ArevaEPRDCPEm Resource

From: Tesfaye, Getachew
Sent: Tuesday, November 17, 2009 4:37 PM
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Subject: U.S. EPR Design Certification Application RAI No. 328 (3961, 3963, 3965), FSAR Ch. 18
Attachments: RAI_328_COLP_3961_3963_3965.doc

Attached please find the subject requests for additional information (RAI). A draft of the RAI was provided to you on November 5, 2009, and discussed with your staff on November 17, 2009. Draft RAI Question 18-60 was modified as a result of that discussion. In addition, the staff has deleted Draft Question 18-69(4) and modified Draft RAI Questions 18-64(1) and (2), 18-66(2), 18-68(2), and 18-69(1) to eliminate duplication, correct typographical errors and/or provide clarification. The schedule we have established for review of your application assumes technically correct and complete responses within 30 days of receipt of RAIs. For any RAIs that cannot be answered within 30 days, it is expected that a date for receipt of this information will be provided to the staff within the 30 day period so that the staff can assess how this information will impact the published schedule.

Thanks,
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Request for Additional Information No. 328 (3961, 3963, 3965), Revision 1

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U. S. EPR Standard Design Certification
AREVA NP Inc.
Docket No. 52-020
SRP Section: 18 - Human Factors Engineering
Application Section: FSAR Ch 18

QUESTIONS for Operating Licensing and Human Performance Branch (AP1000/EPR Projects) (COLP)

18-53

It is the FSAR that the staff evaluates to make a safety determination. Therefore, the FSAR should contain all information (either directly or by reference) the staff uses in its evaluation. A reference to the submitted HFE Design Implementation plan (document no. 118-9047891-001) was not provided in the U.S. EPR FSAR. Include this reference in the FSAR, or clarify why a reference to this document is not, and will not be, included in the FSAR.

18-54

In the HFE Design Implementation Plan, various steps throughout the plan instruct the Responsible HFE Engineer to “audit” various documents. In some steps within each section, as in section 3.7.1 for instance, it explicitly gives guidance to “Audit all…”, but in other sections it just says “audit.” Clarify what the implementation plan is communicating with the word "audit", and indicate if there is a particular process associated with the audit that differs from any indicated in the implementation plan.

Also, when no particular audit process is specified (when the word audit appears by itself), does the Responsible HFE Engineer “audit all,” or is a sample taken of the relevant material to be audited? If sampling is conducted, how is the sample size determined, and what process is used to determine the design aspects to be sampled? Provide clarifying information detailing the scope of the audit term within the implementation plan.

18-55

Section 3.1.1 of the HRA Implementation Plan (IP) provides RAW and FV criteria for the risk-significant human actions (R-S HAs) relative to the Level 1 PRA. It further states that “Similar risk-importance metrics are produced by the Level 2 PRA results, except that the criterion for risk-significance is associated with large release frequency (LRF) instead of CDF.” For clarity, provide the specific criterion for LRF risk-significance noted in the IP.

18-56

1. NUREG-0711 Section 7.4 (1) specifies that risk important actions be developed from the Level 1 (core damage) PRA for internal and external events. Section 3.1.1 of the HRA IP states that human errors are considered risk-significant if

they meet defined RAW and FV values. Clarify that these will include human actions from both the "PRA for Operations at Power" and the "PRA for Other Modes of Operation," namely low power and shutdown operations.

2. NUREG-0711 Section 7.4 (1) specifies that risk important actions be developed from the Level 1 (core damage) PRA for internal and external events. Section 3.1.1 of the HRA IP states that human errors are considered risk-significant if they meet defined RAW and FV values. Clarify that these will include human actions from the external events PRA.
3. Section 3.1 of the HRA IP states that "The HRA will be performed iteratively during the design process." It also states that "New items analyzed during the design process determined through HRA to have *unacceptable risk* will be sent back through the HFE design process along with the applicable performance shaping factors as candidates for design changes." Provide the measure and threshold for *unacceptable risk* as used in this context.
4. NUREG-0711 Section 7.4 (1) specifies that risk important human actions should be identified. Section 1.5 of the HRA IP in the definition of risk-significant human actions states that the initial list of these actions is located in Appendix B; but App. B is not included in Rev. 2. Appendix A of the HRA IP contains a Table titled U.S. EPR HRA Risk-Significant Human Actions, but it is blank and notes that "list to be developed by PRA/HRA." It appears that there are currently HFE activities in progress that need the list as input. Review of FSAR, Chap. 19, Rev. 0 shows tables of HAs with RAW and FV values. Provide a copy of the most current consolidated list of risk-significant human actions.
5. NUREG-0711 Section 7.4 (2) specifies that risk-important HAs should be addressed in (among others) task analyses (TA). Section 1.2.1.4 of the HRA IP addresses input to TA from the HRA. Clarify the HRA IP to specify that there will be a task analysis performed for each R-S HA.
6. NUREG-0711 Section 7.4 (2) specifies that risk-important HAs should be addressed in (among others) procedure development. Clarify the HRA IP to specify that each R-S HA will be addressed in the EPR procedure system.
7. NUREG-0711 Section 11.4.1.2.1 (2) states that all risk-important HAs should be included in the operational conditional sample for developing V&V scenarios. Section 1.2.1.9 of the HRA IP only states that the R-S HAs will be "considered." The HRA IP, Section 3.4, item 3 states that V&V includes test scenarios that assess each R-S HA. Clarify Section 1.2.1.9 to agree with the other references and state that all R-S HAs will be addressed in V&V. Also, add to FSAR Section 18.6.2, last paragraph, that fact that all R-S HAs will be addressed in integrated system validation scenarios.
8. Section 1.2.1.10 of the HRA IP states that the U. S. EPR™ HFE program will require developing construction staging and commissioning plans, including use of a temporary control room during construction. Clarify any use of such a temporary control room and when it would be used.
9. Add the HRA IP as a reference to FSAR Section 18.6.4.

18-57

Section 13.4 of NUREG-0711 Criterion 1 outlines the expected scope for the human performance monitoring program. The criterion states that the performance monitoring strategy should provide reasonable assurance that:

1. The design can be effectively used by personnel, including within the control room and between the control room and local control stations and support centers
2. Changes made to the HSIs, procedures, and training do not have adverse effects on personnel performance
3. Human actions can be accomplished within time and performance criteria
4. The acceptable level of performance established during the integrated system validation is maintained.

Sections 1.3 and 1.4 of the U.S. EPR Human Performance Implementation Plan outlines the scope of the human performance monitoring (HPM) program, and states that monitoring of human performance continues throughout the life of the plant. HPM ensures that the results of the integrated system validation are maintained throughout the life of the plant and that operator performance does not degrade over time. HPM also ensures that issues discovered by personnel are noted, tracked and corrected before plant safety is compromised, and that changes made to the U.S. EPR design do not result in a degradation of human performance. The HPM implementation plan says that the HPM program will ensure that the design can be effectively used by personnel not only in the control room, but also between the control room and local control stations and support centers. The plan will also ensure that changes made to the HSIs, procedures, and training do not adversely affect performance. The plan continues to say that the program will ensure that human actions can be accomplished within the time frame and performance criteria defined in the HRA, and that the acceptable level of performance established during the integrated system verification is maintained. Additionally, the HPM program will ensure that degrading human performance is detected before plant safety is compromised and that identified errors in the design are resolved in a timely manner.

It is unclear to the staff how the implementation plan will ensure that the design can be used effectively over time, how the plan will ensure that changes made to the HSIs, procedures and training do not adversely affect plant performance, or how the HPM program ensures that human actions can be accomplished within the time frame and performance criteria defined in the HRA.

Clarify the scope of the HPM implementation plan and how the program will "ensure" the identified items.

18-58

NUREG-0711 Section 13.4, Criterion 2 states that a human performance monitoring strategy should be developed and documented.

Section 18.12.2 of the U.S. EPR FSAR lists several tools which will be developed to track issues. One tracking tool is a corrective action program (CAP) combined with a means for tracking issues to allow design errors, issues, operator workarounds, operators burdens, and inefficiencies to be captured and addressed. Both the implementation plan and the FSAR describe an operational focus index that will be used to trend performance of an operator's day to day activities.

Several tracking programs are discussed throughout the implementation plan. These include a corrective action program, an HFE tracking system and the operational focus index.

1. The staff requires more information regarding the use of the operational focus index. It is not clear whether this tracking system is used in conjunction with the corrective action program, or if it is a separate tracking database.

2. Clarify the relationship between the operational focus index, the Appendix B CAP program, the QA database described in the V&V plan, and the HFE tracking system. Describe who uses them, how information is captured and what happens with the results.
3. Section 3.1 of the implementation plan implies that the U.S. EPR operators can "choose" to use a separate HFE tracking system or the current corrective actions database. These tracking systems are discussed interchangeably throughout the implementation plan. Section 3.1 also states that to ensure all issues are captured, plant personnel are encouraged to report errors, deficiencies, workarounds, and design inefficiencies. The Appendix B CAP would "require" rather than "encourage" personnel to report errors, deficiencies, workarounds, and design inefficiencies. It is unclear whether use of the Appendix B CAP is mandatory.
4. Clarify the difference between the required appendix B CAP and the HFE tracking system. If there is no difference between them, what is meant by the word "choose?"

18-59

Criterion 2 of NUREG-0711 section 13.4 says that a human performance monitoring strategy should be developed and documented. The Human Performance Monitoring Implementation Plan refers in several places to both an operator focus index and an operational focus index.

Clarify the inconsistent use of this terminology, i.e., operator focus index vs. operational focus index.

18-60

Criterion 3 of NUREG-0711 Section 13.4 states:

The (HPM) program should be structured such that:

- human actions are monitored commensurate with their safety significance
- feedback of information and corrective actions is accomplished in a timely manner
- degradation in performance can be detected and corrected before plant safety is compromised

Section 3.1 of the HPM Implementation Plan discusses the role of the HFE tracking system and the corrective action program with regard to the HPM. Once an issue is identified and is entered into the database or tracking system, a cognizant engineer performs an analysis to determine safety-significance. Issues deemed to have high safety-significance are analyzed further and corrective actions are promptly generated to ensure plant safety isn't compromised. Provide information as to the guidance and training the "cognizant" engineer will receive to perform this analysis, to include details on how the analysis will be performed.

Provide information as to the guidance and training the "cognizant" engineer will receive to perform this analysis, AND include details on how the analysis will be performed.

18-61

Section 11.3 of NUREG-0711 states:

As per Section 1.2.1, item (3) Applicant Submittals, the applicant should provide for staff review an *implementation plan* for HFE V&V. Upon completion of the applicant's efforts, a *results summary report* should be submitted so that the staff can review the applicant's V&V evaluations using the criteria provided in Section 11.4 below.

The FSAR Revision 2 should incorporate an explicit reference of the V&V Implementation plan. The specific implementation plans, used as the basis of the staff's safety determination, should be referenced in the FSAR.

18-62

This Question indicates insufficient information in the V&V Implementation Plan for the general principal derived from NUREG-0711. This is followed by specific examples that arose because the information provided was insufficient for the review. The examples provided do not comprise a complete set of issues for each category. Rather, they are used to illustrate the general issue caused by the missing information. It is the responsibility of the Applicant to apply the general principals illustrated by staff in the examples to determine the full-scope of issues affected by the missing information.

Level of Detail. Many of the details provided essentially restate NUREG-0711 review criteria. The staff cannot perform an implementation plan review when the plan simply restates the staff's review criteria. The NUREG-0711 criteria are used to review information provided by the applicant. For example, 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 to review the acceptability of the operational conditions that have been identified. In many cases, the information currently provided in the plan will be used to *finalize the plan* at a later date. Thus, the IP should contain, for example: an identification of the specific scenarios to be used, the detailed definition of each, the specific performance measures to be used for each scenario and the acceptance criteria to be used for each measure, the measures that will be used to validate or invalidate the design, and the ways in which the data will be analyzed to arrive at conclusions. Examples where more details are required include, *but are not limited to*:

1. Section 18.10.3.4.3 of the FSAR discusses situational related performance shaping factors. This section closely rephrases the guidance provided in NUREG-0711, provided above. The section does indicate that multitasking is an example of high workload conditions. Section 3.5.1.3 of the V&V Implementation Plan closely quotes NUREG-0711; however it neglects discussion of the affects of fatigue and circadian rhythms. Provide discussion of the effects of fatigue and circadian rhythms in this context. Expand discussion of all sections that quote NUREG-0711. In that discussion, place emphasis on factors that are critical to EPR or possibly unique. Staff requests more information describing the incorporation of situational factors into test scenarios.
2. Section 18.10.3.4.21 of the FSAR provides some information regarding certain of the personnel tasks to be assessed. The FSAR states that sample tasks will include those tasks that are found to be difficult to design into the HSI, require significant compromise during the HSI design, and have the potential to cause error because of complexity. Section 3.5.1.2 of the V&V Implementation Plan is quoted almost verbatim from NUREG-0711, Section 11.4.1.2.1, and does not provide more explanation of the information provided in the FSAR. 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 cannot perform an implementation plan review when the plan simply restates the staff's review criteria. The plan should identify operational conditions to be used and how the operational conditions were developed into scenarios. More information is requested that will link the criteria for selection of Operational Conditions to the EPR PRA.

3. The basis of the information required in Section 18.10.3.4.21 of the FSAR for the identification of tasks that are difficult to design into the HSI, require significant compromise, or are complex enough to cause errors is not clear to staff. The HRA Implementation plan is referenced; however, the section does not indicate how scenario development is related to the HRA Implementation Plan. It is not clear to staff which tasks will be used to assess the ability of the system to support a range of cognitive activities. More information is needed on these items. Staff also requires more information regarding the information shared during human interaction and communication methods of interest, the tasks being performed, and the complexity of the messages to be passed. Staff requires more information to determine how high frequency tasks will be identified.
4. Determination and discussion of inclusion of environmental factors in scenarios are not provided with respect to the V&V Implementation Plan, beyond paraphrasing the NUREG-0711 guidance on environmental factors in Section 3.5.13 of the V&V Implementation Plan. Discussion of operations remote from or ancillary to actions in the control room is not provided with respect to scenario development. Staff request that the methods be expanded for inclusion of environmental effects, how they may be simulated, what may be simulated, the limitations of simulation, as well as evaluation of performance of operations remote from or ancillary to the main control room, and considerations relevant to that.

18-63

This Question indicates insufficient information in the V&V Implementation Plan for the general principal derived from NUREG-0711. This is followed by specific examples that arose because the information provided was insufficient for the review. The examples provided do not comprise a complete set of issues for each category. Rather, they are used to illustrate the general issue caused by the missing information. It is the responsibility of the Applicant to apply the general principals illustrated by staff in the examples to determine the full-scope of issues affected by the missing information.

Typos and Errors. There are a number of typos and editorial errors apparent in the document which have the adverse effect of completely changing the intended meaning. In several cases, these errors cause the text to violate the various aspects of the guidance provided by NUREG-0711. Staff must review materials exactly as presented, not based on inference. The following is not a complete set of criteria that are not met due editing issues, nor is it intended to be a complete set. The material needs to be thoroughly reviewed to identify these errors and provide clarification. These errors include, *but are not limited to*:

1. Section 3.6.3, which discusses selection of test participants, combines inappropriately characteristics for the selection of test administrators. As written, this section contradicts the NUREG criteria that test participants will not be members of the design team. Staff request clarification of selection of test participants and test administrators (conductors).
2. Section 3.5.1.2 states that Appendix B has the list of procedure driven tasks that will be used during V&V. However, Appendix B contains the roles and responsibilities of the HF

team. Investigation indicated that the information referenced may be that presented in Appendix C. Staff inquires whether to use Appendix C in place of B.

3. Section 3.6.11 is not relevant to ISV. Is this to be associated with a different component of V&V?
4. Section 3.9.3.3 is referenced multiple times in the plan. The first time it is referred to in HSI scenario design, it is used appropriately to develop one-dimensional scenarios to test HSI design. However, the 2nd and 3rd times Section 3.9.3.3 is referenced, it is used to develop multi-dimensional scenarios. Section 3.9.3.3 is not written to support development of multidimensional scenarios -- it states that only one dimension is to be sampled. A method to develop multidimensional scenarios must be provided if the Applicant will not be able to provide the complete set of scenarios that will be used during V&V.
5. Three potentially separate databases are referenced in this plan and other plans: the HED database, the HFE database, and a QA database. Staff inquires whether these databases are the same but given different names in editing. If they are a single database, one name should be used. If they are different databases, provide an explanation, differentiation, and definition of each.
6. Section 3.6.11.3 states that test data 'should' be analyzed using established analysis techniques. Use of 'should' is inappropriate.
7. In Section 3.9.3.5, the Applicant provides an overview of the process to prioritize HEDs for justification and resolution. The process will consist of justification of HED, determination of whether HEDs have safety consequences (Priority 1), if not then determination of whether the HED has performance consequences (Priority 2), and if none of the above, classification as other. In the HSI Design Implementation Plan, HED categories are referred to with different designations, which has caused some confusion. Please clarify, either by use of one designation or explain the designation process and the categories.

18-64

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Performance Measurement and metrics. NUREG-0711 divides the review criteria for performance measurement into three sections. Section 11.4.3.2.5.1 addresses the measurement characteristics that effect the quality of the performance measures, Section 11.4.3.2.5.2 addresses the identification and selection of variables to represent measures of performance, and Section 11.4.3.2.5.3 addresses the development of performance criteria. Performance metrics must be directly linked to the scenarios tested, and the criterion for success for the scenario. Performance metrics should be linked to HRA, risk important human actions, results of Task Analysis, and/or Operator Experience. These items are not linked to performance metrics in the V&V plan. The V&V plan does not link metrics to scenarios, nor provide discussion of how performance metrics will be used. Discussion of the analysis of performance data and selection of performance metrics neglects discussion of data reliability,

validity, or verification of the conclusions of the analyses. The issues below are representative of deficiencies in these areas, *but are not limited to just these examples:*

1. In section 3.6.12, the Applicant states that validation conclusions will be iteratively documented in the validation output reports during the design process. Staff did not find any discussion of independent verification of analyses in the HF V&V Implementation Plan. Methods to verify and validate conclusions and analyses independent of the process are needed. Reliability and validity of conclusions and data are also not addressed. AREVA is requested to address conclusion reliability and validity. How will metrics be defined for scenarios? Which metrics are linked to which scenarios? What are the success criteria?
2. In Section 3.6.12, the Applicant states that "analysis will determine if data are pass/fail." It is not clear to staff what is meant here. Performance measures should be designated as pass/fail criteria with defined thresholds before the data are collected or analyzed, and the threshold for pass/fail should be set before data collection or analysis. The relationship between the data collected and the performance criteria needs to be defined so that reason for the selection of analysis techniques is transparent. In the V&V plan the analysis providing validation of the performance measures is selected, and that analysis will determine which measures are used for pass/fail determination after the analysis is performed. Performance measures should be identified as pass/fail criteria and the level required for pass prior to the administration of the test. Otherwise it could allow criteria that support the goodness of the design to be picked and performance metrics that question the goodness of the design to be ignored. Provide a method to define or the defining measures that will be used as pass/fail criteria, the scenarios in which they will be used, the thresholds for each, and discuss how the thresholds were derived. Also discuss how the required data for these metrics will be obtained, and how bias will be avoided.
3. In Section 3.6.10.1 of the HF V&V Implementation plan, the Applicant states, "The approach to establishing criteria should be based on the comparisons between the measurement and criteria that are performed (e.g., requirements referenced, benchmarks referenced, normative referenced, and expert-judgment referenced)." Staff does not understand what is meant here. Clarification is required. Which criteria will be performed? How will these be used to establish criteria? Which criteria will be established?
4. Section 3.6.10.1 states a criterion for performance measurement will be established and evaluated as part of test development; ANSI 58.8-1994 will be considered a source for response time criteria. Will reaction time be the only performance measure of interest? Please explain. What sources and metrics will be used to define performance limits beyond reaction time data? It further states that more accurate performance requirements will be defined as a function of the HRA and TA performed for this plant design; however, these data used from these techniques are not identified and the plans are not referenced. More information is therefore needed. Reference the HRA and TA plans. Identify what data from the HRA and TA will be used to define performance requirements.

18-65

This Question indicates insufficient information in the V&V Implementation Plan for the general principal derived from NUREG-0711. This is followed by specific examples that arose because the information provided was insufficient for the review. The examples provided

do not comprise a complete set of issues for each category. Rather, they are used to illustrate the general issue caused by the missing information. It is the responsibility of the Applicant to apply the general principals illustrated by staff in the examples to determine the full-scope of issues affected by the missing information.

Task Analysis. Section 11.4.4.2 (5) and 11.4.2.2.2 (2) and (4) discuss the role of Task Analysis within the HF V&V design. NUREG-0711 states that the HSIs and their characteristics (as defined in the HSI inventory and characterization) should be compared to the personnel task requirements identified in the task analysis. As stated in NUREG-0711, design solutions to correct HEDs should be consistent with system and personnel requirements identified in the Preparatory Analysis (i.e., Operating Experience Review, Function and Task Analysis, and HSI Characterization). Use of the Limited Scope Task Analysis in the V&V is discussed multiple times in the V&V IP; however, its justification is unclear. Issues regarding the use of the Limited Scope Task Analysis in the HFE V&V IP include, *but are not limited to*:

1. What are the bases for the limited scope task analysis? What is the scope? The methods to produce the limited scope task analysis is not documented in V&V or in the Task Analysis Implementation Plans. How will limited scope task analysis be performed? It is not clear that a limited scope task analysis will sufficiently review the entirety of the task to define the interactions occurring at multiple levels (global, situational, detailed) of the scenario. Please clarify how this will be used, and information to determine that the limited task analysis will be sufficient for the application. Staff inquires why limited scope task analysis will be used in place of the information derived from the full scope task analysis.
2. Section 3.9.3.2 of the V&V Implementation plan states it will use dynamic HSI Task Support Verification. What is meant by Dynamic Task Support Verification? Further clarification of its use is required. What is its scope? How is it performed? How does it differ from Task Analysis?

18-66

This Question indicates insufficient information in the V&V Implementation Plan for the general principal derived from NUREG-0711. This is followed by specific examples that arose because the information provided was insufficient for the review. The examples provided do not comprise a complete set of issues for each category. Rather, they are used to illustrate the general issue caused by the missing information. It is the responsibility of the Applicant to apply the general principals illustrated by staff in the examples to determine the full-scope of issues affected by the missing information.

ISV – Validation Testbeds. Section 11.4.3.3.2 of NUREG-0711 addresses the requirements to be met by the validation testbed. There are 2 sections of the HFE V&V IP that address the development of ISV testbeds. While the V&V plan clearly commits to developing at least one full scope simulator, several questions were raised. They include, *but are not limited to:*

1. The V&V Implementation plan states that the full-scope ISV simulator will be completed and certified via the ANSI/ANS-3.5-1998 process prior to the use of the simulator during V&V. However, the NRC does not inspect a simulator to certify it as a plant reference simulator at this time. Please clarify what is meant by certify and the status of the simulator to be used for ISV.

2. In Section 3.6.11 of the V&V Implementation Plan, development of a 'Mockup' is discussed. Section 3.81 discusses the development of a “full-scope simulator.” The Applicant commits to incorporating accurate plant models into both the Mockup and the full-scope simulator as these models become available. How do these two simulators differ? How is the development of the high fidelity simulator related to the development of the mockup? These sections appear to indicate that multiple simulators will be developed at different times. Is this correct? For what tasks will the mockup be used? For what tasks will the simulator be used?
3. What are the relative schedules for the development of the mockup and the full-scope simulator with respect to the other portions of the V&V Implementation plan?

18-67

This Question indicates insufficient information in the V&V Implementation Plan for the general principal derived from NUREG-0711. This is followed by specific examples that arose because the information provided was insufficient for the review. The examples provided do not comprise a complete set of issues for each category. Rather, they are used to illustrate the general issue caused by the missing information. It is the responsibility of the Applicant to apply the general principals illustrated by staff in the examples to determine the full-scope of issues affected by the missing information.

Scenario Assignment, and Crew/Participant Selection and Training. NUREG-0711 divides the review criteria for test design into five sections. Section 11.4.3.2.6.1 addresses coupling crews and scenarios, Section 11.4.3.2.6.2 addresses test procedures, Section 11.4.3.2.6.3 addresses the training of test conductors, Section 11.4.3.2.6.4 addresses the training of test participants, who are separate from test conductors, and Section 11.4.3.2.6.5 addresses the conduct of pilot studies. Section 11.4.3.2.6.1 of NUREG-0711 states that important characteristics of scenarios should be balanced cross crews. Random assignment of scenarios to crews is not recommended. The value of using random assignment to control bias is only effective when the number of crews is quite large. Instead, the validation team should attempt to provide each crew with a similar and representative range of scenarios. Several aspects of the HFE V&V IP are not clear and appear to violate the guidance above. Issues include, *but are not limited to*:

1. As stated in NUREG-0711, Section 11.4.3.2.6.1, random assignment of scenarios is not recommended because the number of crews typically run is not sufficient to automatically average out effects of order or experience. Section 3.5.4 of the V&V Implementation plan states that random assignment of scenarios to participants will be used. It is not clear from the V&V Implementation plan whether a high enough number of crews to balance testing effects will be used. If the number of crews is too small to allow for statistical power to ensure that order effects are not an issue in testing, scenarios order and assignment should be balanced across testing and crews. The validation team should attempt to provide each crew with a similar and representative range of scenarios, balanced across critical characteristics. Provide more information to determine how order effects will be avoided. Provide more information to determine how critical characteristics of scenarios will be balanced across crews.
2. In Section 3.5.4 of the HF V&V IP, staff is not clear whether random selection will be used to select the factors to be combined in a scenario or whether random selection will be used to select from a list of predetermined scenarios. If the first case, staff requests more information to determine how realism of scenarios will be ensured. If the latter case, staff requests more information to determine how multiple variants of the same scenario will be avoided. If an alternate method will be used, it should be described.

Also clarify if the same set of scenarios will be presented across test crews or if new scenarios will be randomly generated for each.

3. Section 3.6.7 states that a procedure will be developed as part of the validation procedure, and that test procedures should minimize the opportunity for participant or administrator bias. The discussion in this section is primarily a restatement of some of the guidance provided in NUREG-0711. More detail is needed regarding the procedures to be followed during validation testing. What considerations should affect interaction between participants and administrators? What considerations will guide how and when will data be collected and stored? What procedures will be followed for documentation of the testing scenarios? Procedures for the documentation of testing irregularities and training on the importance of documenting training irregularities should be presented.
4. Section 3.6.9, Training of Test Participants, states: All test participants will be required to have basic US EPR™ operator training. All participants will have training on screen protocols and HMI interaction processes. They will also have training to help prevent potential human errors. Further information is requested to understand how performance bias will be avoided. At what point relative to performance in the validation test will test participants receive training (immediately before testing, a few weeks before)? On what topics will training be received? How will performance bias due to training be avoided?
5. Section 3.6.8 states an intention to train test administrators on the simulator using scenarios with predetermined malfunctions or by having test administrators perform the test scenarios. An information checklist will be developed from the protocols used to govern interaction with test participants. Plans to train test administrators do not address experimenter bias, importance of documenting problems that occur during testing or how test procedures should be used. Training of test administrators is focused entirely on familiarizing test administrators with the scenarios and workings of the plant and simulator and on how and what information may be communicated between test participants and administrators, which is one purpose of the Pilot Study. More information is requested for the development of procedures, what they should be used to prevent, what characteristics they should have, and how they should be used. More information is needed to determine how experimenter bias will be avoided and what training administrators will receive regarding bias.
6. Discuss how factors such as circadian rhythms, fatigue and environmental effects will be incorporated into scenario development with respect to their related sections.

18-68

This Question indicates insufficient information in the V&V Implementation Plan for the general principal derived from NUREG-0711. This is followed by specific examples that arose because the information provided was insufficient for the review. The examples provided do not comprise a complete set of issues for each category. Rather, they are used to illustrate the general issue caused by the missing information. It is the responsibility of the Applicant to apply the general principals illustrated by staff in the examples to determine the full-scope of issues affected by the missing information.

HED Resolution. Section 11.4.4. of NUREG-0711 states the purpose of the staff's review of the HED Resolution is to ensure that the applicant has adequately evaluated HEDs to determine the need for their correction, identified design solutions to address significant HEDs, and verified the implementation of the design solutions resolving HEDs. HEDs should not be considered in isolation and, to the extent possible, their potential interactions should be considered when

developing and implementing solutions. Issues related to HED Resolutions that were identified include, *but are not limited to*:

1. After the initial comparison of the first HSI to HFE guidelines and determination of an HED, the remainder of the HSI in the set to be evaluated is classified as discrepant, according to the Applicant's procedure (Section 3.9.3.2 HFE Design Verification, Step 3). Staff request clarification regarding Steps 2 & 3.
2. Clarification is needed on whether the justification process for HEDs will include analysis of impact on plant safety and performance. This is presented in Figure 3.1, but not reflected in the text.

18-69

This Question indicates insufficient information in the V&V Implementation Plan for the general principal derived from NUREG-0711. This is followed by specific examples that arose because the information provided was insufficient for the review. The examples provided do not comprise a complete set of issues for each category. Rather, they are used to illustrate the general issue caused by the missing information. It is the responsibility of the Applicant to apply the general principals illustrated by staff in the examples to determine the full-scope of issues affected by the missing information.

HSI Task Support. Section 11.4.2.2.1 of NUREG-0711 states that the objective of this review is to ensure that the applicant verifies that the HSI provides all alarms, information, and control capabilities required for personnel tasks. Section 11.4.2.2.2 criterion 3 states that an HED should be identified when an HSI needed for task performance (e.g., a required control or display) is not available and/or when HSI characteristics do not match the personnel task requirements, e.g., a display shows the required plant parameter but not the range or precision needed for the task. Issues related to these criteria include, *but are not limited to*:

1. Section 3.4.2.2 of the HF V&V Implementation Plan, HSI Task Support Review Criteria, provides 4 questions to be used as criteria for determining the adequacy of HSI. Positive answers to the questions outlined would, in 2 cases, lead to the rejection of designs that meet desired criteria. The V&V Implementation plan indicates that a positive answer to any of these questions would indicate that an HSI deficiency is present, and should be documented in the design process. However, staff points out that positive answers to these questions (2 and 4 in the text) would not identify deficiencies in most properly designed HSI. The questions of interest ask:
    - Does the HSI or HFE feature have proper integration with the rest of the HSI?
    - Does the HSI or HFE feature meet the guidance in the U.S. EPR™ HSI Design Style Guide [9] and the HIS design implementation plan [16], which include the HSI Design Procedures
2. Section 3.9.3.3.2 of the HF V&V Implementation Plan outlines the method to be used by the V&V or HF engineer to perform dynamic HSI Task Support verification using the simulator. Step 2 requires that process monitoring indicators or task goals be developed to benchmark performance. It is not clear to staff how process monitoring indicators will be developed or task goals identified. It is not clear to staff how ‘proper’ allocation of functions will be determined or what is meant by ‘proper’. Nor is it clear how ‘proper’ capture of functional requirements will be assessed. How will ‘proper’ be determined?
3. Section 18.10.3.2 of the FSAR discusses HSI Task Support Verification. The FSAR states that the HSI TSV shows that the HSI provides alarms, information, and control

capabilities required for identified tasks that are performed by personnel and that the characteristics of the alarms, information, and controls conform to the requirements developed during the TA. In Section 3.4.2.1, of the V&V plan, the Applicant states that the HSI Task Support Verification will be performed using a limited scope task analysis conducted during the HSI design. Neither the FSAR nor the V&V Implementation plan indicates how or when the HSI requirements will be defined. This information is needed to determine how this criterion will be met.

18-70

This Question indicates insufficient information in the V&V Implementation Plan for the general principal derived from NUREG-0711. This is followed by specific examples that arose because the information provided was insufficient for the review. The examples provided do not comprise a complete set of issues for each category. Rather, they are used to illustrate the general issue caused by the missing information. It is the responsibility of the Applicant to apply the general principals illustrated by staff in the examples to determine the full-scope of issues affected by the missing information.

Operational Conditions Sampling. Section 11.4.1.1 states that the review should ensure that the applicant has identified a sample of operational conditions that (1) includes conditions that are representative of the range of events that could be encountered during operation of the plant, (2) reflects the characteristics that are expected to contribute to system performance variation, and (3) considers the safety significance of HSI components. These sample characteristics are best identified through the use of a multidimensional sampling strategy to ensure that variation along important dimensions is included in the V&V evaluations. The review criteria, therefore, address the sampling dimensions used and the identification of scenarios based on those dimensions. Issues identified include, ***but are not limited to***:

1. A set of tasks, representative of plant conditions as derived from the Preparatory Analysis (i.e., Operating Experience Review, and Function and Task Analysis should be determined. These scenarios should reflect situational factors known to challenge performance, the full range of personnel tasks and interactions, and environmental conditions, and include tasks determined to be difficult via the Task analysis and HRA. Staff requires that the actual scenarios as selected using the OCS process and to be used in the V&V be provided for staff review. An alternative to full scenarios may be a smaller sample of complete scenarios together with an in-depth discussion of the derivation and sampling techniques for those scenarios be presented in the plan. Scenario development should include discussion of participant recruitment and assignment to scenarios.

2. Staff request that the methods be expanded to include inclusion of environmental effects, including how they may be simulated, what may be simulated, the limitations of simulation.