ArevaEPRDCPEm Resource

From: BRYAN Martin (EXTERNAL AREVA) [Martin.Bryan.ext@areva.com]
Sent: Thursday, September 02, 2010 5:01 PM
To: Tesfaye, Getachew
Cc: DELANO Karen (AREVA); ROMINE Judy (AREVA); BENNETT Kathy (AREVA); PANNELL George (AREVA); Miernicki, Michael
Subject: Response to U.S. EPR Design Certification Application RAI No. 427, FSAR Ch. 18
Attachments: RAI 427 Response US EPR DC.pdf

Getachew,

Attached please find AREVA NP Inc.'s response to the subject request for additional information RAI 427. A complete answer is not provided for 23 of the 23 questions.

The following table indicates the respective pages in the response document, "RAI 427 Response U.S. EPR DC.pdf," that contain AREVA NP's response to the subject questions.

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The schedule for a technically correct and complete response to these questions is provided below.

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RAI 427 18 —213	October 7, 2010
RAI 427 18 —214	October 7, 2010

Sincerely,

Martin (Marty) C. Bryan
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From: Tesfaye, Getachew [mailto:Getachew.Tesfaye@nrc.gov]
Sent: Tuesday, August 03, 2010 2:30 PM
To: ZZ-DL-A-USEPR-DL
Cc: Marble, Julie; Walker, Jacqwan; Junge, Michael; Eudy, Michael; Steckel, James; Colaccino, Joseph; ArevaEPRDCPEm Resource
Subject: U.S. EPR Design Certification Application RAI No. 427 (4729, 4800), FSAR Ch. 18

Attached please find the subject requests for additional information (RAI). A draft of the RAI was provided to you on July 16, 2010, and discussed with your staff on July 29, 2010. No change is made to the draft RAI as a result of that discussion. 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,
Getachew Tesfaye
Sr. Project Manager
NRO/DNRL/NARP
(301) 415-3361

Hearing Identifier: AREVA_EPR_DC_RAIs
Email Number: 1955

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Subject: Response to U.S. EPR Design Certification Application RAI No. 427, FSAR Ch. 18
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From: BRYAN Martin (EXTERNAL AREVA)

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Response to

Request for Additional Information No. 427(4729, 4800), Revision 1

8/3/2010

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

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

Question 18-192:

Follow-up to RAI 328, Question 18-57

This is a follow-up RAI to the applicant's response to question 18-57in RAI Letter 328. After review of the RAI response and the current revision of the HPM Implementation Plan, the staff requests for the applicant to clarify the following:

- The scope of the HPM Implementation Plan (IP) should include the control room, local control stations, and the support centers, according to the first bullet in Section 13.4, Criterion 1 of NUREG-0711. In Section 1.4 of the HPM IP, and in Section 18.12 of the US EPR FSAR, the scope areas mentioned do not include the emergency operations facility (EOF). Please provide clarification for why this was not included within the scope.

Response to Question 18-192:

A response to this question will be provided by October 7, 2010.

Question 18-193:

After review of the revised HPM IP, the staff noticed an incorrect reference to 10 CFR 50.64 in HPM IP Section 1.5.2 “U.S. EPR Licensee.” The staff requests for the applicant to please update the implementation plan to cite the correct regulation.

Response to Question 18-193:

A response to this question will be provided by October 7, 2010.

Question 18-194:

Follow-up to RAI 328, Question 18-60

The staff had the following subsequent RAIs related to the applicant's response to question 18-60 from RAI letter 328:

a. Section 3.2.1 in the HPM IP states that “If an adverse trend is detected, a root cause analysis is performed.” The staff requests for the applicant to please clarify the term adverse in this statement.

b. It states in the response to the original staff request for clarification that the HRA personnel are responsible for performing the analyses associated with HPM. It further states that the plan will be revised to clarify this fact. In section 3.2.1, the same wording is found that was in Rev. 2 of the HPM IP stating that “a root cause analysis is performed by a cognizant HFE engineer.” The staff requests for the applicant to clarify whether the stated revision was meant to revise the statement above, or revise another section in the IP to clarify that the HRA personnel will be responsible for performing the analysis.

Response to Question 18-194:

A response to this question will be provided by October 7, 2010.

Question 18-195:

Follow-up to RAI 328, Question 18-54

In RAI letter 328, the response to RAI 18-54 stated that the operational conditions sampling method will be used as a process for sampling the elements to be verified in the design implementation phase. The staff requests for the applicant to provide further clarification on whether the OCS process will be used for the elements that cannot be verified during the V&V phase. If OCS is used, then please describe how it is used to verify the elements that could not be V&V'd. If the OCS process is not used, then please provide detail describing the sampling methods used for the elements that will not be verified in V&V.

Response to Question 18-195:

A response to this question will be provided by October 7, 2010.

Question 18-196:

NUREG-0711 section 11.4.1.2.1 states:

(3) ... *Environmental factors* - The sample **should include situations** where human performance variation due to environmental conditions such as poor lighting, extreme temperatures, high noise, and simulated radiological contamination can be assessed.

With respect to your V&V plan, Section 3.6.2.2 provides a commitment to meet this criterion as stated in NUREG-0711. Section 3.2.9 states that beyond simulating loss of AC power in the simulator, all external environmental V&V variables are assessed in the operating plant environment, to be accounted for by the licensee. Section 3.2.10 number 1 states that scenarios that include environmental conditions such as noise and distractions that may affect human performance in an actual NPP will not be performed.

The staff requests for the applicant to verify that noise and distractions typical of human performance in an NPP will be included in the scenarios to the degree possible with the simulator to ensure environmental fidelity, and clarify how they will be included in the scenarios. If environmental factors are to be accounted for by the licensee, then please indicate where the COL information item for this is found.

Response to Question 18-196:

A response to this question will be provided by October 7, 2010.

Question 18-197:

NUREG-0711 section 11.4.3.2.4 states:

(3) When evaluating performance associated with operations remote from the main control room, the effects on crew performance due to potentially harsh environments (i.e., high radiation) should be realistically simulated (i.e., additional time to don protective clothing and access radiologically controlled areas).

The staff requests for the applicant to specify where this information is found. If it is not specified, then please describe how it will be included in the simulation.

Response to Question 18-197:

A response to this question will be provided by October 7, 2010.

Question 18-198:

NUREG-0711 section 11.4.3.2.5.2 states:

(1) A hierarchal set of performance measures should be used which includes measures of the performance of the plant and personnel (i.e., personnel tasks, situation awareness, cognitive workload, and anthropometric/physiological factors). Some of these measures could be used as "pass/fail" criteria for validation and the others to better understand personnel performance and to facilitate the analysis of performance errors. The applicant should identify which are in each category.

The staff requests for the applicant to provide the following clarifications:

a. Specify from what will the pre-determined acceptance criteria for Plant level 1 (thermal hydraulic) be derived.

b. Specify what calculated characteristics from the PRA/HRA will be compared to actual performance in the Plant level PRA tier of performance metrics.

c. Specify what does the statement that the 'Task level analysis is largely supplemental in nature' mean? (second set of bullets, 3rd bullet point, page 140 of the V&V plan).

d. In the Task level tier, specify what performance metric will be compared to what aspect of Task Analysis.

e. Specify, what criteria, if any, are pass/fail and which are used to better understand performance at the each level.

Response to Question 18-198:

A response to this question will be provided by October 7, 2010.

Question 18-199:

NUREG-0711 section 11.4.3.2.5.2(2) states: Plant Performance Measurement—Plant performance measures representing functions, systems, components, and HSI use should be obtained.

a. The staff requests for the applicant to specify from where will the criteria used to assess plant performance be derived (e.g., technical specification and safety limit violations). In addition, please specify what types of measures will be used to assess function performance, system performance, component performance and HSI performance. (Note: This was discussed during a teleconference on June 17, 2010.) Please provide detailed, specific examples of these metrics to assess the integrated system for a number of scenarios (such as the scenarios requested in RAI letter 421).

b. Section 3.6.4.7 of the V&V plan indicates that simulator logs and a chronometer will be used to collect system performance measures, and compared to recommendations from guidelines, which is deferred until the simulator is installed at the plant site. The staff requests for the applicant to specify to which guidelines comparisons for system performance will be made. Deferral of determination of error rates and identification of error types to the licensee should be a COL information item. Please specify where is this COL information item can be found.

Response to Question 18-199:

A response to this question will be provided by October 7, 2010.

Question 18-200:

NUREG-0711 section 11.4.3.2.5.2 states:

(4) Cognitive Workload—Personnel workload should be assessed. The approach to workload measurement should reflect the current state-of-the-art.

GOMS (V&V Section 3.6.4.5) is discussed as a direct measure of cognitive workload. GOMS is not a direct measure of workload but a rough estimate of response times. The staff requests for the applicant to specify how GOMS will be used in the measurement of cognitive workload.

Response to Question 18-200:

A response to this question will be provided by October 7, 2010.

Question 18-201:

NUREG-0711 section 11.4.3.2.5.2 states:

(5) Anthropometric and Physiological Factors—Anthropometric and physiological factors include such concerns as visibility of indications, accessibility of control devices, and ease of control device manipulation that should be measured where appropriate. Attention should be focused on those aspects of the design that can only be addressed during testing of the integrated system, e.g., the ability of personnel to effectively use the various controls, displays, workstations, or consoles in an integrated manner.

a. Section 3.6.4.6 of the V&V plan states that an anthropometrics checklist and a questionnaire will be used. The staff requests for the applicant to specify if the anthropometrics questionnaire will be given to all participants. If not, then please specify when it will be administered.

b. In the example questions (section 3.6.4.6), the last question (bullet 5: “Are there any additional plant or system functions/controls /displays that are on the MCC or group view panels?”) does not appear to be correct as there are certainly any number of controls on the MCC or group view panels. The staff requests for the applicant to clarify this issue.

Response to Question 18-201:

A response to this question will be provided by October 7, 2010.

Question 18-202:

NUREG-0711 11.4.3.2.5.3 states:

(1) Criteria should be established for the performance measures used in the evaluations. The *specific* criteria that are used for decisions as to whether the design is validated or not should be specified and distinguished from those being used to better understand the results.

a. The staff requests for the applicant to Define the specific criteria that will be used for decisions with respect to the performance measures. In addition, please specify which measures are used to validate design and which are used to better understand the results.

b. The example questions presented in V&V section 4.3.4.2, use ambiguous terms such as 'adequately', 'timely', 'quickly', 'accurate diagnosis', etc. The staff requests for the applicant to clarify how these terms are operationalized.

Response to Question 18-202:

A response to this question will be provided by October 7, 2010.

Question 18-203:

NUREG-0711 11.4.3.2.5.3 states:

(2) The basis for criteria should be defined, e.g., requirement-referenced, benchmark referenced, normative referenced, and expert-judgment referenced.

Section 4.3.3.1 of the V&V states that acceptable plant performance is determined through an evaluation of the times and values calculated from the HRA/PRA. Average operator actions/system performance must fall within an acceptable range of time and parameter values. Performance is acceptable if 'all assumptions for plant and operator response, including time required for completion of the action are within the values allowed by the PRA/HRA calculations.' Comparison of assumptions to allowed values is unclear. The staff requests for the applicant to specify if observed responses will be compared and to what will the observed responses be compared.

Response to Question 18-203:

A response to this question will be provided by October 7, 2010.

Question 18-204:

NUREG-0711 11.4.3.2.5.3 states:

(2) The basis for criteria should be defined, e.g., requirement-referenced, benchmark referenced, normative referenced, and expert-judgment referenced.

a. Section 4.3.4.4 of the V&V states that the HSI design is validated when operators successfully monitor and control the system to achieve the desired status. These criteria are ‘normative referenced’. The staff requests for the applicant to explain how successful monitoring is operationalized. In addition, please clarify what is meant by the term 'normative referenced'.

b. Section 4.3.5.12 of the V&V states that acceptable cognitive workload has a zone of acceptability in the center, and unacceptable levels at each end of the spectrum. The staff requests for the applicant to specify how this relates to the measure of cognitive workload (NASA-TLX) to be used.

Response to Question 18-204:

A response to this question will be provided by October 7, 2010.

Question 18-205:

NUREG-0711 section 11.4.3.2.6.2 states:

(1) Detailed, clear, and objective procedures should be available to govern the conduct of the tests. These procedures should include:

- The identification of which crews receive which scenarios and the order that the scenarios should be presented.
- Detailed and standardized instructions for briefing the participants. The type of instructions given to participants can affect their performance on a task. This source of bias can be minimized by developing standard instructions.
- Specific criteria for the conduct of specific scenarios, such as when to start and stop scenarios, when events such as faults are introduced, and other information discussed in Section 11.4.3.2.4, Scenario Definition.
- Scripted responses for test personnel who will be acting as plant personnel during test scenarios. To the greatest extent possible, responses to communications from operator participants to test personnel (serving as surrogate for personnel outside the control room personnel) should be prepared. There are limits to the ability to preplan communications since personnel may ask questions or make requests that were not anticipated. However, efforts should be made to detail what information personnel outside the control room can provide, and script the responses to likely questions.
- Guidance on when and how to interact with participants when simulator or testing difficulties occur. Even when a high-fidelity simulator is used, the participants may encounter artifacts of the test environment that detract from the performance for tasks that are the focus of the evaluation. Guidance should be available to the test conductors to help resolve such conditions.
- Instructions regarding when and how to collect and store data. These instructions should identify which data are to be recorded by:
  - simulation computers
  - special purpose data collection devices (such as situation awareness data collection, workload measurement, or physiological measures)
  - video recorders (locations and views)
  - test personnel (such as observation checklists)
  - subjective rating scales and questionnaires.
- Procedures for documentation, i.e., identifying and maintaining test record files including crew and scenario details, data collected, and test conductor logs. These instructions should detail the types of information that should be logged (e.g., when tests were performed, deviations from test procedures, and any unusual events that may be of importance to understanding how a test was run or interpreting test results) and when it should be recorded.

With respect to the pending submission of the applicant's validation scenarios, the staff requests for the applicant to ensure that the above material is included in their scenario descriptions.

Response to Question 18-205:

A response to this question will be provided by October 7, 2010.

Question 18-206:

NUREG-0711 section 11.4.3.2.6 states:

(2) Where possible, test procedures should minimize the opportunity of tester expectancy bias or participant response bias.

With respect to the pending submission of the applicant's validation scenarios, the staff requests for the applicant to ensure that the example scenarios include test procedures that demonstrate how bias will be minimized.

Response to Question 18-206:

A response to this question will be provided by October 7, 2010.

Question 18-207:

NUREG-0711 11.4.3.2.6.3 states:

(1) Participant training should be of high fidelity; i.e., highly similar to that which plant personnel will receive in an actual plant. The participants should be trained to provide reasonable assurance that their knowledge of plant design, plant operations, and use of the HSIs and procedures is representative of experienced plant personnel. Participants should not be trained specifically to perform the validation scenarios.

(2) Participants should be trained to near asymptotic performance (i.e., stable, not significantly changing from trial to trial) and tested prior to conducting actual validation trials. Performance criteria should be similar to that which will be applied to actual plant personnel.

Section 4.5.1.2 of the V&V implementation plan discusses identification, training and use of test participants. The staff requests for the applicant to address following questions related to information provided in this section.

a. Specify wow acceptable stability of performance is determined.
b. Define how training will deviate from 'PWR INITIAL LICENSE TRAINING' if at all.
c. Define how the content of the comprehensive exam will differ from the existing PWR licensing if at all.

Response to Question 18-207:

A response to this question will be provided by October 7, 2010.

Question 18-208:

NUREG-0711 section 11.4.3.2.7 states

(1) Validation test data should be analyzed through a combination of quantitative and qualitative methods. The relationship between observed performance data and the established performance criteria should be clearly established and justified based upon the analyses performed.

With respect to the identified sections of the V&V IP, the staff requests for the applicant to address the following issues:

a. Section 4.3.2.2 states that if core thermal hydraulic limits are exceeded, the scenario will be failed. Please specify from where these core thermal hydraulic limits will be obtained.

b. Section 4.3.3.1 states that for scenario acceptability all *assumptions* for plant and operator response, including time for completion of the action(s) must be within the values allowed by the PRA/HRA calculation. Please verify that the *observed* responses -- not the assumed responses -- will be compared to the response parameters *assumed* in the PRA/HRA. Please clarify which parameters besides time to respond will be compared to the assumptions of the PRA/HRA. In addition, please specify what analyses will be performed.

c. Section 4.3.4.4 states that the HSI design is validated when operators sucessfully monitor and control the system to achieve desired status. Please specify how will this be analyzed.

d. Section 4.3.4.6 states that unclear communication or interference is an acceptance criterion and will result in an HED. Please specify how the bullets in section 4.3.4.5 will be assessed. In addition, please clarify how the observations obtained on the questionnaire in section 4.3.4.5 will be analyzed with respect to the acceptance criteria.

e. Section 4.3.5.10 discusses how pair-wise comparisons will be generated for the 6 dimensions of mental workload assessed by the NASA-TLX. Please specify how the results of the NASA-TLX will be analyzed to yield acceptance or failure. Please also specify what the acceptance criteria is for the NASA-TLX?.

f. Section 4.3.5.10 states that optimal mental workload exists in a zone. Please specify from what will this zone be calculated.

g. Section 4.3.5.11 states that the resolution of mental workload, as assessed with the NASA-TLX has 6 dimensions. The version of the NASA-TLX available from NASA has 7 dimensions. Please list the dimensions to be assessed.

Response to Question 18-208:

A response to this question will be provided by October 7, 2010.

Question 18-209:

NUREG-0711 11.4.3.2.8 states:

(1) The statistical and logical bases for determining that performance of the integrated system is and will be acceptable should be clearly documented.

Section 4.5.1.7 of the V&V IP states that the statistical and logical bases for determining performance are acceptable will be documented. The staff requests for the applicant to state where this information will be documented.

Response to Question 18-209:

A response to this question will be provided by October 7, 2010.

Question 18-210:

NUREG-0711 11.4.4.2 states

(1) HED Justification—Discrepancies could be acceptable within the context of the fully integrated design. If sufficient justification exists, a deviation from the guidelines may not constitute an HED. The technical basis for such a determination could include an analysis of recent literature or current practices, tradeoff studies, or design engineering evaluations and data. Unjustified discrepancies should be identified as HEDs to be addressed by the HED resolution.

The staff has been unable to verify if the above NUREG-0711 criteria have been met in the current V&V IP. The staff requests for the applicant to clarify what techniques (e.g., recent literature, current practices, tradeoff studies, etc.) will be used to for HED justification and where this information can be found. In addition, please provide a revised V&V plan accordingly.

Response to Question 18-210:

A response to this question will be provided by October 7, 2010.

Question 18-211:

NUREG-0711 11.4.4.2 states:

(2) HED Analysis—The following should be included in the HED evaluations:

- Plant system—the potential effects of all HEDs relevant to a single plant system should be evaluated. The potential effects of these HEDs on plant safety and personnel performance should be determined, in part, by the safety significance of the plant system(s), their effect on SAR accident analyses, and their relationship to risk significant sequences in the plant PRA.
- HED scope
  - Global features HEDs—these are HEDs that relate to configurational and environmental aspects of the design such as lighting, ventilation, and traffic flow. They relate to general human performance issues.
  - Standardized features HEDs—these are HEDs that relate to design features that are governed by the applicant's design guidelines used across various controls and displays of the HSI (e.g., display screen organization and conventions for format, coding, and labeling). Because a single guideline may be used across many aspects of the design, a single HED could be applicable to many personnel tasks and plant systems.
  - Detailed features HEDs—these are HEDs that relate to design features that are not standardized, thus [their] generality has to be assessed.
  - Other—this subcategory specifically pertains to HEDs identified from integrated system validation that cannot be easily assigned to any of the three preceding categories.
- Individual HSI or procedure—HEDs should be analyzed with respect to individual HSIs and procedures. The potential effects of these HEDs on plant safety and personnel performance are determined, in part, by the safety significance of the plant system(s) that are related to the particular component.
- Personnel function—HEDs should be analyzed with respect to individual personnel functions. The potential effects of these HEDs is determined, in part, by the importance of the personnel function to plant safety (e.g., consequences of failure) and their cumulative effect on personnel performance (e.g., degree of impairment and types of potential errors).
- HEDs should also be analyzed with respect to the cumulative effects of multiple HEDs on plant safety and personnel performance. While an individual HED might not be considered sufficiently severe to require correction, the combined effect of several HEDs upon the single aspect of the design could have significant consequences to plant safety and, therefore, necessitate corrective action. Likewise, when a single plant system is associated with multiple HEDs that affect a number of HSI components, then their possible combined effect on the operation of that plant system should be considered.
- In addition to addressing the specific HEDs, the analysis should treat the HEDs as indications of potentially broader problems. For example, identifying multiple HEDs

associated with one particular aspect of the HSI design, such as the remote shutdown panel, could also indicate that there are other problems with that aspect of the design, such as inconsistent use of procedures and standards. In some cases, the evaluation of HEDs could warrant further review in the identified areas of concern.

The staff has found that the presentation of the analysis methods presented in Section 3.7 of the V&V IP is insufficient to determine whether the above considerations are included (with the exception of bullet 2). The staff requests for the applicant to provide details regarding inputs and considerations of the HED process with respect to the above criterion.

Response to Question 18-211:

A response to this question will be provided by October 7, 2010.

Question 18-212:

NUREG-0711 11.4.4.2 states:

(3) HED Prioritization—Identification of HEDs for correction should be based upon a systematic evaluation, such as that illustrated in Figure 11.2. Priority 1 HEDs should be those with direct safety consequences and those with indirect or potential safety consequences. HEDs with significant safety consequences are those that affect personnel performance where the consequences of error could reduce the margin of plant safety below an acceptable level, as indicated by such conditions as violations of operating limits, or Technical Specification safety limits or limiting conditions for operations. They include deviations from personnel information requirements or HFE guidelines for personnel tasks that are related to plant safety. These could include the following:

- are required by personnel tasks but are not provided by the HSI
- do not satisfy all personnel information needs (e.g., information not presented with the proper range or precision)
- contain deviations from HFE guidelines that are likely to lead to errors that would prevent personnel from performing the task.

HEDs with indirect safety consequences include deviations from HFE guidelines that would seriously affect the ability of personnel to perform the task. The severity of an HFE guideline deviation should be assessed in terms of the degree to which it contributes to human performance problems, such as workload and information overload.

Priority 2 HEDs should be those that do not have significant safety consequences, but do have potential consequences to plant performance/operability, non-safety-related personnel performance/efficiency, or other factors affecting overall plant operability. These include deviations from personnel information requirements and HFE guidelines for tasks associated with plant productivity, availability, and protection of investment. These HEDs should be considered for correction.

The remaining HEDs are those that do not satisfy the criteria associated with the first and second priorities. Resolution of these HEDs is not an NRC safety concern but may be resolved at the discretion of the applicant.

The staff has found that the information provided in the V&V IP is not sufficient to understand how HEDs are prioritized. The information presented is a subset of the information provided in the criterion. The staff requests for the applicant to provide an explanation of how HEDs are prioritized, and on what criteria they are categorized.

Response to Question 18-212:

A response to this question will be provided by October 7, 2010.

Question 18-213:

NUREG-0711 11.4.4.2 states:

(5) Development of Design Solutions—Design solutions to correct HEDs should be identified. The design solutions 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).

Inter-relationships of individual HEDs should be evaluated. For example, if a single HSI component is associated with multiple HEDs, then design solutions should be considered to address these HEDs together. If a single plant system is associated with multiple HSI components that are associated with HEDs, then the design of the individual solutions should be coordinated so that their combined effect enhances rather than detracts from that system's operation.

The staff has found that the information provided in the V&V IP is a condensation and restatement of the guidance provided by NUREG-0711. The staff requests for the applicant to specify where the discussion is regarding how Design Solutions will be identified. In addition, please specify where is the discussion is regarding how interrelationships between HED will be evaluated.

Response to Question 18-213:

A response to this question will be provided by October 7, 2010.

Question 18-214:

NUREG-0711 11.4.4.2 states:

(6) Design Solution Evaluation—Designs should be evaluated by repeating the appropriate analyses of the V&V. For example, the HSI Task Support Verification should be conducted to provide reasonable assurance that the design satisfies personnel task requirements. Portions of the HFE design verification analysis should be conducted to provide reasonable assurance that the design is consistent with HFE guidelines, and integrated system validation could be conducted to evaluate its usability. When the problems identified by an HED cannot be fully corrected, justification should be given.

Section 3.8.7.4 of the V&V IP states that solutions are evaluated to determine if the solution adequately corrects the HED, does not adversely impact other areas of design, is consistent with the HFE guidelines, and ISV can be conducted to evaluate its usability. The V&V process is then reapplied to the new design.

The staff requests for the applicant to specify the following issues:

a. If the entire V&V process is reapplied.
b. How the impact of the new design solution on other areas of the design is evaluated.
c. If the HED remain open until a design solution that is implemented.
d. What occurs if the HED cannot be fully corrected?
e. How 'adequate correction' is determined and defined.

Response to Question 18-214:

A response to this question will be provided by October 7, 2010.