ArevaEPRDCPEm Resource

From: BRYAN Martin (EXTERNAL AREVA) [Martin.Bryan.ext@areva.com]
Sent: Thursday, January 27, 2011 12:21 PM
To: Tesfaye, Getachew
Cc: DELANO Karen (AREVA); ROMINE Judy (AREVA); NOXON David (AREVA); HOKE Robert (AREVA); RAYMOND Desmond (AREVA); RANSOM James (AREVA); WILLIFORD Dennis (AREVA); HAYS Lynn (AREVA); Ford, Tanya
Subject: DRAFT Response to U.S. EPR Design Certification Application RAI No. 421, FSAR Ch. 18, Supplement 6
Attachments: RAI 421 Response Supplement 6 US EPR DC - DRAFT.pdf

Getachew,

To support the final response date for the remaining questions in RAI 421, attached is a draft response. The draft V&V Plan and the Draft Sample Scenarios that support this response were sent by separate email on January 14, 2011. Let me know if the staff has questions or if this can be sent as a final response.

Thanks,

Martin (Marty) C. Bryan
U.S. EPR Design Certification Licensing Manager
AREVA NP Inc.
Tel: (434) 832-3016
702 561-3528 cell
Martin.Bryan.ext@areva.com

From: BRYAN Martin (External RS/NB)
Sent: Thursday, January 27, 2011 11:39 AM
To: 'Tesfaye, Getachew'
Cc: DELANO Karen (RS/NB); ROMINE Judy (RS/NB); BENNETT Kathy (RS/NB); NOXON David (RS/NB)
Subject: Response to U.S. EPR Design Certification Application RAI No. 421, FSAR Ch. 18, Supplement 5

Getachew,

On July 20, 2010, AREVA NP, Inc. (AREVA NP) provided a technically correct and complete response to one of the 8 questions and a schedule for the remaining 7 questions. On September 15, 2010, October 28, 2010, November 29, 2010, and December 16, 2010 a revised schedule was provided. To allow more time to interact with the NRC staff on the revised U.S. EPR Human Factors Verification and Validation Implementation Plan, a revised schedule for submitting the response to the remaining 7 questions is provided.

The schedule for technically correct and complete responses to these questions is changed and is provided below.

Question #	Response Date
RAI 421 — 18-175	February 28, 2011
RAI 421 — 18-176	February 28, 2011
RAI 421 — 18-177	February 28, 2011
RAI 421 — 18-178	February 28, 2011
RAI 421 — 18-179	February 28, 2011
RAI 421 — 18-180	February 28, 2011
RAI 421 — 18-181	February 28, 2011

Sincerely,

Martin (Marty) C. Bryan
U.S. EPR Design Certification Licensing Manager
AREVA NP Inc.
Tel: (434) 832-3016
702 561-3528 cell
Martin.Bryan.ext@areva.com

From: BRYAN Martin (External RS/NB)
Sent: Thursday, December 16, 2010 2:17 PM
To: Tesfaye, Getachew
Cc: DELANO Karen (RS/NB); ROMINE Judy (RS/NB); BENNETT Kathy (RS/NB); NOXON David (RS/NB); PANNELL George (CORP/QP); 'Miernicki, Michael'; 'Ford, Tanya'
Subject: Response to U.S. EPR Design Certification Application RAI No. 421, FSAR Ch. 18, Supplement 4

Getachew,

On July 20, 2010, AREVA NP, Inc. (AREVA NP) provided a technically correct and complete response to one of the 8 questions and a schedule for the remaining 7 questions. On September 15, 2010, October 28, 2010, and November 29, 2010 a revised schedule was provided. To allow more time to revise the U.S. EPR Human Factors Verification and Validation Implementation Plan and interact with the NRC staff, a revised schedule for submitting the response to the remaining 7 questions is provided.

The schedule for technically correct and complete responses to these questions is changed and is provided below.

Question #	Response Date
RAI 421 — 18-175	January 28, 2010
RAI 421 — 18-176	January 28, 2010
RAI 421 — 18-177	January 28, 2010
RAI 421 — 18-178	January 28, 2010
RAI 421 — 18-179	January 28, 2010
RAI 421 — 18-180	January 28, 2010
RAI 421 — 18-181	January 28, 2010

Sincerely,

Martin (Marty) C. Bryan
U.S. EPR Design Certification Licensing Manager
AREVA NP Inc.
Tel: (434) 832-3016
702 561-3528 cell
Martin.Bryan.ext@areva.com

From: BRYAN Martin (External RS/NB)
Sent: Monday, November 29, 2010 12:46 PM
To: 'Tesfaye, Getachew'
Cc: DELANO Karen (RS/NB); ROMINE Judy (RS/NB); BENNETT Kathy (RS/NB); PANNELL George (CORP/QP)
Subject: Response to U.S. EPR Design Certification Application RAI No. 421, FSAR Ch. 18, Supplement 3

Getachew,

On July 20, 2010, AREVA NP, Inc. (AREVA NP) provided a technically correct and complete response to one of the 8 questions and a schedule for the remaining 7 questions. On September 15, 2010 and October 28, 2010, AREVA NP provided a revised schedule for the remaining questions. To allow additional time to interact with the NRC staff a revised schedule is provided.

The schedule for technically correct and complete responses to these questions is changed and is provided below.

Question #	Response Date
RAI 421 — 18-175	December 16, 2010
RAI 421 — 18-176	December 16, 2010
RAI 421 — 18-177	December 16, 2010
RAI 421 — 18-178	December 16, 2010
RAI 421 — 18-179	December 16, 2010
RAI 421 — 18-180	December 16, 2010
RAI 421 — 18-181	December 16, 2010

Sincerely,

Martin (Marty) C. Bryan
U.S. EPR Design Certification Licensing Manager
AREVA NP Inc.
Tel: (434) 832-3016
702 561-3528 cell
Martin.Bryan.ext@areva.com

From: BRYAN Martin (External RS/NB)
Sent: Thursday, October 28, 2010 5:26 PM
To: 'Tesfaye, Getachew'
Cc: DELANO Karen (RS/NB); ROMINE Judy (RS/NB); BENNETT Kathy (RS/NB); PANNELL George (CORP/QP)
Subject: Response to U.S. EPR Design Certification Application RAI No. 421, FSAR Ch. 18, Supplement 2

Getachew,

On July 20, 2010, AREVA NP, Inc. (AREVA NP) provided a technically correct and complete response to one of the 8 questions and a schedule for the remaining 7 questions. On September 15, 2010 AREVA NP provided a revised schedule for the remaining questions. To allow additional time to interact with the NRC staff a revised schedule is provided.

The schedule for technically correct and complete responses to these questions is changed and is provided below.

Question #	Response Date
RAI 421 — 18-175	November 30, 2010
RAI 421 — 18-176	November 30, 2010

RAI 421 — 18-177	November 30, 2010
RAI 421 — 18-178	November 30, 2010
RAI 421 — 18-179	November 30, 2010
RAI 421 — 18-180	November 30, 2010
RAI 421 — 18-181	November 30, 2010

Sincerely,

Martin (Marty) C. Bryan
U.S. EPR Design Certification Licensing Manager
AREVA NP Inc.
Tel: (434) 832-3016
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Martin.Bryan.ext@areva.com

From: BRYAN Martin (External RS/NB)
Sent: Wednesday, September 15, 2010 4:52 PM
To: 'Tesfaye, Getachew'
Cc: DELANO Karen (RS/NB); ROMINE Judy (RS/NB); BENNETT Kathy (RS/NB); PANNELL George (CORP/QP)
Subject: Response to U.S. EPR Design Certification Application RAI No. 421, FSAR Ch. 18, Supplement1

Getachew,

On July 20, 2010, AREVA NP, Inc. (AREVA NP) provided a technically correct and complete response to one of the 8 questions and a schedule for the remaining 7 questions. The schedule for the remaining 7 questions is being revised to account for the upcoming September 23, 2010 interaction and potential feedback from the staff.

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

Question #	Response Date
RAI 421 — 18-175	October 28, 2010
RAI 421 — 18-176	October 28, 2010
RAI 421 — 18-177	October 28, 2010
RAI 421 — 18-178	October 28, 2010
RAI 421 — 18-179	October 28, 2010
RAI 421 — 18-180	October 28, 2010
RAI 421 — 18-181	October 28, 2010

Martin (Marty) C. Bryan
U.S. EPR Design Certification Licensing Manager
AREVA NP Inc.
Tel: (434) 832-3016
702 561-3528 cell
Martin.Bryan.ext@areva.com

From: BRYAN Martin (EXT)
Sent: Tuesday, July 20, 2010 6:07 PM
To: 'Tesfaye, Getachew'

Cc: DELANO Karen V (AREVA NP INC); ROMINE Judy (AREVA NP INC); BENNETT Kathy A (OFR) (AREVA NP INC); RYAN Tom (AREVA NP INC); PANNELL George L (AREVA NP INC)
Subject: Response to U.S. EPR Design Certification Application RAI No. 421, FSAR Ch. 18

Getachew,

The proprietary and non-proprietary versions of RAI 421 are submitted via AREVA NP Inc. letter, "Response to U.S. EPR Design Certification Application RAI No. 421" NRC10:065, dated July 19, 2010. An affidavit to support withholding of information from public disclosure, per 10CFR2.390(b), is provided as an enclosure to that letter.

The response document provides a technically correct and complete response to 1 (Question 18-174) of the 8 questions to RAI No.421. It also provides a schedule for the remaining 7 questions since technically correct and complete responses to the 7 questions are not provided.

The following table indicates the respective pages in the response document that contain AREVA NP's responses to the subject questions.

Question #	Start Page	End Page
RAI 421 — 18-174	2	2
RAI 421 — 18-175	3	4
RAI 421 — 18-176	5	23
RAI 421 — 18-177	24	28
RAI 421 — 18-178	29	29
RAI 421 — 18-179	30	30
RAI 421 — 18-180	31	31
RAI 421 — 18-181	32	32

A complete answer is not provided for 7 of the questions. The schedule for technically correct and complete responses to these questions is provided below.

Question #	Response Date
RAI 421 — 18-175	September 15, 2010
RAI 421 — 18-176	September 15, 2010
RAI 421 — 18-177	September 15, 2010
RAI 421 — 18-178	September 15, 2010
RAI 421 — 18-179	September 15, 2010
RAI 421 — 18-180	September 15, 2010
RAI 421 — 18-181	September 15, 2010

Sincerely,

Martin (Marty) C. Bryan
U.S. EPR Design Certification Licensing Manager
AREVA NP Inc.
Tel: (434) 832-3016
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Martin.Bryan.ext@areva.com

From: Tesfaye, Getachew [mailto:Getachew.Tesfaye@nrc.gov]
Sent: Monday, June 21, 2010 2:22 PM
To: ZZ-DL-A-USEPR-DL
Cc: Bongarra, James; Marble, Julie; Junge, Michael; Eudy, Michael; Steckel, James; Colaccino, Joseph; ArevaEPRDCPEm Resource
Subject: U.S. EPR Design Certification Application RAI No. 421 (4779,4784), FSAR Ch. 18

Attached please find the subject requests for additional information (RAI). A draft of the RAI was provided to you on June 15, and discussed with your staff on June 17, 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: 2485

Mail Envelope Properties (199EBB4D1CD9644D9472AA84D5D8EFA7164C25)

Subject: DRAFT Response to U.S. EPR Design Certification Application RAI No. 421, FSAR Ch. 18, Supplement 6
Sent Date: 1/27/2011 12:20:53 PM
Received Date: 1/27/2011 12:21:33 PM
From: BRYAN Martin (EXTERNAL AREVA)

Created By: Martin.Bryan.ext@areva.com

Recipients:
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Tracking Status: None
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Tracking Status: None
"HOKE Robert (AREVA)" <Robert.Hoke@areva.com>
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Files	**Size**	**Date & Time**
MESSAGE	10991	1/27/2011 12:21:33 PM
RAI 421 Response Supplement 6 US EPR DC - DRAFT.pdf	674052	

Options
Priority: Standard
Return Notification: No
Reply Requested: No
Sensitivity: Normal
Expiration Date:
Recipients Received:

Response to

Request for Additional Information No. 421(4779, 4784), Revision 1, Supplement 6

6/21/2010

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 18-175:

NUREG-0711 11.4.1.2.1(3) states:

1) The sample should reflect a range of situational factors that are known to challenge human performance, such as:

   - Operationally difficult tasks—the sample should address tasks that have been found to be problematic in the operation of NPPs, e.g., procedure versus situation assessment conflicts. The specific tasks selected should reflect the operating history of the type of plant being validated (or the plant's predecessor).
   - Error-forcing contexts—Situations specifically designed to create human errors should be included to assess the error tolerance of the system and the capability of operators to recover from errors should they occur.
   - High-workload conditions—the sample should include situations where human performance variation due to high workload and multitasking situations can be assessed.
   - Varying-workload situations—the sample should include situations where human performance variation due to workload transitions can be assessed. These include conditions that exhibit (1) a sudden increase in the number of signals that must be detected and processed following a period in which signals were infrequent and (2) a rapid reduction in signal detection and processing demands following a period of sustained high task demand.
   - Fatigue and circadian factors—the sample should include situations where human performance variation due to personnel fatigue and circadian factors can be assessed.
   - 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.

Section 3.2.3 of the Validation & Verification Implementation Plan, Rev. 2 states that the performance shaping factors identified in this criterion will be included in the scenarios. However, Section 3.2.9 of the Validation & Verification Implementation Plan, Rev. 2 states that until start-up and operations, it is not valid to attempt to assess environmental conditions in a simulated environment because the results are not reliable, and are too artificial; and that therefore, the only environmental variable that will be simulated will be loss of AC power. The staff requests for the applicant to clarify this inconsistency. In addition, please specify if all factors identified in the criterion, including environmental factors, will be included in the scenarios.

Response to Question 18-175:

The AREVA NP U.S. EPR Verification and Validation Implementation Plan has been revised, and the proprietary plan is submitted under a separate cover letter. Additional detail has been added to Sections 3.1.4.3 and 3.1.4.4(3) of the plan to address this question. U.S. EPR FSAR Tier 2, Section 18.10.4 has been updated to reference the revised plan. Clarifying changes

were made in U.S. EPR FSAR Tier 1 Section 3.4 and Tier 2, Section 18.10 for consistency with the revised plan.

Table 18-175-1 is provided for information only to indicate where (with clarifying notes) verification and validation (V&V) related questions associated with RAIs 421, 426, 427 and 433 are addressed within the AREVA NP U.S. EPR Verification and Validation Implementation Plan.

FSAR Impact:

U.S. EPR FSAR, Tier 1 Section 3.4 and Tier 2, Section 18.10 will be revised as described in the response and indicated on the enclosed markup.

Table 18-175-1 — Verification and Validation Related Questions

(For Information Only)

RAI #	Question	RAI Text	V&V Plan Section and Notes
421	18-175	NUREG-0711 11.4.1.2.1(3) states: (1) The sample should reflect a range of situational factors that are known to challenge human performance, such as: • Operationally difficult tasks—the sample should address tasks that have been found to be problematic in the operation of NPPs, e.g., procedure versus situation assessment conflicts. The specific tasks selected should reflect the operating history of the type of plant being validated (or the plant's predecessor). • Error-forcing contexts—Situations specifically designed to create human errors should be included to assess the error tolerance of the system and the capability of operators to recover from errors should they occur. • High-workload conditions—the sample should include situations where human performance variation due to high workload and multitasking situations can be assessed. • Varying-workload situations—the sample should include situations where human performance variation due to workload transitions can be assessed. These include conditions that exhibit (1) a sudden increase in the number of signals that must be detected and processed following a period in which signals were infrequent and (2) a rapid reduction in signal detection and processing demands following a period of sustained high task demand. • Fatigue and circadian factors—the sample should include situations where human performance variation due to personnel fatigue and circadian factors can be assessed. • 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. Section 3.2.3 of the Validation & Verification Implementation	3.1.4.3 3.1.4.4(3)

Table 18-175-1 — Verification and Validation Related Questions

(For Information Only)

RAI #	Question	RAI Text	V&V Plan Section and Notes
		Plan, Rev. 2 states that the performance shaping factors identified in this criterion will be included in the scenarios. However, Section 3.2.9 of the Validation & Verification Implementation Plan, Rev. 2 states that until start-up and operations, it is not valid to attempt to assess environmental conditions in a simulated environment because the results are not reliable, and are too artificial; and that therefore, the only environmental variable that will be simulated will be loss of AC power. The staff requests for the applicant to clarify this inconsistency. In addition, please specify if all factors identified in the criterion, including environmental factors, will be included in the scenarios.	
421	18-176	NUREG-0711 11.4.1.2.2 states the results of sampling should be combined to identify a set of scenarios to guide the subsequence analyses. A given scenario may combine many of the characteristics identified by operational event sampling. NUREG-0711 11.4.3.2.4 (1) also states: (1) The operational conditions selected for inclusion in the validation tests should be developed in detail so they can be performed on a simulator. The following information should be defined to provide reasonable assurance that important performance dimensions are addressed and to allow scenarios to be accurately and consistently presented for repeated trials: • description of the scenario and any pertinent "prior history" necessary for personnel to understand the state of the plant upon scenario start-up • specific initial conditions (precise definition provided for plant functions, processes, systems, component conditions and performance parameters, e.g., similar to plant shift turnover) • events (e.g., failures) to occur and their initiating conditions, e.g., time, parameter values, or events • precise definition of workplace factors, such as environmental conditions • task support needs (e.g., procedures and technical	3.5.4.5.1 AREVA NP Document "Sample HFE V&V Scenarios for the U.S. EPR"

Table 18-175-1 — Verification and Validation Related Questions

(For Information Only)

RAI #	Question	RAI Text	V&V Plan Section and Notes
		specifications) • staffing objectives • communication requirements with remote personnel (e.g., load dispatcher via telephone) • the precise specification of what, when and how data are to be collected and stored (including videotaping requirements, questionnaire and rating scale administrations) • specific criteria for terminating the scenario. The staff requests for the applicant to provide a sample of the set of scenarios that will be used in the applicant's Validation & Verification Implementation Plan. The applicant's response regarding these scenarios should include the following information: a) The sample set to include at least 4 different scenarios. b) The sample set should be representative of the variety scenarios that will be generated. c) This sample set of scenarios should include the level of detail that is needed to implement the scenario stated in NUREG 11.4.3.2.4(1). d) The scenarios should include all information outlined in the numbered list contained in sections 3.6.3.5 of the V&V IP R. 2, page 72, and section 4.3.1, (4.3.1.2 thru 4.3.1.13) of same. e) The method used to combine the elements listed in the V&V IP to create the set, written at a level of detail that it may be replicated and repeated.	
421	18-177	NUREG-0711 11.4.1.2.2 (2) states: The scenarios should not be biased in the direction of over representation of the following: • Scenarios for which only positive outcomes can be expected	3.1.4.4(5)

Table 18-175-1 — Verification and Validation Related Questions

(For Information Only)

RAI #	Question	RAI Text	V&V Plan Section and Notes
		• Scenarios that for integrated system validation are relatively easy to conduct administratively (scenarios that place high demands, data collection or analysis are avoided). • Scenarios that for integrated system validation are familiar and well structured (e.g., which address familiar systems and failure modes that are highly compatible with plant procedures such as “textbook” design-basis accidents) • The staff request for the applicant to provide the sampling method that will be used to develop the set of sample scenarios to be used for Verification and Validation in order to demonstrate how sampling bias will be avoided.	
421	18-178	NUREG-0711 section 11.4.2.3.2 states that the criteria for the HFE Design Verification Review Criteria should be identified. Human Factors Engineering Design Verification is discussed in Section 3.5.2 of the V&V IP R. 2. In it, the applicant states that designs are compared to HFE guidelines and those deviations from accepted HFE guidelines, standards, and principles are documented as HEDs. The staff requests for the applicant to identify the document or documents that contain all these accepted guidelines, standards, and principles. (This may be NUREG-0700 or the EPR HFE Style Guide. If another document is used, then please provide a brief justification or rationale.)	3.4
421	18-179	NUREG-0711 section 11.4.2.3.2(4) states that HEDs, should be documented by the applicant in terms of the HSI component involved and how its characteristics depart from a particular guideline. However, the staff cannot find this information in the V&V IP. The staff requests the applicant to identify where this commitment can be found.	3.4.4.4
421	18-180	NUREG-0711 section 11.4.2.3.2(2) states that the characteristics of the HSI components should be compared	3.4.4.2

Table 18-175-1 — Verification and Validation Related Questions

(For Information Only)

RAI #	Question	RAI Text	V&V Plan Section and Notes
		with the HFE guidelines. In addition, for each guideline a determination should be made whether the HSI is acceptable or discrepant from the guideline. However, the staff does not find commitment and process to compare each guideline to the HSI in the V&V IP. The staff request for the applicant to identify where this information can be found.	
421	18-181	Section 3.6.2.3 of the V&V IP R. 2 states that the simulators used in HFE V&V activities are described in section 3.8. However, the staff finds that section 3.8 refers to the final plant HFE/HSI design check; but, it does not provide a description of the simulators. The staff requests for the applicant to correct this reference to indicate that the descriptions of the simulators are found in section 3.9.	3.5.4.1
426	18-182	NUREG-0711 section 11.4.3.2.2(8) states: (8) For important actions at complex HSIs remote from the main control room, where timely and precise human actions are required, the use of a simulation or mockup should be considered to verify that human performance requirements can be achieved. (For less risk-important HAs or where the HSIs are not complex, human performance may be assessed based on analysis such as task analysis rather than simulation.) The staff requests for the applicant to clarify where this criterion is addressed in their application.	3.1.4.2 3.3.4
426	18-183	NUREG-0711 section 11.4.3.2.3(2) states: (2) To properly account for human variability, a sample of participants should be used. The sample should reflect the characteristics of the population from which the sample is drawn. Those characteristics that are expected to contribute to system performance variation should be specifically identified and the sampling process should provide reasonable assurance that variation along that dimension is included in the validation. Several factors that should be considered in determining representativeness include: license and qualifications, skill/experience, age, and general demographics. The staff requests for the applicant to reconcile the inconsistency in the FSAR of not selecting participants on the basis of license and qualifications while	3.5.4.2

Table 18-175-1 — Verification and Validation Related Questions

(For Information Only)

RAI #	Question	RAI Text	V&V Plan Section and Notes
		only using qualified operators. the staff also requests for the applicant to clarify the V&V IP statements that only licensed operators (who will not yet exist) will be used (see section 3.6.3.1; 4.3.1.13). In addition, the staff requests for the applicant to define the techniques (e.g., give the sample bounds) that will ensure that the sample age and demographics are representative of the overall population.	
426	18-184	NUREG-0711 section 11.4.3.2.3(4) states: (4) To prevent bias in the sample, the following participant characteristics and selection practices should be avoided: • participants who are part of the design organization • participants in prior evaluations • participants who are selected for some specific characteristic, such as using crews that are identified as good or experienced. The staff requests for the applicant to identify the sampling practices used to identify participants. In addition, please verify that participants will not be part of the design organization. Section 3.6.3.1 states that 'if the level of experience is considered to be an important variable in the evaluation results, the evaluators may selectively seek out AREVA or industry personnel with the requisite requirements to participate...'. The staff requests for the applicant to verify that the normal selection practice will not be biased toward selecting participants who are identified as good or experienced and that if the impact of experience must be assessed, to avoid a biased sample the effect of experience will be assessed statistically from the overall sample and not via selection practices. If an alternative method will be used, then please include a description and justification.	3.5.4.2
427	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	3.0 U.S. EPR Human Factors Engineering (HFE) Design Implementation

Table 18-175-1 — Verification and Validation Related Questions

(For Information Only)

RAI #	Question	RAI Text	V&V Plan Section and Notes
		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.	Plan – Section 3.3
427	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.	3.1.4.4(3)
427	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	3.5.4.3

Table 18-175-1 — Verification and Validation Related Questions

(For Information Only)

RAI #	Question	RAI Text	V&V Plan Section and Notes
		information is found. If it is not specified, then please describe how it will be included in the simulation.	
427	18-198	NUREG-0711 Section 11.4.3.2.5.2 states: (1) A hierarchal set of perfor¬mance 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.	3.5.4.4 3.5.4.6
427	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	3.5.4.4.1

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		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.	
427	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.	GOMs removed from plan. 3.5.4.4.2 (4)(b)
427	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. Atten¬tion should be focused on those aspects of the design that can only be addressed during testing of the integrated system, e.g., the	3.5.4.4.2(5)

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		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.	
427	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.	3.5.4.4
427	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	3.5.4.4

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		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.	
427	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.	3.5.4.4.2 3.5.4.4.2(4)
427	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	3.5.4.5.1 AREVA NP Document "Sample HFE V&V Scenarios for the U.S. EPR"

Table 18-175-1 — Verification and Validation Related Questions

(For Information Only)

RAI #	Question	RAI Text	V&V Plan Section and Notes
		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 communica¬tions 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., identify¬ing 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	

Table 18-175-1 — Verification and Validation Related Questions

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		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.	
427	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.	3.5.4.5.5 AREVA NP Document "Sample HFE V&V Scenarios for the U.S. EPR"
427	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.	3.5.4.5.6

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		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.	
427	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	3.5.4.4.1 3.5.4.4.2

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		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) WITHDRAWN, 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.	
427	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.	3.5.4.7
427	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	3.6.4.3

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		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.	
427	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	3.6.4.4

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		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	

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		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.	
427	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 conse¬quences 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	3.6.4.5

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		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.	
427	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	3.6.4.7

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		interrelationships between HED will be evaluated.	
427	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.	3.6.4.8
433	18-221	On November 17, 2009, the staff issued RAI 328, Question 18-67 which focused on scenario assignment and crew/participant training and selection. With respect to the applicant's proprietary response to this RAI on March 4, 2010, the staff requests that the first 3 full paragraphs (not	3.5.4.5.6

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		the bulleted information) on page 88 be incorporated by the applicant into the V&V IP.	
433	18-223	NUREG-0711 11.4.2.2.2 states: (1) Criteria Identification—The criteria for Task Support Verification which come from task analyses of HSI requirements for performance of personnel tasks that are selected from operational conditions should be defined. The criteria for Task Support Verification are the HSI requirements identified by task analysis. The staff notes that section 18.10.3.2 of the FSAR discusses HSI Task Support Verification (TSV). This section of the FSAR states that a dynamic TSV is performed when the HSI and simulator designs have evolved to the point that the simulator represents the complete HSI inventory. The staff requests for the applicant to to clarify what a 'dynamic' TSV is. In addition, please clarify if there is also a 'static' TSV and define it accordingly. The staff also notes that section 18.10.3.2 of the FSAR states that the HRA results are an input to the TSV. Please specify what aspects of the HRA results will be used in TSV.	Term “dynamic TSV” removed from plan. 3.3.4
433	18-225	Section 4.2.3.5 of the V&V IP states that HSIs 'may' be evaluated with checklists based on the HSI style guide or NUREG-0700. The staff requests for the applicant to specify which methods will be used to evaluate the HSIs.	3.3.4.1 3.4.4.2
433	18-226	NUREG-0711 11.4.3.2.5.2 states: (2) Plant Performance Measurement—Plant performance measures representing functions, systems, components, and HSI use should be obtained. Section 3.6.4.7 of the V&V IP R.2 indicates that simulator logs and a chronometer will be used to collect system performance measures, and then compared to recommendations from guidelines. It further states that this level of evaluation will be deferred until the simulator is installed at the plant site. The staff requests for the applicant to clarify the intent of these statements. In	3.5.4.4 3.5.4.4.1

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RAI #	Question	RAI Text	V&V Plan Section and Notes
		addition, specify if validation of plant measures will be deferred until the ISV simulator is installed at the plant site. Section 3.6.4.2 states that identification of operator error and error rates will not be performed during simulator evaluation. The staff notes that at other points in the V&V IP Rev. 2, error rates and types are indicated as performance measures. The staff requests for the applicant to specify how and when error rates and identification of errors will be performed.	
433	18-227	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. Section 4.3.2.2 of the V&V IP R.2 states that an acceptance criterion is that 'required actions' are completed within the required time. The staff requests for the applicant to specify how 'required actions' are defined. In addition, specify if 'required actions' include risk-important human actions.	3.5.4.4.1 3.5.4.4.2
433	18-228	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. Section 4.6 of the V&V IP discusses the acceptance criteria for the Plant level measures. These are defined primarily in terms of operator response times. The staff requests for the applicant to clarify that the response of the plant will also be examined.	3.5.4.4.1 3.5.4.6

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RAI #	Question	RAI Text	V&V Plan Section and Notes
433	18-229	NUREG-0711 11.4.3.6.2.5 states: (1) If possible, participants who will operate the integrated system in the validation tests should not be used in the pilot study. If the pilot study must be conducted using the validation test participants, then: • The scenarios used for the pilot study should be different from those used in the validation tests, and • Care should be given to provide reasonable assurance that the participants do not become so familiar with the data collection process that it may result in response bias. Section 4.5.1.3 of the V&V IP R.2 states that personnel used during the pilot testing are not to the same personnel as used in the integrated validation tests. The staff notes that this section goes on to state that if a pilot test participant is used in integrated validation tests that certain steps will be taken. The staff requests for the applicant to clarify if participants, used in the pilot testing, will be allowed to participant in the integrated validation tests.	3.5.4.5.7

Question 18-176:

NUREG-0711 11.4.1.2.2 states the results of sampling should be combined to identify a set of scenarios to guide the subsequence analyses. A given scenario may combine many of the characteristics identified by operational event sampling.

NUREG-0711 11.4.3.2.4 (1) also states:

1) The operational conditions selected for inclusion in the validation tests should be developed in detail so they can be performed on a simulator. The following information should be defined to provide reasonable assurance that important performance dimensions are addressed and to allow scenarios to be accurately and consistently presented for repeated trials:

   - description of the scenario and any pertinent "prior history" necessary for personnel to understand the state of the plant upon scenario start-up
   - specific initial conditions (precise definition provided for plant functions, processes, systems, component conditions and performance parameters, e.g., similar to plant shift turnover)
   - events (e.g., failures) to occur and their initiating conditions, e.g., time, parameter values, or events
   - precise definition of workplace factors, such as environmental conditions
   - task support needs (e.g., procedures and technical specifications)
   - staffing objectives
   - communication requirements with remote personnel (e.g., load dispatcher via telephone)
   - the precise specification of what, when and how data are to be collected and stored (including videotaping requirements, questionnaire and rating scale administrations)
   - specific criteria for terminating the scenario.

The staff requests for the applicant to provide a sample of the set of scenarios that will be used in the applicant's Validation & Verification Implementation Plan. The applicant's response regarding these scenarios should include the following information:

a. The sample set to include at least 4 different scenarios.

b. The sample set should be representative of the variety scenarios that will be generated.

c. This sample set of scenarios should include the level of detail that is needed to implement the scenario stated in NUREG 11.4.3.2.4(1).

d. The scenarios should include all information outlined in the numbered list contained in sections 3.6.3.5 of the V&V IP R. 2, page 72, and section 4.3.1, (4.3.1.2 thru 4.3.1.13) of same.

e. The method used to combine the elements listed in the V&V IP to create the set, written at a level of detail that it may be replicated and repeated.

Response to Question 18-176:

In accordance with the discussion at the NRC public meeting on September 23, 2010, AREVA agreed to provide 3 sample HFE verification and validation (V&V) scenarios for NRC review. These samples are from the following three categories: normal, abnormal, and emergency, and are contained in the document "Sample HFE V&V Scenarios for the U.S. EPR". In addition the AREVA NP U.S. EPR Verification and Validation Implementation Plan has been revised. These proprietary documents are submitted under a separate cover letter. Additional detail has been added to Section 3.5.4.5.1 of the plan and is also provided in the AREVA NP document Sample Human Factors Engineering V&V Scenarios for the U.S. EPR to address this question.

FSAR Impact:

The U.S. EPR FSAR will not be changed as a result of this question.

Question 18-177:

NUREG-0711 11.4.1.2.2 (2) states:

The scenarios should not be biased in the direction of over representation of the following:

- Scenarios for which only positive outcomes can be expected
- Scenarios that for integrated system validation are relatively easy to conduct administratively (scenarios that place high demands, data collection or analysis are avoided).
- Scenarios that for integrated system validation are familiar and well structured (e.g., which address familiar systems and failure modes that are highly compatible with plant procedures such as “textbook” design-basis accidents)

The staff request for the applicant to provide the sampling method that will be used to develop the set of sample scenarios to be used for Verification and Validation in order to demonstrate how sampling bias will be avoided.

Response to Question 18-177:

The AREVA NP U.S. EPR Verification and Validation Implementation Plan has been revised and the proprietary plan is submitted under a separate cover letter. Additional detail has been added to Section 3.1.4.4(5) of the plan to address this question.

FSAR Impact:

The U.S. EPR FSAR will not be changed as a result of this question.

Question 18-178:

NUREG-0711 section 11.4.2.3.2 states that the criteria for the HFE Design Verification Review Criteria should be identified.

Human Factors Engineering Design Verification is discussed in Section 3.5.2 of the V&V IP R. 2. In it, the applicant states that designs are compared to HFE guidelines and those deviations from accepted HFE guidelines, standards, and principles are documented as HEDs. The staff requests for the applicant to identify the document or documents that contain all these accepted guidelines, standards, and principles. (This may be NUREG-0700 or the EPR HFE Style Guide. If another document is used, then please provide a brief justification or rationale.)

Response to Question 18-178:

The AREVA NP U.S. EPR Verification and Validation Implementation Plan has been revised, and the proprietary plan is submitted under a separate cover letter. Additional detail has been added to Section 3.4 of the plan to address this question.

FSAR Impact:

The U.S. EPR FSAR will not be changed as a result of this question.

Question 18-179:

NUREG-0711 section 11.4.2.3.2(4) states that HEDs, should be documented by the applicant in terms of the HSI component involved and how its characteristics depart from a particular guideline. However, the staff cannot find this information in the V&V IP. The staff requests the applicant to identify where this commitment can be found.

Response to Question 18-179:

The AREVA NP U.S. EPR Verification and Validation Implementation Plan has been revised, and the proprietary plan is submitted under a separate cover letter. Additional detail has been added to Section 3.4.4.4 of the plan to address this question.

FSAR Impact:

The U.S. EPR FSAR will not be changed as a result of this question.

Question 18-180:

NUREG-0711 section 11.4.2.3.2(2) states that the characteristics of the HSI components should be compared with the HFE guidelines. In addition, for each guideline a determination should be made whether the HSI is acceptable or discrepant from the guideline. However, the staff does not find commitment and process to compare each guideline to the HSI in the V&V IP. The staff request for the applicant to identify where this information can be found.

Response to Question 18-180:

The AREVA NP U.S. EPR Verification and Validation Implementation Plan has been revised, and the proprietary plan is submitted under a separate cover letter. Additional detail has been added to Section 3.4.4.2 of the plan to address this question.

FSAR Impact:

The U.S. EPR FSAR will not be changed as a result of this question.

Question 18-181:

Section 3.6.2.3 of the V&V IP R. 2 states that the simulators used in HFE V&V activities are described in section 3.8. However, the staff finds that section 3.8 refers to the final plant HFE/HSI design check; but, it does not provide a description of the simulators. The staff requests for the applicant to correct this reference to indicate that the descriptions of the simulators are found in section 3.9.

Response to Question 18-181:

The AREVA NP U.S. EPR Verification and Validation Implementation Plan has been revised, and the proprietary plan is submitted under a separate cover letter. Additional detail has been added to Section 3.5.4.1 of the plan to address this question.

FSAR Impact:

The U.S. EPR FSAR will not be changed as a result of this question.

U.S. EPR Final Safety Analysis Report Markups

11.0 HFE verification and validation is performed in accordance with the prescribed process described in the U.S. EPR Human Factors Verification and Validation (V&V) Implementation Plan.

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12.0 Design implementation is performed in accordance with the prescribed process described in the U.S. EPR HFE Design Implementation Plan.

13.0 Integrated System Validation scenarios are developed in accordance with the U.S. EPR Human Factors V&V Implementation Plan and contain similar content as scenario examples for the U.S. EPR.

3.0 Inspection, Tests, Analyses and Acceptance Criteria

Table 3.4-1 lists the HFE ITAAC.

Table 3.4-1—Human Factors Engineering ITAAC (8 Sheets)

Commitment Wording		Inspections, Tests, Analyses	Acceptance Criteria
12.0	Design implementation is performed in accordance with the prescribed process described in the U.S. EPR HFE Design Implementation Plan.	An analysis of the output summary has been performed. **{{DAC}}**	The output summary report exists that demonstrates: • The design implementation was performed in accordance with the prescribed process for validation that the as-built design conforms to the standard design resulting from the HFE V&V process. • Issues identified in the HFE issues tracking database have been addressed. **{{DAC}}**
13.0	Integrated System Validation scenarios are developed in accordance with the U.S. EPR Human Factors V&V Implementation Plan and contain similar content as scenario examples for the U.S. EPR.	An analysis of the output summary has been performed.	The output summary report exists that demonstrates: • V&V scenarios developed based on sampling dimensions described in the U.S. EPR Human Factors V&V Implementation Plan. • V&V scenarios incorporated scenario definition, performance measure, test design, and data analysis, and interpreted in accordance to the U.S. EPR Human Factors V&V Implementation Plan. • HFE scenarios are performed on a validation test bed in accordance with the U.S. EPR Human Factors V&V Implementation Plan. **{{DAC}}**

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Next File

18.10 Verification and Validation

Human factors engineering (HFE) verification and validation (V&V) consists of techniques used to establish that the design of the HSI meets HFE design requirements and supports the performance of personnel tasks. V&V also establishes that the HSI design adheres to established human factors practices and meets all operational requirements.

HFE V&V consists of a variety of activities, many of which are executed at the end of design activities. Evaluations are performed at various points throughout the design process to minimize the number of deviations revealed during HFE V&V.

18.10.1 Objectives

The first objective of HFE V&V is to establish that the design of the HSI meets design requirements. To verify the HSI design requirements, V&V demonstrates that:

- Required control capabilities and displayed quantities are provided.
- Each part of the HSI is configured as intended, as required by design-specific HFE guidance, and as described in the style guide (see Section 18.7.6.1) and industry standard practices.
- Conflicts between the various requirements and specifications have been addressed and resolved.

The second objective of HFE V&V is to establish that the HSI is effective in supporting the performance of personnel tasks. To validate that the HSI supports task performance, the entire system is tested to establish that the integrated functionality of individual requirements provides the functions and achieves the performance needed. HFE validation considers the HSI and the operators as a single system (i.e., a team type human-machine environment).

18.10.2 Scope

The HFE V&V process applies to HSIs (i.e., controls, displays, and alarms) in the MCR, the RSS, appropriate local control stations (LCS) and functions considered critical to plant safety (i.e., risk-important HAs are specific targets to require sample V&V activities).

HFE V&V is also applied to the following features of the design or changes to the design: RAI 421 Q 18-175

- Procedures (~~hard copy and~~ computer-based).
- Crew coordination and communication.

- Display navigation, information retrieval, and access to controls.
- Automation and the features of automation including monitoring and control.
- Layout, configuration, and anthropometrics of workplaces and workstations and the features and equipment required for those spaces (e.g., laydown areas, access and egress, radios, phones, and hard copies of procedures and drawings).
- Workplace environment (e.g., lighting, temperature, noise).
- Provisions for routine tests and maintenance.
- Effectiveness of training materials.

The techniques for HFE V&V are described in Section 18.10.3. Application of the various techniques to different aspects of the HFE design is included in the description of the technique.

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18.10.3 Methodology

There are a large number of HSI components used in the U.S. EPR. Each HSI component represents at least one personnel task; therefore, a large number of events could be encountered during operation of the plant. It is neither practical nor appropriate to evaluate every scenario to confirm the adequacy and effectiveness of the HSI and establish that the performance requirements are met for each operating condition. Operational condition sampling (OCS) (see Section 18.10.3.5) is used to choose a representative set of HSIs to be verified and validated.

The ~~first~~second step in verification is to identify the HSI components that are subject to verification. The HSI inventory and characterization activity describes the HSI displays, controls, and related equipment within the scope of the HSI design to be verified. HSI inventory and characterization is described in Section 18.10.3.2.

The ~~second~~third step in verification is the HSI task support verification (TSV) used to establish that the HSI provides the alarms, information, and control capabilities required as a result of the functional requirements analysis (FRA), functional allocation (FA), and TA activities. TSV is also used to establish that the characteristics of those alarms, information, and controls conform to the requirements developed during the TA. HSI TSV is described in Section 18.10.3.3.

HFE design verification (DV) (see Section 18.10.3.4) verifies that the characteristics of the HSI and the environment in which it is used conform to the established design-specific state-of-the-art HFE guidelines, as described in the style guide (see Section 18.7.6.1) and the industry standard practices in accordance with NUREG-0700 (Reference 1).

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~~There are a large number of HSI components used in the U.S. EPR. Each HSI component represents at least one personnel task; therefore, a large number of events could be encountered during operation of the plant. It is neither practical nor appropriate to evaluate every scenario to confirm the adequacy and effectiveness of the HSI and establish that the performance requirements are met for each operating condition. Operational condition sampling (OCS) (see Section 18.10.3.5) is used to choose a representative set of scenarios for validation.~~

Performance-based tests are used to evaluate an integrated system design to determine if the HSI supports safe operations of the plant. This ISV evaluates those aspects of design that can not be assessed analytically. The goal is to test the integration of personnel and plant systems and to validate the integration of the design with personnel actions, plant response, HSIs, and procedures. ISV is performed using a high-fidelity simulator. Generally, ISV participants are operators with training and qualifications consistent with the description in Section 13.2. Multiple groups of operators are used for ISV scenarios so that results are not biased towards well-qualified crews. Details on ISV are provided in Section 18.10.3.6.

Human engineering discrepancy (HED) resolution is performed iteratively throughout the HSI design process so that issues are identified and corrected early. Some HEDs identified during verification are resolved prior to proceeding with validation of the HSI design. HEDs are not considered in isolation and, to the extent possible, their potential interactions are considered when developing and implementing solutions. More details on HED resolution are provided in Section 18.10.3.7.

The final step in verification is the design implementation activity, which confirms that the design description and documentation match the installed configuration and completes any V&V activities that could not be performed prior to installation. Any discrepancies identified at this stage are resolved by updating the appropriate documentation before the design is ready for operation. Design implementation is described in Section 18.11.

18.10.3.1 Operational Conditions Sampling

The U.S. EPR has a large number of HSI components. Hundreds of personnel tasks will be encountered during operation of the plant. Sampling of the operational conditions is used to choose a representative set of HSIs for V&V. There are three sampling dimensions addressed in the identification of HSIs for V&V:

- Personnel tasks.
- Plant conditions.
- Situational factors known to challenge personnel performance.

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18.10.3.1.1 Personnel Tasks

The HFE and Control Room Design Team addresses those personnel tasks that are related to the use of the HSI. As a minimum, the tasks identified in analysis activities associated with EOP development and risk-significant HAs (see Section 18.6) are included in the sample. The sample set of tasks is augmented to include tasks that:

- Are found to be particularly difficult to design into the HSI.
- Require significant compromise during the HSI design.
- Have the potential to cause user errors because of its complexity.

Tasks that use design features retained or modified during the design process, because of the OER analysis, are included in the sample set to confirm the adequacy of the design to resolve the issue or the need for further consideration or tracking.

The other personnel tasks considered for inclusion in the sample are as follows:

- Range of procedure-guided tasks.
- Range of knowledge-based tasks that are not well defined by detailed procedures. Knowledge-based decision-making involves greater reasoning concerning safety and operating goals and the various means of achieving them. A situation may require knowledge-based decision-making if the rules do not fully address the problem, or the selection of the appropriate rule is not clear.
- Human cognitive activities:
  - Detection and monitoring.
  - Situation assessment.
  - Response planning.
  - Response implementation.
  - Obtaining feedback.
- Range of human interactions – interactions among plant personnel, including tasks that are performed independently by individual crew members and tasks that are performed by crew members acting as a team.
- Tasks that are performed with high frequency.

18.10.3.1.2 Plant Conditions

The sample set includes representative plant conditions as appropriate for the HSI to be verified and validated. These include normal operating events such as:

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- Plant startup.
- Plant shutdown or refueling.
- Significant changes in operating power.
- Failure events (i.e., instrument failures, HSI failures, and other system component failures).
- Transients and accidents:
  - Transients (e.g., turbine trip, loss of off-site power, station blackout, loss of all feedwater, loss of service water, loss of power to selected buses or MCR power supplies, and safety and relief valve transients).
  - Accidents (e.g., main steam line break, positive reactivity addition, control rod insertion at power, anticipated transient without scram (ATWS), and various-sized loss-of-coolant accidents).
  - Reactor shutdown and cooldown using the RSS.
- Reasonable, risk-significant, and beyond-design-basis events determined from the PRA.
- Consideration of the role of the equipment in achieving plant safety functions and the degree of interconnection with other plant systems.

18.10.3.1.3 Situational Related Performance Shaping Factors

Situational related performance shaping factors can negatively impact operator performance. Situational factors known to challenge human performance are included in the sample as follows:

- Operationally difficult tasks - tasks that have been found as problematic in the operation of complex HSIs (e.g., use of a procedure versus assessment of a situation based on operator knowledge and awareness).
- High workload conditions - situations where human performance can vary because of high workload and multitasking situations.
- Varying workload situations - where human performance can vary because of workload transitions.
- Varying crew size.
- Fatigue - situations where human performance can vary because of personnel fatigue.

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- Environmental factors - situations where human performance can vary because of environmental conditions such as poor lighting, extreme temperatures, high noise, and simulated radiological contamination.

The sample also includes error-forcing context situations specifically designed to create human errors in order to assess the error tolerance of the system and the capability of operators to recover from random errors.

18.10.3.1.4 Identification of Scenarios

When the complete set of operational condition samples is developed, the results are combined to identify a set of scenarios for ISV. The following criteria are used to fully define the scenarios to be validated.

- A given scenario identified for ISV that combines multiple characteristics of each dimension.
- A scenario defined to allow, where practicable, repetition with multiple ISV participants to establish consistency of results. The scenario definition includes, as a minimum:
  - A description of the scenario mission and any pertinent situational history necessary for operators to understand the state of the plant upon scenario startup.
  - Specific start conditions.
  - Events (e.g., failures) that will occur and their initiating condition(s).
  - Precise definition of workspace factors such as environmental conditions.
  - Communication requirements with remote personnel.
  - Crew behavior requirements.
  - Data to be collected by the observers including how they were collected and where they were captured and stored.
  - Criteria required for terminating the scenario.
  - Task support needs.
  - Staffing objectives.
- The scenarios selected are not biased towards:
  - Positive outcomes.
  - ISV that is administratively easy to conduct scenarios.

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– ISV that is familiar and well-structured scenarios (i.e., textbook design basis accidents).

18.10.3.2 HSI Inventory and Characterization

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The HSI inventory and characterization activity describes HSI components and related equipment associated with personnel tasks that are within the scope of the HSI design to be verified. The complete inventory is created from the HSI task support requirements determined during task analysis. ~~by filtering certain portions of the instrumentation and controls (I&C) input/output (I/O) database which receives information from~~ The accuracy of the inventory is confirmed by comparing it to sources such as system description documents, design specifications, equipments lists, and process and instrumentation drawings. ~~The accuracy of the inventory is confirmed by comparing it with similar data from predecessor designs and HSI elements described in the design specifications for the HSIs.~~ The inventory includes aspects of the HSI that are used for interface management such as navigation and display retrieval in addition to those that control the plant.

The inventory provides an accurate and complete description of the HSI components and includes the following information:

- A unique component identification code, which includes the associated plant system and subsystem.
- Associated personnel function/subfunction.
- The type of component.
- Component characteristics such as:
  - Display functionality.
  - Control functionality.
  - User-system interactions and dialog types.
  - Location within the display screen hierarchy.
  - Physical location.
  - Associated operator response time for critical human tasks.

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The HSI inventory identifies aspects needed to verify that the interface meets its requirements. The focus is on characterizing the HSI and not the technical features of the devices that comprise the HSI. Photographs or copies of HSI~~process information and control system (PICS) and safety information and control system (SICS)~~ screens and samples of ~~SICS~~ hardwired components are included in the inventory.

When the HSI inventory is fully defined, HFE DV is used to confirm that each individual component conforms to established HFE guidelines.

18.10.3.3 HSI Task Support Verification

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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. ~~TSV does not identify HSI elements not needed to support personnel tasks unless additional activities are performed, such as annotating panel or screen display drawings. For the U.S. EPR, HSI elements that do not support personnel tasks are identified during the HSI design.~~ The number of HSI elements or screens is reduced if the HFE and Control Room Design Team determines that an excessive number of display elements or screens interfere with operator awareness or leads to information overload issues. Individual HSI elements are arranged on screens according to criteria established in the style guide (see Section 18.7.6.1) while screens are arranged in layers of a hierarchy (see Section 18.7.6.1.2). HSI elements that are not needed to support personnel tasks are minimized on control screens that are most often used, and are shown in detail on control screens in lower levels of the hierarchy.

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Initial TSV is performed early in the HSI design process to provide information for HSI screen layout. Initial TSV uses the results of the HSI inventory and characterization, the operating procedures, the TAs performed for those ~~operating procedures~~HSIs, and the HRA results. Preliminary versions of system description documents, process and instrumentation drawings, logic diagrams, and hardware and software specifications also provide input. The initial TSV confirms that the inventory of HSI elements support personnel tasks as defined by the procedures, design goals, and analysis. The initial TSV verifies completeness of the HSI inventory; therefore, no performance measures are developed for this activity.

A dynamic TSV is performed when the HSI and simulator designs have evolved to the point that the simulator represents the complete HSI inventory. The dynamic TSV confirms that HSI components meet the specified operability requirements (e.g., response time, accuracy, precision) for selected tasks. A set of performance measures derived from performance requirements contained in the applicable hardware and software design specifications, and from the style guide (see Section 18.7.6.1) is defined prior to starting the dynamic TSV. These performance measures cover quantitative parameters, limits, and tolerances concerning performance such as completion time, range, accuracy, precision, frequency, and percent completion. To perform the dynamic TSV, test personnel are placed in-the-loop on the simulator. Task requirements not met by the inventory are identified with an HED and tracked until they are resolved or justification for no resolution is complete.

18.10.3.4 Design Verification

The HFE DV evaluates the final design against the design requirements and the design specifications. Design requirements are derived from the style guide (see Section 18.7.6.1)~~ and NUREG-6393 (Reference 2)~~. HFE guidelines in the style guide cover the following aspects of HSI design:

- Global features – room layout panel configuration (e.g., anthropometrics, and ergonomics), work environment (e.g., lighting, space, air conditions, and sound levels) and inter-personnel communication that support users of HSI (e.g., equipment functionality, and ease of use).

- Standardization features – HSI characteristics and conventions (e.g., coding conventions, display formatting, navigation, and alarm hierarchy) are those features that are designed using HFE guidelines applied across individual control and display elements. For example, the display labeling is standardized based on the style guide.

- Detailed features – HSI features not addressed by general HFE guidelines.

The design verifiers define the criteria for the verification and capture them in a checklist of the relevant style guide requirements. Final design documentation such as panel drawings or mockups and screen shots are also used. The designers justify and document instances where the design deviates from the specifications or established practices. HSI design specifications capture performance requirements, and those requirements define the performance measures for the DV.

The DV consists of comparing the characteristics of the HSI components with the design requirements. An HED is generated when an HSI component does not conform to the operational requirements as defined in the ~~validated procedure guidelines (i.e., derived in~~ TA~~)~~, HFE design specifications, or the style guide.

HEDs are also identified for:

- Failure to meet crew-identified functionality in addition to that specified by system designers.

- Poor integration with the rest of the HSI.

- Poor integration with procedures and training.

- Failure to meet guidance in the HSI style guide and the HSI Design Implementation Plan (Reference 3).

HEDs are documented and evaluated to determine the extent of the condition. For example, if the elements of a particular display ~~screen~~ are not in compliance with the required color coding scheme, other similar display<u>s</u> ~~screens~~ are evaluated to establish that there are no generic implications. HEDs identified during DV do not always

warrant a design change; if, for example, an HSI layout is not consistent with the style guide but is consistent with the physical plant, changing the HSI layout to meet the style guide requirement could adversely effect operator acceptance of that HSI layout and lead to errors in usage. It is also possible for HFE DV to uncover limitations in the style guide requirements if the DV is well documented and reasonable designer decisions conflict with the guidance. HED resolution in this case could involve a revision to the style guide. For an explanation of the HED resolution process, see Section 18.10.3.7.

18.10.3.5 ~~Operational Conditions Sampling~~

~~The U.S. EPR has a large number of HSI components. Hundreds of personnel tasks will be encountered during operation of the plant. Sampling of the operational conditions is used to choose a representative set of scenarios for validation. There are three sampling dimensions addressed in the identification of scenarios for the ISV:~~

- ~~Personnel tasks.~~
- ~~Plant conditions.~~
- ~~Situational factors known to challenge personnel performance.~~

18.10.3.5.1 ~~Personnel Tasks~~

~~The HFE and Control Room Design Team addresses those personnel tasks that are related to the use of the HSI. As a minimum, the tasks identified in analysis activities associated with EOP development (see Section 18.8) and risk-significant HAs (see Section 18.6) are included in the sample. The sample set of tasks is augmented to include tasks that:~~

- ~~Are found to be particularly difficult to design into the HSI.~~
- ~~Require significant compromise during the HSI design.~~
- ~~Have the potential to cause user errors because of its complexity.~~

~~Tasks that use design features retained or modified during the design process, because of the OER analysis, are included in the sample set to confirm the adequacy of the design to resolve the issue or the need for further consideration or tracking.~~

~~The other personnel tasks considered for inclusion in the sample are as follows:~~

- ~~Range of knowledge-based tasks that are not well defined by detailed procedures. Knowledge-based decision-making involves greater reasoning concerning safety and operating goals and the various means of achieving them. A situation may require knowledge-based decision-making if the rules do not fully address the problem, or the selection of the appropriate rule is not clear.~~

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- Human cognitive activities:
  - Detection and monitoring.
  - Situation assessment.
  - Response planning.
  - Response implementation.
  - Obtaining feedback.
- Range of human interactions – interactions among plant personnel, including tasks that are performed independently by individual crew members and tasks that are performed by crew members acting as a team.
- Tasks that are performed with high frequency.

18.10.3.5.2 Plant Conditions

The sample set includes representative plant conditions as appropriate for the HSI to be validated. These include normal operating events such as:

- Plant startup.
- Plant shutdown or refueling.
- Significant changes in operating power.
- Failure events (i.e., instrument failures, HSI failures, and other system component failures).
- Transients and accidents:
  - Transients (e.g., turbine trip, loss of off-site power, station blackout, loss of all feedwater, loss of service water, loss of power to selected buses or MCR power supplies, and safety and relief valve transients).
  - Accidents (e.g., main steam line break, positive reactivity addition, control rod insertion at power, anticipated transient without scram (ATWS), and various sized loss-of-coolant accidents).
  - Reactor shutdown and cooldown using the RSS.
- Reasonable, risk-significant, and beyond-design-basis events determined from the PRA.
- Consideration of the role of the equipment in achieving plant safety functions and the degree of interconnection with other plant systems.

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18.10.3.5.3 Situational-Related Performance Shaping Factors

Situational related performance shaping factors can negatively impact operator performance. Situational factors known to challenge human performance are included in the sample as follows:

- Operationally difficult tasks – tasks that have been found as problematic in the operation of complex HSIs (e.g., use of a procedure versus assessment of a situation based on operator knowledge and awareness).
- High workload conditions – situations where human performance can vary because of high workload and multitasking situations.
- Varying workload situations – where human performance can vary because of workload transitions.
- Fatigue – situations where human performance can vary because of personnel fatigue.
- Environmental factors – situations where human performance can vary because of environmental conditions such as poor lighting, extreme temperatures, high noise, and simulated radiological contamination.

The sample also includes error-forcing context situations specifically designed to create human errors in order to assess the error tolerance of the system and the capability of operators to recover from random errors.

18.10.3.5.4 Identification of Scenarios

When the complete set of operational condition samples is developed, the results are combined to identify a set of scenarios for ISV. The following criteria are used to fully define the scenarios to be validated.

- A given scenario identified for ISV that combines multiple characteristics of each dimension.
- A scenario defined to allow, where practicable, repetition with multiple ISV participants to establish consistency of results. The scenario definition includes, as a minimum:
  - A description of the scenario mission and any pertinent situational history necessary for operators to understand the state of the plant upon scenario startup.
  - Specific start conditions.
  - Events (e.g., failures) that will occur and their initiating condition(s).
  - Precise definition of workspace factors such as environmental conditions.

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- ~~Communication requirements with remote personnel.~~
- ~~Crew behavior requirements.~~
- ~~Data to be collected by the observers including how they were collected and where they were captured and stored.~~
- ~~Criteria required for terminating the scenario.~~
- ~~Task support needs.~~
- ~~Staffing objectives.~~

- ~~The scenarios selected are not biased towards:~~
  - ~~Positive outcomes.~~
  - ~~ISV that is administratively easy to conduct scenarios.~~
  - ~~ISV that is familiar and well-structured scenarios (i.e., textbook design basis accidents).~~

18.10.3.6 Integrated System Validation

ISV is a performance-based evaluation of integrated system design and human task performance to establish that the HSI is operable within performance requirements and supports safe operation of the plant. The ISV addresses the following:

- Adequacy of the entire HSI configuration for achievement of the HFE program goals.
- Confirmation of allocation of functions and the structure of tasks assigned to personnel and machine.
- Adequacy of staffing and HSI that support tasks.
- ~~Adequacy of procedures and operating instructions.~~ ← RAI 421 Q 18-175
- Validation of the dynamic aspect of HSI for task accomplishment.
- Identification of aspects of the integrated system that may negatively affect integrated system performance.

The goals of ISV are to:

- Test the integration of personnel and plant systems.
- Validate the integration of the design with:
  - Personnel actions.

- Plant response.
- HSIs.
- ~~Procedures.~~ RAI 421 Q 18-175

ISV is performed using a high-fidelity simulator. ISV seeks to confirm the adequacy of the HSI and the human performance assumptions, so appropriate performance measures are selected to include both HSI and human performance issues. ISV performance measurement is complex and addresses the following areas:

- Operational safety and task performance (e.g., avoidance of errors, alarm conditions, technical specification violations, response time, task completion time, and procedure compliance).
- Human error.
- Situational awareness.
- Operator workload.
- Crew communications and coordination.
- Anthropometrics (i.e., accessibility and operability of controls and visibility and readability of indicators).
- Display validation (i.e., behavior of the graphics, which is part of the overall HSI performance).

Tools and methods used to validate the conceptual design (i.e., ISV type activities performed prior to the final design) include interviews, questionnaires, checklists, walk-throughs, talk-throughs, static mockups, part-task simulators, and the full-scope simulator.

The scope of the ISV includes the MCR, the RSS, and appropriate LCS.

The simulator testing environment can not fully replicate the actual MCR environment considering that factors such as noise, lighting, temperature, and stress have an affect on operator performance in real situations. Simulator testing environments can also bias operator behavior because during a simulator test scenario, the operator is likely to anticipate the occurrence of an abnormal condition and be more attentive. This potential for bias is considered when evaluating test results. The guidance from NUREG-6393 (Reference 2) is used to avoid selecting scenarios which introduce bias.

Formal ISV tests are performed using the plant simulator with a representative set of realistic scenarios selected from OCS input to confirm that the HSIs, ~~the procedures,~~ RAI 421 Q 18-175

the function allocation, and the task design also supports the operator during task performance.

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Since it is the purpose of the ISV to demonstrate that the design is an effective interface, it is important to establish that problems such as inadequate training or incomplete, unproven procedures are not encountered during the tests because correct interpretation of the results of the validation becomes more difficult. ~~Another goal of ISV is to validate the effectiveness of procedures and operator training.~~

Initial design ISV activities such as evaluation of display navigation are conducted throughout the design phases without operating procedures via techniques such as interviews, walk-throughs, and laboratory simulators.

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Some problems are revealed during training. If, for example, it is discovered that operators have difficulty learning how to use certain features of the HSI or experience other challenges, HEDs are written to document the HSI problems. ~~As described in Section 18.9, the HFE and Control Room Design Team provides input to the training program to identify useful areas of focus for HFE V&V activities.~~ As issues develop they are evaluated so that decisions can be made to proceed with ISV or consider design changes based on preliminary results.

18.10.3.6.1 Validation Team

The Validation Team for ISV is an independent, multi-discipline team which includes significant involvement of the HFE and Control Room Design Team. To minimize the potential for bias, evaluations are performed independently. The Validation Team includes personnel with expertise in test and evaluation, test design, test procedure development, performance measures, and data analysis.

18.10.3.6.2 Scope

ISV considers actions required to be performed by operators to safely operate the plant during each plant operation mode and actions required to respond to a design basis event or an ATWS condition. Before performing any evaluations, HEDs identified during previous V&V efforts are resolved or retained for consideration after the ISV operational assessment.

18.10.3.6.3 Pilot Study

A pilot study is conducted prior to validation testing. The pilot study provides an opportunity to assess the adequacy of the test design, performance measures, and data collection method. The participants who will operate the integrated system in the validation test will not be used in the pilot study.

18.10.3.6.4 ISV Test Objectives

Detailed test objectives are developed prior to validation testing and define a systematic approach that relates scenario characteristics and performance measurement criteria. The objectives are developed to provide evidence that the integrated system adequately supports plant personnel in the safe operation of the plant. The objectives include the following:

- Validate the role of plant personnel.
- Validate that for each human function, the design provides adequate alerting, information, control, and feedback capabilities during normal plant evolutions, transients, design basis accidents (DBA), and select risk-significant events that are beyond design basis.
- Validate that the shift staffing, assignment of tasks to crew members, and crew coordination (both within the control room as well as between the control room and local control stations and support centers) is acceptable. This includes validation of the nominal shift levels, minimal shift levels, and shift turnover.
- Validate that specific personnel tasks can be accomplished within time and performance criteria, with a high degree of operating crew situation awareness, and with acceptable workload levels that provide a balance between a minimum level of vigilance and operator burden. Validate that the operator interfaces minimize operator error and provide for error detection and recovery capability when errors occur.
- Validate that the functional requirements are met for the major HSI features such as group-view displays, alarm systems, safety parameter display system functions, general display systems, computer-based procedures, controls, communication system, and EOP-related LCSs.

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- Validate that the control room operators can make effective transitions between the HSI features (e.g., group-view display, alarm systems, SICS, PICS, procedures, controls, communication systems) in the accomplishment of their task and that interface management tasks such as display configuration and navigation are not a distraction or cause undue burden.
- Validate that the integrated system performance is tolerant of failures of individual HSI features.
- Identify aspects of the integrated system (e.g., staffing, communication, and training) that may negatively impact integrated system performance.
- Validate the adequacy of the HSI configuration to achieve the HFE V&V objectives.
- Confirm that HSI task verification has been properly performed including, FRA, FA, and ~~partial scope~~ TA.

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- Validate the ability of the HSI to support the staff in accomplishing their tasks.
- Validate staffing goals.
- Validate the adequacy of computer-based procedures ~~and operating instructions~~.
- Validate the dynamic aspect of HSI for task accomplishment.
- Validate HRA assumptions.
- Evaluate and demonstrate that systems are error-tolerant to human and system failures.
- Validate that normal and minimum staff configurations are considered.

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18.10.3.6.5 Strategy

ISV is performed on a high-fidelity simulator and includes the following steps:

- Develop detailed test objectives.
- Verify that the test bed meets the requirements in 10 CFR 50.34(f)(2)(i).
- Verify that previously generated HEDs have been addressed or are tracked for further consideration.
- Select participants:
  - Test participants are qualified operators that represent plant personnel who will interact with the HSI (e.g., operators currently licensed on similar plant designs rather than training or engineering personnel).
  - Test conductors are trained and qualified in the usage of test procedures, error introduction by inaccurate testing procedures, and importance of testing documentation.
  - Normal crew configuration is present for the test (see Section 18.7.2).
  - Sample participants for the validation test are randomly chosen to avoid significant overlap with regard to:
    - ~~Operator license and qualification.~~
    - Age.
    - Skill and experience.
    - General demographics.
    - Test participants:

- Are not a part of the design organization.
- Have not been involved in prior evaluations.
- Were not selected based on a specific characteristic.

- Select and define scenarios from OCS.
- Develop test procedures.
- Develop human performance measures.
- Establish that test personnel and test participants have been properly trained.
- Conduct a pilot study to assess test design, performance measures, and data collection methods.
- Initiate simulation and conduct study.
- Analyze data, validate HRA assumptions, make appropriate design changes, as required.
- Create validation output reports.

18.10.3.6.6 Test Procedure

As part of the validation, a procedure is developed to govern how tests are conducted. Test procedures describe how tests are to be conducted. It is important that validation testing is conducted without bias to performance data. It is necessary that test procedures are detailed, clear, and easily understandable. When possible, test procedures minimize the opportunity of tester expectancy bias or participant response bias. Procedures that describe how tests are to be conducted are developed to meet the following objectives:

- Identify the crew that will receive the scenario and the order the scenario is to be presented.
- Detailed and standardized instructions for briefing the participants. This source of bias is minimized by developing standard instructions.
- Specific criteria for scenarios, such as when to start and stop the scenario, and when events are introduced.
- Guidance on when and how to interact with participants when simulator or testing difficulties occur.
- Detailed information for personnel outside of the control room as to what information they can provide, as well as a script with acceptable responses to likely questions. There are limits to preplanning communications because personnel may ask questions or make requests that were not anticipated.

Next File

- Procedures for documentation (i.e., identify and maintain test record files including staff and scenario details, data collected, and test conductor logs).
- Instructions regarding when and how to collect and store data. The instructions identify which data are to be recorded by one or more of the following:
  - Simulator computers.
  - Special purpose data collection devices.
  - Video recorders (location and views).
  - Test personnel in real time (observation checklist).
  - Subjective rating scales and questionnaires.

18.10.3.6.7 Data Analysis, Interpretation and Validation Conclusions

ISV test data is analyzed through the use of quantitative and qualitative methods. Analysis will determine whether performance measures are pass/fail. Conservatism is built into the data analysis and interpretation to allow real-world performance differences and the margin of error associated with testing. Failed performance measures are tracked by the HED process. Prior to formal ISV, pilot testing Human Engineering Deficiency (HED)s resulting from failed performance measures are resolved. The data analysis and the validation of converging performance measures are independently verified to be in conformance with the HFE program elements in accordance with the AREVA NP Design Control QA process.

The logical basis for performance measures validation and associated testing is documented and defined in engineering documentation. Performance measure validation also considers additional factors that could potentially invalidate results. For example, aspects of the test not well controlled, and differences between the ISV simulator and actual As-Built control station under real operating plant conditions are areas that require additional consideration prior to forming validation conclusions. Validation conclusions will be iteratively documented in validation output reports throughout the design process. HEDs will be created whenever HSI issues or personnel deficiencies are identified. The appropriate design ~~or procedure~~ changes will then be initiated as required.

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18.10.3.7 Human Engineering Discrepancy Resolution

HEDs refer to deficiencies in the HSI design with respect to HFE issues. During the design phases, HEDs are captured in the HFE Issues Tracking Database (see Section 18.1.4). When the U.S. EPR operator has assumed responsibility for maintaining design documentation, HEDs are tracked via the site-specific corrective actions program (see Section 18.12.3).

2. NUREG-6393, "Integrated System Validation: Methodology and Review Criteria," U.S. Nuclear Regulatory Commission, September 1995.

3. U.S. EPR Human System Interface Design Implementation Plan, AREVA NP Inc., ~~2009~~2010. RAI 421 Q 18-175

4. U.S. EPR Human Factors Verification and Validation Implementation Plan, AREVA NP Inc., ~~2009~~2011. RAI 421 Q 18-175