risk importance identification values.”*
- In the RAI response to Comment 9 on p. 21, sentence 2 is not clear. The staff was not able to find the information in Table 19.2-3 as described.*

GEH Response

Responses to these questions resulted in changes to NEDO-33267 and DCD-18.7 as provided in attachments.

Bullet 1

How were items selected for the tables in Chapter 19?

For the Tables in DCD Chapter 19 risk significance is defined in terms of risk increase (RAW) and risk contribution (FV). Also, an increase in CDF risk of greater than or equal to $1 \text{ E-}7/\text{year}$ is considered risk significant for the design certification ESBWR PRA. For the Tables in Chapter 19 and in NEDO-33201R2, the risk important items are developed using an expert panel based on a review of the risk importance measures for each PRA input. The tables in Chapter 19 no longer contain the details of risk importance analysis, they are in NEDO-33201R2 chapter 17.

What are the criteria and thresholds?

The criteria and thresholds used in developing the list of HIs for HFE review are described in Chapter 19.2.

Are the human interactions (HIs) in the table risk-important?

The Tables in Chapter 19 address insights drawn from review of the risk results and do not contain quantitative links to the risk measures. One insight is that there are no risk significant human actions identified in the PRA. These high level HI descriptions of potentially risk important actions in predecessor BWR PRAs are related to specific components in the ESBWR. The risk important human interactions from analysis of the ESBWR PRA results are provided in NEDO-33201R2 in Table 17.1-3 and additionally in Table 17.2-5. These HIs are considered to be risk important human actions for evaluation in the HFE task analysis. The potentially risk important HIs used in the HFE evaluation of risk important human actions are also provided in the HRA results summary report.

The human interactions that are used as inputs to the PRA are provided in Table 6.3-3 in NEDO-33201R2 and provide additional potentially risk important HIs.

Are they the only risk-important HIs?

No, additional potentially risk important actions are identified during the TA process, the OER process and observations of simulated scenarios. These actions will be evaluated using automation and HSI improvement to minimize potential errors. Additional PRA modeling is used to assess the quantitative importance.

The Tables in Chapter 19 provide qualitative summaries of risk insights based on the evaluation of importance measures. They do not include the quantitative risk importance measure results. Chapter 17 of NEDO-33201R2 provides risk importance information on human interactions in Tables 17.1-3 and 17.2-5. The human interactions listed in Table 17.1-3 are based on the human error risk thresholds. HIs from the PRA are classified as risk important HAs when their FV measure of importance exceeds a threshold of 0.1 or when their RAW exceeds a threshold of 2.0 when generated from the PRA models as listed in the HRA summary report.

The following text change is made to the LTR in 3.2.1.1 paragraphs 1 and 2.

The ESBWR PRA defines potentially risk-significant structures, systems, and components (SSC) and HI events and information that contribute to CDF and LRF using conservative thresholds, such as FV greater than 0.01, and a RAW greater than 5.0 for individual basic events and a RAW greater than 50.0 for common cause failure events (NEDO-33201R2 Chapter 17). These risk importance threshold values are established to meet PRA goals and support the identification of potentially risk important human interactions.

The risk important HIs from analysis of PRA results are provided in NEDO-33201R2 in Table 17.1-3 and additionally in Table 17.2-5 post-initiator actions. These are considered to be risk important human actions for evaluation in the HFE task analysis. Potentially risk important HIs that are used as inputs to the PRA are provided in Table 6.3-3 in NEDO-33201R2. The risk important HIs used in the HFE evaluation of risk important human actions are also provided in the HRA results summary report.

Bullet 2

The term “the quantitative PRA risk importance identification values.” has been replaced with the “risk importance threshold (or cutoff)” to provide a quantitative measure for classifying HAs as risk important and taking action in the design to reduce the risk importance to as low as practical. An example change is: “The risk importance threshold values are established to meet PRA goals and support the identification of potentially risk important human interactions.”

Bullet 3

The importance measures for the PRA and the HRA have different uses as explained in a revision to the description as follows in Section 3.2.1.1 Paragraph 3 as contrasted with paragraph 1.

The goal of the HRA and HFE operational analysis in DCD Chapter 18 is to verify that the means are provided in the plant design to keep the quantitative risk importance of all potentially risk important human interactions modeled in the PRA as low as practical. For the purpose of human reliability analysis and human factors engineering, HIs with a FV value greater than 0.1 or a RAW value greater than 2.0 are classified as important to risk

DCD/LTR Impact

DCD Tier 2, Section 18.7.1 and 18.7.2 will be revised as noted above in Revision 5.

LTR NEDO-33267, Rev 2 has been revised as noted in the text boxes for revision 3.

RAI Number 18.7-8

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.

GE Response (see also RAI 18.7-10 bullet 5)

The PRA takes advantage of the specialized ranking tools that can be used to rank the inputs to the PRA model relative to their importance. For example, the following three processes are used within the PRA models to determine the importance of human actions that are modeled as basic events. These are:

- (4) Fussell-Vesely (FV) Importance is the relative contribution to the system failure probability from a basic event failure at its estimated failure probability,
- (5) Risk Achievement Worth (RAW) is the factor increase in the system failure probability when a basic event (or group of basic events) is assumed to be failed, and
- (6) Risk Reduction Worth (RRW) is the factor decrease in the system failure probability when a basic event (or group of basic events) is assumed to succeed.

These importance evaluation processes represent simple ways of evaluating the impact of human errors that are represented in the PRA model on the top event such as system availability or core damage frequency (CDF). Other forms of importance measures have been developed. When human action basic events are in cutsets below the top 1000 contributors and the CDF (or large early release frequency (LERF)) is well within the NRC guidelines in RG 1.174, then the human action basic events are not considered risk important. Sensitivity analysis is given to human action basic events in the top 100 risk contributors using any of the importance measures described. This discussion will be added to Section 4 in the next revision to NEDO-33267.

DCD/LTR Impact

LTR NEDO-33267, Rev. 0 will be revised as described above.

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

RAI Number 18.7-8 Supplement 1

The specifics of the RAI were not addressed. The specific importance measures (IMs) to be used were not given. Cutoff values were not provided. Further, the answer proposes a new method for eliminating the need to consider R-I HAs, based on counting the number of cutsets, that has not been reviewed by the NRC and, upon initial consideration, appears inappropriate. The discussion of sensitivity analysis in the response is not clear.

GEH Response

Chapter 18 Roadmap Document								
RAI NO	SEC	#	NRC Supplemental	DocName/ Question	Resolved	Plan	Section	Resolution Description
18.7-8	7	8	N	LTR NEDO-33267	From GE response	33267	3.2	Para change per RAI
18.7-8	7	8	Y	Use of Risk Measures	From GE response	33267	3.2.1	Addressed in last paragraph of 3.2.1

RAI Number 18.7-8 Supplement 2

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.

GEH Response

GEH will add a new Subsection 3.2.1.1 of NEDO 33267 to describe the IM goals.

GEH will add a new section 3.2.1.2 of NEDO 33267 to describe the identification of potential risk important human interactions (HIs).

GEH will add a new section 4.1.1 into NEDO 33267 to describe the details of the identification process and criteria for evaluating potentially risk important HIs, and section 4.1.2 to provide criteria for evaluating the HI failure probability being lower than the screening value.

DCD/LTR Impact

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

LTR NEDO-33267, Rev 2 will be revised as noted above and shown in the attached markup (see Attachment).

RAI Number 18.7-8 Supplement 3

MFN 08-298 provides responses to RAIs 18.7-8 S02 and 18.7-9 S03. Both of these address the methodology and criteria by which the risk-important human actions will be identified. These responses provide markups to the NEDO-33267 which add more detail including six revised pages for the topical report. There are some aspects of the RAI responses that need additional clarification.

- *Clarify the use of three thresholds for risk achievement worth (RAW) (2.0, 5.0 and 50) and two thresholds for Fussell-Vesely importance measure (FV) (0.01 and 0.1).*
- *The terminology used for risk-important actions is not the same in NEDO-33267 and the other human factors engineering implementation plans (e.g., task analysis and training). The other plans all use risk-important human actions, but the latest markup for NEDO-33267 does not. Please clarify specifically what values in NEDO-33267 define the risk-important actions and ensure that the terminology is consistent.*
- *Confirm that the intent of the method at the end of NEDO-33267, Section 3.2.1.1, is to define a risk-important action if either RAW or FV meets the criteria. The markup pages submitted use “and” rather than “or.”*
- *The top of page 31 uses the words “such as the shutdown PRA analysis.” What are the others?*
- *The end of NEDO-33267, Section 3.2.1.1, discusses “ensuring that risk impact is reduced to below cutoffs.” Is this truly the intent; what if this cannot be reasonably accomplished?*

GEH Response

Bullet 1

The first paragraph in section 3.2.1.1 has been replaced with the following two paragraphs (1 & 3) to describe the different thresholds for RAW and FV values used for PRA purposes and for HFE purposes.

The ESBWR PRA defines potentially risk-significant structures, systems, and components (SSC) and HI events and information that contribute to CDF and LRF using conservative thresholds, such as FV greater than 0.01, and a RAW greater than 5.0 for individual basic events and a RAW greater than 50.0 for common cause failure events (NEDO-33201R2 Chapter 17). These risk importance threshold values are established to meet PRA goals and support the identification of potentially risk important human interactions.

The goal of the HRA and HFE operational analysis in DCD Chapter 18 is to verify that the means are provided in the plant design to keep the quantitative risk importance of all potentially risk important human interactions modeled in the PRA as low as practical. For the purpose of human reliability analysis and human factors engineering, HIs with a FV value greater than 0.1 or a RAW value greater than 2.0 are classified as important to risk

Bullet 2

The terminology used for risk-important human actions in NEDO-33267 is made consistent with the other LTRs in the definition section and in application in the report. A new definition for risk important HIs has been added to the list of definitions. The term risk important HA is used to classify those actions whose FV is greater than 0.1 and whose RAW is greater than 2.0 after design improvements have been applied such as automation or HSI interface improvement and whose importance measures have been reduced to as low as practical. The terms potentially risk important HIs (from the PRA) and potential risk important HAs (from the TA, OER, simulator observation) apply to actions examined in the HFE process and considered in the PRA for modeling and risk importance quantification.

Risk-important human actions: actions that are performed by plant personnel to provide reasonable assurance of plant safety. Actions may be made up of one or more tasks. There are both absolute and relative criteria for defining risk important actions. From an absolute standpoint, a risk important action is any action whose successful performance is needed to provide reasonable assurance that predefined risk criteria are met. From a relative standpoint, the risk important actions may be defined as those with the greatest risk in comparison to all human actions. The identification can be done quantitatively from risk analysis and qualitatively from various criteria such as task performance concerns based on the consideration of performance shaping factors. (NUREG-0711).

Risk-important human interactions: a group of human actions that must be performed successfully by plant personnel, in the context of a PRA, to prevent core damage or large releases. The HI becomes risk important when its risk value exceeds predefined risk criteria. The identification is done quantitatively from the PRA and HRA and qualitatively from various criteria such as task performance concerns based on the consideration of PSFs (adapted from NUREG-1764 and NUREG-0711).

Bullet 3

A HA or HI is classified as a risk-important human action if either the RAW or FV meets the threshold values. This is clarified in the text by changing the word “and” to “or.”

See second paragraph in text box of Bullet 1.

Bullet 4

The list of PRA analyses in section 3.2.1.1 is the complete list. The words “such as” are replaced with “and” the shutdown PRA. Change in last sentence of 4th paragraph of 3.2.1.1 is shown below.

These models include the CDF for level 1 internal events, LRF for level 2, all of the external events such as fire and flooding, and the shutdown PRA.

Bullet 5

A discussion of applying the risk measure threshold values has been added to section 3.2.1.2 to describe the application process.

The HIs from the PRA are evaluated for feasibility using the qualitative criteria in Section 4.1. On a relative scale, the risk important HIs identified in the PRA with a FV greater than 0.1 or RAW greater than 2.0 for CDF and LRF are subjected to the greatest detail in the HFE operational assessment and HSI design to ensure that their risk impact is reduced to as low as practical.

The goal of keeping the risk importance measure as low as practical is met by ensuring that information for identifying, planning, and implementing the needed human action within the time permitted is provided in the design or by providing automated support to carry out the needed action. For example, the design ensures that the operator can identify the need for manual actions through the HSI, plan through procedures and training, and implement with tools as needed.

If the human interaction can't be automated or partly automated to reduce the importance value below the threshold (i.e., either RAW or FV continues to exceed the risk importance threshold criteria for human actions of FV equals 0.1 or RAW equals 2.0), then the action is classified as a risk important human action. Risk important human actions receive individual HFE emphasis during task analysis to define special needs for training, priority in procedures, and during HSI design for clarity of cues and information feedback, and ease of implementation to increase the likelihood of success.

DCD/LTR Impact

DCD Tier 2, Section 18.7.1 and 18.7.2 will be revised as above in Revision 5.

LTR NEDO-33267, Rev 2 has been revised to revision 3 as noted in the text boxes.

NRC RAI 18.8-2

An implementation plan should provide step-by-step, specific guidance on how to perform the HSI design. The current document stops short of providing step-by-step procedures. To illustrate, in Section 4.2.3, the plan advises its user to design the Man-Machine Interface Systems (MMIS) giving due consideration to the "centralized or local philosophy," but the philosophy for the ESBWR is not provided. Much of the plan identifies considerations for design without providing designers with the basis or procedures to make decisions based on the considerations. Another example is that the "Auditory environment of the HSI is designed considering a relevant database of human capabilities and characteristics" (p. 24). Absence of these types of specific procedural steps will make this document difficult for users and the intended methodology may be incorrectly and inconsistently applied.

Special attention should be made to ensuring that the methodology used to address the General Human Factors Engineering (HFE) Requirements described in NEDO-33268, Section 3.3.3 is presented. Section 3.3.3 follows closely the staff's review criteria for HSI Design. However, the high-level discussion in 3.3.3 does not provided the methodological details as to how these commitments are achieved. While some the considerations are addressed in later sections of the NEDO, others are not. For example, Section 3.3.2 discusses General Electric's commitment to develop a concept of operations. However, none of the subsequent plan material or documentation descriptions address concept of operations. Please, provide step-by-step, specific guidance on how to perform the HSI design.

GE Response

NEDO-33268 is not a step-by-step, specific guidance manual on how to perform the HSI design or evaluation. NEDO-33268 is being revised to provide the description of the implementation process that will develop the Human-System Interface Design for the ESBWR. This document will provide directions to develop the step-by-step, specific guidance manual referred to as the ESBWR Human Factors Guidance Manual. Neither NEDO-33268 Rev 2 nor the ESBWR Human Factors Guidance Manual has been written at present.

DCD Impact/LTR Impact

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

LTR NEDO-33268 Rev. 2 will include a revision as described above.

NRC RAI 18.8-2 S01

In the initial RAI, the staff raised a concern about the lack of a detailed step-by-step methodology of HSI design. GEH's response to this question indicated that NEDO-33268 is a high-level document and that it will be revised to provide step-by-step guidance to develop the ESBWR Human Factor (HF) Guidance Manual that will include a style guide.

At the July 2007 HFE Audit, GEH said the detailed steps are in detailed work plans. The staff reviewed one sample work plan (for allocation of function), but that plan provided little additional guidance to that found in the implementation plan.

The HSI Design Implementation Plan, NEDO-33268, Revision 2, does not mention a Guidance Manual nor does it make reference to an HSI Design Work Plan. It does discuss the development of a style guide, but such a document would not typically include the detailed step-by-step design guidance to be used by engineers. Thus the initial concern still exists. To illustrate: The steps for developing a concept design are listed on Page 19. Step 3 addressed the alarm system design. The step says "The alarm system is defined including conceptual display hierarchy, presentation, and layout." This is a high-level step description that could not be used by an engineer to develop an alarm concept design.

Please clarify where the methodology to address HSI design is made available to the design team. The staff will need to review that document(s) before the review of the HSI design element can be completed. Note that many of the following HSI Design RAIs reflect concern over the lack of detail in the methodology description provided in NEDO-33268, Revision 2.

Similar issues arise when considering the development and use of the style guide. It is discussed in Sections 3.2 and 4.2 of NEDO-33268, Revision 2. However, little information is provided regarding its structure, content, level of detail and usage by the design team. NEDO-33268, Revision 2, contains many high-level guidelines pertaining to the HSI rather than the process. What is the relationship between these guidelines and those that will be developed for the style guide? Note that many of the responses to the RAIs for this section indicated that the details will be provided in the HF Manual (style guide). The treatment of Guidance in the Revision 0 Sections 5 and 6 seem to follow this approach (they were removed from the NEDO, see RAI 18.8-36). Yet much of this guidance is still in the NEDO. For example, the response to RAI 18.8-22 concerning operator access to suppressed alarms indicated that the topic would be addressed in the manual. The GEH Roadmap stated that the style guide has the details. But it is, in fact, addressed in NEDO-33268, Revision 2 (on Page 70, last bullet above Workstations). Please clarify the relationship between the HIS guidelines in NEDO-33268 and those to be included in the style guide. Also, many of the individual guidelines are expressed in high-level form rather than specific design descriptions. At what level of specificity will the style guide guidance be presented?

Additionally, in NEDO-33268, Revision 2, the Tables, Figures, and Appendix may have been overlooked. There are three tables, but none are referenced in the document. The Appendix is not referenced. All six figures are referenced, but not always correctly. For example, on Page 14 a reference is made to Fig 3. That was correct for Revision 0, but should be changed to Fig 4 in new version. This should be addressed in the next revision.

GEH Response

We agree and have addressed the three separate questions associated with this RAI.

C. The first question posed in this RAI is, “Please clarify where the methodology to address HSI design is made available to the design team.”

ESBWR human-system interface work instructions will be used by the design team to guide: (1) Concept Design, (2) HSI Specific Guidance – Style Guide, and (3) HSI Detailed Design and Iteration as specified in separate sections within the Human-System Interface Design Implementation Plan. HSI Tests and Evaluations per NUREG-0711 will be built into each of these three successive phases. Additionally, the processes that are being used in the overall HSI design approach are being implemented in accordance with Reg. Guide 1.206.

GEH has standardized its terminology for project and technical documentation to be clearer and more consistent. The documentation for the Human-System Interface (HSI) design portion of Human Factors Engineering (HFE) are as follows:

5. ESBWR **Design Control Document**, Tier 2 Chapter 18 Human Factors Engineering, 26A6642BX, Revision 4, September 2007
6. ESBWR **Man-Machine Interface System and Human Factors Engineering Implementation Plan**, NEDE-33217P, Class III (proprietary), Revision 3, March 2007, and NEDO-33217, Class I (non-proprietary), Revision 3, March 2007.
7. ESBWR **Human-System Interface Design Implementation Plan**, NEDO-33268, Class I (non-proprietary), Revision 2, March 2007.
8. ESBWR **human-system interface work instructions**, Class III (proprietary).

The ESBWR **human-system interface (HSI) work instructions** replace what has been referred to previously as a guidance manual or work plan – these latter two terms will no longer be used.

The ESBWR HSI **work instructions** provide the methodology only. The overall approach to work instructions is to provide designers with a step-by-step approach in sufficient detail to complete the task consistently without compromising the ability of the designer to use good engineering judgment.

D. The ESBWR HSI **Style Guide**, discussed in response to the next part of this RAI question, is the design requirements document only, and does not describe the methodology. **The second question posed is, “At what level of specificity will the style guide guidance be presented?”**

The HSI Style Guide contains the following guidelines and requirements. Associated design requirements will be entered into an industry-standard software requirements tracking/traceability tool:

The HSI Style Guide is a compilation of requirements and direction provided by regulatory documents (such as NUREG 0700 and NUREG 0711) that addresses two general areas of HSI/HFE design:

Hardware Characteristics: The hardware characteristics of the ESBWR HSI include display legibility and visual acuity, input devices, the visual display hardware, and general characteristics associated with hardware used in the control and display of

ESBWR Software Characteristics: Includes consideration for screen structure and contents, alphanumeric characters, icons and symbols, data display, data entry and point selection, user guidance, screen organization, visual encoding (including enhancement coding), information and screen formats and the overall presentation of the graphical interface, and response times. User dialogue is defined within the style guide relative to how the menus and details of actions appear to the operator and how they are encoded. Display formats and navigation within those displays are included for the various types of displays anticipated for ESBWR.

C. The third question concerns Tables, Figures and the Appendix and notes that may have been overlooked in Revision 2.

Tables 1-3, Figures 3-6, and the Appendix should have been deleted from Revision 2. Any remaining references to them will be removed in our next editorial pass as the contents are described adequately in text.

Figures 1 and 2 will remain, and we will ensure that they are numbered, labeled, and called out appropriately in the text:

Figure 1 HFE Process

Figure 2 Human-System Interface Design Implementation Process

DCD Impact/LTR Impact

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

LTR NEDO-33268, Revision 2 will be revised for item “C” as noted in attached markup (See Attachment 1).

NRC RAI 18.8-2 S02

GEH's response partially clarified Part B of the staff's question regarding the level of style guide specificity. GEH indicated that the guide will consist of a compilation of requirements from NUREG-0700 and -0711 that are entered into an industry-standard software requirements tracking/traceability tool. GEH's response provided general information about the contents of the guide. However, NUREG-0700 guidance is often presented at a high-level (since it is used to review many different design implantations). The staff expects the style guide to be specific to the ESBWR design; i.e., described at a level to ensure consistency in application across users of the guide. As an example, NUREG-0700 Guideline 4.1.4.2-1 indicates that "General HSI features (e.g., a data display zone, control zone, or message zone) should be displayed in consistent locations from one display to another." A design specific implementation of this guideline would be "Each screen will be divided onto four zones: the upper zone provides a label and identifying information, a left zone providing navigation controls, a lower zone providing alarms and status messages, and a large center zone displaying user selected information."

Please clarify whether GEH's style guide will simply repeat the guidance in NUREG-0700 or if GEH will provide ESBWR specific guidance on how the guidance is applied to the design. In addition, GEH's response did not "clarify the relationship between the HSI guidelines in the NEDO and those to be included in the style guide." Please provide the clarification as requested.

GEH Response

GEH recognizes that NUREG-0700 is a guideline for review of the human system interface and not a project specific style guide or functional specification. For sections of NUREG-0700 that provide high-level guidance, such as that cited in the RAI above, the ESBWR style guide provides the specific requirements necessary to assure consistent implementation. In some instances NUREG-0700 provides functional specification type guidance and the ESBWR style guide may appropriately echo it. For example, NUREG-0700 contains several guidelines related to the capability of a video display unit (VDU) such as "1.6.1-6 VDU Image Linearity" that may be directly quoted, including the "Additional Information" statement, in the ESBWR style guide. In this case the information in the "Additional Information" statement within the NUREG contains adequate specific guidance for use by the ESBWR design team while providing flexibility for technology selection.

The HSI NEDO, in general, provides high-level requirements for items that are to be included in the HSI style guide. The HSI style guide will provide the more detailed ESBWR specific HSI requirements for these items. In some instances, however, it is appropriate to provide more specific examples of the HSI design requirement within the NEDO to better show the intended considerations. In these cases the specific items in the NEDO are also included in the HSI style guide so that the design team does not have to access multiple documents to find ESBWR specific HSI guidelines and requirements.

DCD/LTR Impact

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

No changes to the subject LTR will be made in response to this RAI.

NRC RAI 18.11-21

NEDO-33276, Section 4.3.4.3 discusses participants in validation exercises. The section simply states that V&V teams will be made up of GE personnel, GE subcontractors, and COL holder personnel. However, this section does not describe the types of personnel that will actually serve as operating crews for the simulations. Nor is any information provided on how the sample of participants will be constructed. Please provide information as to what types of personnel will participate in validation tests and how they will be sampled.

GE Response

The HFE V&V teams performing qualitative validation of display usability for a wide range of tasks in the mockup, part task and full scope simulators will include GE personnel, COL Holder personnel (operations, maintenance, training, QA, etc.), and GE subcontractors. The personnel selected for the validation will include BWR/ABWR/ESBWR trainers, people with SRO licenses at various nuclear plants, start up engineers, I&C engineers, PRA/HRA engineers and Human Factors engineers. The crews will include former SROs and people training to be ESBWR operators and SROs. For mock-ups and part task simulations one simulated crewmember at a time might be sufficient to test the MMIS for a single system. In the case of a full scope simulator a minimal crew of three would be used to test the MMIS.

The observers will be selected as appropriate from HFE staff experienced in Human Factors, C&I, Nuclear Engineering, System Engineering, Plant Operation, Computers, Procedures, Training, PRA/HRA, SPDS, System Safety Engineering, Maintainability, and Reliability.

DCD/LTR Impact

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

LTR NEDO-33276, Rev 0 section 4.3.4.3 will be revised as described above at the next revision.

NRC RAI 18.11-21 S01

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:

- *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*

NEDO-33276 should be revised to provide the information or indicate that the detailed V&V implementation plan will address these participant sampling considerations.

GEH Response

Validation testing as discussed in NEDO-33276, Section 4.4 applies to testing and validation of the integrated system to ensure that it can adequately support plant personnel in the safe operation of the plant.

The following changes will be made to NEDO-33276, Rev 1:

- A. In section 4.4.3, first paragraph, second sentence, change the word “the” to “integrated system”
- B. The second paragraph will be revised as noted in the attached markup.
- C. The following paragraphs will be added to NEDO-33276, Section 4.4.3 to address the question “How the sample of participants will account for human variability”:

“A full scope simulator is used to test the HSI of multiple systems. For full scope simulator tests, all participants have previously undergone ESBWR operator training. To properly account for human variability, the sample of participants used in testing reflects the characteristics of the population from which the sample is drawn.

The characteristics expected to contribute to system performance variation are specifically identified. These characteristics are taken into account during sampling to ensure that variation along those dimensions is included in the validation. These characteristics are determined from operator experience and task analysis and include:

5. License and qualifications
6. Skill and experience

7. Age
8. General demographics”

D. The following paragraphs will be added to NEDO-33276, Section 4.4.3 to address the question “How minimum and normal crew configurations will be assembled and what they will consist of”:

“In the case of full scope simulator HSI testing, a minimum crew configuration of two and a normal crew configuration of three are tested.

In the full scope simulator, a normal crew of three is used to test the HSI, as determined in NEDO-33266. This crew consists of: two licensed Reactor Operators and one Senior Reactor Operator (SRO). The first licensed Reactor Operator is assigned to normal control actions at the MCR HSI. The second licensed Reactor Operator is assigned to control of testing, surveillance and maintenance activities. This crew operates the ESBWR during all phases of normal plant operation, abnormal events, and emergency conditions.

A minimal crew of two is used to test HSI capabilities in a condition in which one of the normal crew licensed reactor operators has become incapable of performing operating procedures due to accident, illness, etc. This crew consists of one SRO and one licensed Reactor Operator.”

E. The following paragraphs will be added to NEDO-33276, Section 4.4.3 to address the question “How sampling bias will be prevented”:

“Randomized sampling should be used to select participants from a population representative of the plant personnel who interact with the HSI. To prevent sampling bias, use of the following should be avoided:

1. Participants who are part of the design organization.
2. Participants who were involved in prior design evaluations.
(However, participants may perform a training evaluation following ESBWR operator training.)
3. Participants who were selected for some specific characteristic
(selecting only good or experienced crews.)”

More detailed information regarding participant sampling and crew configurations will be provided in the HFE Verification and Validation work instructions.

DCD/LTR Impact

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

LTR NEDO-33276, Rev 1 will be revised as noted in the attached markup.

NRC RAI 18.11-21 S02

GEH's response to RAI 18.11-21, Supplement 1, addressed several aspects of human variability in validation testing of an integrated system. The only remaining question is the number of crews GEH plans to use for integrated system validation. Please indicate how many crews will participate in the testing.

GEH Response

GEH will use a minimum of three crews for integrated system validation. This decision is made based on the following considerations:

1. When deciding on the number of crews to be used in integrated system validation, a compromise is made between beginning validation testing earlier in the design process and waiting long enough to obtain a sufficient number of trained crewmembers.

The average number of crews employed in a typical operating power plant is five. Selecting a minimum of three crews for validation testing achieves a compromise between testing early and training crews by representing greater than half the average number of crews in a real plant.

2. The more variable test participant performance, the greater the sample size required to adequately represent human variability.

Because integrated system testing requires comprehensive knowledge of the systems included in the test, test participants receive formal classroom and simulator training. At the conclusion of training, the selected test participants have completed sufficient ESBWR specific training to exhibit an acceptably stable level of performance across trials. A result of this training is the reduction of task performance variance.

3. The amount of covariation between personnel and system variability - The less sensitive the integrated system performance is to human performance, the less that variation needs to be assessed and the lower the needed sample size.

Because the integrated system of the ESBWR is to be automated to an extensive degree, the impact of operator input on system performance is attenuated, allowing for the selection of a smaller number of crews.

4. Crew homogeneity – The greater the extent to which crew members are similar to each other along the personnel dimensions that contribute to task performance variance, the lower sample size need be.

The characteristics that contribute to task performance variation are identified and taken into account during sampling, ensuring that variation along those

dimensions is included in integrated system validation. However, due to the training and qualification requirements for integrated validation test participants, variability among participants may be limited.

5. Test design – The test design employed impacts the sample size needed.

Because of the threat to statistical conclusion validity posed by low sample size, tests measuring performance were constructed to accommodate a small number of crews. Because of insufficient power to reject the null hypothesis, integrated system validation tests do not rely on statistical significance to validate or invalidate the design.

6. The Ability to Generalize - Because low sample size hinders the ability to make generalizations from observed test performance to real world performance, using the greatest number of crews possible is desirable for validation. However, as sample size may be limited, consideration of this will be taken into account when interpreting test results.

DCD / LTR Impact

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

LTR NEDO-33276, Rev 1 is being completely re-written and will incorporate the information presented above. To specify the minimum number of crews to be used during integrated system validation testing, NEDO-33276, section 5.4.2.2 will be revised as indicated in the attached markup.

NRC RAI 18.11-25

Three additional areas of evaluation are discussed and performance measures are identified: automation, procedures, and displays. It is not clear that these represent three areas of performance measurement or three aspects of the design that will be evaluated.

In either event, the following additional information is requested.

- D. Automation - NEDO-33276, Section 4.3.4.7.7 provides a list of performance measures for automation, such as operator cognition. Please indicate how these items will actually be measured.*
- E. Procedures - NEDO-33276, Section 4.3.4.4.8 discusses the validation of operating procedures. The section indicates that the validation is completed during operator training phases. What training phases are being referred to in this statement? Section 4.3.4.7.8 on performance measures for operating procedures, states "refer to operate a performance measures regarding situation awareness." Please explain this statement. Based on the earlier discussion of situation awareness, the questions asked of operators appear to relate to awareness of plant status. How then can they be used to validate procedures?*
- F. Displays - NEDO-33276, Section 4.3.4.7.9 states that there are no performance measures for graphical displays. Please explain.*

GE Response

- D. The following statement will be added to NEDO-33276, Section 4.3.4.7.7, "Observers will measure operator cognition and monitoring of automated states as indicated by the MMIS by observation of when the operators acknowledge changes in operational mode, by release of automation break points, or by debrief of the operators at the end of the simulation response session."
- E. The training phases are those shown in Figure 2 of NEDO-33276. They consist of using the three types of simulation interfaces (e.g., GETS mockups for simulation of system operation (SOPs), BS for simulation of alarms (AOPs) and FSS for all others.

Validation of procedures confirms that the procedures such as EOP flowcharts effectively integrate with the MCR MMIS arrangement and work environment. The methods used in the situational awareness based on the MMIS information will be applied to determine position in the procedures. In addition the procedure validation addresses usability of layout space in the MCR and that procedure names and symbol match the names and symbols in the MMIS.

- F. The word "human" will be inserted after "no" in the 1st line of 4.3.4.7.9. The following paragraph will be added to NEDO-33276, Section 4.3.4.7.9:

“However, the graphical displays on the MMIS provide situational awareness to the operators. Therefore, display cues and navigation must support timely operator actions. The performance measures for graphical displays are that the status of valves and pumps is known during all phases of a control interaction. Color changes and symbol changes that represent the system configuration are consistent throughout the VDUs. Each stage of a control action is clearly observable through MMIS (e.g., selection of a controlled element, defining the action to take, sending the signal, feedback on the change and verification of the position during the change period, and the final new state).”

DCD/LTR Impact

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

LTR NEDO-33276, Rev 0 will be revised as described above at the next revision.

NRC RAI 18.11-25 S01

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.

GEH Response

A. Operating Procedures

NEDO-33276, Section 4.4.7.8 references situational awareness performance measures (Section 4.4.7.3). To clarify which of these performance measures also apply to procedures, the applicable performance measures for procedure integration V&V will be stated in Section 4.4.7.8. Other applicable performance measures will also be added to this list.

The following will be added to NEDO-33276 Section 4.4.7.8:

“Procedure validation confirms that the procedures, such as EOP flowcharts, effectively integrate with the MCR MMIS arrangement and work environment. Procedure integration with the HSI will be evaluated by analysis of one or more of the following measures at different phases of the V&V:

1. Timing of operator actions (i.e., how long a procedure took compared with how long a procedure should have taken)
2. Appropriateness of operator actions
3. Consequences (good or bad) of operator actions
4. Observation of operator actions, procedure use and communications
5. Compatibility of procedures with HSIs (e.g., checking that the procedure names and symbols match the names and symbols in the MMIS)
6. Post scenario video reviews and interviews

Measures of performance are the operator's effectiveness at tasks that include:

3. Selecting a procedure. An example is:
 - a. Referring to, and transitioning among the appropriate procedures in a timely manner.
4. Executing a procedure, which includes:

- a. Adhering to procedures, cautions, and limitations (i.e., no deviating even if the deviation appears to have no detrimental consequences).
- b. Executing procedural steps in correct sequence.
- c. Including all procedural steps
- d. Locating and accessing controls and information correctly and efficiently.
- e. Using controls in a timely and effective manner.

Observers will record operator actions, procedure use, and communications. The amount of time taken to complete a task will be recorded, along with any errors of omission or commission. Observers will record details of occurrences in which procedures do not match the HSI. Operator feedback will be used to supplement observations.”

B. Display Validation

The following will be added to NEDO-33276 Section 4.4.7.9:

“The quality of the graphical displays is assessed relative to operator performance. The measures used to quantify tasks are chosen to reflect the important aspects of the task with respect to operator and system performance, such as:

1. Enhanced ease of operating procedures use
2. Reduced time demands
3. Increased accuracy
4. Reduced errors (graphical displays allow operators only to perform correct behaviors)
5. Reduced cognitive demands
6. Quantified benefits (how much more can be accomplished by operators using graphical displays)
7. Observed use of graphical displays
8. Evaluated graphical display efficacy (are graphical displays acting as a job performance aid or detriment)
9. Post scenario video reviews and interviews”

DCD/LTR Impact

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

LTR NEDO-33276, Rev 1 will be revised as noted in the attached markup (See Attachment 1).

NRC RAI 18.11-25 S02

GEH's response to RAI 18.11-25, Supplement 1, addressed the aspect of the question associated with procedures. The staff needs additional clarification with regard to performance measures for displays. A list of measures is provided such as: enhanced ease of operating procedures use, reduced time demands, and increased accuracy, and reduced cognitive demands. Many of the measures are stated in relativistic terms, such as reduced time demands. For these measures, the question arises " compared with what?" That is, for example, reduced time demands compared with what? Performance measures stated in relative terms are generally used when the performance of a system is being compared with another system. For example, one might look to see if the new HSI design reduces time demands compared with an old HSI design. However, the overall GEH validation methodology is not one based on comparisons. Please clarify how these measures will be quantified.

GEH Response

The concerns expressed in RAI 18.11-25 S02 regarding the use of relativistic terms for display performance measures are no longer applicable. In response to RAI 18.11-24 S01, the sections of NEDO 33276 regarding performance measures were rewritten to identify a hierarchical set of performance measures and to provide a clear picture of the range of measures to be used.

Displays represent one of the areas to be validated during integrated system validation testing. For each integrated system, the applicable displays are represented with the appropriate fidelity in the simulator testbed.

Based on the content of NEDO 33276, rev 2, section 5.4.4, displays are validated using performance measures that include the following:

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- **Cognitive Workload:** The displays give the crew the ability to perform the information processing required to achieve task goals. Because excessive cognitive workload is associated with decreased situation awareness and decreased ability to perform safety significant tasks, knowledge of an operator's mental workload is required to ensure that it is within acceptable limits.

Task analysis is used to determine the critical tasks requiring workload assessment.

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- **Anthropometric and Physiological Factors:** The displays give the crew the ability to effectively use the integrated system. Integrated validation testing focuses on the aspects of anthropometrics as they apply to the integrated system of displays and controls. Effectiveness is measured using a combination of quantitative and qualitative measurements.

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If anthropometric design of the physical panels and layout of elements in the control room degrade crew performance such that procedures cannot be accomplished correctly and within time constraints, the integrated design (including displays) fails validation. This criteria is based on established operating procedures and timelines.

DCD / LTR Impact

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

LTR NEDO-33276, Rev 1 is being completely re-written and will incorporate the information presented above.

NRC RAI 18.11-32

A methodology for the evaluation and resolution of HEDs identified as part of the V&V process is not fully described. NEDO-33276 states "Significance Category is a temporary field for potentially future HED compilation, ranking and screening purposes. It is a methodology to rank or prioritize new and unresolved issues in terms of their significance and potential impact on plant safety and performance. The intent is to facilitate evaluation and resolution of HEDs in a manner consistent with the guidelines of NUREG-0700 and NUREG 0711. The Significance Category methodology is depicted in Figure 3." Figure 3 provides an outline of a categorization methodology, but it does not stand alone.

- C. While the staff agrees on the importance of ranking and prioritizing HEDs, the method by which this valuation will take place should be described in order for the staff to determine whether or not, the methodology is consistent with the review criteria in NUREG 0711.*
- D. Regarding Figure 3, what is the significance of an HED being classified into the different category levels, that is, what are the design implications of the various categories?*

GE Response

Figure 3 will be modified as follows:

- C. The process in Figure 3 will be revised to address the safety and risk significance of each HED as outlined in NUREG-0711R2. In this case the HEDs are classified by safety significance rather than error potential. The design implications are that the MMIS will be prioritized to address the human actions, which most impact safety and risk and are, required for operation.*
- D. Figure 3 of NEDO-33276 shows how the HEDs can be screened for their potential impact on human error which is not necessarily linked to risk and safety significance. Thus, from a human performance monitoring viewpoint Figure 3 provides a link between the HFEITS HED data set and the human performance monitoring implementation plan. It is expected that resolution of HEDs by enhanced MMIS display and features will reduce the human error probability for the key actions, the human performance monitoring system will benefit from a listing of actions whose MMIS has been improved as a basis for selecting the action. Moreover, the human performance monitoring task will be able to demonstrate the enhanced impact of the MMIS features used in resolution of HEDs.*

DCD/LTR Impact

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

LTR NEDO-33276, Rev 0 will be revised as described above at the next revision.

NRC RAI 18.11-32 Supplement 1

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.

- D. Is there a provision for justifying a discrepancy, e.g., deviation from the style guide with justification?*
 - E. 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?*
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- F. 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?*

GEH Response

Questions A. / B. / C.

Deviations from the style guide will be required and need to be justified. The style guide requirements statement will be removed from Figure 4 in order to provide a more inclusive review and follow-up flow path and to more accurately match DCD and NUREG-0711 requirements.

The following revisions will be made to NEDO-33276, Rev 1 to clarify this position:

- 3. Figure 4 will be replaced in its entirety. See new Figure 4 Attachment.
- 4. Section 4.6 will be revised in its entirety and will include two new subparagraphs: See new Section 4.6 Attachment.
 - 4.6.1 Evaluation of HFE Issue Safety and Risk Importance Category 1 and 2
 - 4.6.2 Normal Engineering Processing Category 3 and 4.

Note: While this RAI indicates that NEDO-33226 is the affected document, the response from GEH is written under the assumption that this RAI was intended to refer to NEDO-33276. Therefore GEH's response is based on the content in NEDO-33276.

DCD/LTR Impact

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

LTR NEDO-33276, Rev 1 will be revised as noted above and shown in the attached markups of new Figure 4 and revised section 4.6 (see Attachment).

NRC RAI 18.11-32 S02

GEH's response RAI 18.11-32, Supplement 1, proposed an extensive revision to Section 4.6 of NEDO-33276 and Figure 4 that graphically depicts the risk significance methodology.

Regarding RAI subpart A, GEH's revision to Section 4.6 and Figure 4 does not address discrepancy justification.

Regarding RAI subpart B, GEH's revision to Section 4.6 and Figure 4 does not clarify the staff's concern about evaluation departures from HFE guidelines

Regarding RAI subpart C, GEH has deleted specific solutions from the process and Figure 4.

Revised Sections 4.6.1 and 4.6.2 provide a more general process for addressing HEDs and finding an engineering solution that is acceptable.

The revised methodology requires additional clarification. Each of the decision blocks is not clearly described in the text, for example:

- Figure 4 begins with a decision block for "HED Valid?" What is the analyst evaluating at this point and how is the decision made. The write-up of the methodology is Section 4.6 begins with the second decision block "HFEITS Pri 1 or 2?" Thus no guidance is provided to the analyst.*
- Regarding the second decision block "HFEITS Pri 1 or 2?," how does the analyst make the decision whether the HED is Category 1 or 2? It appears the risk significance methodology results in a sorting of HEDs into four risk significance categories (see the bottom of Figure 4). If so, why is there a sorting at the top of the methodology?*
- Decision block 3 is "HED addressed in PRA R-1 list or DB events?" How is this assessment made by the analyst?*
- How are more general HEDs evaluated? For example, departures from HFE guidance may result in a design deficiency that impacts multiple human actions. Some of these actions may be risk important, while others may not.*

Please provide additional clarifications to address the areas discussed above.

GEH Response

To reflect the level of detail required for an Implementation plan, the text document organization, and figures of NEDO-33276 were revised. The concerns expressed in RAI 18.11-32 S02 regarding HED resolution methodology have been resolved in NEDO 33276, Rev. 2.

Based on the content of NEDO 33276, Rev. 2, Section 6, and Figure 4 concerns regarding HED resolution are addressed as follows:

NRC: Regarding RAI subpart A, GEH's revision to Section 4.6 and Figure 4 does not address discrepancy justification.

GEH: Addressed in Figure 4 and Section 6.4.2:

The first step in the HED identification and resolution process is a determination regarding whether or not the discrepancy can or should be justifiably accepted as-is. If sufficient justification exists, a deviation from established HFE guidelines may not constitute a HED. The technical basis for determining if a HED is justifiable should include an analysis of recent literature or current practices, tradeoff studies, and/or HFE or design engineering evaluations and data.

No HEDS that constitute safety concerns (either direct or indirect) or performance problems (either plant or personnel) can be justified. HEDs that deviate from HFE principles or the ESBWR style guide but are shown to have inconsequential impact on task support or integrated system operations can be accepted as-is and documented. If a HED is justified, its associated HFEITS entry is closed after documentation is complete. An example of this might be a HED that, while it deviates from a HFE principle, does not have an adverse impact on safe and efficient plant operation when evaluated in the context of the fully integrated design.

NRC: Regarding RAI subpart B, GEH's revision to Section 4.6 and Figure 4 does not clarify the staff's concern about evaluation departures from HFE guidelines.

GEH: A new Figure 4 was created that provides a means for resolution of all HEDs, those relating and not relating to style guide compliance. Thus, this concern is addressed by the new figure.

NRC: Regarding RAI subpart C, GEH has deleted specific solutions from the process and Figure 4.

GEH: Addressed in Figure 4, Section 6.4.5, and Section 6.4.6:

Using all of the information gathered during analysis and cause determinations (if required) solutions to the identified discrepancies are developed. Actions are developed for each aspect of the HED that represents a correction opportunity. Actions are developed to address the HED symptoms and causes identified and to prevent recurrence of the deviation or limit the effects of recurrence.

HED resolution corrective actions are developed taking into account the aggregate affect of all open HEDs impacting the system, components, human systems interfaces (HSIs), procedures, or processes they are developed to address. Design solutions are analyzed

using industry operating experience and the appropriate HFE design processes including, where appropriate:

- Functional requirements analysis.
- Allocation of function.
- Task analysis.
- Procedures development.
- Training development.
- HSI design.
- Staffing and qualification.

Where a variety of possible corrective actions exist, corrective actions are chosen that strike a balance among the safety significance of the HED, the resources required for implementation, and the effectiveness of the corrective action.

Solutions selected may include:

- Design change to the system or component.
 - Software change.
 - Reevaluation in the operations analysis process resulting in reallocation or task redesign.
-
- Procedure change.
 - Training change.
 - HSI design change.
 - Staffing and qualification change.
 - Other actions resulting from analysis of the HED.

HED resolution corrective actions are implemented using the appropriate human factors engineering design process. Corrective actions are input into the appropriate human factors engineering design process for implementation and proceed normally through the remainder of the human factors engineering design process.

If, for example, a HED resolution corrective action is input into allocation of function and changes an allocation, this change may require additional action in downstream processes such as task analysis, HSI design, software design, procedures, training, staffing and qualifications, and verification and validation.

HED resolution corrective actions are tracked until completed and their completion is scheduled commensurate with the HED significance and its impact upon other scheduled activities. For example, corrective actions for priority 1 and 2 HEDs should be completed prior to performance of integrated system validations involving the human system interfaces, systems, or tasks they impact. HED corrective actions not resolved

prior to related integrated system validations may require additional integrated system validation test performances.

HED resolutions that require the “as built” control room to complete are implemented as part of the design implementation process. Verification and validation requirements that must be met as part of the verification of the effectiveness of the HED corrective actions are identified and are completed after the design is implemented.

NRC: Figure 4 begins with a decision block for “HED Valid?” What is the analyst evaluating at this point and how is the decision made. The write-up of the methodology in Section 4.6 begins with the second decision block “HFEITS Pri 1 or 2?” Thus no guidance is provided to the analyst.

GEH: Addressed in Section 6.4.1:

A discrepancy is a HED if it constitutes a departure from some benchmark of system design suitability for the roles and capabilities of the human operator. This may include a deviation from a standard or convention of human engineering practice, an operator preference or need, or an instrument/equipment characteristic that is implicitly or explicitly required for an operator's task but is not provided to the operator (NUREG 0700, Rev 2).

NRC: Regarding the second decision block “HFEITS Pri 1 or 2?,” how does the analyst make the decision whether the HED is Category 1 or 2? It appears the risk significance methodology results in a sorting of HEDs into four risk significance categories (see the bottom of Figure 4). If so, why is there a sorting at the top of the methodology?

GEH: The concern regarding sorting at the top of the methodology in the previous version of Figure 4 is no longer applicable to the revised Figure 4, in which HEDs are prioritized and sorted only once.

HED prioritization is addressed in Figure 4 and Section 6.4.3:

An initial analysis of the HED is performed to provide analysts a general overall perspective of the discrepancy. The scope and impact of the HED both alone and in the context of any other open HEDs against the system are taken into consideration. If the HED addresses a global or standard design feature and therefore potentially affects more than one system, the full impact of the HED must be investigated and understood so as to accurately determine the HED's impact, and priority. The perspective gained during this initial analysis is then used to identify similar or related discrepancies that may indicate cross cutting or programmatic problems. If any such discrepancies are noted during trend analysis, the potential adverse trend is entered into human factors engineering issue tracking system (HFEITS) for resolution.

Specific information considered during analysis includes:

- Discovery method – what activity identified the HED.

- System or systems affected.
- Scope – whether the HED affects global, standardized, or detailed design features and therefore how far reaching its consequences or effects may be.
- HSIs affected.
- Personnel functions or tasks affected.
- Procedures or training affected.
- Cumulative impact of HED in the context of other open HEDs affecting the same design features, functions, or processes.

The perspective gained during initial analysis is also used to prioritize the HED and thereby determine the depth and breadth of its resolution requirements. HEDs are prioritized to ensure that resources are applied in a risk informed manner. Prioritization levels and criteria are as follows:

Priority 1 - Safety Consequences (either direct or indirect)

A condition (equipment, HSI, procedure, training, or staffing deviation, deficiency, or nonconformance) or adverse trend that has the potential to impact plant risk or safety or safety-related systems, structures, or components. Examples include:

- Equipment or HSI design deficiencies or discrepancies that could lead to safety system, train, or component inoperability, unavailability, or unexpected operation.
- A HED that impacts a system, component, or human action determined in HRA/PRA as risk important and drives risk importance above cutoff.
- A HED that reduces the plant margin of safety below an acceptable level, as indicated by such conditions as violations of operating limits, or tech spec limits, or limiting conditions of operation (NUREG 0711, Rev 2).
- Adverse HED trends, that if found to be present in safety related systems could lead to safety system, train, or component inoperability, unavailability, or unexpected operation.
- Procedure deficiencies or discrepancies in documents relied upon to mitigate transients and design basis accidents.
- Training deficiencies or discrepancies that could cause or contribute to the conditions noted above.
- Staffing and qualification deficiencies or discrepancies that could cause or contribute to the conditions noted above.
- A group of HEDs that when considered together could cause or contribute to the conditions noted above.

Priority 2 - Plant or Personnel Performance Impact

A condition (equipment, HSI, procedure, training, or staffing deviation, deficiency, or nonconformance) or adverse trend that does not have significant safety consequences, but

does have potential consequences to plant or personnel performance or efficiency. Examples include:

- Equipment or HSI design deficiencies or discrepancies that deviate from personnel information requirements or HFE guidelines for tasks associated with plant productivity, availability, or protection of investment.
- Equipment or HSI design deficiencies or discrepancies that could lead to significant non-safety system, train, or component inoperability, unavailability, or unexpected operation.
- The HED impacts a system, component, or human action determined in HRA/PRA as risk important but does not drive risk importance above cutoff.
- Adverse HED trends, that if found to be present in significant non-safety systems could lead to system, train, or component inoperability, unavailability, or unexpected operation.
- Procedure deficiencies or discrepancies in documents relied upon to mitigate transients, abnormal events, and failures involving significant non-safety equipment.
- Training deficiencies or discrepancies that could cause or contribute to the conditions noted above.
- Staffing and qualification deficiencies or discrepancies that could cause or contribute to the conditions noted above.
- A group of HEDs that when considered together could cause or contribute to the conditions noted above.

Priority 3 - Enhancement (Neither safety consequential or impacting performance)

A condition (equipment, HSI, procedure, training, or staffing deviation, deficiency, or nonconformance) or adverse trend that deviates from the style guide or HFE principles that has neither significant safety nor plant or personnel performance consequences.

Priority 4 - Other (Not a safety, performance or enhancement)

A condition or adverse trend that does not deviate from the style guide or HFE principles and that has neither significant safety nor plant or personnel performance consequences.

NRC: Decision block 3 is "HED addressed in PRA R-1 list or DB events?" How is this assessment made by the analyst?

GEH: Due to the revision of Figure 4 and Section 6, this concern no longer applies. HEDs are assessed in terms of HRA/PRA in the following ways.
Section 6.4.3:

Priority 1 – Safety Consequences (either direct or indirect)

A HED that impacts a system, component, or human action determined in HRA/PRA as risk important and drives risk importance above cutoff.

Priority 2 – Plant or personnel Performance Impact

The HED impacts a system, component, or human action determined in HRA/PRA as risk important but does not drive risk importance above cutoff.

NRC: How are more general HEDs evaluated? For example, departures from HFE guidance may result in a design deficiency that impacts multiple human actions. Some of these actions may be risk important, while others may not.

GEH: A revision of Figure 4 and Section 6 provides a means for resolution of all types of HEDs, those that affect risk important human actions and those that do not. Thus, this concern is addressed by the revised Figure 4 and Section 6.

Section 6.4:

The HED identification and resolution process uses a structured approach that ensures methodical and consistent treatment of identified discrepancies, analysis and development of resolutions, verification of discrepancy resolution, and thorough documentation. All HEDs are entered into the HFEITS database, which guides the HED identification and resolution process.

The major HED identification and resolution process steps, as shown in Figure 4, include:

- HED identification.
- Entry into HFEITS and determination if the discrepancy can justifiably be accepted as-is.
- Initial analysis and prioritization of HED based upon impact on plant safety, task performance, HSI design, and personnel performance.
- Cause determinations appropriate for HED priority.
- Developing HED solutions.
- Implementing HED resolutions.
- Evaluating the effectiveness of HED resolutions.
- Documenting the HED resolution.

GEH, as custodian of the HFEITS, performs verification for the discrepancies that are resolved prior to plant startup. The COL applicant performs verification of any discrepancies thereafter.

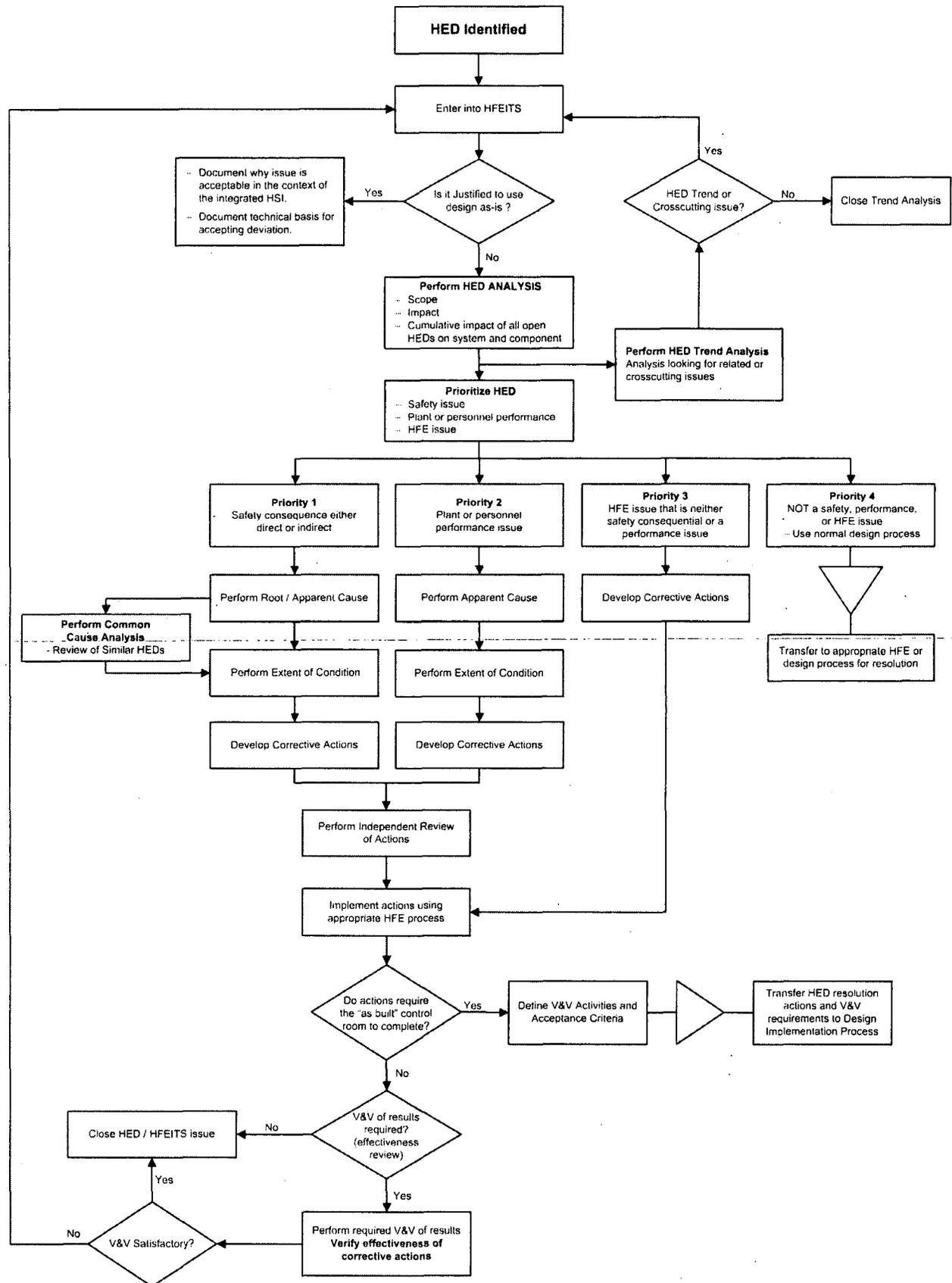


Figure 4 HED Resolution Process

DCD / LTR Impact

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

LTR NEDO-33276, Rev 1 is being completely re-written and will incorporate the information presented above.

NRC RAI 18.12-4

NEDO-33278, Section 1.3 identifies the COL as the lead and manager of this effort. However, in Section 4.1.3, it appears that GE may be conducting these evaluations. Please clarify the roles of the COL and GE in this process.

GE Response

Since this activity will occur after the COL submittal, it is considered the COL holder's lead. However, Section 4.1.3 refers to the members of the HFE team as the resources. Currently the HFE team does consist of GE and COL representatives, and COL membership will increase as time continues. At the Design Implementation, there will be both GE and COL membership, and the HFE Team will still be guided by the established processes and procedures outlined in the MMIS and HFE Implementation Plan. Either qualified COL holder or GE personnel on the HFE team may perform the roles of Task Leader, Responsible Engineer, etc.

DCD/LTR Impact

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

~~No changes to the subject LTR will be made in response to this RAI.~~

NRC RAI 18.12-4 S01

(1) Section 1.2 of NEDO-33278 Rev-2 describes a somewhat different organization than was identified in the RAI response. It states that the verifications are the responsibility of the COLOG. Clarify the role of the COLOG and the COL license applicant.

(2) Section 1.2 of NEDO-33278 Rev-2 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.

GEH Response

- (1) The role of the COL Owners Group (COLOG) was established after the writing of the NEDO-33278 Rev 1 and the response to the original RAI. The role of the COLOG is described in the MMIS and HFE Implementation Plan (NEDO-33217 Rev 3) sections 3.1.4, 3.1.4.2(15), and 3.1.4.2(16) with additional details in the Human Performance Monitoring Implementation Plan (NEDO-33277 Rev 2). The COL license applicant has the responsibility to comply with the regulatory obligations of the design implementation activity, with the COLOG serving as the entity that facilitates and supports the performance of the activity.

The NEDO-33278 will be revised in the next revision to the document, as noted in the attached markups, to clarify that the COL applicant (with the support of the COLOG) is responsible for the design implementation of new plants constructed from the ESBWR standard design.

- (2) The wording of the scope is not clear and NEDO-33278 will be revised in the next revision to the document, as noted in the attached markup, to clarify that the design implementation applies to all new plants constructed from the ESBWR standard design.

DCD/LTR Impact

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

LTR NEDO-33278, Rev 2 will be revised as noted in the attached markup (See Attachment 1).

NRC RAI 18.12-4 S02

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.

(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?

(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.

GEH Response

- (3) The section was amended in supplement 1 to this RAI to indicate that the COL applicant (with the support of the COLOG) has the responsibilities. GEH wants to amend the wording in the response from "COL applicant" to "COL holder" and "COLOG" to "COL owner's group". The COLOG is the name given to the owner's group that will support the COL holder in the completion of the design implementation. The verifications are the responsibility of the COL holder. To avoid confusion, the term "COLOG" will be replaced with "COL owner's group" throughout the NEDO-33278 and globally replaced in the NEDO-33277 and NEDE/NEDO-33217P, the only other HFE plan documents that contain the term "COLOG". No attachments for the global replacements are provided.
- (4) GEH agrees that all new plants based on the ESBWR standard plant design need to be verified. Supplement 1 to this RAI addressed this issue and the response is repeated below. See the attachment and response to RAI 18.12-4 S01.

RAI 18.12-4 S01 response stated:

"The wording of the scope is not clear and NEDO-33278 will be revised in the next revision to the document, as noted in the attached markup, to clarify that the design implementation applies to all new plants constructed from the ESBWR standard design."

DCD/LTR Impact

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

LTR NEDO-33278, Rev 2 will be revised as noted in the attached markup (See Attachment 1).

LTR NEDO-33277, Rev 2 will be revised as described above.

LTR NEDO/NEDE-33217P, Rev 3 will be revised as described above.

NRC RAI 18.12-4 S03

GEH provided a response to RAI 18.12-4 S01 in MFN 07-499 and an updated response (18.12-4 S02) in MFN 08-088. The GEH response in MFN 07-499 is acceptable to the staff and included a hand markup of NEDO-33278. However, GEH provided a slightly different response in MFN 08-088 and included a redline-strikeout version of the changes to NEDO-33278 which needs clarification.

In MFN 07-499, GEH deleted NEDO-33278, Section 1.1, "Purpose," item 4, "Transfer design implementation responsibility to the COLOG [combined operating license owner's group]." Such a deletion is appropriate since GEH clarified in the RAI response that design implementation is the responsibility of the COL applicant, not the COLOG. However, the updated response in MFN 08-088 retains item 4. This is inconsistent with the RAI response and other changes made to NEDO-33278 in MFN 08-088. Please clarify the role of the COL applicant and the COL owner's group.

GEH Response

In Rev 3 of the LTR item 1.1(4) "~~Transfer design implementation responsibility to the COLOG.~~" has been deleted. The responsibility for design implementation remains with the COL Holder.

DCD/LTR Impact

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

LTR NEDO-33278, Rev 3 will be revised as described above.

MFN 08-481

Attachment 1

Markups and Added Text for RAIs

18.7-7 S03, 18.7-8 S03, 18.11-21 S02

Markups and Added Text for RAIs

18.7-7 S03 and 18.7-8 S03

Verified DCD and LTR changes associated with this RAI response are identified in the enclosed DCD or LTR markups by enclosing the text within a black box. The marked-up pages may contain unverified changes in addition to the verified changes resulting from this RAI response. Other changes shown in the markup(s) may not be fully developed and approved for inclusion in DCD Revision 5 or respective LTR.

the same risk criteria as equipment when evaluating their risk importance and taking actions to manage the risk.

3.2.1.1 ~~Quantitative Goal and Application~~ Use of Importance Measure

~~The ESBWR PRA defines potentially risk significant SSC and HI events and information using conservative thresholds such as FV greater than or equal to 0.01, and a RAW greater than or equal to 5.0 for individual events and a RAW greater than or equal to 50 for common cause failures. The quantitative goal for ESBWR HFE program is to keep the quantitative risk importance of all potentially risk important HIs below a RAW value of 2.0 and a FV value of 0.1. These two risk IMs represent the range of conditions for setting limits on the risk contribution for human interactions. The goals are met by providing levels of automation to support the HI and ensuring that the task can be identified through the HSI, planned through training and procedures, and implemented with tools as needed.~~

The ESBWR PRA defines potentially risk-significant structures, systems, and components (SSC) and HI events and information that contribute to CDF and LRF using conservative thresholds, such as FV greater than 0.01, and a RAW greater than 5.0 for individual basic events and a RAW greater than 50.0 for common cause failure events (NEDO-33201R2 Chapter 17). These risk importance threshold values are established to meet PRA goals and support the identification of potentially risk important human interactions.

The risk important HIs from analysis of PRA results are provided in NEDO-33201R2 in Table 17.1-3 and additionally in Table 17.2-5 post-initiator actions. These are considered to be risk important human actions for evaluation in the HFE task analysis. Potentially risk important HIs that are used as inputs to the PRA are provided in Table 6.3-3 of NEDO-33201R2. The risk important HIs, used in the HFE evaluation of risk important human actions, are also provided in the HRA results summary report.

The goal of the HRA and HFE operational analysis in DCD Chapter 18 is to verify that the means are provided in the plant design to keep the quantitative risk importance of all potentially risk important human interactions modeled in the PRA below a FV value of 0.1 and RAW of 2.0 as low as practical. For the purpose of human reliability analysis and human factors engineering, a human interaction HIs with a FV value greater than 0.1 or a RAW value greater than 2.0 is are considered to be classified as important to risk. The goals are met by ensuring that information for identifying, planning and implementing the needed action within the time permitted is provided in the design or by providing automated support to carry out the needed action. For example, the operator can identify the need for manual actions through the HSI, plan through procedures and training and implement with tools as needed.

~~GEH commits to using each individual PRA model for CDF and LRF to evaluate HI importance. The importance of each modeled HI is measured using the RAW and FV risk importance ranking at each stage of PRA development. Each importance measure is individually applied to the top event of all ESBWR PRA submodels that include the CDF for level 1 internal events, LRF for level 2, all of the external events such as fire and flooding, and special analysis such as the shutdown PRA analysis. The individual PRA application models are used to compare each HI event with the top event total to ensure that the potentially important HIs modeled do not exceed~~

the quantitative limits for HI contribution to the risk. GEH commits to using each individual PRA model for CDF and LRF to evaluate HI importance. The importance of each modeled HI is measured using the RAW and FV risk importance ranking at each stage of PRA development, and when the PRA results are combined into a total risk model. Each importance measure is individually applied to the top event of all ESBWR PRA submodels. These models include the CDF for level 1 internal events, LRF for level 2, all of the external events such as fire and flooding, and the shutdown PRA.

The individual PRA application models are used to compare each HI event with the top event total to ensure that all potentially important HIs are ranked by their risk importance measures.

The risk impact of potentially risk important HIs is evaluated for the beyond design basis events using a relative risk approach. First, potentially risk sensitive actions that support ESBWR safety for beyond design basis events are identified in both the PRA and through the top down HFE operational analysis. Sensitivity analyses using the FV, RAW and RRW described above on the basic events related to HIs are used to create a listing of top risk contributors on a relative basis. This listing is generated in the PRA and is compared with the top down operational analysis to identify gaps and support requantification for the PRA. On a relative scale, the HIs with a FV greater than 0.1 and RAW of 2.0 for CDF and LRF are subjected to the greatest detail in the HFE tasks to ensure that their risk impact is reduced to below the cutoff values, even though the absolute risk values are far below regions I and II described in NUREG-1764.

3.2.1.2 Application Process

The application process for evaluating potentially risk important HIs involves three main steps: These are: identifying potentially risk important the HIs, evaluating the HIs against qualitative and quantitative criteria, and verifying that the quantified HIs are classified as risk important or are is below the threshold importance measures these quantitative IM cutoff values. The HFE program addresses the verification that the potentially risk important HIs can be carried out using the HSI, procedures, the implementation interface and other features identified in the PRA accident context. Also, the potentially risk important HIs are used during V&V simulations to verify that the control room interface and procedures support the assigned HEP for the HI.

Potentially risk sensitive actions that support ESBWR safety are identified through the top down HFE operational analysis and in the PRA for beyond design basis events. Sensitivity analyses using the FV and RAW importance measures described above on the basic events related to HIs are used to populate a list of relative risk contributors. This listing is generated from the PRA models and is compared with the top down operational analysis to identify gaps in the identification of potentially risk important actions and support requantification of the PRA HIs.

The risk impact of potentially risk important HIs is evaluated using both feasibility criteria and the relative risk listing.

The HIs from the PRA are evaluated for feasibility using the qualitative criteria in Section 4.1. On a relative scale, the risk important HIs identified in the PRA with a FV greater than 0.1 or RAW greater than 2.0 for CDF and LRF are subjected to the greatest detail in the HFE operational assessment and HSI design to ensure that their risk impact is reduced to as low as practical.

The goal of keeping the risk importance measure as low as practical is met by ensuring that information for identifying, planning, and implementing the needed human action within the time permitted is provided in the design or by providing automated support to carry out the needed action. For example, the design ensures that the operator can identify the need for manual actions through the HSI, plan through procedures and training, and implement with tools as needed[GWH27].

If the human interaction can't be automated or partly automated to reduce the importance value below the threshold (e.g., either RAW or FV continues to exceed the risk importance threshold criteria for human interactions of FV equals 0.1 or RAW equals 2.0), then the action is classified as a risk important human action. Risk important human actions receive individual HFE emphasis during task analysis to define special needs for training, priority in procedures, and during HSI design for clarity of cues and information feedback, and ease of implementation to increase the likelihood of success.

In the case of the ESBWR the passive features and automation virtually eliminate the need for the safety-related human actions required for design basis events (e.g., manually start a safety system). These design features reduce the CDF to a mean value much lower than the predecessor plants used as the basis for the NRC risk regions in RG 1.174. As a result, the baseline risk boundaries ~~boundaries for the ESBWR associated with the risk regions in RG 1.174~~ are far below the boundaries for regions I and II following the risk mapping process described in NUREG-1764. ~~are far above the ESBWR baseline risk.~~ Hence, the ESBWR basic events representing potentially risk important HIs do not become important contributors to plant risk on an absolute basis.

The HFE program addresses the verification that the potentially risk important HIs can be carried out using the HSI, procedures, the implementation interface, and other features needed to manage accidents. The PRA scenarios provide situational conditions for developing an error forcing context that is used to verify design defenses against error modes in risk important HIs. Also, the potentially risk important HIs are used during V&V simulations to validate that the control room interface and procedures support the assigned human error probability (HEP) for the HI.

3.2.2 HRA Quantification

There are a number of HRA modeling approaches that can be used to produce the basic event quantifications that are modeled in the PRA. Table 1 provides a classification of HRA quantification approaches based on the number of key probability elements (Px) in the HRA models. Currently available HRA models contain from one to four probability elements or nodes that can be used for quantification for a task. These elements are classified in Table 1 based on descriptions of the cognitive and implementation steps required to carry out an action task. Examples of the method for each Px are provided in Appendix A. The examples are not expected to cover all modeling approaches because within the community of HRA analysts there are varying viewpoints on the depth of HRA needed for PRAs. The consideration of Px permits the development of new methods for quantification. HRA models with two or more quantification nodes can satisfy the ASME PSA Category II and III requirements [ASME-RA-S-2002], if the effort is placed on collecting plant specific data as listed in the requirements.

Post-initiator human failure events: human failure events that represent the impact of human errors committed during actions performed in response to an accident initiator (ASME-RA-S-2002).

Pre-initiator actions: human activities such as maintenance, testing and calibration conducted during normal operation can either correct a previously unrevealed fault or lead to inoperable equipment without causing a transient. The important errors are those that defeat redundant or diverse systems required for safety and leave the system in an unrevealed fault state (i.e., Type A human actions with latent human errors).

Pre-initiator human failure events: human failure events that represent the impact of human errors committed during actions performed prior to the initiation of an accident, (e.g., during maintenance or the use of calibration procedures), (ASME-RA-S-2002).

Primary tasks: those tasks performed by the operator to supervise the plant; i.e., monitoring, detection, situation assessment, response planning, and response implementation (NUREG-1764).

Reactor safety: power reactors have been and can continue to be built and operated safely, with no undue risk to public health and safety, provided the established elements of power reactor safety are honored. ~~the development of a reactor design that is built and operated to pose no undue risk to public~~ (ANS position ~~paper~~ statement 51, 2007). This means that the core is protected from damage under design basis events and the risk from PRA core damage sequences is mitigated through design features, backup systems and operator actions. Additional protection from radiation release is from the containment barrier.

Recovery action: a human action performed to regain equipment or system operability from a specific failure or human error in order to mitigate or reduce the consequences of the failure (ASME-RA-S-2002).

Recovery: a general term describing restoration and repair acts required to change the initial or current state of a system or component into a position, or condition needed to accomplish a desired function for a given plant state (ASME-RA-S-2002).

Remote Shutdown System (RSS): panels, and applicable Local Control Stations located outside the MCR.

Response: a reaction to a cue for action in initiating or recovering a desired function.

Revealed fault: a system or plant fault that is immediately detectable by observation or instruments. They stem from either hardware faults or human induced initiators (Type B human errors).

Risk: probability and consequences of an event, as expressed by the risk triplet that is the answer to the following three questions: (1) What can go wrong? (2) How likely is it? and (3) What are the consequences if it occurs?

Risk-important human actions: actions that are performed by plant personnel to provide reasonable assurance of plant safety. Actions may be made up of one or more tasks. There are both absolute and relative criteria for defining risk important actions. From an absolute

standpoint, a risk important action is any action whose successful performance is needed to provide reasonable assurance that predefined risk criteria are met. From a relative standpoint, the risk important actions may be defined as those with the greatest risk in comparison to all human actions. The identification can be done quantitatively from risk analysis and qualitatively from various criteria such as task performance concerns based on the consideration of performance shaping factors. (NUREG-0711).

Risk-important human interactions: a group of human actions that must be performed successfully by plant personnel, in the context of a PRA, to prevent core damage or large early releases. Both absolute and relative criteria are used to define risk important HAs. The HI becomes risk important when its risk value exceeds ~~From an absolute standpoint, a risk-important HA is one whose successful performance is needed to ensure that predefined risk criteria are met. From a relative standpoint, the risk-important actions constitute the most risk-significant human action identified. Actions may be made up of one or more tasks. The identification can be done quantitatively from the risk-PRA and HRA analysis and qualitatively from various criteria such as task performance concerns based on the consideration of Pests-PSFs (adapted from NUREG-1764 and NUREG-0711).~~

Safety functions: those functions that serve to ensure higher-level objectives and are often defined in terms of a design basis event (a boundary or entity that is important to plant integrity and the prevention of the release of radioactive materials) (adapted from NUREG-1764).

Safety related task: a task that is required to be performed to achieve a safety function defined in the design basis events. Safety related operator tasks qualitatively include those required to start, control and stop equipment in order to meet the design basis event radiological limits. The use of automated systems for starting, controlling and stopping systems in design basis events limits the need for a safety related operator task.

Safety systems: those systems that are designed to prevent or mitigate a design-basis accident (adapted from ASME-RA-S-2002).

Safety-related operator action: a manual action required by plant emergency procedures that is necessary to cause a safety-related system to perform its safety-related function during the course of any Design Basis Event. The successful performance of a safety-related operator action might require that discrete manipulations be performed in a specific order (NUREG-1764). Use of passive and automated systems removes the need for safety related operator actions.

Screening analysis: an analysis that eliminates items from further consideration based on their negligible contribution to the probability of a significant accident or its consequences (ASME-RA-S-2002).

Screening criteria: the values and conditions used to determine whether an item is a negligible contributor to the probability of an accident sequence or its consequences (ASME-RA-S-2002).

Secondary tasks: those tasks that the operator must perform when interfacing with the plant, but are not directed to the primary task. Secondary tasks may include: navigating through and paging displays, searching for data, choosing between multiple ways of accomplishing the same task, and making decisions regarding how to configure the interface (NUREG-1764).

Markups and Added Text for RAI

18.11-21 S02

- License, qualifications, and shift staffing – There must be at least one SRO and one or two operators in each crew.
- Skill and experience – A range of skill and plant operating experience is included to represent the experience levels of potential population users. Operational personnel selected to participate in operational tests exhibit a mix of high and low skill levels to approximate the range of capability found in operational personnel.
- Age – The distribution of user population age is represented in the participant group.
- Population demographics – The participant subject pool is drawn from a randomly selected sample of operators representing the population demographics of operators (age, gender, ability, and so forth)

5.4.2.2 Minimal and Normal Crew Configurations

During full scope simulator HSI testing, a minimum number of three crews and a minimum crew configuration of two and a normal crew configuration of three are tested. Additionally, some scenarios are conducted with the addition of a shift manager and/or a shift technical advisor.

In the full scope simulator, a normal crew of three is used to test the HSI, as determined in NEDO-33266. This crew consists of: two licensed operators and one SRO. The first operator is assigned to normal control actions at the MCR HSI. The second operator performs plant control duties as directed and is assigned to control of testing, surveillance, and maintenance activities. This crew operates the ESBWR during all phases of normal plant operation, abnormal events, and emergency conditions.

A minimal crew of two is used to test HSI capabilities in a condition in which one of the normal crew operators has become incapable of performing operating procedures due to accident, illness, and so forth. This crew consists of one SRO and one operator.

5.4.2.3 Prevention of Sampling Bias

Randomized sampling is used to select participants from a population representative of the plant personnel who interact with the HSI. To prevent sampling bias, the following personnel are ineligible for participation:

- Participants who are part of the design organization.
- Participants who were involved in prior design evaluations. However, participants may perform a training evaluation following ESBWR operator training.
- Participants who were selected for some specific characteristic (selecting only good or experienced crews.)

5.4.3 Scenario Definition and Documentation

The integrated system validation scenarios selected during the operational conditions sampling and scenario development process are defined so that they can be performed on a simulator. Scenario definition is used to provide a consistent, objective, and high fidelity environment in which to validate performance of the integrated systems.

MFN 08-481

Enclosure 3

Affidavit

GE Hitachi Nuclear Energy

AFFIDAVIT

I, **David H. Hinds**, state as follows:

- (1) I am the General Manager, New Units Engineering, GE Hitachi Nuclear Energy (GEH) 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 MFN 08-481, Mr. James C. Kinsey to U.S. Nuclear Regulatory Commission, entitled *Response to Portion of NRC Request for Additional Information Letter No. 178 Related to ESBWR Design Certification Application – Human Factors Engineering - RAI Numbers 18.7-7 S03, 18.7-8 S03, 18.8-2 S02, 18.11-21 S02, 18.11-25 S02, 18.11-32 S02, and 18.12-4 S03*– GEH Proprietary Information, dated July 2nd, 2008 is delineated by a [[dashed underline inside double square brackets.⁽³⁾]]. Figures and large equation objects 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, 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, 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 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. 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, by the manager of the cognizant marketing function (or his delegate), and by the Legal Operation, 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 the software plans to the GEH ESBWR.

The development of the evaluation process along with the interpretation and application of the regulatory guidance 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.

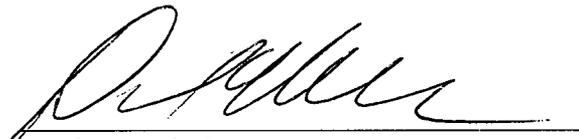
The precise value of the expertise to devise an evaluation process and apply the correct analytical methodology is difficult to quantify, but it clearly is substantial.

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 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 2nd day of July 2008.

A handwritten signature in black ink, appearing to read 'D. Hinds', written over a horizontal line.

David H. Hinds
GE Hitachi Nuclear Energy