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Proprietary Notice

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

MFN 08-672

Docket No. 52-010

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U.S. Nuclear Regulatory Commission
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Subject: Response to Portion of NRC Request for Additional Information Letter No. 201 Related to ESBWR Design Certification Application – Human Factors Engineering - RAI Numbers 18.11-3 S02, 18.11-4 S02, 18.11-19 S02, 18.11-22 S02, 18.11-24 S02, and 18.11-27 S02

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 (RAI) dated June 3, 2008, (Reference 1) for RAIs 18.11-3 S02, 18.11-4 S02, 18.11-19 S02, 18.11-22 S02, 18.11-24 S02, and 18.11-27 S02.

The GEH responses to RAIs 18.11-3 S01, 18.11-4 S01, 18.11-22 S01, and 18.11-27 S01 were previously provided via Reference 2 in response to Reference 3. Reference 4 provided the original response to the RAIs, as requested in Reference 5.

The GEH responses to RAIs 18.11-19 S01 and 18.11-24 S01 were previously provided via Reference 6 in response to Reference 3. NRC letter No. 153 (Reference 3) superseded the wording in RAIs 18.11-19 S01, and 18.11-24 S01. Reference 4 provided the original response to these RAIs, based on the NRC's original request (Reference 5).

Enclosure 1 contains the RAI responses for RAIs 18.11-3 S02, 18.11-4 S02, 18.11-19 S02, 18.11-22 S02, 18.11-24 S02, and 18.11-27 S02.

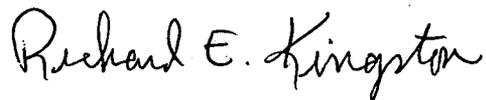
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Enclosure 2 contains GE Hitachi Nuclear Energy (GEH) proprietary information as defined by 10 CFR 2.390. GEH customarily maintains this information in confidence and withholds it from public disclosure. A non-proprietary version is provided in Enclosure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

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

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

Sincerely,



Richard E Kingston
Vice President, ESBWR Licensing

References:

1. MFN 08-499, *Request for Additional Information Letter No.201 Related to ESBWR Design Certification Application*, dated May 28, 2008
2. MFN 08-156, Letter from James C. Kinsey to Nuclear Regulatory Commission, *Response to Portion of NRC Request for Additional Information Letter No. 153 Related to ESBWR Design Certification Application – Human Factors Engineering – RAI Numbers 18.4-26 S01, 18.11-3 S01, 18.11-4 S01, 18.11-22 S01, and 18.11-27 S01*, dated April 14, 2008
3. MFN 08-130, Letter from U.S. Nuclear Regulatory Commission to Robert E. Brown, GEH, *Request For Additional Information Letter No. 153 Related To ESBWR Design Certification Application*, dated February 12, 2008
4. 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
5. MFN 06-386, *Request for Additional Information Letter No.74 Related to ESBWR Design Certification Application*, dated October 11, 2006

6. MFN 08-172, *Response to Portion of NRC Request for Additional Information Letter Nos. 129 and 153 Related to ESBWR Design Certification Application – Human Factors Engineering - RAI Numbers 18.9-2 S01, 18.11-7 S01, 18.11-19 S01, 18.11-23 S01, 18.11-24 S01, 18.11- 26 S01, and 18.11-29 S01*, dated April 16, 2008

Enclosures:

1. MFN 07-672 - Response to Portion of NRC Request for Additional Information Letter No. 201 Related to ESBWR Design Certification Application ESBWR Human Factors Engineering - RAI Numbers 18.11-3 S02, 18.11-4 S02, 18.11-19 S02, 18.11-22 S02, 18.11-24 S02, 18.11-27 S02
2. MFN 07-672 – Attachments for Supporting RAIs 18.11-3 S02, 18.11-4 S02, 18.11-19 S02, 18.11-22 S02, 18.11-24 S02, and 18.11-27 S02 – GEH Proprietary Information
3. MFN 07-672 – Attachments for Supporting RAIs 18.11-3 S02, 18.11-4 S02, 18.11-19 S02, 18.11-22 S02, 18.11-24 S02, and 18.11-27 S02 – Non Proprietary Version
4. Affidavit – MFN 07-672

cc: AE Cubbage USNRC (with enclosures)
RE Brown GEH/Wilmington (with enclosures)
DH Hinds GEH/Wilmington (with enclosures)
eDRF 0000-0088-2722

Enclosure 1

MFN 08-672

Response to NRC Request for Additional Information

Letter No. 201

Related to ESBWR Design Certification Application

Human Factors Engineering

RAI Numbers

**18.11-3 S02, 18.11-4 S02, 18.11-19 S02, 18.11-22 S02,
18.11-24 S02, 18.11-27 S02**

For historical purposes, the original text of RAIs 18.11-3, 18.11-4, 18.11-19, 18.11-22, 18.11-24, 18.11-27 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

18.11-3

NRC RAI 18.11-3

NEDO-33276, Sections 4.2.1 and 4.3.1.4.1 describes the sampling dimensions and indicates that a "multidimensional sampling strategy" (p. 18) will be used. Section 4.3.1.4.1, Items 1 through 3 largely restate the dimensions listed in NUREG-0711 (as presented in the sections below). While this is acceptable, the methodology or strategy that will be used to identify the sample of operational conditions that will reflect these dimensions is not identified. In the absence of such methodology, the staff has no basis to determine whether the sample characteristics described will be achieved. Please describe the method that will be used to select the set of operational conditions along the sampling dimensions described in NEDO-33276.

GE Response

The multidimensional sampling strategy for establishing the sample of required operator actions for specific plant conditions to be used during simulations uses the actions defined as required to achieve the safety functions from the operations analysis.² The strategy will also sample human back up actions to automatic systems, actions required during normal startup, shutdown, and trip simulation scenarios. The strategy includes the use of risk important actions required in scenarios that lead to core damage as quantitatively identified in the PRA/HRA. The strategy also includes actions identified thru the OER process and a sampling of actions that exercise the use of the MMIS information and control features.

The method for selecting the actions to be sampled will incorporate the actions into a set of scenarios that cover all important actions, information, and control features that are tested under different conditions during each of the three V&V simulation phases. The final set of scenarios defined for use in the integrated validation phase will satisfy the criteria for the range of plant conditions, personnel tasks, and situational factors known to challenge personnel performance, and the combined set of sequences will comprise all of the HSI and actions represented in the information and control needs derived from the operations analysis.

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 18.11-3 S01

NRC Summary Text:

Operational conditions sampling: Sampling Dimensions

NRC Full Text:

NEDO-33276, Rev. 1 provides a high-level summary of the sampling dimensions in Section 4.1.4.1. Items 1 through 3 in the section largely restate the review criteria for sampling dimensions in NUREG-0711 (Section 11.4.1.2). The staff cannot perform an implementation plan review when the plan simply restates the staff's review criteria. The plan should identify the operational conditions to be used for V&V and the process by which the sampling dimensions were used to identify them. The staff can then use the NUREG-0711 criteria in NUREG-0711 to review the acceptability of the operational conditions that have been identified.

GEH Response

To reflect the level of detail required for an Implementation plan, both the text and document organization in NEDO-33276 will be revised. The final organization is incomplete, but the revision will include a section that details how operational condition sampling dimensions are used in the integrated system validation process.

The text below will be inserted in the Operational Condition Sampling section.

The purpose of the operational condition sampling process is to ensure that a broad and representative range of operating conditions are included in the sample population used to select integrated system validation scenarios. To ensure a representative sample that emphasizes safety significance, risk, and challenges to the operating crew, a weighted list of operational conditions is developed.

The ESBWR operational condition sampling process occurs in four major phases:

- Define weighting factors to be used in integrated system validation scenario selection.
- Define the minimum conditions and tasks to be represented in the scenarios selected for the integrated system validation.
- Develop a representative population of operational conditions and tasks from which to select integrated system validation scenarios.
- Select weighted scenarios from the defined population to be used to validate the integrated ESBWR systems and their controls.

Define Weighting Factors

The scenario selection process uses multidimensional selection criteria to identify integrated system validation scenarios that maximize relevance and significance while insuring all operational condition diversity is met. To accomplish this the following weighting factors will be used to sort scenarios (list presented in order of lowering weight):

- HRA/PRA significance of the event scenario
- Presence of PRA/HRA risk important human actions
- Presence of D3 credited human actions
- Task analysis results indicating high work load, high stress, or the presence of a critical task
- ESBWR Knowledge and Abilities (K/A) catalog importance ranking of task elements

These factors are used later in the process to select the most significant and relevant scenario when analysts encounter situations where more than one scenario can be used to validate the same operational conditions.

Define minimum conditions and tasks:

The following operational conditions or tasks are present in at least one integrated system validation scenario:

- Each human action identified in the HRA/PRA, DCD, and the NRC safety evaluation report (once written) as being risk important
- Each first of a kind system used in the ESBWR design
- Each leg of the EOP/SAMG flow charts
- Each safety system
- Support system failures affecting other systems (i.e. electrical, cooling water, and control air systems)
- Each major area of the HSI (QDCIS, NDCIS, RSS, MCR side panels, WDP)
- Plant startup from cold shutdown to critical
- Power ascension from critical to 100%
- Plant shutdown from 100% to cold shutdown

- Failure of NDCIS
- At least one error-forcing situation in each of the following areas:
 - 1) Administrative
 - 2) General plant maneuvering
 - 3) Emergency
 - 4) Abnormal
 - 5) Alarm response
 - 6) Normal operations
 - 7) Surveillance, test, and maintenance
 - 8) Chemistry, radiochemical, and radioactivity control
- At least one procedure from every procedure class is exercised, including:
 - 1) Administrative
 - 2) General operating procedures (i.e., startup, shutdown, and power maneuvering)
 - 3) Emergency operating procedures
 - 4) Abnormal operating procedures
 - 5) Alarm response procedures
 - 6) System operating procedures
 - 7) Surveillance, test, and maintenance procedures (those portions involving the MCR, RSS, or risk significant LCS)
 - 8) Chemistry, radiochemical, and radioactivity control procedures (if not represented in the classes above)
- Communications involving each of the following in at least one scenario:
 - 1) Between control room personnel
 - 2) Between control room personnel and field operators
 - 3) Between control room personnel and emergency support centers
 - 4) Between control room personnel and plant management
 - 5) Between control room personnel and other organizations such as NRC or local authorities
- Instances of high and varying workload in at least one scenario in each of the following areas:
 - 1) Administrative
 - 2) General plant maneuvering
 - 3) Emergency
 - 4) Abnormal
 - 5) Alarm response
 - 6) Normal operations
 - 7) Surveillance, test, and maintenance
 - 8) Chemistry, radiochemical, and radioactivity control
- Instances of fatigue and circadian factors in at least one scenario in each of the following areas:

- 1) Administrative
- 2) General plant maneuvering
- 3) Emergency
- 4) Abnormal
- 5) Alarm response
- 6) Normal operations
- 7) Surveillance, test, and maintenance
- 8) Chemistry, radiochemical, and radioactivity control

Develop a representative population of operational conditions and tasks

In order to develop a satisfactory multidimensional sampling of conditions that results in the selection of integrated system scenarios that thoroughly evaluate the ESBWR design, one or more operational conditions or tasks representing each of the following are identified:

Plant control

- Design basis accidents identified in the ESBWR DCD
- Additional risk important scenarios within the scope of the EOPs and SAMGs
- License basis document abnormal operational occurrences
- Additional risk important abnormal events and transients within the scope of AOPs
- Additional risk important equipment degradations and failures within the scope of ARPs
- Normal plant operating manipulations ranging from cold shutdown/refueling to full power operations

Personnel tasks

- Human actions identified in the HRA/PRA, DCD, and the NRC safety evaluation report (once written) as being risk important.
- Historically problematic tasks as identified in the operating experience reports generated using the ESBWR operating experience process.
- Procedures from each class used in the operation of the plant including administrative, emergency, abnormal, alarm response, general operating, system operating, surveillance and testing, maintenance, chemistry control, and radiation control (those portions involving the MCR, RSS, or risk significant LCS)

- Knowledge-based tasks as identified in the ESBWR task analysis. Tasks in this population are those that analysts identified as containing relative or probabilistic decisions during detailed task analysis
- Tasks representing a broad range of human cognitive activities. Tasks in this population are those that analysts identified as containing the following attributes as in the response requirements portion of detailed task analysis:
 1. Detection and monitoring
 2. Diagnosis and situational assessment
 3. Decision making and planning
 4. Plant manipulation
 5. Monitoring plant response
- Tasks involving a range of human interactions and communications as identified in the ESBWR task analysis. Tasks in this population are those that analysts identified as containing communication interactions between the primary task performer and other personnel.
- Tasks performed with high frequency as identified in the ESBWR task analysis. Tasks in this population are those that analysts identified as having high repetition in the response requirements portion of detailed task analysis.

Situational factors

- Operationally difficult tasks as identified in the operating experience reports generated using the ESBWR operating experience process.
- Scenarios specifically designed to generate human errors. This allows error tolerance and error recovery to be evaluated.
- Scenarios performed with varying crew sizes. Variance between minimum and nominal crew size as discussed elsewhere in NEDO-33276.
- Instances of high workload as identified in the ESBWR task analysis. Tasks in this population are those that analysts identified as high workload in the workload determination portion of detailed task analysis.
- Instances of varying workload. Tasks in this area can vary by their nature (i.e. a scram during normal operations, or the cessation of work following the shutdown of a system the crew is controlling), or may vary due to sequencing high and low workload tasks.
- Fatigue and circadian factors. Tasks in this population are those performed with crews that are fatigued and off their normal circadian sleep cycles, prior to the performance of the scenario.

- Environmental factors such as poor lighting, high noise, radiological contamination, or other factors such as operator physical position identified in the ESBWR task analysis. Tasks in this population are those that analysts identified as having environmental factors of interest in the hazards or other factors portion of detailed task analysis.

Select weighted scenarios for use in integrated system validation

Scenarios are selected from the representative population that together fulfill all of the minimum condition and task requirements. When more than one scenario could be used to validate an operational condition or task, the scenario with the highest multidimensional weight is selected.

The scenario selection process uses multidimensional selection criteria to identify integrated system validation scenarios that maximize relevance and significance while insuring all operational condition diversity is met. To accomplish this the following weighting factors will be used to sort scenarios (list presented in order of lowering weight):

- HRA/PRA significance of the event scenario
- Presence of PRA/HRA risk important actions
- Presence of Defense-in-Depth and Diversity (D3) credited human actions
- Task analysis results indicating high work load, high stress, or the presence of a critical task
- ESBWR K/A catalog importance ranking of task elements as defined in the training analysis portion of detailed task analysis

DCD Impact

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

LTR NEDO-33276, Rev 1 will be revised with the inserted text provided above.

NRC RAI 18.11-3 S02

In their response to the RAI, GEH provided detailed information as to the factors to be used as part of the process to identify operational conditions. This acceptably addresses the staff's question concerning how the sampling strategy is used to identify operational conditions. However, the staff's RAI indicated that "The plan should identify the operational conditions to be used for verification and validation (V&V) . . . "

Note that the staff has accepted the use of implementation plans for design certification because they describe the detailed methodology with which the results will be developed. Thus for example, a task analysis implementation plan describes the methodology by which task analysis is performed. When the applicant uses the plan, they produce the task analysis results. This is not the case for the current GEH V&V implementation plan. The staff position is that the V&V plan will identify the specific operational conditions to be used, the scenarios to be used, the measures of performance to be collected for each scenario, and, the specific criteria to be used to evaluate the acceptability of the design. Is the requested level of detail available in a V&V work instruction? If the information is not available at this time, add a COL item to provide the information with the COL application for staff review and prior to conducting V&V activities.

GEH Response

GEH contends that the methodology contained in this implementation plan is at a sufficient level to assure that scenarios and associated elements developed from it will comply with the guidance in NUREG-0711 and ensure a quality validation activity. It should also be noted that GEH will provide a detailed report of the scenario development and resulting test plan in the V&V RSR, ESBWR Design Control Document Tier 1 Table 3.3-1 ITAAC item 9, and that the process is open for staff review or audit.

To support the staff's evaluation of the level of detail of the V&V Implementation Plan, NEDE/NEDO-33276P, this response provides a roadmap guide in the form of the flow chart included as Attachment 1.

The Operational Conditions Sampling and Scenario Development chart provides the sections in the implementation plan that address RAIs 18.11-3 S02, 18.11-4 S02, and 18.11-22 S02. This flow chart summarizes the methodology for identifying and developing the operational scenarios and provides the corresponding paragraph numbers in the implementation plan defining the detailed methodology. The last box in the chart lists the documents, with the plan's corresponding paragraph numbers, generated to define the scenario and support its successful execution.

By following the outlined operational conditions sampling process, the resulting operational conditions will represent a wide variety of significant demands to challenge system performance.

DCD 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.

RAI

18.11-4

NRC RAI 18.11-4

NEDO-33276, Section 4.3.1.4.2 describes the identification of scenarios. The section restates the two criteria from NUREG-0711. While this is acceptable, the methodology that will be used to develop the scenarios is not identified. In the absence of such methodology, the staff has no basis to determine whether the scenarios developed will acceptably meet the criteria. Please describe the method that will be used to develop the scenarios reflect the scenario characteristics described in NEDO-33276.

GE Response

V&V scenarios will be developed to call on the required human actions for normally operating the plant (e.g., startup and shutdown using manual trip, monitoring actions, surveillance actions, and tagging control processes). Scenarios will be developed to trigger each representative alarm type to verify the process for entering and acting upon the AOPs. Scenarios will be developed to verify human actions needed to monitor and respond to the design basis events; they will exercise all entry conditions and required actions in each EOP. Scenarios based on risk important PRA/HRA cutsets will be used to develop a set of ESBWR specific malfunctions for use in V&V simulations. The library of malfunctions and their combined use will support V&V and future training exercises.

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 18.11-4 S01

NRC Summary Text:
Operational Conditions Sampling: Scenario Identification

NRC Full Text:

NEDO-33276, Rev. 1 provides a high-level summary of the scenario identification in Section 4.1.4.2. The section largely restates the review criteria for scenario identification in NUREG-0711 (Section 11.4.1.3). The staff cannot perform an implementation plan review when the plan simply restates the staff's review criteria. The plan should identify scenarios to be used and how the selected operational conditions were developed into scenarios. The plan should also identify how bias was avoided in the development of scenarios. The staff can then use the criteria in NUREG-0711 to review the acceptability of the scenarios that have been identified.

GEH Response

To reflect the level of detail required for an Implementation plan, both the text and document organization in NEDO-33276 will be revised. The final organization is incomplete, but the revision will include a section that details how selected operational conditions are developed into scenarios and how bias is avoided during scenario development in the integrated system validation process.

The text below will be inserted in the Operational Condition Sampling section.

The list of integrated system validation scenarios selected earlier in the V&V process inputs into the scenario development process described below.

Integrated system validation scenarios that exercise the selected operational conditions are developed using a structured process to ensure consistency, quality, and the minimization of bias. Procedures governing the performance of the integrated system validation process contain guidance regarding the requirements for development and documentation of all scenario attributes including:

- Objectives
- Initial conditions
- Selecting and documenting events
- Scenario attributes, both qualitative and quantitative
- Determining scenario endpoint
- Validation of the scenario itself
- Critical task determination

Each of the major activities that contribute to dynamic simulator scenario development is completed in accordance with the ESBWR simulator scenario development guide and is summarized below.

Identifying Scenario Objectives

Scenarios are assigned a predetermined set of specific objectives based upon the events that take place during the scenario and the attributes, abilities, procedures, and training to be validated. The basic objective of the scenarios is to evaluate the operators' ability to effectively use the ESBWR HSI to respond to the event being simulated. Specifically, each scenario validates the attributes of the associated HSIs and procedures, and the operators' training experiences with them, through observations of:

- Operator knowledge of integrated plant operations (gained through training)
- Operator ability to use the integrated HSI to gather, interpret, and validate indication and plant performance data
- Operator ability to diagnose abnormal plant conditions
- Operator ability to formulate mitigation strategies
- Operator ability to locate and use the appropriate procedures
- Operator ability to use the integrated HSI to implement the chosen mitigation actions
- Operator ability to effectively communicate within the control room environment

Additionally, each scenario contains objectives specific to the operational conditions and events that are contained in it, including:

- Validation of the ability to meet event and scenario acceptance criteria
- Validation of the ability to meet supplemental event and scenario criteria

Initial conditions

Scenarios are assigned a predetermined set of initial conditions established to allow the simulated scenario to commence realistically. The initial conditions are representative of typical plant status that would exist in the ESWBR at the time in the plant operating cycle in which the scenario is to take place. Additional initial conditions are included for realism and may include tagged out components or systems, in progress maintenance, or testing. To eliminate predictability, some initial conditions that have no bearing on subsequent scenario events are included. Specific initial conditions that are to be covered in the scenario shift turnover are identified.

Selecting and documenting events

After initial conditions are established, a sequence of events designed to achieve the scenario's objectives is developed. Each event either directly supports or contributes to the support of one or more objectives. Scenarios are developed so that various systems are affected by each type of event, such as:

- Degradation or failure of instruments, controls and components
- Major plant transients and accidents
- Normal plant maneuvering

Realistic conditions of this kind limit the predictability, recognizability, and potential bias from operator expectations of scenario event timelines. Some scenarios incorporate equipment failures that cause or exacerbate problems in other systems. This practice allows validation of the operators' understanding of system and component interactions, integrated system operations, and the integrated HSI performance across a broad range of conditions.

Scenarios are not a series of totally unrelated events. Integrated system validation scenarios are designed to flow from event to event, giving operators sufficient time to:

- Analyze what has happened
- Evaluate consequences of actions they might take (or inaction)
- Assign priorities to the event based upon plant conditions at the time
- Determine a course of action
- Implement the actions
- Observe and evaluate the plant's response

Scenario designers pre-determine each planned operation, malfunction, and transient and document them as a scenario timeline.

In addition to administrative data associated with the scenario, documentation includes:

- Event descriptions
- How and when the event is initiated
- A listing of the event cues, indications, and symptoms that are available to operators
- Expected actions to be taken
- Expected communications
- Procedures to be used
- Scenario endpoint
- Required operator actions to be observed, including any critical tasks contained within the scenario
- Other variable actions and behaviors that provide useful basis for evaluating operator and integrated HSI performance

Scenario Attributes, Both Qualitative and Quantitative

Integrated system validation scenarios are constructed to accurately test:

- Each individual operator's abilities and skills
- Crew member's team dependent abilities and skills
- The integrated HSIs support of safe and efficient operation
- Procedures
- Staffing and qualification criteria

Each scenario is of sufficient length, scope, and complexity to allow differentiation between acceptable and unacceptable performance. Scenario attributes consist of both qualitative and quantitative elements. Experienced scenario developers use scenario attributes to both construct and assess the quality of ESBWR integrated system validation scenarios. This assessment, combined with scenario validation, ensures the scenario is an acceptable tool to validate the integrated HSI and crew operating it. The following attributes used to develop and assess scenario acceptability are described in greater detail in the ESBWR Scenario development procedures:

Scenario Qualitative Attributes:

- **Realism/Credibility** – Initial conditions, external communications, plant response, and other similar scenario details are sufficiently similar to actual plant performance that the crew performance observed is representative of what can be expected in an operating ESBWR.
- **Event Sequencing** – Event sequencing supports the scenario objectives. Order of events can affect complexity and some events build upon the aftermath of others. Additionally, some scenario objectives may seek to validate the crew's ability to respond to simultaneous events.
- **Simulator Modeling** – The simulator model used in the scenario retains its ANS-3.5 fidelity and is not altered simply to derive the desired scenario results.
- **Evaluating Competencies** – Scenarios are of sufficient duration, complexity, and diversity that the competencies and attributes to be validated during the scenario can be adequately assessed.
- **Level of Difficulty** – Scenarios are sufficiently difficult to adequately validate that the integrated HSI and the crew's ability to safely and efficiently meet the scenario objectives. Scenarios that are too easy or too difficult are not effective discriminators.

Scenario Quantitative Attributes:

- **Normal Evolutions** – A sufficient number of normal system manipulations are incorporated into the scenario to meet the objective of validating the integrated HSI and its use.
- **Number and Sequence of Malfunctions** – The number of equipment malfunctions incorporated into the scenario and the sequence in which they are presented varies between scenarios and validates response to both minor inconveniences and loss of significant safety equipment and indications.
- **Abnormal Events and Major Transients** – The number, severity, and sequence of abnormal and major events adequately exercises the areas contained in the scenario

validation objectives. The abnormal and major transients contained in the scenario meet the objective of validating the integrated HSI and its use.

- **EOPs and Contingencies Used** – The scenario is constructed so as to fully exercise any EOPs or contingencies designated as validation objectives for the scenario. The EOP exercises contained in the scenario meet the objective of validating the integrated HSI and its use.
- **Total Run Time and Run Time in EOPs** – Typical scenario run time is approximately 60-90 minutes though some scenarios may require either more or less time based upon their content. The scenario duration is sufficient to meet the objective of validating the integrated HSI and its use.
- **Critical Tasks** – The number of critical tasks contained in a scenario and scenario difficulty varies but is also adjusted to ensure that scenarios are not so easy nor so difficult that they are not valid measures of performance. Scenario critical tasks and difficulty is sufficient to meet the objective of validating the integrated HSI and its use.

Determining scenario endpoint

A scenario endpoint is selected and documented. The endpoint specified identifies a particular plant condition, procedural step, plant parameter, or other clearly recognizable condition. The endpoint parameter is specifically selected to allow completion of all scenario objectives prior to scenario termination.

Validation of the scenario

The structure, timeline, flow, and all other aspects of integrated system validation scenarios are validated prior to use of the scenario in ESBWR V&V. Scenario validation ensures that the scenario runs as intended and that supporting scenario development and execution materials are accurate.

Critical task determination

Critical tasks are those human dependant actions or controlled parameters that evaluate crew performance on tasks that are safety significant to the plant or to the public. As such, critical tasks are objective measures for determining whether the performance of the integrated HSI, crew, or individual is satisfactory or unsatisfactory.

The following attributes used to identify and document critical tasks are described in greater detail in the ESBWR Scenario development procedures. Critical tasks contain all of the following elements:

- **Safety Significance** – A task where performance, or omission by an operator will result in direct adverse consequences or significant degradation in the mitigative capability of the plant.
- **Cueing** – External stimulus must prompt at least one operator to perform the task.

- **Measurable Performance Indicators** – The task must consist of positive action taken by at least one operator that an observer can objectively identify.
- **Performance Feedback** – The task must provide at least one member of the crew with feedback information regarding the affect of the crew's action or inaction in relation to the critical task.

Bias

Bias represents any influence, condition, or set of conditions that singly or together distort the data. Bias can produce systematic (but unexpected) variation in a research finding, and can invalidate any conclusions made based on a biased sample. Therefore, when selecting operational conditions and developing scenarios, care must be taken to avoid creating a biased sample.

Measures Taken to Eliminate or Control Bias During Scenario Development

The professionals on the ESBWR HFE evaluation team, control scenario bias through a number of means. These include:

- Procedurally controlled scenario development and validation process
- Validation tests performed using scenarios that are developed by selecting from the full range of operational conditions, and that cover a representative range of conditions
- Scenario validation, which includes an evaluation of scenario attributes and their distribution
- Pilot studies to identify possible sources for scenario bias and develop controls

After scenario development is complete, the resulting set of scenarios are evaluated for selection bias in any of the following areas:

- Scenarios for which only positive outcomes are expected – This is avoided in part by selecting operating conditions for use in scenarios identified in the PRA/HRA as risk important, risk important accident scenarios within the scope of EOPs and SAMGs, and conditions known to challenge human performance, and by including these conditions in scenarios. This type of bias is also avoided by following the “backcasting” methodology described below.
- Scenarios are relatively easy to conduct administratively (scenarios that place high demands, data collection or analysis are avoided) – scenarios are developed that best accommodate all of the selected tasks and conditions, not which scenarios are the easiest to conduct.

- Scenarios that are familiar and well structured (i.e., which address familiar systems and failure modes that are highly compatible with plant procedures such as “textbook” design-basis accidents) – because scenarios are developed from selected operational conditions, and because event sequencing is built in as part of scenario definition, it is not expected for scenarios to follow highly familiar sequences.

“Backcasting”

- Part of the scenario identification and development process involves “backcasting.” Backcasting involves identifying a future state (both desirable and undesirable) as identified in SAMGs, EOPs, AOPs, ARPs, and Normal operating conditions, and constructing paths that connect the specified end condition to the conditions and actions required to achieve or avoid them.
- This approach can reduce the risks of hidden bias in construction of scenarios. By selecting both desirable and undesirable outcomes, and by developing scenarios with conditions and events that vary the likelihood of reaching the outcome, a representative and balanced set of scenarios is identified.

If development bias is detected, scenarios will be analyzed for alternatives to create a more fair and representative range of events. Any occurrences of significant sampling bias should be logged as issues in the HFEITS for tracking and resolution.

DCD Impact

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

LTR NEDO-33276, Rev 1 will be revised with the inserted text provided

NRC RAI 18.11-4 S02

In their response to the RAI, GEH provided detailed information as to the scenario development process. However, the staff's RAI indicated that "The plan should identify scenarios to be used . . . "

As described in RAI 18.11-3 S02, please provide the specific scenarios for verification and validation (V&V) in the V&V implementation plan. If the information is not available at this time, add a COL item to provide the information with the COL application for staff review and prior to conducting V&V activities.

GEH Response

GEH contends that the methodology contained in this implementation plan is at a sufficient level to assure that scenarios and associated elements developed from it will comply with the guidance in NUREG-0711 and ensure a quality validation activity. It should also be noted that GEH will provide a detailed report of the scenario development and resulting test plan in the V&V RSR, ESBWR Design Control Document Tier 1 Table 3.3-1 ITAAC item 9, and that the process is open for staff review or audit.

To support the staff's evaluation of the level of detail of the V&V Implementation Plan, NEDE/NEDO-33276P, this response provides a roadmap guide in the form of the flow chart included as Attachment 1.

The Operational Conditions Sampling and Scenario Development chart provides the sections in the implementation plan that address RAIs 18.11-3 S02, 18.11-4 S02, and 18.11-22 S02. This flow chart summarizes the methodology for identifying and developing the operational scenarios and provides the corresponding paragraph numbers in the implementation plan defining the detailed methodology. The last box in the chart lists the documents, with the plan's corresponding paragraph numbers, generated to define the scenario and support its successful execution.

By following the outlined scenario development process, the resulting scenarios will represent the aspects of operational conditions that have a significant effect on human performance.

DCD 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.

RAI

18.11-19

NRC RAI 18.11-19

NEDO-33276 does not address how important actions at complex HSIs remote from the main control room will be addressed in validation. Specific operational conditions and scenarios to be used in validation have not yet been identified, it is not possible to know what important actions remote from the control room should be represented. Please provide information as to how it will be determined which actions outside the control room should be included in validation scenarios and how these actions will be modeled.

GE Response

The part task simulations and full scope test scenarios will be developed to address actions that are defined in four categories. The first set comes from the operational analysis as shown in Figure 2 of NEDO-33276. The second set comes from PRA/HRA identified risk important actions that involve multiple actions in the same scenario from different locations. The third set comes from specific actions identified in the procedures for systems or integrated plant actions.

The fourth set of actions are based on events and experience. The design of the ESBWR attempts to minimize complex actions by providing a large time interval to take the action, by using natural circulation for cooling and maintaining a passive heat removal system for decay heat. The validation of actions begins with the part task simulator which provides an accurate control room interface for each system. In this case outside actions at local system control stations are estimated using drawings or mockup panels. The validation of integrated actions begins with the full scope simulator (which may use electronic versions of back panels and the RSS).

If some complex actions could not be fully validated during full scope simulation the process can be extended to the plant itself to verify that complex coordinated actions between the control room and local stations can be carried out using the plant procedures and MMIS.

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 18.11-19 S01

NRC Summary Text:

Validation Testbeds: Validation Simulator and Simulation of remote actions

NRC Full Text:

This follow-up RAI on testbeds has two parts:

1. Regarding the testbed to be used for integrated system validation, Section 3.4 of NEDO-33276 states that integrated system validation is performed using dynamic HSI prototypes and high-fidelity simulators. Section 4.3.4 describes a variety of test beds that are to be used to address the different objectives of the validation program. Three of the main simulation facilities to be used in this program are the GEH Test System, Baseline Simulator (BS), and the Full Scope Simulator (FSS), described in Sections 4.3.5.2, 4.3.5.3, and 4.3.5.4, respectively. These simulators provide incremental levels of fidelity, and the BS and FSS models are ANSI/ANS-3.5 compatible.

While ANSI/ANS 3.5 compatibility provides an acceptable basis for an integrated system validation testbed as described in NUREG-0711, the BS does not provide the full control room HSI. Thus, based on the staff's validation testbed criteria in NUREG-0711, Section 11.4.3.2.2, only the FSS is suitable for implementing integrated system validation. While the other simulators can provide valuable information to GE during their test and evaluation program, the final validation addressed in NUREG-0711 should be performed using the FSS. GEH should clarify the role of the FSS in the final validation. In addition, in response to RAI 18.10-1 GEH submitted the Attachment to MFN 07-625 in which simulation capabilities are defined, including a Part Task Simulator, Full-Scope Simulator, and Site Specific Training Simulator. The BS is not included in this response. Please describe how these descriptions correspond to those provided in NEDO-33276 and provide any changes to descriptions in NEDO-33276 that may be necessary to reconcile the two documents.

2. Regarding the simulation of remote actions, Section 4.3.4.1 indicates that actions at local system control stations are evaluated using drawings or mockup panels, but no information as to what evaluations are performed or how the actions will be analyzed. This statement is in the HFE Design Verification section rather than an integrated system validation section. Beyond this statement, no information about the treatment of local actions is provided. Please identify what remote actions are needed for the scenarios to be used in validation testing and provide information as to how these actions will be modeled and evaluated for validation.

GEH Response

To reflect the level of detail required for an Implementation plan, both the text and document organization in NEDO-33276 will be revised. The final organization is incomplete, but the revision will include a section that defines testbeds and how they are

used in the HFE V&V process. In the same section, the information on how the Remote Shutdown Panel and risk significant local control panels are evaluated will be addressed.

- 1) GEH clarified the types of simulators used in the ESBWR design development in changes made to NEDO-33275, Rev 1, ESBWR HFE Training Development Implementation plan in response to RAI 18.10-1 S02. In that RAI, GEH defines part task, full scope, and site specific training simulators and removed references to GEH Test System and Baseline Simulators.

Simulators used in HFE V&V activities are described below using the above conventions.

The text below will be inserted in the Integrated System Validation section.

Part Task Simulator

Purpose

The Part Task Simulator (PTS) is a tool used by the Human Factors Engineering group for the development and testing of Human System Interface display screens, initial development and testing of the plant normal, abnormal, and emergency operating procedures, and the initial development of operations training material.

The PTS has the plant and system fidelity deemed necessary to allow for simulating normal plant operation, including plant heatup and startup, maneuvering at power, and plant shutdown and cooldown. Additionally, the PTS simulates plant responses to design basis Abnormal Operational Occurrences (AOOs) and accidents.

On a case by case basis, for the systems they model with the required fidelity, part task simulators can be shown to be high fidelity (in accordance with ANSI and Reg Guide 1.149).

Properties

The simulation software for the PTS contains the simulation models resulting from the initial system design of the systems deemed necessary for the PTS, along with generic or simplified models of the remainder of the plant systems.

The hardware for the PTS consists of enough table/desk space and Visual Display Units to simulate one console section of the preliminary ESBWR control room design, along with the required input devices and computers.

The PTS has an instructor station providing the required basic functions (establishing desired initial conditions, backtracking, snap-shot storage, and trending) as determined by the HFE group.

Scope

The PTS software contains the initial system design simulation models for the systems deemed necessary for normal plant operations, along with generic or simplified models as required for the remaining systems. The systems selected as necessary for the PTS include the normal BWR heat cycle and required auxiliaries, control and protection systems, and ECCS systems.

The PTS contains the initial Human System Interface for the plant systems, including VDUs and input devices.

Full Scope Simulator

Purpose

The Full Scope Simulator (FSS) is a high fidelity (in accordance with ANSI 3.5 and Reg Guide 1.149) ESBWR simulation tool used by the Human Factors Engineering group for the validation of the control room design, the validation of plant normal, abnormal, and emergency operating procedures, and the validation of operations training material.

The FSS is able to perform normal, abnormal, and emergency plant operations, and is ANSI 3.5 certified. Those full scope simulators that are used for training are also Regulatory Guide 1.149 compliant.

Properties

The simulation software for the FSS contains the simulation models for the ESBWR plant systems included in the detailed system design along with generic or simplified models of the remainder of the plant systems.

The hardware for the FSS consists of a full-scale mockup of the ESBWR control room.

The FSS has an instructor station providing the full functionality required for ANSI 3.5 certified training simulators.

Scope

The FSS contains the simulation models for the ESBWR plant systems.

The FSS contains the ESBWR Human System Interface for the plant systems, including VDUs and input devices.

Site Specific Training Simulator

Purpose

The Site Specific Training Simulator provides a full scope simulation tool for conducting licensed operator training activities, completing control manipulations for operator license applicants, and conducting license operator operating tests.

In addition to the systems contained in the ESBWR design, the site specific training simulator simulates site support systems and infrastructure necessary for the operation of the ESBWR. The Site Specific Training Simulator is ANSI 3.5 certified and Reg Guide 1.149 compliant.

Properties

The simulation software for the Site Specific Training Simulator provides the plant operational functionality and fidelity required by ANSI 3.5 certification and Reg Guide 1.149. The software for the systems simulates the detailed system design. The remaining systems are modeled either statically or using simplified models.

The hardware for the Site Specific Training Simulator is developed using the same control room design, and the same materials and manufacturing techniques as the actual ESBWR control room hardware.

The Site Specific Training Simulator has an instructor station providing the full functionality required for ANSI 3.5 certified training simulators.

Scope

The Site Specific Training Simulator is an ANSI 3.5 certified and Reg Guide 1.149 compliant full scope simulator for operator training and testing.

The Site Specific Training Simulator contains consoles and panels with the same form, fit, and feel as the ESBWR main control room.

Use of Simulators in Integrated System Validation

Part task and full scope simulators that have not been shown to be high fidelity (by meeting the requirements of ANSI 3.5 and Reg Guide 1.149) for the systems to be tested cannot be used for formal integrated system validation. Such simulators are used for other testing or data gathering activities that do not require a high fidelity simulator.

The simulator testbeds used to perform integrated system validation must provide the fidelity required for the validation being conducted to be meaningful and valid. Demonstrating that a testbed meets the requirements of ANSI 3.5 and Reg Guide 1.149

provides assurance of high fidelity in accordance with common industry and regulatory standards and definitions.

Integrated system validations of limited scope (for example, testing the integrated system controlling control rod movement) may be performed on a part task simulator that meets ANSI 3.5 and Reg Guide 1.149 fidelity requirements for the systems that affect the validation scenario.

Integrated system validations whose scope is the complete integrated HSI are performed on a high fidelity full scope simulator that meets the requirements of ANSI 3.5 and Reg Guide 1.149

- 1) Remote actions will be addressed in the ESBWR V&V process as outlined below.

The text below will be inserted in the Integrated System Validation section.

Remote Shutdown System

The remote shutdown panel is verified in accordance with the task support verification and HFE design verification processes. Additionally, integrated system validation of the remote shutdown panel is performed utilizing a high fidelity remote shutdown panel simulator meeting the requirements of ANSI 3.5 and Reg Guide 1.149.

Risk Significant Local Control Panels

Risk significant local control stations and their HSIs are verified in accordance with the task support verification and HFE design verification processes. Additionally, integrated system validations that require actions to be performed at local control stations are performed utilizing action durations, simulated feedback indications in the HSI (if any), and communication mechanisms used in the plant. All of the factors associated with local operations incorporated into a scenario are specified, in detail, in the scenario guide written to govern performance of the simulation. The scenario validation process verifies that remote manual action cues, indications, communications, and feedback built into the scenario guide are accurate and timely. In this way, scenarios that contain remote actions are accurately rendered and support validation of the integrated system HSI.

DCD Impact

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

LTR NEDO-33276, Rev 1 will be revised with the inserted text provided above.

NRC RAI 18.11-19 S02

Part 1 of the RAI response the staff finds acceptable.

In part 2 of the RAI response, GEH provided general information concerning their treatment of local actions in validation scenarios. However, the staff's RAI asked GEH to "identify what remote actions are needed for the scenarios to be used in validation testing and provide information as to how these actions will be modeled and evaluated for validation."

As described in RAI 18.11-3 S02, please provide a specification of the precise actions that will be modeled in specific scenarios for verification and validation (V&V) in the V&V implementation plan. If the information is not available at this time, add a COL item to provide the information with the COL application for staff review and prior to conducting V&V activities.

GEH Response

GEH contends that the methodology contained in this implementation plan is at a sufficient level to assure that scenarios and associated elements developed from it will comply with the guidance in NUREG-0711 and ensure a quality validation activity. It should also be noted that GEH will provide a detailed report of the scenario development and resulting test plan in the Verification and Validation (V&V) Results Summary Report (RSR), ESBWR Design Control Document Tier 1 Table 3.3-1 ITAAC item 9, and that the process is open for staff review or audit.

To support the staff's evaluation of the level of detail of the V&V Implementation Plan, NEDE/NEDO-33276P, this response provides a roadmap guide in the form of a flow chart, included as Attachment 1.

The Development of Integrated System Validation (ISV) Remote Action Models chart (Attachment 1) outlines the steps described in the corresponding paragraph numbers of the plan to address how remote actions are defined, developed, and modeled.

By following the outlined remote action development process (Attachment 1), the ISV scenarios that contain remote actions will be accurately rendered and support validation of the integrated system Human System Interface (HSI).

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.

RAI

18.11-22

NRC RAI 18.11-22

While NEDO-33276, Section 4.3.4.5 lists generic considerations for scenario development, NEDO-33276 does not address the specific scenarios to be used in validation or how they will be defined. Please provide information on the specific scenarios to be used in validation and how they will be defined.

GE Response

The following paragraphs will be added to section 4.3.4.5:

“Specific scenario details are not included in this implementation plan as they will be developed as the ESBWR design progresses. The scenarios will be defined to challenge the human actions identified through the operational analysis, the risk important PRA/HRA actions, and the OER and procedural actions. The scenarios will address normal startup and shutdown for each system and the plant. The scenarios will include each initiating event group that is expected to impact power operation, and is modeled in the PRA. The risk important sequences that lead to core damage will be evaluated. Complex sequences will be developed considering realistic loss of electrical power events, fires and floods that impact a zone or an adjacent zone. Computer control system faults identified through experience will be developed.”

DCD/LTR Impact

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

LTR NEDO-33276, Rev 0 section 4.3.4.5 will be revised as described above at the next revision.

NRC RAI 18.11-22 S01

*NRC Summary Text:
Scenario Definition*

NRC Full Text:

In RAI 18.11-4, the staff asked how the selected operational conditions were developed into scenarios. This RAI addresses the detailed definition of the scenarios so they can be run on the validation testbed. GEH's response to the original RAI indicated that specific scenario details are not included in the implementation plan as they will be developed as a part of the ESBWR design process. While in the context of a programmatic review, the staff agreed that this level of detail would be premature at this point in the process, GEH should provide this information if the staff is to conduct an Implementation Plan level review. The descriptions should provide sufficient detail so they can be reviewed using the criteria in NUREG-0711, Section 11.4.3.2.4.

GEH Response

To reflect the level of detail required for an Implementation plan, both the text and document organization in NEDO-33276 will be revised. The final organization is incomplete, but the revision will include a section that details how validation scenarios are defined.

The text below will be inserted in the Operational Condition Sampling section.

Scenario Definition

The purpose of scenario definition is to provide a consistent, objective, and high fidelity environment in which to validate performance of the integrated systems.

The defined scenarios involve major plant evolutions or transients, and reinforce team concepts and identify the role each individual plays within the team.

For each scenario, the following information is developed and provided:

- A coversheet and revision log
- An administrative information sheet
- Console operator instructions
- Evaluator information sheet
- One or more event guides
- Scripting for communications with outside personnel expected to take place during the scenario
- A critical task (CT) summary
- Shift briefing/ transfer of authority information (plant turnover sheets may be used)

- Questionnaires for determining where and when HFE aspects of the HIS contribute to problems with response to the various tasks/events during the scenario (provided for crew members, console operators, and trained observers)
- Termination criteria for completion of the scenario

In addition, the following information is established for each scenario:

- Event and task fidelity in scenario development
- Realistic simulation of remote responses during scenarios
- Staffing objectives

Coversheet

The coversheet contains the following information:

- Title and number of the simulator exercise
- Revision level of the document
- Date of the current revision
- The program for which the simulator exercise was designed
- Signature blocks for the author, validator, and customer representative, as appropriate

Administrative Information Sheet

The administrative information sheet should contain the following information:

- Title of the evaluation guide
- Approximate length of the scenario
- Scenario objectives (as required)
- References used to develop the attributes of the scenario. The list should include specific plant procedures, industry and plant events.
- A scenario summary that provides a brief description of initial plant conditions, a sequential listing of the events or evolutions encountered during the scenario, and additional key points of interest to be observed during the scenario (a sequenced list including starting conditions, percent power, BOL/EOL, major equipment out-of-service and major malfunctions that will occur).

Console Operator Instructions

Console operator instructions provide a detailed "road map" of planned events for a given scenario. The instructions provide the following information:

- The initial conditions to be established, which include: the initial simulator setup to be used, any malfunctions, remote functions or overrides to be inserted, and the equipment configurations (such as valve or handswitch positions and clearance tags).

- The timing or event sequence for the entry of malfunctions, with a brief description of the failure (including associated details such as: severity, ramp rates, delay times, and any other needed defining factors).
- The remote functions that may be used to support event recovery or inplant actions.
- Specific information on simulator configuration (including workplace factors such as environmental conditions).
- A list of task support needs such as specific procedures or documents needed for the scenario beyond the Tech Specs and procedures normally available to the crew in the simulator or control room.

Evaluator Information Sheet

The information sheet provided to the V&V team members contains the following information:

- The crew assignments, as designated by the V&V team lead
- Any special instructions or simulator limitations that are unique to the scenario
- Directions for shift briefing
- Specific information on simulator configuration (including workplace factors such as environmental conditions)
- Termination cues (as applicable)
- Reactivity/control manipulations covered by the scenario

Event Guide

The event guide contains a description of each event or major evolution to be conducted during a testing scenario. Each event or evolution and the key actions performed therein by specific crew members are identified.

Additional spaces are provided for comments by the trained observers and the V&V team members. A section is also provided for additional information regarding role-play cues, specific actions to evaluate, and/or additional crew directions. The event guide provides for the designation of conservative decisions/actions.

The event guide contains the following information:

- Event title
- The expected crew member actions
- Comments, notes and evaluation section
- Termination cues (on the last event guide used during the exercise)
- Critical tasks and associated acceptance criteria
- All applicable Technical Specifications and other regulatory requirements
- All applicable radiological emergency plan classifications

Critical Task Summary

The V&V team uses a critical task (CT) summary to identify safety significant tasks that should occur during each scenario. CTs provide objective measures by which evaluators can determine if the integrated system does or does not support satisfactory crew performance.

A critical task must include the following elements:

- Safety significance to the plant or the public
- Appropriate cues to at least one operator
- Measurable performance indicators
- Feedback for at least one operator regarding the crew's action or inaction

Safety Significance

In reviewing the proposed CTs, scenario developers assess each task to determine if it is essential to safety. A task is essential to safety if, in the judgment of scenario developers, improper performance or omission of the task results in direct adverse consequences or significant degradation in the mitigative capability of the plant.

For example, a task is classified as a safety significant CT if incorrect performance of that task leads to:

- Degradation of any barrier to fission product release
- Degradation to a safety system or emergency power capacity
- A violation of a safety limit
- Incorrect reactivity control (such as failure to initiate Standby Liquid Control)
- A significant reduction of safety margin beyond that which is irreparably introduced by a scenario

A task is also classified as a safety significant CT if failure to perform that task leads to the inability of a crew to:

- Effectively direct or manipulate engineered safety feature (ESF)
- Control a parameter that results in any condition described in the previous paragraph
- Recognize a failure or an incorrect automatic actuation of an ESF system or component
- Take one or more actions that would prevent a challenge to plant safety
- Prevent inappropriate actions that create a challenge to plant safety (such as an ESF actuation)

Appropriate Cues

For a CT to be considered valid, an external stimulus prompts at least one crew member to perform the task. The cue provides initial conditions and prompts the operators to respond by taking certain actions. The cue need not indicate the task as "critical."

Measurable Performance Indicators

The scenario developer establishes measurable performance indicators for each CT. A measurable performance indicator consists of positive actions that an examiner can objectively identify as being taken by at least one member of the crew.

Examples of measurable performance indicators include:

- Control manipulations such as a manual reactor trip or the start of a safety system
- Verbal reports or notifications of abnormal parameters or conditions such as "all control rods are not inserted" or "containment pressure is greater than 2 psi"

Feedback

Feedback allows the operator to determine if actions/manipulations have corrected the adverse trend or component failure he attempted to correct. Examples of feedback include:

- Reversal of water level trend after the initiation of a standby pump
- Rising system flow after opening a bypass valve, etc.

Shift Briefing Information/Transfer of Authority

The shift briefing included in the scenario guide will provide the crew with the conditions of the plant when they assume control (this includes plant parameters appropriate to the scenario such as power, level, pressure, load, mode, etc).

Also provided will be any Tech Spec limiting conditions of operation (LCO) conditions and required actions currently in effect and, any equipment out of service due to preventative or corrective maintenance. Any normal evolutions expected of the crew during the shift are listed. The briefing can be removed from the scenario and used by the crew for their briefing prior to assuming shift.

No indication of the expected events or final outcome of the scenario will be provided by the briefing.

Questionnaires

Questionnaires request input from each crew member, console operator, and evaluator to identify any problems experienced during each event in the scenario and any

issues/concerns to be resolved. The questions used should address specific events or actions required during the scenario and note any problems in recognizing or responding to these events.

Evaluator notes taken during the scenario can be used to aid crew members in recalling items/actions that presented any unexpected challenges.

Event and Task Fidelity

The scenarios for integrated system validation use the results of the HFE Task Analysis for the various ESBWR systems as one basis for scenario development.

Each scenario should include normal, abnormal and emergency events requiring crew response. The actions taken by each crew member will be tasks that can be traced to the Task Analysis results.

Realistic Simulation of Remote Responses

Responses requested from outside personnel or external agencies use time delays before completion is reported to the crew. Time for gathering tools and/or procedures necessary for task completion and delays associated with the radiological and environmental conditions in the area are realistically simulated.

The times noted during the development and verification of the procedures required for task completion are used when applicable and available.

Staffing Objectives

Staffing for performance of integrated system validation testing scenarios use licensed personnel for crew members or participants enrolled in training classes for the purpose of ESBWR licensing. Crews are selected to ensure that both experienced and new operators are evaluated and provide input on the HFE aspects of the controls. Test participants are not allowed to act as a crew member in a given scenario more than once.

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

DCD Impact

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

LTR NEDO-33276, Rev 1 will be revised with the inserted text provided above.

NRC RAI 18.11-22 S02

In their response to the RAI, GEH provided detailed information as to their approach to defining validation scenarios. However, the staff's RAI requested "the detailed definition of the scenarios so they can be run on the validation testbed."

As described in RAI 18.11-3 S02, please provide descriptions of the actual scenarios to be run on the validation testbed for verification and validation (V&V) in the V&V implementation plan. If the information is not available at this time, add a COL item to provide the information with the COL application for staff review and prior to conducting V&V activities.

GEH Response

GEH contends that the methodology contained in this implementation plan is at a sufficient level to assure that scenarios and associated elements developed from it will comply with the guidance in NUREG-0711 and ensure a quality validation activity. It should also be noted that GEH will provide a detailed report of the scenario development and resulting test plan in the V&V RSR, ESBWR Design Control Document Tier 1 Table 3.3-1 ITAAC item 9, and that the process is open for staff review or audit.

To support the staff's evaluation of the level of detail of the V&V Implementation Plan, NEDE/NEDO-33276P, this response provides a roadmap guide in the form of the flow chart included as Attachment 1.

The Operational Conditions Sampling and Scenario Development chart provides the sections in the implementation plan that address RAIs 18.11-3 S02, 18.11-4 S02, and 18.11-22 S02. This flow chart summarizes the methodology for identifying and developing the operational scenarios and provides the corresponding paragraph numbers in the implementation plan defining the detailed methodology. The last box in the chart lists the documents, with the plan's corresponding paragraph numbers, generated to define the scenario and support its successful execution.

By following the outlined operational conditions sampling process, the resulting operational conditions will represent a wide variety of significant demands to challenge system performance.

By following the outlined scenario development process, the resulting scenarios will represent the aspects of operational conditions that have a significant effect on human performance. Thus, by following the processes outlined in the V&V, as delineated in Attachment 1, the resulting scenarios used for integrated system validation testing will satisfy the requirements laid forth in NUREG 0711, Rev2.

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.

RAI

18.11-24

NRC RAI 18.11-24

NEDO-33276, Section 4.3.4.4 does describe in varying levels of detail, the types of performance measures that will be used. These measures include some of the types of measures identified in the criterion. However, it is not clear that a full range of measures will be included. Please provide additional information on the performance measures to be used in validation. Specific questions are identified below:

- A. Plant/system level measures - measures of plant and system performance were not addressed. Please, justify.*
- B. Operator task measures - NEDO-33276, p. 14 lists the performance measures used to determine the validity of the MCR, RSS, and LCS designs. Operator task performance is not included in the list, yet it is included in list of measures on page 45. However, while the term "task performance" is included in the title of Section 4.3.4.4.1, it does not address what measures will be taken and how they will be determined. Section 4.3.4.7.1 identifies a list of task related measures; however, the tasks for which these measures will be taken are not identified. Please identify the tasks that will be evaluated during integrated system validation.*
- C. Situation awareness - Section 4.3.4.4.3 describes the evaluation of situation awareness. The section indicates that the Situation Awareness Control Room Inventory (SACRI) method will be used. However, in Section 4.3.4.7.3, the measurement of situation awareness is discussed. This section indicates that situation awareness is subjectively evaluated on the basis of correctness to test subject responses to questions asked during the test scenarios. Is this statement referring to SACRI method identified in the earlier section? The latter section also describes many other indications of situation awareness. How will all these methods be combined to assess overall situation awareness? If the SACRI method is used, additional details about its implementation should be provided. Please indicate how questions will be developed for each scenario used in the evaluation and what criteria will be used to judge whether or not, the level of situational awareness is acceptable?*
- D. Operator workload - Section 4.3.4.4.4 discusses the assessment of operator workload. This section provides a cross reference to the task analysis implementation plan for a discussion of workload assessment methods. In Section 4.3.4.7.4 performance measures for workload are discussed. It indicates that workload will be assessed using a rating scale method and actual operator performance during test scenarios. The rating scale method identified is the NASA TLX. In addition, a list of activities to evaluate is provided. The list includes evaluating navigation, evaluating information gathering, evaluating plant conditions, alarm interaction, analyzing information needed to assess plant situation, and analyzing the memory demands to perform operational tasks. How*

will each of these be evaluated? And how will they be integrated, along with rating scale evaluations, to determine the acceptability of workload?

- E. Crew communication and coordination - Section 4.3.4.4.5 indicates that crew, communication and coordination will be subjectively evaluated on the basis of the crew's demonstrated performance during training exercises. Please explain why training exercises are being used for this evaluation and not integrated system validation trials? In Section 4.3.4.7.5, it states that crew communication and coordination are subjectively evaluated on the basis of how well crews exhibited a number of characteristics related to teamwork, such as effective leadership, well defined roles and responsibilities, teamwork, open dialogue, etc. Please indicate how the nine items listed in this section will be measured and how they will be evaluated?*

GE Response

- A. In the case of plant/system level measures the impact of transients such as loss of electrical power have little impact on the ESBWR core damage frequency because of the natural circulation and passive cooling features of the plant. Thus temperature changes to the core are calculated to be very slow for all but a very few hypothetical accidents. The main issue for operators' use of the MMIS is to monitor the plant state and backup automatic actions if necessary. The MMIS should permit the operators to control key plant parameters and maintain them within allowed conditions. Such parameters include power level (neutron flux), turbine generator status, isolation, relief and safety valve positions, control rod positions, pump states, feedwater flow, core flow rates and isolation condenser heat transfer.
- B. The scope listed in 3.1.1 and 4.3.4.1 will be reconciled. The first sentence in Section 4.3.4.1 will be modified to "Simulations will be used by plant personnel to demonstrate successful task performance on operational events to validate the ability of operators to use the MMIS to support safe plant operations."
- The operator tasks that will be evaluated during integrated system validation are those that are defined through the operational analysis, through the PRA/HRA as risk important actions, and those directly called out in the procedures.
- C. The first paragraph in Section 4.3.4.7.3, will be changed to:
"The ability of the MMIS to support situational awareness is subjectively evaluated by analysis of one or more of the following measures at different phases of the V&V.
- Timing of operator cues and operator actions,

- Appropriateness of operator actions
- Consequence (good or bad) of operator actions,
- Observation of operator actions, procedure use and communications,
- Freezing the simulator after an operator cue has been simulated and querying the operator about plant status, and/or
- Post scenario video reviews and interviews.”

If more than one operator with suitable training cannot take appropriate corrective actions within an appropriate time window, the observation will be considered for documentation as an HED on the MMIS.

- D. The workload rating scales will be used to qualitatively assess high or low or not applicable ratings in each area. The ratings will be integrated by converting the workload ratings to a fraction of the time involved over the simulated event time. Then the workload formula in section 4.3.4.6.4 will be applied.
- E. The objective here is to verify that the MMIS promotes good communication and coordination of the crew as part of the integrated system evaluation. Of the nine good communication principles five relate to the MMIS. Section 4.3.4.4.5 will be modified to indicate how the five items listed in this section will be measured and evaluated as follows:

“MMIS support for crew communication and coordination are subjectively evaluated on the basis of how well crews exhibit the following:

1. MMIS supports well-defined roles and responsibilities are executable from the assigned station (simulated transients require infrequent movement from the control station).
2. MMIS supports crew teamwork by providing information needed by the individual team members working as a team.
3. MMIS permits two operators to use the same information (e.g., displays, alarms, procedures) at the same time so that operators are able to identify, analyze, plan and implement responses based on information from the work station displays.
4. MMIS permits proactive monitoring and observation (to enhance situation awareness and progress assessment monitoring is from the local workstation).
5. MMIS is organized for efficient movement between information pages, panels and control screens at workstations (only use several screen maneuvering actions to adjust screens to find information during a simulated event).”

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 18.11-24 S01

In the original RAI, the staff requested information on the selection of performance measures. For the staff to perform an implementation plan review, GEH should identify the hierarchal set of performance measures (including plant/system level performance, operator task performance, situation awareness, operator workload, and anthropometric/physiological factors) that will be used in validation tests. The response should provide a clear picture of the range of measures to be used (consistent with NUREG-0711, Section 11.4.3.2.5.2).

GEH's response to this RAI should consider the specific issues identified in the original RAI in RAI Letter 74.

GEH Response

To reflect the level of detail required for an Implementation plan, both the text and document organization in NEDO-33276 will be revised. The final organization is incomplete, but the revision will include a section that establishes a hierarchal set of performance measures, as described below.

(Note: as RAI 18.11-23 S01, RAI 18.11-24 S01, and RAI 18.11-26 S01 are related areas, GEH recommends that the responses to these RAIs be evaluated together).

The text below will be inserted in the Integrated System Validation section.

The plant/system performance measures selected for integrated validation are represented by a tiered system, based on the prevention or mitigation of transients and accidents, as described in DCD Tier 2, Chapter 15 – Transient Analysis. Tasks and events with high PRA/HRA risk significance are selected for measurement.

A. Plant – Core Thermal-Hydraulic Condition

The ability of the crew to maintain core thermal-hydraulic condition within acceptable limits is used as a plant-level performance measure during integrated system validation testing.

TRACG analyses are used to establish thermal-hydraulic parameters that must be kept within a defined limit to prevent core damage. Event analyses are used to determine the specific amount of time allowed to initiate an automatic or manual action in order to maintain these parameters within that calculated limit. Thus, plant level performance is measured in terms of the time required to complete these actions.

To measure performance, the time taken by the crew or automation to initiate the established required actions during a simulated scenario is compared to the calculated time requirements.

B. Plant – PRA/HRA

The response of the integrated plant to abnormal conditions and transients is tested to validate that system manipulations produce the expected or predicted plant responses.

To test PRA/HRA assumptions, scenario events are selected that contain PRA risk significant tasks. The responses of the integrated plant and systems (including operator actions) to the selected events are recorded and evaluated in terms of the times and values assumed in the PRA/HRA.

Average times and values are established across crews for each scenario.

C. Personnel Tasks

HFE task analysis of required system manipulations and monitoring during normal, transient, abnormal, and emergency conditions provides the necessary basis for the procedures directing operator actions in response to the aforementioned conditions. Thus, task criteria are created that can be used to evaluate the ability of the operators to monitor system parameters and system responses to actions and/or operator manipulations.

Personnel task measures are established from the parameters indicated during task analysis as being used to determine a successful sequence change for the integrated system (i.e., the parameters used during task analysis to verify stable system operation in the desired sequence).

The average number calculated from the total number of successful system sequence changes is used as one method of evaluating crew task performance. Other task performance measures include time to complete task, errors observed during task performance, frequency of task performance and any additional items the task analysis team may deem necessary to validate integrated plant and HSI design.

To measure personnel task performance, observations, performed by trained observers using evaluation checklists, and videotaped sessions are compared against saved simulator data. Data is also gathered from crew questionnaire responses pertaining to manipulations that require a more fine-grained analysis. The following are representative of questions appearing on the checklists/questionnaires:

• Understanding of Plant and System Responses

- o Did the crew locate and interpret control room indicators correctly and efficiently to ascertain and verify the status/operation of plant systems?
 - 3 = Each crewmember located and interpreted instruments accurately and efficiently.
 - 2 = Some crewmembers committed minor errors in locating or interpreting instruments or displays. Some crewmembers required assistance.

- 1 = The crewmembers made serious omissions, delays, or errors in interpreting safety-related parameters.
- o Did the crew demonstrate an understanding of the manner in which the plant, systems, and components operate, including setpoints, interlocks, and automatic actions?
 - 3 = Crewmembers demonstrated thorough understanding of how systems and components operate.
 - 2 = The crew committed minor errors because of incomplete knowledge of the operation of the system or component. Some crewmembers required assistance.
 - 1 = Inadequate knowledge of safety system or component operation resulted in serious mistakes or plant degradation.
- o Did the crew demonstrate an understanding of how their actions (or inaction) affected systems and plant conditions?
 - 3 = All members understood the effect that actions or directives had on the plant and systems.
 - 2 = Actions or directives indicated minor inaccuracies in individuals' understanding, but the crew corrected the actions.
 - 1 = The crew appeared to act without knowledge of or with disregard for the effects on plant safety.

• **Diagnosis of Events and Conditions Based on Signals or Readings**

- o Did the crew recognize off-normal trends and status?
 - 3 = Recognized status and trends quickly and accurately.
 - 2 = Recognized status and trends at the time of, but not before, exceeding established limits.
 - 1 = Did not recognize adverse status and trends, even after alarms and annunciators sounded.
- o Did the crew use information and reference material (prints, books, charts, emergency plan, implementation procedures) to aid in diagnosing and classifying events and conditions?

- 3 = Made accurate diagnosis by using information and reference material correctly and in a timely manner.
- 2 = Committed minor errors in using or interpreting information and reference material.
- 1 = Failed to use, or misused, or misinterpreted information or reference material that resulted in improper diagnosis.

o Did the crew correctly diagnose plant conditions based on control room indications?

- 3 = Performed timely and accurate diagnosis.
- 2 = Committed minor errors or had minor difficulties in making diagnosis.
- 1 = Made incorrect diagnosis, which resulted in incorrect manipulation of any safety control.

• **Control Board Operations**

o Did the crew locate controls efficiently and accurately?

- 3 = Individual operators located controls and indicators without hesitation.
- 2 = One or more operators hesitated or had difficulty in locating controls.
- 1 = The crew failed to locate control(s), which jeopardized system(s) important to safety.

o Did the crew manipulate controls in an accurate and timely manner?

- 3 = The crew manipulated plant controls smoothly and maintained parameters within specified bounds.
- 2 = The crew demonstrated minor shortcomings in manipulating controls, but recovered from errors without causing problems
- 1 = The crew made mistakes manipulating control(s) that caused safety system transients and related problems.

o Did the crew take manual control of automatic functions, when appropriate?

- 3 = All operators took control and smoothly operated automatic systems manually, without assistance, thereby averting adverse events.
- 2 = Some operators delayed or required prompting before overriding or operating automatic functions, but avoided plant transients where possible.
- 1 = The crew failed to manually control automatic systems important to safety, even when ample time and indications existed.

A. Supplemental

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

1. Crew Communications and Coordination

Crew communication and coordination are subjectively evaluated with rating scales, using trained observers and videotaped testing sessions, to determine how well crews exhibit the following (Rated on a 3-point rating scale, where 1 = Poor, 2 = Average, and 3 = Good):

- Effective leadership and clear chain of command. Cooperation and composure under supervisor's direction without micromanagement
- Well-defined roles and responsibilities
- Teamwork. The crew performs as an integrated unit and interacts effectively (i.e., everyone contributing, supporting and backing each other up as needed, ease of task delegation, using a consensus approach to problem solving and decision making, informing key personnel outside the control room)
- Open dialogue (sharing information and knowledge)
- Use of same information (displays, alarms, procedures)
- Clear directions and repeat-backs (confirmations, acknowledgements)
- Correct, accurate, concise, and relevant information exchange
- Efficient movement of crew members between panels and workstations

Observers supplement this data, using behaviorally anchored rating scale checklist questions:

- Did the crew exchange complete and relevant information in a clear, accurate, and attentive manner?
 - 3 = Crew members provided relevant and accurate information to each other.
 - 2 = Crew communications were generally complete and accurate, but sometimes needed prompting, or the crew failed to acknowledge the completion of evolutions, or to respond to information from others.
 - 1 = Crew members did not inform each other of abnormal indication(s) or action(s). Crew members were inattentive when important information was requested.

- Did the crew keep key personnel outside the control room informed of plant status?
 - 3 = Crewmembers provided key personnel outside the control room with accurate, relevant information throughout the scenarios.
 - 2 = In minor instances, the crew needed to be prompted for information and/or provided some incomplete/inaccurate information.
 - 1 = The crew failed to provide needed information.

- Did the crew ensure receipt of clear, easily understood communications from the crew and others?
 - 3 = The crew requested information/clarification when necessary and understood communications from others.
 - 2 = In minor instances, the crew failed to request or acknowledge information from others.
 - 1 = The crew failed to request needed information, or was inattentive when information was provided; serious misunderstandings occurred among crewmembers.

2. Situation Awareness

Situation Awareness represents the ability of operators to understand and communicate past and present events or states and to predict future ones. An objective measure of situation awareness is obtained by directly comparing operators' reported SA to reality.

With this technique, a human-in-the-loop simulation is frozen at randomly selected times and the system displays are blanked while the operators quickly answer questions about their current understanding of the situation. After a testing session, operators' perceptions about a situation are compared to the reality of the situation (as determined by information recorded on the simulation computers). Comparing the data in this manner provides an objective, unbiased assessment of SA (Endsley, 1995).

Procedure

During testing, crews should attend to tasks as during all other simulations, with SA questions being considered secondary. No displays or visual aids should be visible while participants are answering questions (therefore, screens should be blank during testing, or subjects should be asked to turn away from screens). If participants do not know or are uncertain about the answer to a question, they are encouraged to make their best guess. If participants are not comfortable enough to make a guess, they are permitted to skip that question and move on to the next question. Talking or sharing of information between participants is not permitted. All participants are queried at the same time.

During a freeze point, all screens should go blank except for one screen in a central location at each workstation. On this screen a series of situational awareness questions are presented, and the operators type in/ select their responses.

Selecting Freeze Points

Using the established list and sequence of events occurring during each scenario, points before or after an event are identified. Selection of time points that occur during a significant event should be avoided, due to the fact that operators could use freeze time to consider what event is occurring and may devise plans of actions that would not occur if operators had not been given extra time to think and plan.

Out of the population of time points that meet the aforementioned criteria, a number of time points should be randomly selected. The number of freeze points should be proportional to the length of the scenario. No greater than two stops should be performed during a 15 minute interval. The total number of stops should be kept to the minimum needed to achieve an adequate range of situation awareness data samples. Excessive scenario freezing should be avoided in order to maintain low testing impact on operator performance and to maintain test environment fidelity.

Freezes should generally last less than two minutes, and regardless of the number of questions presented, at least 5 seconds should be given before a scenario is resumed after a freeze. Operators should not be aware of when exact freeze points are going to occur.

Selecting Questions

Questions given during a freeze point are relevant to the information that is available to operators prior to that freeze point. Questions should be constructed in terms of operating procedures and phrased using language standard to the nuclear industry.

Questions during each freeze point cover three different levels of situation awareness: perception of data, comprehension of meaning, and projection of the near future. Questions include how the system is functioning and system status.

Situation Awareness questions reflect requirements that are developed based on information provided by task analysis, training, and operating procedures. These requirements indicate what information an operator would need to be aware of in order to successfully complete all of the required tasks in a scenario.

Performance Measures

The operators' situation awareness, as determined by answers to freeze point questions, are compared to situation information recorded on the simulation computers just prior to, and at the same point in time as the freeze.

Situation awareness should be measured in terms of:

1. Perception of data:

- The proportion of correct answers relative to the total amount of data requested by the freeze point questions for each scenario
 - o The proportion of unanswered data questions relative to the total number of data questions
 - o The proportion of incorrect answers relative to the total number of data questions

2. Comprehension of meaning:

- Awareness is adequate to correctly comprehend the meaning of the data attended to (Yes/No)
 - o Accurate or inaccurate judgment of plant/ plant system status
 - o Accurate or inaccurate selection of procedure in response to data.

Projection of the near future:

- Awareness is adequate to correctly predict events occurring in the plant in the near future (based on data attended to and conclusions drawn from that data) (Yes/No)

- o Accurate or inaccurate selection of procedure in response to data.
- o Accurate or inaccurate prediction of plant/ plant system status in the near future.

Perceived operator information, as determined by the above analysis, should be compared to the information requirements needed to select the appropriate procedures to follow, and to successfully complete required tasks, as determined by the task analysis and operating procedures.

Supplemental Situation Awareness Information

Because situation awareness data using freeze points is not used during significant events, supplemental data is used to measure operator situation awareness during events.

During events, subjective SA data is gathered by trained observers using behavioral measures. Observers will infer SA from the actions that operators chose to take, based on the assumption that good actions (i.e., following the correct procedure) will follow from good SA and vice-versa.

During scenario events, trained observers should observe and rate operator behaviors during task performance. Ratings should be conducted using a five point behaviorally anchored rating scale (1= very poor, 5= very good) to rate the degree to which individuals are carrying out actions and exhibiting behaviors that would be expected to promote the achievement of higher levels of SA. The list of SA indicative behaviors should be developed using information from task analysis, training, and established operating procedures.

2. Workload

Workload represents the cost incurred by an operator to achieve a particular level of performance. Workload can be divided into two elements: physical workload and cognitive workload.

A. Physical Workload

Because of the digital nature of the ESBWR control room, physical workload is not expected to be a significant contributing factor to operator performance. However, to ensure that physical workload does not negatively impact crew performance, physical workload evaluations should be conducted during validation testing.

Performance Measures

To evaluate physical workload impact on operator performance, video recordings and trained observers are used to identify conditions that represent any of the following (number of occurrences per day are predicted using the sample of occurrences during the time frame of a scenario):

Force

A. Heavy, frequent, or awkward lifting:

- o Any lift of 75 pounds or more
- o Lifting 55 pounds or more 10 times per day
- o Lifting 10 pounds or more 2 times per minute over 2 hours total per day
- o Lifting 25 pounds or more 25 times per day and lift is
 - above the shoulders
 - below the knees
 - at arms length

B. High hand force:

- o Task results in any of the following for more than 2 hours per day:
 - Pinching an unsupported object(s) weighing 2 or more pounds per hand, or pinching with force of 4 or more pounds per hand
- o Gripping an unsupported object(s) weighing 10 or more pounds per hand, or gripping with a force of 10 pounds or more per hand

C. Repeated impact:

- o Using the hand or knees as a hammer more than 10 times per hour for more than 2 hours total per day

Posture

D. Awkward posture - tasks that results in any of the following postures for more than 2 hours per day:

- o Working with the hand(s) above the head or the elbow(s) above the shoulder(s)
- o Repetitively raising the hand(s) above the head or the elbow(s) above the shoulder(s) more than once per minute
- o Working with the neck bent more than 45° (without support or the ability to vary posture)
- o Working with the back bent forward more than 30° (without support, or the ability to vary posture)
- o Squatting, Kneeling

Repetitiveness

E. Highly repetitive motion:

- o Using the same motion with little or no variation every few seconds (excluding keying activities) for more than 2 hours total per day
- o Intensive keying or use of mouse for more than 4 hours total per day

Vibration

- High hand or whole body vibration:
 - o Using hand tools that typically have high vibration levels more than 30 minutes total per day
 - o Using hand tools that typically have moderate vibration levels more than 2 hours total per day.

The type, frequency, and context of high physical workload occurrences are documented on a checklist. To determine weight, vibration, and other environmental characteristics that impact workload, measurements may be taken by trained observers before or after a scenario. Measurements should be conducted in a manner that does not interfere with simulator testing activities.

A. Cognitive Workload

Mental or cognitive workload refers to the information processing resources required of an operator in achieving 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. Because of the relationship between cognitive workload and situation awareness, both measures should be evaluated in the context of one another.

Selecting Tasks

Task analysis is an important component of workload measurement. Task analysis is used to determine the critical tasks requiring workload assessment. As such, the results of the operational analysis, including task analysis is used as a screening mechanism by which tasks, scenarios, and situations can be meaningfully selected for cognitive workload assessment.

Tasks known to be free from time pressure, complicated evolutions, and/or considered failsafe, along with other predetermined parameters are screened and eliminated from cognitive workload assessment.

Then, tasks are chosen that are the most meaningful relative to garnering information relative to mental loading, including tasks that may have the possibility of error, burden the operator, have associated time pressures or other constraints.

Performance Measures

Cognitive workload for each of the selected tasks is measured by the NASATLX. The NASA-TLX is a subjective measurement of workload. It consists of a multidimensional scale with 6 dimensions of factors related to mental workload (Hart, 2006). To measure cognitive workload within the integrated system, a digital version of

the NASA-TLX is used in which individual, task, and overall cognitive workload are recorded:

- At the end of each selected task, a screen in a central location at each operator workstation appears that displays the six NASA-TLX questions (see Figure 2). For each question, the operator clicks the area on the scale that he/she thinks most accurately describes his or her experience on the task that was just completed.
- Since the term mental workload can be interpreted somewhat differently among respondents, personal opinion on what mental workload means for them is taken into the final calculation of the NASA-TLX score, by deriving an overall workload score for each task based on a weighted average of ratings within each participant on the six subscales.
- To obtain weights for each of the 6 workload dimensions per operator, per task, pair wise comparisons are made between each of the dimensions. This is accomplished using follow-up screens in which two dimensions are both displayed, and the operator is asked to choose which of the 2 dimensions contributed more to workload for that task.
- When the weights are applied to the results of the initial operator ratings for each of the six dimensions, a measure of overall cognitive workload is derived.

3. Anthropometrics

HSI anthropometrics are evaluated as part of HSI development (see NEDO-33268, ESBWR Human System Interface Design Implementation Plan) and HFE design verification to ensure compliance to the anthropometric guidelines contained in the ESBWR HFE Style guide.

System-specific and integrated validation testing confirms during simulation the adequacy of the HSI anthropometric design for the population of operators participating in all phases of verification and validation activities.

Validation tests to ensure that no significant negative impact on crew performance occurs within the context of the integrated system, and that no problems arise during HSI use that may not have been evident when HSI components were verified without reference to specific tasks.

Review of anthropometric data should be done in conjunction with physical workload posture data.

Procedure

After test participants have been selected for integrated system validation activities, physical measurements are taken of each participant using tape measures and/ or calibrated anthropometric tools.

Physical Measurements are selected from the following:

Stature	Thigh Thickness	Shoulder-Grip Length
Eye Height	Upper Leg Length	Hand Length
Shoulder Height	Seat Length	Hand Breadth
Elbow Height	Knee Height	Foot Length
Hip Height	Seat Height	Foot Breadth
Knuckle Height	Shoulder Breadth	Span
Sitting Height	Hip Breadth	Elbow Span
Sitting Eye Height	Upper Arm Length	Vertical Grip Reach (standing)
Sitting Shoulder Height	Elbow-Fingertip Length	Vertical Grip Reach (sitting)
Sitting Elbow Height	Upper Limb Length	

Measurements for each participant are entered into an electronic database along with a unique participant tracking number.

Physical measurements for each participant are used to supplement anthropometric observations (using trained observers and/or videotaped sessions) and self-report questionnaires to validate the anthropometrics of the integrated system. If anthropometric issues arise for a test participant, that participant's physical measurements are referenced to better understand the problem.

Performance Measures

Integrated validation testing focuses on the aspects of anthropometrics as they apply to the integrated system of displays and controls. This is measured by how effectively operators can use the integrated system. Effectiveness is measured using a combination of quantitative and qualitative measurements.

The following are recorded (along with time and task) by trained observers during simulation and/or using videotaped simulations:

- Number of times the operator has to reposition to accomplish task (lateral, leaning, or standing/stooping)

- o Changing posture in order to see displays
- o Changing posture in order to move between controls or between displays and controls
- Operator posture during tasks (using 5-point rating scale where 1 = Very poor and 5 = Very good)
 - o Brief description of type of posture problem(s)
- Written description of any additional significant anthropometric problems as identified by trained observers, such as:
 - o Visibility of displays being obstructed by operators reaching across displays to engage controls. (This is especially important when working with fine motion controls and feedback from control input is provided through the obstructed display.)
 - o Interference with controls created by reaching for other controls. (i.e., inadvertent pressing of keys on a keyboard when reaching for a control switch on panel)

Observer data is supplemented with post-scenario operator questionnaires:

- Operators are asked to rate each anthropometric element using a 5-point rating scale (1 = Very poor, 5 = Very good). Questionnaire items include:
 - o Reach and accessibility of control devices
 - o Visibility of indications
 - o Distance
 - o Seating comfort
 - Work surface height
 - Chair adjustability
 - Overall level of comfort
 - o Ease of control
 - o Ease of device manipulation
 - o Overall perception of system usability
 - o Overall satisfaction with workspace layout
- Additional comments

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Figure 2

(Note: Figure 2 removed for clarity. Refer to MFN 08-172 for figure 2.)

DCD/LTR Impact

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

LTR NEDO-33276, Rev 1 will be revised with the inserted text provided above.

The included Figure 2 will also be inserted.

RAI 18.11-24 S02

In their response to this RAI, GEH provided a description of the performance measures for plant/system level performance, operator task performance, crew communication/coordination, situation awareness, workload, and anthropometric/physiological factors) that will be used in validation tests. While this information sometimes provides the specific measures the staff requested, at other times the descriptions do not provide specific detail. In addition, from the write-up provided, it was not always clear how the measures are to be quantified; and, per RAI 18-11-26, what specific criteria will be used to evaluate the acceptability of the design.

As described in RAI 18.11-3 S02, please provide specific quantitative performance measures and specific criteria that will be used to evaluate the acceptability of the design in the V&V implementation plan. If the information is not available at this time, add a COL item to provide the information with the COL application for staff review and prior to conducting V&V activities.

GEH Response

GEH contends that the methodology contained in this implementation plan is at a sufficient level to assure that scenarios and associated elements developed from it will comply with the guidance in NUREG-0711 and ensure a quality validation activity. It should also be noted that GEH will provide a detailed report of the scenario development and resulting test plan in the V&V RSR, ESBWR Design Control Document Tier 1 Table 3.3-1 ITAAC item 9, and that the process is open for staff review or audit.

To support the staff's evaluation of the level of detail of the V&V Implementation Plan, NEDE/NEDO-33276P, this response provides a roadmap guide in the form of flow charts, included as Attachment 1 and Attachment 2.

The Developing and Implementing Plant Performance Measures chart (Attachment 1) outlines the steps described in the corresponding paragraph numbers of the plan to address the plant/system level performance measures. The specific measures are provided and the detailed steps by which specific values are obtained are defined.

In a similar fashion, the Developing and Implementing Personnel Task Performance Measures chart (Attachment 2) outlines the steps and corresponding paragraph numbers for defining the personnel task performance measures.

Attachment 1 and Attachment 2 combine to provide the sections in the plan that address RAI 18.11-24 S02 concerning performance measures.

By following the outlined performance measure development process, the resulting performance measures will adequately represent performance of the plant and personnel.

DCD 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.

RAI

18.11-27

NRC RAI 18.11-27

NEDO-33276 does not provide detailed information on test design. Please provide descriptions of the methodology used for the following aspect of test design:

- *presentation of scenarios to crews*
- *test procedures*
- *training of test conductors*
- *training of test participants*
- *pilot studies.*

GE Response

NEDO-33276 will add a section on test design in the next revision to address the issues identified:

A. Presentation of scenarios to crews

A discussion prior to the simulations will be conducted to describe the overall objective of the testing process which is to validate the MMIS and for operating team to consider difficulties and issues they have in using the MMIS for the planned scenarios (e.g., normal operational startups, shutdowns, accidents from full power or partial power, and management of outage conditions). A shift turnover process will be used to define the plant status including possible equipment tagouts. The use of the simulation freeze capability for questions about situational awareness is discussed.

B. Test procedures

A simulation scenario known to the observers is selected from at least five different ones. The simulation start will be announced.

The initial condition will last for several minutes before any new malfunction is introduced. Recording of plant alarms, screen changes, control actions and key parameter traces is maintained throughout the simulator training interface. The timing for each malfunction will be entered from a preset file that permits each simulation to be repeated for other crews. The simulation continues until the planned actions are completed and the plant reaches a stable state. Records of the simulation from the simulation are saved in an electronic file for future use. The operators are debriefed after the simulation to obtain information that made control tasks difficult.

C. Training of test conductors

The test conductors include the simulator operator, training instructors, and observers with control room and simulator observation experience. The training of the this team can be performed by setting up scenarios with set malfunctions, or by running through existing scenarios to define possible and expected responses based on procedures and general operating rules. Also, protocols such as how to interact with the crew during the simulation, non-intrusive locations, use of recording devices, development of the information check list for taking notes during the simulation, and focus on the MMIS, procedure or tasks of importance for the specific simulation.

D. Training of test participants

The test participants should have had basic operator training on ESBWR technology, use and meaning of the screen protocols and MMIS interaction processes, have completed training on each procedure to be used, and have training on potential human errors (e.g., STAR).

E. Pilot studies.

Initial pilot studies on use of the MMIS by the designers and the HFEs can be used to test out scenarios and interactions on computers that provide simulation capability. The pilot studies address resolution of issues identified early in the process.

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.

RAI 18.11-27 S01

NRC Summary Text:
Test Design

NRC Full Text:

In the original RAI the staff requested the detailed test design methodology. In NEDO-33276, Rev. 1, GEH added a new section 4.4.9 to present a high level description of test design. However, GEH should provide the detailed information requested if the staff is to conduct an Implementation Plan level review. Please provide descriptions of the following aspect of test design (consistent with NUREG-0711, Section 11.4.3.2.6):

- *presentation of scenarios to crews*
- *test procedures*
- *training of test conductors*
- *training of test participants*
- *pilot studies*

GEH Response

To reflect the level of detail required for an Implementation plan, both the text and document organization in NEDO-33276 will be revised. The final organization is incomplete, but the revision will include a section that details how scenario presentation, test procedures, training (of both test administrators and participants), and pilot studies are used in the integrated system validation process.

The text below will be inserted in the Integrated System Validation section.

Test Design

Test design is the process of developing the integrated validation test such that the required attributes for scenario assignment, the qualifications of the test conductors and training and briefing of participants permit the observation of integrated system performance in a manner that avoids or minimizes bias, confounds, and noise (error variance).

Coupling Crews and Scenarios

The coupling of crews and scenarios determines how the test participants experience the test scenarios.

Scenario Assignment

Scenario assignment to crews is made prior to the initiation of the integrated test sequence. Depending upon the number of available crews during testing, some crews may not participate in all scenarios. The set of scenarios, selected by the validation team and presented to a crew, should be carefully balanced to ensure that each crew receives a similar and representative range of scenarios (difficult scenarios are not only assigned to above average crews). To establish adequate test data reliability, each validation scenario should be run on a minimum of three crews.

Scenario balance among crews is maintained by providing the validation team with a checklist for making assignments. This checklist requires scenario selection to be based on scenario complexity, operating conditions, and expectations during the scenario (i.e. each crew receives scenarios that test their abilities and plant responses during normal, abnormal and emergency plant conditions). The checklist also ensures that the crews do not repeat scenarios.

Presentation of the same scenario to the same crew for a second time may not occur in the context of integrated system validation.

Scenario Sequencing

The validation team should balance the order in which scenarios are presented to crews. The same type of scenario is not presented in the same linear position (i.e. avoiding always presenting the easy scenarios first) and the scenario sets do not always occur in the same sequence. Control of scenario sequencing also serves to minimize any bias resulting from crew expectations of scenario type.

Test Procedures

The following outlines steps that are taken to perform evaluation procedures for HFE validation activities using the simulators:

1. A simulation scenario that evaluates the ESBWR features being considered is assigned to a crew. An alternate scenario selected using the same criteria and methodology and that evaluates the same ESBWR features as the primary scenario is designated for use should it become necessary. These scenarios should be known to the test conductors and observers, but not to the participating crew.
2. Each crew is briefed prior to the performance of a scenario. The briefing procedure follows a detailed script that is prepared during scenario development. At a minimum, these briefings should describe the following:
 - Test objectives

- Crew assignments
 - Plant status with any expected normal operations for the crew
 - Use of human performance tools during manipulations
 - Test conductor/participant interface after scenario initiation
3. The crew enters the simulator and performs a walkdown of the simulator panels, a verification of initial conditions, and a shift turnover.
 4. The scenario is conducted according to the applicable scenario guide. This guide delineates the manipulations required by the simulator operator and the expected simulator responses to these manipulations.

If the simulator fails to perform as expected, the operator should request instruction or corrective actions from the lead test conductor. If the failure cannot be resolved, or if the test conductors feel the failure has invalidated the scenario as an evaluation tool, the scenario is terminated. An alternate scenario may be selected for evaluation of the crew and integrated HSI.

5. The scenario guide also includes the following information:
 - A coversheet and revision log
 - An administrative information sheet
 - Console operator instructions including timeline and manipulations required for initiation of the scenario events
 - Evaluator information sheet
 - Event guides with expected crew and simulator responses
 - Scripting for required communications with outside personnel during the scenario
 - Critical task summary for determination of satisfactory crew/simulator response to events
 - Shift briefing / transfer of authority information
 - Questionnaires to be used in association with the scenario
 - Termination criteria for completion of the scenario

- Questionnaires for specific crew positions that request responses on events that required increased situational awareness or that caused a significant change in operator workload
6. Data collection during performance of a scenario uses methods to minimize bias in both the conductors and participants in the test. Automatic collection by videotaping and recording of plant parameters and control board manipulations in response to event initiation is used to the maximum extent possible. The videotape system and simulator times are synchronized so that event response can be recreated.

Test conductors receive training in the methodology for minimizing conductor-to-participant interactions during scenario events. Training in techniques for measuring conditions such as situational awareness and cognitive workload are provided. This includes training for automatic measuring instruments.
 7. A scenario should continue until the planned actions are completed and the termination criteria in the scenario guide are met.
 8. If deemed necessary during testing, the simulator may be frozen at any point in order to question crewmembers or resolve issues. Planned 'freezes' of the simulator after scenario events that have increased cognitive workload may also be used.
 9. If simulator or testing difficulties arise, the difficulty is documented. When or how test personnel interact with crewmembers is guided by established procedures.
 10. All records and results from the integrated validation tests are retained for review.
 11. The operators are debriefed after a scenario to gather information about events and required actions that resulted in problems manipulating controls or obtaining data required to perform these actions.

Briefing Participants

A standardized discussion prior to a simulation is conducted to describe the overall objective of the testing process. The crew is instructed to consider difficulties and issues they have while using the HSI during the testing scenario (e.g., normal operational startups, shutdowns, accidents from full power or partial power, management of outage conditions, etc). A shift turnover process is used to define the plant status including possible equipment tagouts. The use of the simulation freeze capability for questions about situational awareness is discussed. The crew is instructed to refrain from discussion of the scenario with other test personnel until all test crews have performed the scenario.

Conducting Scenarios

For details regarding specific criteria for the conduct of scenarios, such as when to start and stop scenarios, when events are introduced, etc., see "Scenario Definition."

Scripts

When possible, test personnel role-playing plant personnel during test scenarios should adhere to prepared scenario scripts when interacting with crew members. Scenario guides provide responses to likely crew questions. Responses should only provide information that would normally be available in a real plant situation. These guides also establish delay times, both due to environmental conditions and to the complexity/ location of the selected task, before completion of the task is reported. Some remote tasks requested are not performed due to expected plant conditions or the availability of equipment requested. These remote tasks are delineated in the scenario guide along with the required reports and time delays.

If a crew member asks a question that requires input not covered by a script, the test personnel should attempt to respond to the question in manner consistent with how such a question would be addressed in a real plant. In addition, any such occurrences should be documented, and if deemed necessary, additional scripts should be written.

Interaction of Test Conductors with Test Participants

Once scenario testing has begun, test conductors and participant interactions should only occur if required by the scenario (i.e. the crew requests input from an outside source that requires a meeting in the control room). These interactions are scripted in the scenario guide. Protocols such as when and how to interact with the crew during the scenarios, non-intrusive locations, and unobtrusive use of recording devices are part of test conductor training.

If interaction is required due to failure of the scenario to run as expected or simulator problems due to simulator operator error, test conductors should follow established procedures and minimize the impact of the situation or error on crew performance. If the failure or error affects the usefulness of a scenario as an evaluation tool, test conductors should freeze the simulator and determine if the remaining events in the scenario can still allow an evaluation to occur. If not, the crew should receive a replacement scenario.

Data Collection

Validation activities with the Part Task Simulator (ANSI/ANS-3.5 compliant) and the Full Scope Simulator use the following:

1. Videotaping – Each scenario run is recorded from the start of a simulation until the stop of the simulation. At least one video camera is positioned to record a general overview of the control room, including general crew task performance and movement. In addition, where deemed applicable, an additional camera or

cameras are placed to record specific crew actions or specific panels. Decisions regarding additional cameras are made on a case-by-case basis.

2. Data collection forms and checklists – to be completed by observers
3. Interviews using established analysis tools such as the NASA Task Load Index (TLX) to supplement analytic data. Interviews are conducted after scenario completion or during a scenario freeze
4. Questionnaires – to be completed by crew members
5. Simulator recording of chronological event logs
7. Simulator recordings (logs) of process variables
8. Written observations, notes and commentary – to be completed by observers
9. Timelines of operator activities while performing tasks identified in the TA and PRA/HRA, used to identify periods of overloading and underloading. The timelines show phasing, frequency, durations, and time limits for tasks. Other actions (reactions to secondary effects, diagnostic actions), if defined, can be included in the timeline.
9. Operator movement pattern diagrams may be developed using videotapes and visual observation records. However, because operating experience has shown that MCR traffic and crew movement patterns are generally not significant in modern digital control rooms, movement pattern diagrams may be developed to resolve HEDs or related issues, but are not developed as part of routine validation testing.

TRAINING

Test Conductors

The test conductors include V&V team members, simulator operators, training instructors, and observers with control room and simulator observation experience. Test conductors will receive training similar to the training required by ACAD97-014 for simulator instructors/evaluators prior to initiation of the integrated validation tests. Some components of this training include:

- Planning and coordinating simulator sessions
- Observing operator performance
- Evaluating operator performance

- The use and importance of test procedures
- Experimenter bias and the types of errors that may be introduced into test data through the failure of test conductors to accurately follow test procedures or interact properly with participants.
- The importance of accurately documenting problems that arise in the course of testing, even if due to test conductor oversight or error.
- Test conductors should be qualified as simulator operators and familiar with the capabilities of the partial scope or full scope simulator.

Also included in training are protocols such as when and how to interact with the crew during the simulation, non-intrusive locations, use of recording devices, development of the information check list for taking notes during the scenario, and focus on the HSI, procedure or tasks of importance for the specific scenario.

Test Participants

Test participant training may vary based on the experience and education of the individual and the requirements of the integrated validation tests. Integrated system testing using part task simulator requires comprehensive knowledge of the systems included in the test. This knowledge is attained through formal classroom and simulator training. After training is complete, a comprehensive examination on the received training and job performance measures for system manipulations on the simulator will be conducted to prove the success of the training.

Test participants who will be used during the full scope simulator integrated validation tests will be trained as follows:

- Test participants that were licensed on previous generation BWRs are required to receive ESBWR systems training, procedure training and simulator training for familiarization with the controls for the specific ESBWR systems. This training is similar to existing BWR license training in content.
- Test participants with no previous BWR operating experience are required to receive additional training for BWR general fundamentals. The ESBWR systems and procedure training required for these personnel is similar to existing BWR initial license training. The formerly licensed personnel should attend integrated plant simulator training with the new trainees to promote teamwork and allow the new trainees to benefit from their experience.
- All personnel receive a comprehensive operating test in the full scope simulator before participating in the full scope simulator V&V testing.

Pilot Testing

A pilot study will be performed prior to the initiation of the V&V process in the simulator. This study is used to test the process for determining adequate design and determining the correct data collection techniques.

Components and requirements of a pilot study include:

- Scenario guides written to the same level of complexity as the guides prepared for the actual V&V testing.
- Crew composition and numbers for test participants are equivalent to the actual V&V testing. This includes all necessary training and testing as referenced above.
- Test conductor training and expectations for the conduct of the pilot tests are maintained at the same level as the actual testing.
- Data collection setups, methods and determination if validation criteria are met will match those used in actual testing.

Personnel used during pilot testing should not be the same personnel to be used as test participants during integrated validation tests. If integrated validation test personnel must be used, the scenario sets must be different from those developed for the integrated validation test, and participant exposure to the data collection process should be minimized.

DCD Impact

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

LTR NEDO-33276, Rev 1 will be revised with the inserted text provided above.

NRC RAI 18.11-27 S02

In their response to the RAI, GEH provided additional information on test design methodology. However, the staff's RAI requested the detailed test design to be followed. For example, the RAI response indicates that "The set of scenarios, selected by the validation team and presented to the crew, should be carefully balanced to ensure that each crew receives a similar and representative range of scenarios..." While the staff agrees with this objective, as described in RAI 18.11-3 S02, the staff needs to see the specific assignment of scenarios to crews to determine whether this objective is achieved. Please provide the specific test procedures, etc. that will be used to conduct the validation test. If the information is not available at this time, add a COL item to provide the information with the COL application for staff review and prior to conducting V&V activities.

GEH Response

GEH contends that the methodology contained in this implementation plan is at a sufficient level to assure that scenarios and associated elements developed from it will comply with the guidance in NUREG-0711 and ensure a quality validation activity. It should also be noted that GEH will provide a detailed report of the scenario development and resulting test plan in the V&V RSR, ESBWR Design Control Document Tier 1 Table 3.3-1 ITAAC item 9, and that the process is open for staff review or audit.

To support the staff's evaluation of the level of detail of the V&V Implementation Plan, NEDE/NEDO-33276P, this response provides a roadmap guide in the form of a flow chart, included as Attachment 1.

The Test Design Development chart (Attachment 1) outlines the steps described in the corresponding paragraph numbers of the plan to address test design methodology. As a part of test design, the process by which crews are assigned to scenarios is illustrated in this chart, along with the corresponding paragraph numbers. Likewise, this chart provides a roadmap through the development of test procedures, test personnel and participant training, and pilot testing.

By following the outlined test design process, the resulting integrated system validation tests will be performed in a manner that minimizes bias, confounds, and error variance.

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.

Enclosure 3

MFN 08-672

**Attachments for Supporting RAIs
18.11-3 S02, 18.11-4 S02, 18.11-19 S02, 18.11-22 S02,
18.11-24 S02, and 18.11-27 S02**

Non-Proprietary Version

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MFN 08-672

Enclosure 4

Affidavit

GE-Hitachi Nuclear Energy Americas LLC

AFFIDAVIT

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

- (1) I am the General Manager, New Units Engineering, GE-Hitachi Nuclear Energy Americas LLC (“GEH”). I have been delegated the function of reviewing the information described in paragraph (2) which is sought to be withheld, and have been authorized to apply for its withholding.
- (2) The information sought to be withheld is contained in Enclosure 2 of GEH’s letter, MFN 08-672, Richard E Kingston to Nuclear Regulatory Commission, entitled *Response to Portion of NRC Request for Additional Information Letter No. 201 Related to ESBWR Design Certification Application – Human Factors Engineering - RAI Numbers 18.11-3 S02, 18.11-4 S02, 18.11-19 S02, 18.11-22 S02, 18.11-24 S02, 18.11-27 S02*, October 9, 2008. GEH text proprietary information in Enclosure 2, which is entitled “Attachments for Supporting RAIs 18.11-3 S02, 18.11-4 S02, 18.11-19 S02, 18.11-22 S02, 18.11-24 S02, and 18.11-27 S02”, is identified by a dark red dotted underline inside double square brackets [[This sentence is an example.^{3}]]. Figures and large equation objects containing GEH proprietary information are identified with double square brackets before and after the object. In each case, the superscript notation ^{3} refers to Paragraph (3) of this affidavit, which provides the basis for the proprietary determination.
- (3) In making this application for withholding of proprietary information of which it is the owner or licensee, GEH relies upon the exemption from disclosure set forth in the Freedom of Information Act (“FOIA”), 5 USC Sec. 552(b)(4), and the Trade Secrets Act, 18 USC Sec. 1905, and NRC regulations 10 CFR 9.17(a)(4), and 2.390(a)(4) for “trade secrets” (Exemption 4). The material for which exemption from disclosure is here sought also qualify under the narrower definition of “trade secret”, within the meanings assigned to those terms for purposes of FOIA Exemption 4 in, respectively, Critical Mass Energy Project v. Nuclear Regulatory Commission, 975F2d871 (DC Cir. 1992), and Public Citizen Health Research Group v. FDA, 704F2d1280 (DC Cir. 1983).
- (4) Some examples of categories of information which fit into the definition of proprietary information are:
 - a. Information that discloses a process, method, or apparatus, including supporting data and analyses, where prevention of its use by GEH’s competitors without license from GEH constitutes a competitive economic advantage over other companies;
 - b. Information which, if used by a competitor, would reduce his expenditure of resources or improve his competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product;
 - c. Information which reveals aspects of past, present, or future GEH customer-funded development plans and programs, resulting in potential products to GEH;

- d. Information which discloses patentable subject matter for which it may be desirable to obtain patent protection.

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

- (5) To address 10 CFR 2.390(b)(4), the information sought to be withheld is being submitted to NRC in confidence. The information is of a sort customarily held in confidence by GEH, and is in fact so held. The information sought to be withheld has, to the best of my knowledge and belief, consistently been held in confidence by GEH, no public disclosure has been made, and it is not available in public sources. All disclosures to third parties, including any required transmittals to NRC, have been made, or must be made, pursuant to regulatory provisions or proprietary agreements which provide for maintenance of the information in confidence. Its initial designation as proprietary information, and the subsequent steps taken to prevent its unauthorized disclosure, are as set forth in paragraphs (6) and (7) following.
- (6) Initial approval of proprietary treatment of a document is made by the manager of the originating component, the person most likely to be acquainted with the value and sensitivity of the information in relation to industry knowledge, or subject to the terms under which it was licensed to GEH. Access to such documents within GEH is limited on a "need to know" basis.
- (7) The procedure for approval of external release of such a document typically requires review by the staff manager, project manager, principal scientist, or other equivalent authority for technical content, competitive effect, and determination of the accuracy of the proprietary designation. Disclosures outside GEH are limited to regulatory bodies, customers, and potential customers, and their agents, suppliers, and licensees, and others with a legitimate need for the information, and then only in accordance with appropriate regulatory provisions or proprietary agreements.
- (8) The information identified in paragraph (2) above is classified as proprietary because it identifies details of GEH ESBWR methods, techniques, information, procedures, and assumptions related to the application of human factors engineering to the GEH ESBWR.

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

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

The research, development, engineering, analytical and NRC review costs comprise a substantial investment of time and money by GEH.

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

GEH's competitive advantage will be lost if its competitors are able to use the results of the GEH experience to normalize or verify their own process or if they are able to claim an equivalent understanding by demonstrating that they can arrive at the same or similar conclusions.

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

I declare under penalty of perjury that the foregoing affidavit and the matters stated therein are true and correct to the best of my knowledge, information, and belief.

Executed on this 9th day of October, 2008.

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

David H. Hinds
GE-Hitachi Nuclear Energy Americas LLC