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18 HUMAN FACTORS ENGINEERING

This chapter of the Safety Evaluation Report (SER) provides the staff's review of the U.S. EPR Human Factors Engineering (HFE) Program as part of the design certification review being conducted by the U.S. Nuclear Regulatory Commission (NRC) under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

18.0 Review Considerations

18.0.1 Purpose of Review

The overall purpose of the HFE review is to verify:

- The applicant has integrated HFE into plant development, design, and evaluation.
- The applicant has provided HFE products (e.g., human system interfaces (HSIs), procedures, and training) that allow safe, efficient, and reliable performance of operation, maintenance, test, inspection, and surveillance tasks.
- The HFE program and its products reflect state-of-the-art human factors principles and satisfy all specific regulatory requirements.

18.0.2 Areas of Review

NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," (hereafter referred to as NUREG-0800 or the SRP), Chapter 18, "Human Factors Engineering," identifies 12 areas of review for successful integration of human characteristics and capabilities into nuclear power plant design. These areas of review correspond to the 12 elements of an HFE program identified in NUREG-0711, "Human Factors Engineering Program Review Model," Revision 2 and include:

- HFE Program Management
- Operating Experience Review
- Functional Requirements Analysis and Function Allocation
- Task Analysis
- Staffing and Qualifications
- Human Reliability Analysis
- Human-System Interface Design
- Procedure Development
- Training Program Development

- Human Factors Verification and Validation (V&V)
- Design Implementation
- Human Performance Monitoring

The above elements are evaluated in Sections 18.1 through 18.12 of this report. Each section includes a discussion of regulatory criteria that are specific to the HFE element being evaluated, a summary of relevant technical information, and the staff's technical evaluation.

18.0.3 Regulatory Basis

The following NRC requirements apply to all of the areas of review that are referred to in Section 18.0.2 of this report:

- 10 CFR 52.47, "Contents of applications; technical information," requires that applications for design certification of new reactor designs meet the technically relevant portions of the Three Mile island (TMI) requirements contained in 10 CFR 50.34(f), "Additional TMI-Related Requirements," (except for 10 CFR 50.34(f)(1)(xii), (f)(2)(ix), and (f)(3)(v)). The staff bases its HFE review on current regulatory requirements established post-TMI in 10 CFR 50.34(f). The staff reviews HFE aspects of new control rooms to verify that they reflect state-of-the-art human factors principles as required by 10 CFR 50.34(f)(2)(iii) and that personnel performance is appropriately supported. 10 CFR 50.34, "Contents of applications, technical information," also requires a safety parameter display system (SPDS), automatic indication of bypassed and operable status of safety systems, and monitoring capability in the control room for a variety of system parameters.
- For plants licensed under 10 CFR Part 52, the requirements of 10 CFR 50.34(f) are incorporated via 10 CFR 52.47 and 10 CFR 52.79, "Contents of applications; technical information in final safety analysis report." Meeting these requirements provides evidence that plant design, staffing, and operating responsibilities are acceptable and that there is reasonable assurance that plant safety will not be compromised by human error or by deficiencies in human-system interfaces, considering both hardware and software.

The staff evaluated whether the application complies with the above NRC requirements based on the guidance provided in NUREG-0800, Chapter 18. NUREG-0711, Revision 2 provides the guidance criteria to conduct and document the HFE evaluations that follow in Sections 18.1 through 18.12 of this report. A regulatory criteria section based on the objectives of review that are taken from the corresponding section of NUREG-0711 is included in each of these sections. These objectives provide a high level summary of the detailed review criteria that are used in the evaluation. In addition, for a limited number of specific topics, the staff used criteria from other review guidance documents. These criteria are identified in the specific sections where they apply.

18.0.4 Levels of Review

The staff may perform three different levels of review depending on the type of information provided: Complete element level, implementation plan (IP) level, and programmatic level.

For the U.S. EPR, the applicant provided information for at least implementation plan or complete element level reviews. Therefore, the programmatic level review was not used.

A complete element level of review is performed when the applicant has completed the HFE activity by addressing all criteria associated with the activity and submitted a description of it, with products, for staff review. If the staff determines that the applicant has met all of the NUREG-0711 criteria, then the applicant's description of the activity is acceptable.

An implementation plan level of review is performed when the applicant has not completed an HFE activity. NUREG-0711, Page 2, states:

An implementation plan gives the applicant's proposed methodology for meeting the acceptance criteria of the element. An implementation plan review gives the applicant the opportunity to obtain staff review of and concurrence in the applicant's approach before conducting the activities associated with the element. Such a review is desirable from the staff's perspective because it provides the opportunity to resolve methodological issues and provide input early in the analysis or design process when staff concerns can more easily be addressed than when the effort is completed.

Table 18.0-1 summarizes the level of review that the staff performed for each of the 12 HFE areas of review related to the U.S. EPR design certification.

Table 18.0-1 Levels of HFE Review

HFE Area	Level of Review
HFE Program Management	Complete Element
Operating Experience Review	Implementation Plan
Functional Requirements Analysis and Function Allocation	Implementation Plan
Task Analysis	Implementation Plan
Staffing and Qualifications	Implementation Plan*
Human Reliability Analysis	Implementation Plan
Human-System Interface Design	Implementation Plan
Procedure Development	See Chapter 13
Training Program Development	See Chapter 13
Human Factors Verification and Validation	Implementation Plan
Design Implementation	Implementation Plan
Human Performance Monitoring	Implementation Plan

*The staff notes that for the staffing and qualifications activity, the applicant did not provide an IP but rather a technical report, summary-level document. Nonetheless, the information provided in the document contained detail sufficient to warrant an IP level of staff review.

18.0.5 Inspections, Tests, Analyses, and Acceptance Criteria

The applicant has identified inspection, test, analysis, and acceptance criteria (ITAAC) for each HFE element that has an IP, with the exception of the Procedures and Training elements which do not have ITAAC because they are operational programs¹ and the Human Factors Engineering Program Management element because the staff reviewed it at a complete element level. The ITAAC are contained in the Final Safety Analysis Report (FSAR) Tier 1, Section 3.4, "Human Factors Engineering." The staff's evaluation of these ITAAC is discussed in Section 14.3.9 of this report. The acceptance criteria of the ITAAC are linked closely to the IPs. Since the key technical information for each HFE element is contained in the associated IP and the acceptance criteria of the ITAAC are linked to the IP, each IP is designated as Tier 2*. This designation prohibits changes to the IP without prior NRC approval. The expiration date of the Tier 2* designation is after completion of the IP and related ITAAC, typically upon a Commission finding on ITAAC in accordance with 10 CFR 52.103(g), "Operation under a combined license."

18.0.6 Use of Design Acceptance Criteria for Human Factors Engineering

For the review of design certification applications, the staff uses design acceptance criteria (DAC), as described in SECY-92-053, "Use of Design Acceptance Criteria during 10 CFR Part 52 Design Certification Reviews," February 19, 2002. DAC are considered a special kind of ITAAC and are used in lieu of detailed design information in the HFE area. The staff uses the DAC process because providing detailed design information is not practicable for applicants using technologies that change so rapidly that the design may have become obsolete between the time the NRC certifies the design and the time a plant is eventually built. For Chapter 18 of this report, the use of the acronym ITAAC refers to all ITAAC including DAC.

18.1 Human Factors Engineering Program Management

18.1.1 Regulatory Criteria

HFE Program Management (HFEPM) is evaluated based on the criteria provided in NUREG-0711, Chapter 2, "HFE Program Management," Section 2.4, "Review Criteria," and SRP Section 18.II.A.1. Specifically, the staff confirms that the design certification applicant has provided an HFE program that, if properly implemented, will ensure that an applicant (for a design certification or combined license (COL)) has an HFE design team with the responsibility, authority, placement within the organization, and composition to verify that the design commitment to HFE is met. Also, the staff confirms that the HFE program contains a plan to guide the team to provide reasonable assurance that the HFE program is properly developed, executed, overseen, and documented. Additionally, the staff confirms that this plan describes the technical program elements that are relied upon to ensure that all aspects of the HSI, procedures, and training are developed, designed, and evaluated based on accepted HFE principles.

¹ Commission guidance: SECY-02-0067, "Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) for Operational Programs (Programmatic ITAAC)," April 15, 2002; SECY-04-0032, "Programmatic Information Needed for Approval of a Combined License Without Inspections, Tests, Analyses and Acceptance Criteria," February 26, 2004; SECY-05-0197, "Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria," October 28, 2005; and the respective Staff Requirements Memoranda.

18.1.2 Summary of Technical Information

HFPEM is described in FSAR Tier 2, Section 18.1, "Human Factors Engineering Program Management." This section incorporates by reference "U.S. EPR HFE Program Management Plan," December 16, 2010 (referred to as the HFPEM IP). The staff reviewed the HFPEM IP along with the following U.S. EPR documents:

- FSAR Tier 2, Section 18.1
- AREVA NP, Inc., Quality Assurance Plan (QAP) for Design Certification of the U.S. EPR Topical Report, Revision 2, December 2008 (ANP-10266)

The staff focused its review on evaluating the above information with respect to the review criteria in NUREG-0711, Chapter 2, and SRP Section 18.II.A.1.

18.1.3 Staff Evaluation

The staff performed a complete element level review as described in NUREG-0711 and Section 18.0.4 of this report. The staff evaluated the area of HFPEM based on the applicable review criteria in NUREG-0711, Section 2.4 for this element (reproduced below).

HFPEM review topics include the following:

- General HFE program goals and scope (six review criteria)
- HFE team and organization (four review criteria)
- HFE process and procedures (six review criteria)
- HFE issues tracking (four review criteria)
- Technical program (three review criteria)

18.1.3.1 *General HFE Program Goals and Scope*

NUREG-0711 includes six criteria for this topic. The sixth criterion addresses plant modifications and is not applicable to new reactors, thus the staff evaluated the first five criteria as discussed below.

Criterion 1

HFE Program Goals – The general objectives of the program should be stated in 'human-centered' terms, which, as the HFE program develops, should be defined and used as a basis for HFE test and evaluation activities. Generic 'human-centered' HFE design goals include the following:

- personnel tasks can be accomplished within time and performance criteria
- the HSIs, procedures, staffing/qualifications, training and management and organizational support will support a high degree of operating crew situation awareness

- the plant design and allocation of functions will maintain operation vigilance and provide acceptable workload levels i.e., to minimize periods of operator underload and overload
- the operator interfaces will minimize operator error and will provide for error detection and recovery capability

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.1.1.1, "Goals," indicates that the goal of the HFE program is to provide task support and safe and efficient access to control plant processes and equipment. HFEPM IP, Section 2.1 expands this to state, "the goal of the HFE program is to provide the plant operators and technicians with task support and access to the information required...[and] establishes the time and performance criteria for required equipment operations via human reliability analyses and recognized guidelines." This statement expands upon the guidance provided by NUREG-0711. The applicant continues by committing to the HFE goals as stated in NUREG-0711.

The applicant's goals may serve as the basis for HFE test and evaluation activities. As stated in the HFEPM IP, the goals of the plan are stated in terms relative to the performance of the plant personnel with respect to performance time, potential for error, workload, vigilance and error. These are presented in human-centered terms and address the four directives given in the NUREG-0711 guidance. As written, these goals can serve as high level HFE objectives for tests and evaluations. Accordingly, the staff finds FSAR Tier 2, Section 18.1.1.1, and the HFEPM IP treatment of this criterion acceptable.

Criterion 2

Assumptions and Constraints - An assumption or constraint is an aspect of the design, such as a specific staffing plan or the use of specific HSI technology that is an *input* to the HFE program rather than the result of HFE analyses and evaluations. The design assumptions and constraints should be clearly identified.

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.1.1.2, "Assumptions and Constraints," presents a discussion of the assumptions underlying the HFE program. The assumptions provided include discussion of: staffing levels in the main control room (MCR) (which references FSAR Tier 2, Section 18.5, "Staffing and Qualifications"); selection of the safety information and control system (SICS) and process information control system (PICS), which occurred prior to full definition of HFE design-specific attributes so development activities have not been based on HFE design-specific attributes; the SICS platform, which is centered on use of the qualified display system (QDS); and integration of the local control stations (LCSs) with PICS to minimize differences in human machine interface (HMI) platforms in control rooms.

FSAR Tier 2, Section 18.1.1.2 states that further assumptions and constraints are provided in HFEPM IP, Section 2.2, "Design Assumptions and Constraints." HFEPM IP, Section 2.2 states that these assumptions do not represent the results of evaluations or analyses but are used as input in the HFE Program, as well as for HSI and control room design. Following this section are subsections covering multiple aspects of the plant design: Standard Design Features, Main Control Room, Technical Support Center (TSC), remote shutdown station (RSS),

Instrumentation and Control Service Center (I&CSC), HSI, Process Information and Control System, Plant Overview Panel, Safety Information and Control System, Alarm System, Instrumentation and Control (I&C) Architecture, and Plant Identification Coding. These subsections provide general or high level information on the location of a feature, the use or operation of the feature, design capabilities, and interaction with other systems or features. HFEPM IP, Section 2.2.2 is titled, "Concept of Operation Assumptions," and the subsections that follow describe the operating philosophy of the plant. These subsections are titled: Section 2.2.2.1, "Staffing," Section 2.2.2.2, "Operating Philosophy," Section 2.2.2.2.1, "Procedures," Section 2.2.2.2.2, "Alarms," Section 2.2.2.2.3, "Normal Operations," Section 2.2.2.2.4, "Abnormal Operations and Incidents," and Section 2.2.2.2.5, "Emergency Operations and Accidents."

In Section 2.2.2, the applicant states that the assumptions identified above are the starting point and are subject to changes based on additional analysis and evaluations during detailed design. Based on this statement, the staff did not find the descriptions represented a commitment to use those features described in Section 2.2.2 and requested additional information from the applicant. In Request for Additional Information (RAI) 348, Questions 18-90 and 18-93, the staff requested that the applicant clarify how and where changes to the assumptions in Section 2.2.2 would be documented. The staff also requested that the applicant indicate if the assumptions and constraints provided are complete as presented or identify any remaining assumptions and constraints being assumed; and clarify the extent to which the information provided in Section 2.2.2 could change during the design process.

In a March 4, 2010, response to RAI 348, Questions 18-90 and 18-93, the applicant stated that changes made to these assumptions can be done throughout the entire HFE analysis and evaluations and that the HFE design process will be followed with changes documented throughout the design process elements. The applicant stated that assumptions could change based on the results of analyses or evaluation; however, the goal is to design the plant as close to the assumptions as possible. The applicant also stated that the assumptions and constraints presented in HFEPM IP, Section 2.2 are complete as presented and deviation from the assumptions is expected to be minimal and properly justified based on information from analyses or evaluations. Deviations are documented in the human engineering discrepancy (HED) process. Assumptions and constraints are, therefore, clearly documented. In addition, as part of the applicant's March 4, 2010, response to RAI 348, Question 18-90, the applicant revised their HFEPM IP, Section 18.1.1.2, "Assumptions and Constraints," to remove the discussion of specific examples of assumptions and constraints described in the first paragraph of the staff's evaluation of this criterion. The staff finds this acceptable because the assumptions and constraints are provided in FSAR Tier 2, Section 18.7.2 and HFEPM IP, Section 2.2. The staff finds the applicant's response to RAI 348, Questions 18-90 and 18-93 acceptable and considers RAI 348, Question 18-93 resolved. **RAI 348, Question 18-90 is being tracked as a confirmatory item** to ensure that the FSAR is revised accordingly.

The staff finds FSAR Tier 2, Section 18.1.1.2 and HFEPM IP treatment of this criterion related to assumptions and constraints affecting the HFE design acceptable.

Criterion 3

Applicable Facilities - The HFE program should address the main control room, remote shutdown facility, technical support center (TSC), emergency operations facility (EOF), and local control stations (LCSs).

Staff Evaluation of Criterion 3

HFEPM IP, Section 2.3.1 states that the HFE Program applies to the design of the MCR, the TSC, the I&CSC, the RSS, and those LCSs that provide computer-based HSI. The applicant states that design of LCSs that provides non-computer based HSI (e.g., manipulation of manual valves) will be accomplished concurrent with the applicable system and following the guidance in the HSI Style Guide developed by the HFE team that provides HFE bases design specifications for the design of the HSI portion of the LCS.

FSAR Tier 2, Section 18.1.1.3, "Applicable U.S. EPR Facilities," indicates that the scope of the HFE program includes the MCR, TSC, RSS, design of the LCSs, and I&CSC. The EOF will be the responsibility of the COL applicant, but the HFE and Control Room Design team provide guidance to that design.

FSAR Tier 2, Section 18.1.1.3 contains COL Information Item No. 18.1-2, from FSAR Tier 2, Chapter 1, Table 1.8-2, "U.S. EPR Combined License Information Items," which states:

A COL applicant that references the U.S. EPR design certification will be responsible for HFE design implementation for a new Emergency Operations Facility (EOF) and/or Operational Support Center (OSC) and changes resulting from the addition of the U.S. EPR to an existing EOF and/or OSC.

Accordingly, the staff finds FSAR Tier 2, Section 18.1.1.3 and HFEPM IP treatment of this criterion acceptable because the applicant has described a program that addresses the applicable facilities that are specified in NUREG-0711.

Criterion 4

Applicable HSIs, Procedures, and Training - The applicable HSIs, procedures, and training included in the HFE program should include all operations, accident management, maintenance, test, inspection and surveillance interfaces (including procedures).

Staff Evaluation of Criterion 4

FSAR Tier 2, Section 18.1.1.4, "Applicable Human Systems Interfaces, Procedures, and Training," provides the scope of the HFE program with respect to these items. FSAR Tier 2, Section 18.1.1.4 includes HSIs, procedures, and training for processes involved in controlling the plant. The plant systems identified in FSAR Tier 2, Section 18.1.1.4 include those for normal operating conditions; tests, inspections, surveillances, and maintenance; and abnormal, emergency and accident conditions, as identified in the criterion. FSAR Tier 2, Section 18.1.1.4 expands on the criterion to identify the PICS, SICS, and LCS. It specifies that the HFE program will apply the appropriate HFE principles and techniques to developing operating procedures and the operator training program.

HFEPM IP, Section 2.4 describes the scope of these elements to include: HSI procedures, and training on system functions to monitor and control plant processes and equipment. The system functions on which personnel are trained include those for normal operating modes and those for tests, inspections, surveillance, and maintenance during abnormal, emergency, and accident conditions. This also includes HSI for PICS, SICS, and LCS. The description states that HSIs for non-I&C systems, such as manual valve operators, will follow guidelines established by the HFE team.

In RAI 348, Question 18-96, the staff requested that the applicant clarify the scope of the HFE Program to state whether HSI associated with non- I&C systems are included in the scope of the IP. In a March 4, 2010, response to RAI 348, Question 18-96 the applicant indicated that the HFE Program covers both I&C and non-I&C systems. Since these are different systems with physically different operating contexts, the applicant has created separate guidance for their design. HFEPM IP, Section 2.4 also states that design of manual valve operators will follow guidelines established by the HFE design team. The staff reviewed the guidelines for non-I&C systems and finds that the application of the HFE Program to all aspects identified in the criterion is clear in both the FSAR and in the HFEPM IP. Based on the applicant's March 4, 2010, response, the staff finds RAI 348, Question 18-96 resolved.

In addition, as part of the applicant's March 4, 2010, response to RAI 348, Question 18-90, the applicant revised HFEPM IP, Section 18.1.1.4, "Applicable Human System Interfaces, Procedures, and Training," to remove the discussion related to procedures and training because these two topics are operational programs and the responsibility of the COL applicant. The staff finds this acceptable because removal of these topics from FSAR Tier 2, Chapter 18 conforms to the NRC position on operational programs. **RAI 348, Question 18-90 is being tracked as a confirmatory item** to ensure that the FSAR is revised accordingly.

The staff finds FSAR Tier 2, Section 18.1.1.4 and HFEPM IP treatment of this NUREG-0711 criterion acceptable.

Criterion 5

Applicable Plant Personnel - Plant personnel who should be addressed by the HFE program include licensed control room operators as defined in 10 CFR Part 55 and the following categories of personnel defined by 10 CFR 50.120: nonlicensed operators, shift supervisor, shift technical advisor, instrument and control technician, electrical maintenance personnel, mechanical maintenance personnel, radiological protection technician, chemistry technician, and engineering support personnel. In addition, any other plant personnel who perform tasks that are directly related to plant safety should be addressed.

Staff Evaluation of Criterion 5

FSAR Tier 2, Section 18.1.1.5, "Applicable Plant Personnel," provides a list of applicable plant personnel defined in 10 CFR Part 55, "Operators' Licenses," and 10 CFR 50.120, "Training and qualification of nuclear power plant personnel." This list includes all the personnel categories defined in NUREG-0711. In HFEPM IP, Section 2.5, "Applicable Plant Personnel," the applicant clearly identifies the requirements of 10 CFR Part 55 and 10 CFR 50.120, as well as calling out all the categories of personnel defined by the criterion. The list covers the categories of personnel discussed in NUREG-0711. The applicant expands on this guidance to include any personnel who perform tasks that impact plant safety. Accordingly, the staff finds FSAR Tier 2, Section 18.1.1.5 and HFEPM IP treatment of this criterion related to applicable plant personnel

acceptable because the applicant has described a program that addresses the applicable plant personnel as specified in NUREG-0711.

18.1.3.2 HFE Team and Organization

Criterion 1

Responsibility - The team should be responsible (with respect to the scope of the HFE program) for (a) the development of all HFE plans and procedures; (b) the oversight and review of all HFE design, development, test, and evaluation activities; (c) the initiation, recommendation, and provision of solutions through designated channels for problems identified in the implementation of the HFE activities; (d) verification of implementation of team recommendations; (e) assurance that all HFE activities comply with the HFE plans and procedures; and (f) scheduling of activities and milestones.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.1.2, "Human Factors Engineering and Control Room Design Team Organization," states that the HFE and Control Room Design Team is responsible for overseeing aspects of the design and construction of the facility that are in accordance with 10 CFR 50.34(f)(3)(vii), and as described in NUREG-0800, Section 13.1.1, "Management and Technical Support Organization."

This information is reiterated in HFEPM IP, Section 3.0, which expands this description of HFE team responsibility. The stated responsibilities include all those provided in NUREG-0711. The scope of the team's responsibility includes the control room design for location and accessibility, layout of the control room, attributes of the physical environment, and layout of workspaces. With respect to HSI design, responsibility includes basic concepts and detailed design for information displays, controls, and alarms for control rooms and control stations; coding and labeling conventions; and design of the screen based HSI, including standardization of the dialogues for access to information and layout. Therefore, the responsibilities of the HFE team, as provided in the plan, are detailed and provide information in accordance with NUREG-0711 guidance. Accordingly, the staff finds FSAR Tier 2, Section 18.1.2 and HFEPM IP treatment of this criterion related to HFE team responsibilities acceptable.

Criterion 2

Organizational Placement and Authority - The primary HFE organization(s) or function(s) within the organization of the total program should be identified, described, and illustrated (e.g., charts to show organizational and functional relationships, reporting relationships, and lines of communication). When more than one organization is responsible for HFE, the lead organizational unit responsible for the HFE program plan should be identified. The team should have the authority and organizational placement to provide reasonable assurance that all its areas of responsibility are accomplished and to identify problems in the implementation of the overall plant design. The team should have the authority to control further processing, delivery, installation, or use of HFE products until the disposition of a nonconformance, deficiency, or unsatisfactory condition has been achieved.

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.1.2, "Human Factors Engineering and Control Room Design Team Organization," states that the HFE and Control Room Design Team is multi-disciplinary and responsible for overseeing aspects of the design and construction of the U.S. EPR in accordance with 10 CFR 50.34(f)(3)(vii), and as described in NUREG-0800, Section 13.1.1, "Management and Technical Support Organization." A description of the organizational placement and authority is provided in HFEPM IP, Section 3.0.

HFEPM IP, Section 3.0 states that the HFE team follows the same design processes as other engineering disciplines. The HFE Engineering Design Lead (EDL) is responsible for HSI integration and control room design for the overall plant design and tracks HFE issues. The EDL also coordinates activities and schedules with the other disciplines. HFEPM IP, Figure 3-1, "HFE Organization," presents the organizational structure, communications and support linkages for HFE with respect to the other project divisions (I&C, LCS design, etc.). Organizational responsibility and communication links are presented in the figure. While the EDL and the Responsible Technical Manager (RTM) communicate, neither has functional responsibility over the other. The EDL is the technical project manager responsible for integration of the HSI and control room design, and for tracking HFE issues. This provides the HFE team authority and placement to provide reasonable assurance that problem areas of implementation are accomplished and to identify problems in the implementation, because the EDL reports to the Manager of U.S. EPR Integration and communicates with the Manager of the U.S. EPR Project, while the RTM reports independently to the Manager of I&C Engineering. The EDL is responsible for coordinating activities with multiple disciplines and managing schedules. Since the EDL is responsible for providing budget, schedule, and oversight of the technical details of the U.S. EPR design, there is reasonable assurance that the EDL has sufficient authority to control processing, delivery, installation, and use of HFE products until nonconformance, deficiency, or unsatisfactory condition has been achieved. Accordingly, the staff finds FSAR Tier 2, Section 18.1.2, and HFEPM IP treatment of this criterion related to organizational placement and authority of the HFE team acceptable.

Criterion 3

Composition - The HFE design team should include the expertise described in the Appendix [to NUREG-0711].

Staff Evaluation of Criterion 3

FSAR Tier 2, Section 18.1.2 states that the HFE and Control Room Design Team is multi-disciplinary. The expertise described in NUREG-0711, Appendix A is adopted by the HFEPM IP. The HFE design team provides expertise in project management, systems engineering, nuclear engineering, I&C, architecture engineering, human factors, plant operations, procedure development, computer systems, training, system safety engineering, maintenance/inspection, and reliability/availability engineering. The FSAR Tier 2, Section 18.1.2 description indicates that the minimum qualifications presented in NUREG-0711 will be satisfied collectively by the team, in compliance with the criteria in NUREG-0711. HFEPM IP, Figure 3-3, "HFE Team Composition," illustrates the areas of expertise held between HFE team members and HFE management. While the description states that greater emphasis is placed on experience than on education, the team members will also have the education that is called for by NUREG-0711. Accordingly, the staff finds FSAR Tier 2, Section 18.1.2 and HFEPM IP treatment of this criterion related to HFE team composition acceptable.

Criterion 4

Team Staffing - Team staffing should be described in terms of job descriptions and assignments of team personnel.

Staff Evaluation of Criterion 4

HFEPM IP, Section 3.4, "Team Staffing," describes team assignments and job descriptions for the U.S. EPR project. The description states that job descriptions and team assignments evolve as the project progresses. The HFE Team is divided into analysis and design functions, each with a supervisor. The analysis supervisor is responsible for planning and analysis of operating experience review (OER), functional requirements analysis and function allocation (FRA/FA), task analysis (TA) (to include staffing and qualifications), and human reliability analysis (HRA). The design supervisor is responsible for system platform design and equipment specifications, HSI layout, control room layout, and serves as the interface with other disciplines that have a relationship with control room design (e.g., Heating Ventilation Air Conditioning (HVAC), radiological protection, etc.). Senior team members are system engineers or system managers for each of the control rooms and HSI platforms in the HFE program. These managers perform the analysis and design of their portion of the design. Other members serve as support, task managers, and program managers as needed. The HFE Responsible Technical Manager integrates these activities and provides program level documentation.

Job descriptions for the HFE design and HFE Analysis Supervisors are provided in terms of high level work responsibilities. System managers' jobs are described in general terms as responsible for the general activities of their designs. High level responsibilities associated with team positions (e.g., provides input to the design of HSI equipment) are given; however, assignment of team members to tasks was not clear. In RAI 348, Question 18-99, the staff requested that the applicant provide more information to understand the job descriptions and assignments of team members with respect to team member skills and qualifications for the various HFE element activities. The staff also requested that the applicant link team member qualifications to job descriptions and assignments of the HFE elements. In a March 4, 2010, response to RAI 348, Question 18-99, the applicant stated that the qualifications of the personnel assigned to each task are described within the various implementation plans. This response was determined to be unacceptable by the staff.

In a March 4, 2010, response to RAI 348, Question 18-90, the applicant expanded the information provided in HFEPM IP, Figure 3-2, "HFE Qualification / Task Matrix," to show the relationships between HFE team assignments and qualifications. The changes made to the figure and accompanying text in HFEPM IP, Revision 2 are sufficient for describing the team staffing considerations because the job descriptions and team personal assumptions are in accordance with the NUREG-0711 criterion. Since the FSAR changes associated with RAI 348, Question 18-90 have not been submitted to the NRC as final, **RAI 348, Question 18-90 is being tracked as a confirmatory item** to ensure that the FSAR is revised accordingly. The staff considers RAI 348, Question 18-99 resolved because the applicant explained in its response to RAI 348, Question 18-90 how team member qualifications are linked to job descriptions and HFE element assignments using Figure 3-2. Accordingly, the staff finds FSAR Tier 2, Section 18.1.2 and HFEPM IP treatment of this criterion related to HFE team staffing acceptable because the applicant has provided a program that describes team staffing as specified in NUREG-0711.

18.1.3.3 *HFE Process and Procedures*

Criterion 1

General Process Procedures - The process through which the team will execute its responsibilities should be identified. The process should include procedures for:

- assigning HFE activities to individual team members
- governing the internal management of the team
- making management decisions regarding HFE
- making HFE design decisions
- governing equipment design changes
- design team review of HFE products

Staff Evaluation of Criterion 1

HFEPM IP, Section 4.0, "HFE Process and Procedures," states that the HFE team responsibilities include development of procedures, guidelines, and HFE documentation. HFEPM IP, Figure 4-2, "HFE Program Implementation," relates each element activity to its responsible organization. HFEPM IP, Section 4.0 states that team assignments are included in HFE work plans that are developed and maintained by the HFE team under the direction of the RTM. The HFE work plans govern procedures for equipment design changes and design review boards. Work plans address assignments in terms of roles and responsibilities for activities, internal management of the team, management decisions regarding HFE, workflow including required input and methods, work product, and review of the work.

HFEPM IP, Section 4.0 states that the HSI and control room will be designed in accordance with Topical Report ANP-10266, Revision 2, "AREVA NP, Inc. Quality Assurance Plan (QAP) for Design Certification of the U.S. EPR Topical Report," December 17, 2008. The staff reviewed the QAP in ANP-10266 and for the following reasons, finds that it provides overall QA for the program. In ANP-10266, the responsibility to identify quality problems, initiate, recommend or provide solutions to identified problems, verify the implementation of solutions, and control processing, delivery, or installation of non-conforming items is assigned to the QA organization. The QA organization has access to all levels of management to resolve problems, and the responsibility to bring problems that cannot be resolved at its level to higher management. The information covered in the work plans includes the information specified by the above criterion and extends the scope to include descriptions of the work product, individual HFE review, and HFE input. However, the staff determined that more information was needed to address assignment of HFE activities. As indicated in RAI 348, Question 18-99, the staff requested that the applicant provide information defining team assignments in terms of qualifications and how tasks are assigned to HFE team members.

In a March 4, 2010, response to RAI 348, Question 18-99, the applicant expanded the explanations provided in HFEPM IP, Figure 3-2, "HFE Qualification / Task Matrix," to show the relationships between HFE team assignments and individual qualifications. The changes made to the figure and accompanying text in HFEPM IP, Revision 2 are sufficient for describing how

the team will execute its responsibilities in response to this NUREG-0711 criterion. Therefore, the staff considers RAI 348, Question 18-99 resolved. Accordingly, the staff finds FSAR Tier 2, Section 18.1.3 and the HFEPM IP treatment of this criterion to describe the process through which the HFE team will execute its responsibilities acceptable.

Criterion 2

Process Management Tools - Tools and techniques (e.g., review forms) to be utilized by the team to verify they fulfill their responsibilities should be identified.

Staff Evaluation of Criterion 2

HFEPM IP, Section 3.0, "HFE Team and Organization," states that the HFE team is required to follow the same design process as the other engineering disciplines and is accountable for the quality of its work in accordance with the QA Process. Tools identified for process management include design documentation, verification checklists, upgrade lists (a method to track open items in design documents), and plant level design freezes (in which no further changes are made to all or a portion of the design until a set milestone is reached). Other tools are provided in the implementation plans and work plans, described under the previous criterion. HFE requirements are documented in the implementation plans, System Design Requirements Documents (SDRDs), and HSI Style Guide. In HFEPM IP, Section 4.1, "General Process Procedures," the description also indicates that design review boards are used, where applicable.

Design verification is also addressed in the design control process (discussed in HFEPM IP, Section 4.5.1, "U.S. EPR Design Control"), which is part of the QA Process. The staff reviewed the QA provisions in ANP-10266, "Quality Assurance Process (QAP)," that are specified for Program Management Tools. The design control process is used for design verification and analysis activities, which are also covered in the QA process. ANP-10266 indicates that verification methods include independent review of analyses, as well as verification testing, and that calculations can be used to establish or verify design bases.

The QAP also discusses the use of prototypes (paper representations) of the HSI, mockups (virtual representations using computer-aided design software (CAD) software and physical representations), and simulations of the full system for evaluation and verification of designs. The tools identified in the QAP to verify and evaluate design completeness are varied and available to designers and reviewers at multiple times during the design process. The level of available prototyping, mock up, and simulation would increase during the design process. Techniques also include calculations. The staff reviewed the QAP to assess these tools. ANP-10266 states that Design Review Boards must document comments, and the responsible technical manager must resolve them as necessary to close out the design review. ANP-10266 further states that documents are reviewed by a qualified reviewer other than the document preparer. Design analyses and calculations are documented in a manner to allow independent verification, and are independently reviewed. The QAP describes a variety of tools and techniques to be used by the team in satisfying their assigned responsibilities.

The descriptions provided in the QAP identify tools and techniques for use by the team to verify they fulfill their responsibilities and are satisfactory to meet this NUREG-0711 criterion for providing the necessary process management tools. Accordingly, the staff finds FSAR Tier 2, Section 18.1.3 and HFEPM IP treatment of this criterion acceptable.

Criterion 3

Integration of HFE and Other Plant Design Activities - The integration of design activities should be identified, that is, the inputs from other plant design activities to the HFE program and the outputs from the HFE program to other plant design activities. The iterative nature of the HFE design process should be addressed.

Staff Evaluation of Criterion 3

FSAR Tier 2, Section 18.1.3.2, "Integration of HFE with Other Plant Design Activities," addresses integration of HFE activities with other engineering processes and activities. FSAR Tier 2, Section 18.1.3.2, indicates that the HFE and Control Room Design Team follows the same design processes as other engineering disciplines, and verifies its work in accordance with the QAP. FSAR Tier 2, Section 18.1.3.2 states that while I&C engineering develops I&C designs, HFE integrates the designs with the HSI, and designs and creates the layout of the control rooms in an iterative process.

HFEPM IP, Section 4.3, "Integration of HFE and Other Plant Design Activities," states that system interface documents produced by system discipline engineers, will be used to coordinate among disciplines for systems, structures, and components whose design bases cross multiple engineering disciplines. HSI engineering activities are integrated via cross discipline review and system interface documents. The HFE team integrates I&C system designs with control room layout and design.

In RAI 348, Question 18-101, the staff requested that the applicant clarify how the HFE team incorporates information from the I&C design organization, as well as from other engineering disciplines. In a March 4, 2010, response to RAI 348, Question 18-101 the applicant indicated that the system description documents (SDDs) are the engineering interface documents. These documents provide information on any one system for each of the design disciplines. The information included in the SDDs conforms to the SDD writer's guide, which is also used to confirm that all design bases are included. This technique provides reasonable assurance that the inputs from other design activities will be identified for the HFE program and allows for the iterative nature of the process. FSAR Tier 2, Figure 18.1-1, "HFE Program Milestones," identifies HFE activities and their relative schedules.

The QAP (ANP-10266) also provides a design control process that integrates design control measures, provides for coordination among participating design organizations, and provides for the review, approval, release, distribution, and revision of design documents. The HFEPM IP identifies the following documents as inputs to the HFE design: Plant technical requirements, system design requirements, system descriptions, design drawings, design analyses, computer program documentation, and specifications and procedures.

To determine how the applicant addressed the iterative nature of the design process, in RAI 349, Question 18-99, the staff requested that the applicant provide information defining how the HFE program elements are iterative with respect to the program milestones. In a March 4, 2010, response to RAI 348, Question 18-99, the applicant expanded the explanations provided in HFEPM IP, Sections 4.3, "Integration of HFE and Other Plant Design Activities," and 4.4, "HFE Program Milestones." To better emphasize the inclusion of other disciplines in the iterative design process and how the process itself is iterative, the applicant enhanced HFEPM IP, Figure 4-2, "HFE Program Implementation," using an improved color-coding scheme. The changes made to Figure 4-2, and accompanying text in HFEPM IP, are sufficient for describing the iterative nature of the HFE Program elements referred to above. Therefore,

the staff considers RAI 348, Question 18-99 resolved. Since the applicant integrates other disciplines into the HFE design process, as discussed above, and also describes the iterative nature of that process, the staff finds FSAR Tier 2, Section 18.1.3 and HFEPM IP treatment of this criterion related to integrating HFE and other design activities acceptable.

Criterion 4

HFE Program Milestones - HFE milestones should be identified so that evaluations of the effectiveness of the HFE effort can be made at critical check points and the relationship to the integrated plant sequence of events is shown. A relative program schedule of HFE tasks showing relationships between HFE elements and activities, products, and reviews should be available for review.

Staff Evaluation of Criterion 4

FSAR Tier 2, Section 18.1.3.3, "HFE Program Milestones," addresses identification of milestones to evaluate the effectiveness of the HFE program. FSAR Tier 2, Figures 18.1-1, "Human Factors Program Milestones," and 18.1-2, "HFE Design Control Process," provide a graphical representation of the relative timeline of activities, relationships of activities, and products that are used as input into other activities. In the HFEPM IP, a relative timeline of the HFE program is provided in Figure 4-1, "Human Factors Program Timeline." These milestones can serve as validation points for the effectiveness of the HFE program until a design certification is referenced by a COL applicant. The cited figures in the FSAR and HFEPM IP address the information requested in the NUREG-0711 criterion. Accordingly, the staff finds FSAR Tier 2, Section 18.1.3 and HFEPM IP treatment of this criterion related to HFE program milestones acceptable.

Criterion 5

HFE Documentation - HFE documentation items should be identified and briefly described along with the procedures for retention and access.

Staff Evaluation of Criterion 5

HFEPM IP, Section 4.5, "HFE Process and Documentation," provides descriptions of the documentation used for HFE and control room design. The documentation includes plant technical requirements, system design requirements, system descriptions, design drawings, design analyses, computer program documentation, specifications, and procedures. Revisions to these documents are considered design changes and require the same approval process as the original documents. Brief descriptions of all of these documents are included. These documents are primarily retained in the Record Management System (with the exception of the design drawings, which are included in the SDD or other HFE documentation). These documents are controlled in accordance with the QAP (ANP-10266). Document control is discussed in QAP, Section 6.0, and includes updating, accumulating, and distributing design control documents, along with other document types, including procurement documents. Documents are distributed to and used by personnel performing quality related work. Measures are established to ensure that documents are reviewed for adequacy and approved for release by authorized personnel to individuals and locations that rely upon the documents for work activities. Documents are released via Document Release Notices or Applicable Document Lists. Document control is performed, for example, in accordance with 10 CFR Part 50, Appendix B, Criterion VI, "Document Control," and ANSI/ASME NQA-1-1994, Basic Requirement 6, "Document Control." Accordingly, the staff finds FSAR Tier 2, Section 18.1.3

and the HFEPM IP treatment of this criterion related to HFE documentation acceptable because the applicant has described a program for HFE documentation that is in accordance with NUREG-0711.

Criterion 6

Subcontractor HFE Efforts - HFE requirements should be included in each subcontract and the subcontractor's compliance with HFE requirements should be periodically verified.

Staff Evaluation of Criterion 6

FSAR Tier 2, Section 18.1.3.5, "Subcontractor HFE Efforts," states that subcontractor HFE efforts are subject to the QAP provisions, just as are other subcontractor efforts. HFEPM IP, Section 4.6, "Subcontractor HFE Efforts," indicates that suppliers (subcontractors) will ensure that their products meet the specifications of the procurement documents. With regard to subcontractor HFE efforts, HFE requirements are included in each contract through the equipment specifications. The applicant's HFE Responsible Technical Manager (RTM) approves and is ultimately responsible for any work products from the HFE Team. Accordingly, the staff finds FSAR Tier 2, Section 18.1.3 and HFEPM IP treatment of this criterion related to subcontractor HFE efforts acceptable because the applicant has described a program for subcontractor-related HFE efforts that is in accordance with NUREG-0711.

18.1.3.4 *HFE Issues Tracking*

Criterion 1

Availability - A tracking system should be available to address human factors issues that are (a) known to the industry (defined in the Operating Experience Review element, see [Section 18.2 of this report] and (b) identified throughout the life cycle of the HFE aspects of design, development, and evaluation. Issues are those items that need to be addressed at some later date and thus need to be tracked to provide reasonable assurance that they are not overlooked. It is not necessary to establish a new system to track HFE issues that is independent from the rest of the design effort. An existing tracking system may be adapted to serve this purpose (such as a plant's corrective action program (CAP)).

Staff Evaluation of Criterion 1

HFEPM IP, Section 5.0, "HFE Issues Tracking," states that the HFE Tracking Database will be used throughout the development cycle to identify and track outstanding HFE issues. Issues that meet or exceed the threshold established by the design team are entered into the HFE Tracking Database. Inputs to the HFE Tracking Database include HEDs, Design Review Board results, and cross-discipline reviews not incorporated by the design process. Supporting documentation may also be entered in the database. For each issue, the HFE Tracking Database documents include: Date the issue was entered; any supporting information such as attachments documenting the issue; assigned issue evaluator and issue owner; proposed resolutions; design team acceptance/rejection; actual resolutions; actions taken; and affected documents. Deviations from the standard design are identified for the design review and issue resolution process. This database is administered and managed by the RTM with assistance from a database administrator. The database administrator does not have to be a member of the HFE team. Others who provide input to the system include the issue initiator, issue

evaluator, and issue owner. The staff concludes that use of the HFE tracking database is an acceptable method to identify and track issues throughout the design cycle because the database is designed to track issues identified from operating experience and the corrective action program. In particular, input of HEDs to the HFE Tracking Database, which is used to track HEDs identified in other elements of the design process, will provide a means for issues to be identified throughout the life cycle of design and development, and provides reasonable assurance that issues will be tracked and followed until resolution and closure. Accordingly, the staff finds FSAR Tier 2, Section 18.1.4 and HFEPM IP treatment of this criterion related to the availability of an HFE tracking system acceptable because the applicant has provided a description of an HFE tracking system that is in accordance with NUREG-0711.

Criterion 2

Method - The method should document and track HFE issues from identification until the potential for negative effects on human performance has been reduced to an acceptable level.

Staff Evaluation of Criterion 2

HFEPM IP, Section 5.0 states that identified issues will be entered into the HFE Tracking Database, which is available throughout the lifecycle of the HFE program for the U.S. EPR. Any deviation from or non-compliance with HFE guidelines would be identified for the design review and resolution process. Anyone associated with the design effort can identify an issue for review at any time. HFEPM IP, Section 5.2, "Method," discusses the method for identification, tracking, and resolution of the issue. The method indicates that the issue remains open in the HITS until it is resolved to the satisfaction of the Responsible Technical Manager with assistance from the Issue Evaluator and Issue Owner. Issue closeout with proper documentation calls for approval from both the RTM and the HITS Administrator. The applicant has provided a method, as described in the HFEPM IP, that documents and tracks HFE issues from identification until the potential for negative effects on human performance has been reduced to an acceptable level. Accordingly, the staff finds FSAR Tier 2, Section 18.1.4 and HFEPM IP treatment of this criterion related to the HFE tracking system method acceptable.

Criterion 3

Documentation - Each issue or concern that meets or exceeds the threshold established by the design team should be entered into the system when first identified, and each action taken to eliminate or reduce the issue or concern should be thoroughly documented. The final resolution of the issue should be documented in detail, along with information regarding design team acceptance.

Staff Evaluation of Criterion 3

HFEPM IP, Section 5.3, "Documentation," identifies the information that is documented and tracked for each issue that is entered into the database. For each issue, the following fields are documented:

- Date the issue was entered
- Any supporting information, such as attachments documenting the issue
- Assigned issue evaluator and issue owner

- Proposed resolutions
- Design team acceptance/rejection
- Actual resolutions
- Actions taken
- Affected documents

In addition, the staff notes that the database can document more than one possible solution for the issue as applicable, as well as the process taken to resolve the issue and details of the implemented solution, including its relation to other documents. The description indicated that anyone can identify an issue to be documented. Any deviation from or non-compliance with the HFE guidelines are documented as issues for resolution. Accordingly, the staff finds FSAR Tier 2, Section 18.1.4 and HFEPM IP treatment of this criterion related to HFE design issue documentation acceptable because the applicant has provided a description of a document database that is in accordance with NUREG-0711.

Criterion 4

Responsibility - When an issue is identified, the tracking procedures should describe individual responsibilities for issue logging, tracking and resolution, and resolution acceptance.

Staff Evaluation of Criterion 4:

HFEPM IP, Section 5.4, "Responsibility," addresses the responsibilities of those personnel involved in the resolution and tracking of issues. The identified personnel include the RTM, Database Administrator, Issue Initiator, Issue Evaluator, and Issue Owner. Individual responsibilities for each role are identified in HFEPM IP, Section 5.4, and the relationships between the roles are clear. Accordingly, the staff finds FSAR Tier 2, Section 18.1.4 and HFEPM IP treatment of this criterion related to individual responsibilities for the tracking system acceptable because the applicant has described a process for individual responsibilities related to tracking and resolving HFE issues that is in accordance with NUREG-0711.

18.1.3.5 *Technical Program*

NUREG-0711 includes five criteria for this topic. The fourth and fifth criteria address plant modifications and are not applicable to new reactors, thus only the first three criteria are evaluated below.

Criterion 1

The general development of implementation plans, analyses, and evaluation of the following should be identified and described:

- operating experience review
- functional requirements analysis and function allocation
- task analysis

- staffing and qualifications
- human reliability analysis
- HSI design
- procedure design
- training design
- human factors verification and validation
- design implementation
- human performance monitoring

Staff Evaluation of Criterion 1

HFPEM IP, Section 6.1, "Implementation Plans, Analyses, and Evaluations," describes the development of implementation plans for each of the programmatic elements stated in the criterion in accordance with the HFE process specified in NUREG-0711. The stated purposes of the IPs are to provide the interface among the elements, objectives and scope of the element, methods for implementing the elements, and generation of results and documentation for each element. IPs will guide definition of HFE requirements; design of HSI and control room layouts, operating procedures, and development of training materials; and design, validation, implementation, and monitoring. FSAR Tier 2, Figure 18.1-2 depicts the development of the IP for the Design Control process. The IP for each element contains the process to define how its content will be evaluated.

HFPEM IP, Section 4.5.6, "Design Analyses," discusses the use of design analyses to assess results from OER, FRA/FA, Task Analysis (including staffing and qualifications), and HRA. Descriptions of the analyses and evaluations used to address each programmatic element are included and reviewed as appropriate in each element's IP. Accordingly, the staff finds FSAR Tier 2, Section 18.1.5 and HFPEM IP treatment of this criterion related to the general development of implementation plans acceptable because the applicant has provided a program for preparing implementation plans that is in accordance with NUREG-0711.

Criterion 2

The HFE requirements imposed on the design process should be identified and described. The standards and specifications that are sources of HFE requirements should be listed.

Staff Evaluation of Criterion 2

HFPEM IP, Section 6.2, "HFE Requirements," states that HFE requirements will be documented in implementation plans, SDRDs, and HFE guidelines such as the HSI Style Guide. This section also provides the high level HFE guidance for the HSI design. HFPEM IP, Sections 6.2.1 thru 6.2.9, provide the high level HFE guidance for environmental aspects of the design (e.g., mechanical properties and dimensions of the work environment).

In RAI 348, Question 18-105, the staff requested that the applicant provide standards and sources of HFE requirements. In a March 4, 2010, response to RAI 348, Question 18-105, the applicant indicated that the sources of HFE requirements (e.g., standards, specifications, etc.), are identified in each of the IPs that are applicable to the specific NUREG-0711 technical topic being addressed. These sources are typically listed as references at the end of each FSAR section or IP. The staff finds this response acceptable to address this NUREG-0711 criterion, and, therefore, considers RAI 348, Question 18-105 resolved. Accordingly, the staff finds FSAR Tier 2, Section 18.1.5 and the HFEPM IP treatment of this aspect of the criterion related to requirements for HFE design acceptable because the applicant has identified and described in the FSAR and associated IP, the HFE requirements that are imposed on the U.S. EPR design process, and identified standards and specifications that are sources for these HFE requirements in a manner consistent with this NUREG-0711 criterion.

Criterion 3

HFE facilities, equipment, tools, and techniques (such as laboratories, simulators, rapid prototyping software) to be utilized in the HFE program should be specified.

Staff Evaluation of Criterion 3

HFEPM IP, Sections 6.3 and 4.2 specify the tools and techniques to be used in the HFE program. FSAR Tier 2, Section 18.1.5.3, "HFE Program Element Documentation," references FSAR Tier 2, Section 18.10, "Verification and Validation," which describes the uses of HFE facilities such as mockups and simulators as well as methods and tools employed for the various testing and validation techniques.

HFEPM IP, Section 6.3, "HFE Facilities, Equipment, Tools, and Techniques," identifies and discriminates among prototypes, mockups, and simulations as tools to be used to provide feedback and evaluation of design solutions. The IP indicates that the tools to be used in this regard include mockups (paper-based, static representations) of components, a part task simulator (simulation of a set or small group of systems and HSI), and a full-scope simulator compliant with ANSI 3.5-2009: Nuclear Power Plant Simulators for Use in Operator Training and Examination.

HFEPM IP, Section 4.2 discusses the use of checklists, upgrade lists, and design level freezes as tools and techniques to be used in the HFE Program. Specific tools and techniques for each HFE programmatic element are specified in the implementation plans identified in Section 6.1 and in the work plans used to support the IP. Accordingly, the staff finds FSAR Tier 2, Section 18.1.5 and HFEPM IP treatment of this criterion related to the use of facilities, equipment, tools, and techniques used in developing the HFE program acceptable because the applicant has specified a process for using these applications that is in accordance with NUREG-0711.

18.1.4 Other Documents Subject to Review

18.1.4.1 *FSAR Tier 1, Section 3.4, "Human Factors Engineering"*

FSAR Tier 1, Section 3.4.1, "Description," provides a high-level discussion of the Human Factors Program Plan. Since HFEPM was reviewed at a completed element level, there are no ITAAC associated with this area. FSAR Tier 1, Table 3.4-1, "Human Factors Engineering

ITAAC,” contains the ITAAC that are proposed for HFE. The staff’s evaluation of these ITAAC is provided in Section 14.3.9 of this report.

18.1.4.2 Related Documents

The staff’s review also included the following documents related to the applicant’s Human Factors Engineering Program FSAR section and IP:

- Inheritance Implementation Plan
- Initial Staffing Assumptions for the U.S. EPR
- Concept of Operations for the U.S. EPR Control Room

18.1.5 Combined License Information Items

Table 18.1-1 provides a list of HFEPM-related COL information item numbers and descriptions from FSAR Tier 2, Table 1.8-2, “U.S. EPR Combined License Information Items”:

Table 18.1-1 U.S. EPR Combined License Information Items

Item No.	Description	FSAR Tier 2 Section
18.1-1	A COL applicant that references the U.S. EPR design certification will execute the NRC-approved HFE program as described in this section.	18.1
18.1-2	A COL applicant that references the U.S. EPR design certification will be responsible for HFE design implementation for a new Emergency Operations Facility (EOF) and/or Operational Support Center (OSC) and changes resulting from the addition of the U.S. EPR to an existing EOF and/or OSC.	18.1.1.3

The staff finds the above descriptions complete. Also, the descriptions adequately describe actions necessary for the COL applicant. No additional COL information items need to be included in FSAR Tier 2, Table 1.8-2 for HFEPM considerations.

18.1.6 Conclusions

The staff evaluated Program Management with respect to HFE, at a complete element level using the review criteria in NUREG-0711, Section 2.4. Section 18.0.4 of this report provides a discussion of review levels. For the reasons set forth above, the staff finds that the applicant’s FSAR and HFEPM IP proposed for the U.S. EPR design certification have identified general HFE program goals and scope, specified an acceptable HFE team and organization, implemented appropriate HFE processes and procedures, developed an HFE issues tracking system, and established an acceptable HFE technical program. As discussed in Section 18.0.5 of this report, the HFEPM IP is designated as Tier 2*, which ensures that the IP will be implemented by the COL applicant. Furthermore, because the HFEPM IP is designated as Tier 2*, the COL applicant cannot make changes to the IP without obtaining prior NRC approval. Therefore, the staff concludes that HFE considerations with respect to program management

have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.

18.2 Operating Experience Review

18.2.1 Regulatory Criteria

HFE operating experience is evaluated based on the criteria provided in NUREG-0711, Chapter 3, "Operating Experience Review," Section 3.4, "Review Criteria," and SRP Section 18.II.A.2. NUREG-0711, Section 3.4 specifies the review criteria that pertain to the staff's evaluation of HFE operating experience. Specifically, the staff confirms that the applicant has identified and analyzed HFE-related problems and issues associated with previous designs that are similar to the current design under review. In this way, negative features associated with predecessor designs may be avoided in the current design while retaining positive features.

18.2.2 Summary of Technical Information

HFE operating experience is described in FSAR Tier 2, Section 18.2, "Operating Experience Review." This section incorporates by reference "U.S. EPR Human Factors Operating Experience Review Implementation Plan," December 16, 2010 (referred to as the OER IP). The staff reviewed the OER IP along with other documents that pertain to the staff's review of HFE operating experience as discussed in the subsections that follow. The staff focused its review on evaluating the information provided based on the review criteria in NUREG-0711, Chapter 3 and SRP Section 18.II.A.2.

18.2.3 Staff Evaluation

The staff performed an implementation plan level of review as described in NUREG-0711 and Section 18.0.4 of this report. This section presents the applicable review criteria from NUREG-0711, followed by an evaluation of each. Operating experience review topics include the following:

- Scope
- Issue Analysis, Tracking, and Review

18.2.3.1 *Scope*

Criterion 1

Predecessor/Related Plants and Systems - The review should include information pertaining to the human factors issues related to the predecessor plant(s) or highly similar plants and plant systems. For a review of plant modifications, the scope of the OER should be focused to provide information relevant to the plants' systems, HSIs, procedures, or training that are being modified. It should address the operating experience of the plant that will be modified, including experiences with the systems that will be modified, and with technologies that are similar to those under consideration for it. Some useful information may be found in the plant's CAP. Also, when personnel are unfamiliar with the proposed technology, attention should be paid to the operating experience of other plants that already have the technology.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.2 states that the operating experience review “associated with HFE identifies HSI design issues that affect safety.” The OER identifies past performance information from earlier designs. Performance information from predecessor designs is identified at the start of the design process and used to improve the plant design.

The staff reviewed the OER IP, which describes the methodology for conducting, documenting, and tracking OER activities. The OER IP identified that operational and design information are based on the European N4 and Konvoi plants, which are, in turn, based upon Westinghouse pressurized water reactor (PWR) plants currently operating in the U.S. The IP indicates that the U.S. EPR human factors OER will utilize operating experience (OE) obtained from operating plants using similar technology or systems, such as computer based procedure systems as will be implemented by the U.S. EPR design. The IP lists the following applicable data sources: (1) European N4 and Konvoi; (2) highly similar PWR plants; (3) boiling water reactor (BWR) plants using similar systems; and (4) corrective action programs and modernization programs related to HFE issues/challenges that have been experienced with other similar systems at nuclear power plants.

Criterion 1 addresses the use of predecessor designs or similar technology and systems. Since there are no U.S. EPR plants currently operating, the majority of OER will rely on the use of similar operating European plants and currently operating U.S. plants with similar design features. The OER IP calls for data to be captured from licensee event reports (LERs) and NUREG documents for pertinent systems and components that relate to CAP or modernization program considerations. While the applicant cannot rely completely on currently available predecessor information for OER, data that are collected from similar operating plants and systems, and information from LER and CAP can be used in the OER evaluation. Since the applicant provided information pertaining to predecessor plants and highly similar plants to the U.S. EPR design, the staff finds the FSAR and the OER IP treatment of this criterion related to predecessor/related plants and systems acceptable.

Criterion 2

Recognized Industry HFE Issues –NUREG/CR-6400, (Higgins and Nasta, 1996) issues should be addressed. The issues are organized into the following categories:

- unresolved safety issues/generic issues
- TMI issues
- NRC generic letters and information notices
- reports of the former NRC Office for Analysis and Evaluation of Operational Data
- low power and shutdown operations
- operating plant event reports

Staff Evaluation of Criterion 2

OER IP, Sections 3.2.2.1 through 3.2.2.6 address each of the categories given above. The considerations that are addressed by the OER IP in these sections are summarized as follows:

- OER IP, Section 3.2.2.1 lists a variety of unresolved and generic safety issues that will be addressed. These issues include: (1) Station blackout; (2) criteria for safety-related operator actions; (3) reactor coolant pump seal failure; (4) generic implications of the anticipated transient without SCRAM (ATWS) event at the Salem Nuclear Power Plant; and (5) accident management. The resolutions of these safety issues are provided in NUREG-0933, "A Prioritization of Generic Safety Issues," Supplement 31, July 31, 2007. The OER IP includes consideration of these issues in addressing HFE for the U.S. EPR design. The staff finds that the applicant has included unresolved and generic issues in its OER IP which is in accordance with this NUREG-0711 criterion.
- OER IP, Section 3.2.2.2 lists the Three Mile Island nuclear plant issues that will be reviewed for HFE applicability to the U.S. EPR design. These include: (1) High pressure coolant injection and reactor core isolation cooling separation; (2) a study of the automatic depressurization system; (3) selection and display of important safety parameters and their integration into the overall design of the control room; and (4) automatic indication of bypassed and inoperable systems. These TMI items are described in NUREG-0933, and the OER IP includes consideration of these issues in addressing HFE for the U.S. EPR design. Other TMI items that must be addressed in accordance with 10 CFR 50.34 requirements that are not addressed by the OER IP are addressed elsewhere in this report. For example, TMI Action Item I.A.4.2, "Simulator Capabilities," is addressed in Chapter 13, "Conduct of Operations," of this report and Action Item I.C.1, "Guidance for Evaluation and Development of Procedures," is addressed under Section 18.8 of this report. The staff finds that the applicant has included TMI issues in its OER IP that are in accordance with this NUREG-0711 criterion.
- OER IP, Section 3.2.2.3 shows the NRC generic letters (GLs) and information notices (INs) that the applicant reviewed for HFE applicability to the U.S. EPR design. Examples of GLs and INs provided by the applicant include GL 2007-01, "Inaccessible or Underground Power Cable Failures That Disable Accident Mitigation Systems or Cause Plant Transients," and IN 93-81, "Implications of Engineering Expertise on Shift." The staff finds that the applicant has included NRC generic letters and information notices in its OER IP that are in accordance with this NUREG-0711 criterion.
- OER IP, Section 3.2.2.4 addresses performance issues that were identified by the NRC former Office for Analysis and Evaluation of Operational Data (AEOD). The purpose of the AEOD program was, in part, to identify and evaluate human performance issues and to make recommendations as appropriate. Much of the work that was done by AEOD in this area is summarized in NUREG-1275, Volume 8, "Operating Experience Feedback Report: Human Performance in Operating Events," December 1992. The OER IP includes consideration of the issues that are summarized in NUREG-1275, Volume 8, in addressing HFE for the U.S. EPR design. The staff finds that the applicant has included reports of the former NRC Office of Analysis and Evaluation of Operational Data in its OER IP in accordance with this NUREG-0711 criterion.

- OER IP, Section 3.2.2.5 addresses HFE considerations associated with low power and shutdown operations. Issues that have been identified are arranged into the following categories: (1) Outage management and planning; (2) operator training; (3) procedures; (4) instrumentation; (5) equipment; and (6) communication. Operating experience related to low power and shutdown operations is summarized in NUREG-1449, “Shutdown and Low Power Operation at Commercial Nuclear Power Plants in the United States,” September 1993. The OER IP includes consideration of the relevant issues that are summarized in NUREG-1449 addressing HFE for the U.S. EPR design. The staff finds that the applicant has included HFE considerations associated with low power and shutdown operations in the OER IP in accordance with this NUREG-0711 criterion.
- OER IP, Section 3.2.2.6 provides a list of operating plant event reports, their websites, and searchable key words that will be reviewed for applicability to the U.S. EPR design. Event reports containing information related to the following areas are included: (1) Main control room; (2) system insights; (3) component insights; and (4) local control stations. Key words for performing searches include alarms, annunciation, instrumentation failures, displays, normal plant, control/automation, evolutions, job aids, human factors, human errors, transients, communication, accidents, training, HSI equipment, procedures, and process failures. The staff finds that the applicant has addressed operating plant event reports in the OER IP in accordance with this NUREG-0711 criterion.

The scope and extent of the applicant’s OER IP addressed the complete range of industry experience related to HFE, consistent with NUREG/CR 6400 and NUREG-0711. This range includes unresolved safety issues/generic issues; TMI Issues; NRC Generic Letters and Information Notices; reports from the former NRC Office of Analysis and Evaluation of Operational Data, low power and shutdown operations; and operating plant event reports. Accordingly, the staff finds the FSAR and the OER IP treatment of this criterion related to recognized industry issues acceptable.

Criterion 3

Related HFE Technology - The OER should address related HFE technology. For example, if touch screen interfaces or computerized procedures are planned, HFE issues associated with their use should be reviewed.

Staff Evaluation of Criterion 3

OER IP, Section 3.2.3 describes related HFE technology that will be reviewed for addressing this criterion. Because information concerning advanced HFE technology may not be available from predecessor or similar plants, the OER IP also makes use of operating experience from non-nuclear industries. These non-nuclear industries include chemical and fossil plants, the airline industry, and the space industry. The OER IP includes analyses of HFE technology for the following equipment:

- Qualified display systems
- Intelligent computer-based procedures (electronic procedures with links to other documents or that have the capability to check critical operator actions)
- Touch screen interfaces

- Plant overview panels
- Multi-screen displays

OER IP, Section 3.2.3.2 includes a list of databases from which operating experience associated with advanced HFE technology may be derived. This list includes websites for the U.S. Chemical Safety and Hazard Investigation Board, the National Transportation Safety Board (NTSB), and the National Aeronautics and Space Administration (NASA). These databases contain a variety of HFE-related topics including HSI issues, training, communication, procedures, and crisis handling. HFE issues that are identified from the websites of these other industries will be screened and entered into the OER tracking system for the U.S. EPR. The list of industries and databases that are included in the OER IP is comprehensive and includes information that is relevant to HFE and HSI technology. Accordingly, the staff finds the FSAR and the OER IP treatment of this criterion addressing related HFE technology acceptable.

Criterion 4

Issues Identified by Plant Personnel - Personnel interviews should be conducted to determine operating experience related to predecessor plants or systems. The following topics should be included in the interviews as a minimum:

- Plant Operations
 - normal plant evolutions (e.g., startup, full power, and shutdown)
 - instrument failures (e.g., safety-related system logic and control unit, fault tolerant controller (nuclear steam supply system), local “field unit” for multiplexer (MUX) system, MUX controller (balance of plant), break in MUX line)
 - HSI equipment and processing failure (e.g., loss of video display units, loss of data processing, loss of large overview display)
 - transients (e.g., turbine trip, loss of offsite power, station blackout, loss of all feedwater, loss of service water, loss of power to selected buses or control room (CR) power supplies, and safety/relief valve transients)
 - accidents (e.g., main steam line break, positive reactivity addition, control rod insertion at power, control rod ejection, anticipated transients without scram (ATWS), and various-sized loss-of-coolant accidents (LOCAs))
 - reactor shutdown and cooldown using remote shutdown system
- HFE Design Topics
 - alarm and annunciation
 - display
 - control and automation

- information processing job aids
- real-time communications with plant personnel and other organizations
- procedures, training, staffing/qualifications, and job design

Staff Evaluation of Criterion 4

OER IP, Section 3.2.4.1 describes the type of data and information collected from participant observation and operator interviews. The IP recognizes that operators are the best source for identifying design issues that could cause unexpected, inappropriate, or risky actions during plant operation. The OER IP indicates that operators will be interviewed from operating nuclear power plants, decommissioned nuclear power plants, and fossil fuel plants; and that Nuclear Navy operators will also be interviewed. The OER IP discusses topics for which specific questions will be developed. These topics include normal plant evolutions; instrument failures; HSI equipment and processing failures; transients; accidents; reactor shutdown and cooldown using remote shutdown system; alarms and annunciation; operating displays; control and automation; information processing and job aids; real-time communications with plant personnel and other organizations; and procedures, training, staffing/qualifications, and job design.

OER IP, Section 3.2.4.2.1 discusses developing questions for plant operations. For events such as accidents or transients, questions to be developed will assess what plant operators observed, the actions they took and the reasons for those actions, what they may have missed in completing these actions, and why they believed the actions taken were appropriate. The purpose of these questions is to better understand how to handle events and to determine what might be improved in the design.

OER IP, Section 3.2.4.2.2 states that questions will be developed to assess the use of HSI and plant operator experience with specific HSI. The interviewer will listen to solutions proposed by the operators to determine their needs. Suggestions from plant operators for making improvements will be noted for further analysis.

The OER IP calls for specific events of interest to be recreated in a simulation environment. The operators who take part in these simulations will be interviewed and the findings will be noted and adopted to the U.S. EPR design.

The OER IP covers a wide range of interview topics including those given above from NUREG-0711 for this criterion. In addition, the OER IP broadens the scope of operator interviews by also calling for interviews of operators from non-nuclear power plants, as well as from the U.S. Navy. By calling for interviews of plant operators from a variety of plant types and by covering a broad range of interview topics, the OER IP ensures that a complete and comprehensive collection of operator insights will be gathered and included in the HFE assessment for the U.S. EPR design.

Since the application addresses issues identified by plant personnel through the use of personnel interviews in accordance with the applicable NUREG-0711 criterion, the staff finds the FSAR and the OER IP treatment of this criterion related to conducting personnel interviews acceptable.

Criterion 5

Risk-Important Human Actions - The OER should identify risk-important HAs that have been identified as different or where errors have occurred. The human actions should be identified as requiring special attention during the design process to lessen their probability.

Staff Evaluation of Criterion 5

OER IP, Section 3.2.5 “identifies human actions (HA) that have caused errors in past designs. Risk-important HA are defined as actions that are performed by plant personnel that provide a reasonable assurance of safety.” These HAs are analyzed through the HRA/PRA program. The IP states that HAs identified through OER will be entered into the OER tracking database, including the following information which will allow for analysis in the human reliability analysis/probabilistic risk analysis (HRA/PRA) program: (1) The scenario in which the HA was implemented; (2) if the HA was successfully completed, what aspect of the design is implied in the completeness of the action; and (3) root cause analysis for HAs that were unsuccessful.

The OER IP indicates that the term “risk-significant” in relation to HA is described in the HRA IP, and is discussed in Section 18.6 of this report. An HRA is the quantitative assessment of those HA that pose a risk to the safe operation of the plant, and must be analyzed. In OE IP, Section 3.2.5, “Risk-important Human Actions From Existing Nuclear Plants,” the applicant stated:

Risk-important HAs are those actions that if performed incorrectly by plant personnel could impact plant safety. Potentially risk-significant HAs should be provided from HRA/PRA for help in search criteria [Reference 14]. The actions thought to be risk-important are then sent to HRA/PRA for evaluation. This is in accordance with NUREG-0933 Task HF7.

Since the OER IP outlines a set of criteria for collection and analysis of risk important HAs identified during the operating experience collection process that is in compliance with this NUREG-0711 criterion and will reduce the probability of errors in connection with such HAs, the staff finds the FSAR and OER IP treatment of this criterion acceptable.

18.2.3.2 Issue Analysis, Tracking, and Review

Criterion 1

Analysis Content - Issues should be analyzed with regard to the identification of:

- human performance issues, problems, and sources of human error
- design elements that support and enhance human performance

Staff Evaluation of Criterion 1

OER IP, Section 3.3, “Screening Criteria,” and OER IP, Section 3.4, “OE Analysis,” describe a process that the applicant will use to analyze issues associated with human performance issues, problems, and sources of human error. OER IP, Section 4.0 states that the “results of the U.S. EPR OER are used as design input.” The OER IP also calls for development of a

tracking database that is populated with all OE extracted from databases and operator interviews. The tracking database will also include relevant industry history.

Accordingly, the staff finds the FSAR and the OER IP treatment of this criterion related to analysis content acceptable because the applicant has described a process to analyze issues related to human performance, problems, and sources of human error that meets this NUREG-0711 criterion.

Criterion 2

Documentation – The analysis of operating experience should be documented in an evaluation report.

Staff Evaluation of Criterion 2

OER IP, Section 4.1.1 states that an OER report data sheet will be completed for all applicable OE issues. The report data sheet will be created for both HFE and non-HFE issues. The information will then be entered into the tracking system from the data sheet. The tracking system will be available to the entire design team and will include information such as the event date, an abstract of the issue, and applicability to the U.S. EPR design. Once issues are entered into the database, those related to human factors are assigned to an HFE engineer for evaluation. In the evaluation stage, the team will determine if any lessons learned from the issue have already been incorporated into the U.S. EPR design. Those not yet incorporated, will be kept open in the tracking system for resolution during the final design stage.

OER IP, Section 4.2 describes a final summary report outline that discusses the results of the human factors OER, a listing of the databases used for searches, and a list of the documents analyzed. Resolution of significant issues that will be implemented based on the OER review will include a description of the design implementation. The resolutions of issues that will be implemented in the future are given with their planned implementation date and a tracking number. This report is maintained in the applicant's records management system.

Accordingly, the staff finds the FSAR and the OER IP treatment of this criterion acceptable because the applicant will document the analysis of OE in a final summary report outline which satisfactorily addresses this NUREG-0711 criterion.

Criterion 3

Incorporation Into the Tracking System - Each operating experience issue determined to be appropriate for incorporation in the design (but not already addressed in the design) should be documented in the issue tracking system.

Staff Evaluation of Criterion 3

OER IP, Section 4.1 describes a method of collecting, documenting, and tracking both HFE and non-HFE related OE. The use of data sheets for collection of data, and incorporation into the tracking system is in compliance with the guidance found in NUREG-0711 for this criterion. The OER IP calls for the tracking system to be used to monitor and ensure appropriate incorporation of the OE data into preliminary and final stages of the design. A final report will be generated to describe the design changes and will track future design changes. This report will be maintained in the applicant's records management system.

Accordingly, the staff finds the FSAR and the OER IP treatment of this criterion related to incorporating operating experience into the issue tracking system acceptable because the applicant has described a documentation method that is in accordance with NUREG-0711.

18.2.4 Other Documents Subject to Review

18.2.4.1 FSAR Tier 1, Section 3.4, "Human Factors Engineering"

FSAR Tier 1, Table 3.4-1, "Human Factors Engineering ITAAC," contains the ITAAC that are proposed for HFE. The staff's evaluation of these ITAAC is provided in Section 14.3.9 of this report.

18.2.5 Combined License Information Items

There are no COL information items related to this area of review. The staff determined that no COL information items need to be included in FSAR Tier 2, Table 1.8-2, "U.S. EPR Combined License Information Items," for HFE operating experience review.

18.2.6 Conclusions

The staff evaluated OER with respect to HFE, at an IP level using the review criteria in NUREG-0711, Section 3.4. Section 18.0.4 of this report provides a discussion of review levels. The staff determined that the OER IP that is proposed for the U.S. EPR will ensure that plant operating experience is adequately considered and addressed, thereby minimizing HFE-related problems and issues that have occurred in the past. As discussed in Section 18.0.5 of this report, the OER IP is designated as Tier 2* which ensures that the IP will be implemented by the COL applicant. Furthermore, because the OER IP is designated as Tier 2*, the COL applicant cannot make changes to the OER IP without obtaining prior NRC approval. Therefore, the staff concludes that HFE considerations with respect to OER have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.

18.3 Functional Requirements Analysis and Functional Allocation

18.3.1 Regulatory Criteria

HFE functional requirements analysis and functional allocation is evaluated based on the criteria provided in NUREG-0711, Chapter 4, "Functional Requirements Analysis and Function Allocation," Section 4.4, "Review Criteria," and SRP Section 18.II.A.3. NUREG-0711, Section 4.4 specifies the review criteria that pertain to the staff's evaluation of this HFE area of consideration. Specifically, the staff confirms that (1) the applicant has defined the plant's functions that must be performed to satisfy plant safety objectives, and (2) the allocation of those functions to human and system resources has resulted in a role for personnel that takes advantage of human strengths and avoids human limitations.

18.3.2 Summary of Technical Information

HFE functional requirements analysis and functional allocation are described in FSAR Tier 2, Section 18.3, "Functional Requirements Analysis and Functional Allocation." FSAR Tier 2,

Section 18.3.2, "Functional Requirements Analysis Methodology and Results Summary," incorporates by reference, "U.S. EPR Functional Requirements Analysis and Function Allocation Implementation Plan," December 16, 2010 (referred to as the FRA/FA IP). The staff reviewed the FRA/FA IP along with other documents that pertain to the staff's review of HFE functional requirements analysis and functional allocation as discussed in the sections that follow. The staff evaluated the information provided based on the review criteria in NUREG-0711, Chapter 4 and SRP Section 18.II.A.3.

18.3.3 Staff Evaluation

The staff performed an implementation plan level of review as described in NUREG-0711 and Section 18.0.4 of this report. This section presents the applicable review criteria from NUREG-0711 followed by an evaluation of each. Note that the eleventh criterion that relates to this area of review pertains to plant modifications, and is not applicable to new reactor design certifications. Thus, this criterion is not included in the staff's evaluation.

Criterion 1

Functional requirements analysis and function allocation should be performed using a structured, documented methodology reflecting HFE principles. An example functional allocation process and considerations is shown in Figure 4.1 [of NUREG-0711]. The functional requirements analysis and function allocation may be graded based on:

- the degree to which functions of the new design differ from those of the predecessor
- the extent to which difficulties related to plant functions were identified in the plant's operating experience and will be addressed in the new design

Staff Evaluation of Criterion 1

To address this criterion of demonstrating that the functional requirements analysis and functional allocation are performed using a structured, documented methodology incorporating HFE principles, FSAR Tier 2, Section 18.3 begins with a brief introduction defining the activities of FRA and FA and a statement of objectives and scope for each. FSAR Tier 2, Section 18.3.1, "Objectives and Scope," indicates that the purpose of the FRA/FA IP is to establish methods, criteria, and guidance for FRA and FA for the U.S. EPR plant design. FRA identifies those functions that are performed to satisfy plant safety and power generation objectives. The plan describes how those defined functions are allocated among systems and trains, to automatic, group-level, and component-level control in order to meet regulatory requirements. The plan uses FA to capitalize on human abilities and promote situational awareness.

FSAR Tier 2, Section 18.3.2, "Functional Requirement Analysis Methodology and Results Summary," and FRA/FA IP, Section 3.0, further elaborate on the method proposed to conduct a functional requirements analysis. The applicant divides the FRA into three levels of functions: plant functions, system functions, and component functions. The FRA starts with studying system interdependence, interaction, and defense-in-depth at the plant level. Then FRA focuses on the functions assigned to physical plant systems and equipment.

Plant-level FRA (PFRA) and system functional requirements analysis (SFRA) are followed by a system function gap analysis (SFGA). During this process, system functions are identified and

the differences between PFRA and SFGA are mapped to one another. The relationships between plant functions and system functions are then reconciled. The output of this “gap analysis” is used to ensure that plant design goals are met, and that any differences between plant functions and system functions are reconciled as design inputs. The FRA/FA IP includes Figure 3-1, “Overall General Layout of FRA and Gap Analysis,” which graphically explains the methodology. FRA/FA IP, Section 3.1.4, “The Structure,” explains the process that is graphically presented in Figure 3-1, “Overall General Layout of FRA and Gap Analysis.”

The staff finds the FSAR and FRA/FA IP treatment of this criterion for using a structured, documented methodology reflecting HFE principles to perform a functional requirements analysis and functional allocation in the FRA/FA process acceptable because the applicant has provided a documented methodology that is structured in so far as it provides for mapping the PFRA to the SFGA, identifying differences, and reconciling them to ensure plant functions are accomplished. Accordingly, the applicant’s FRA/FA IP treatment of this criterion is in accordance with NUREG-0711.

Criterion 2

The functional requirements analysis and function allocation should be kept current over the life cycle of design development and held until decommissioning so that it can be used as a design basis when modifications are considered. Control functions should be re-allocated in an iterative manner, in response to developing design specifics, operating experience, and the outcomes of ongoing analyses and trade studies.

Staff Evaluation of Criterion 2

FRA/FA IP, Section 1.5.2, states: “Functional requirements analysis and function allocation are kept current over the life cycle of the plant. The design from development through decommissioning is monitored. The FRA/FA results are used as design basis for modifications.”

The staff finds the FSAR and FRA/FA IP treatment of this criterion for keeping the FRA and FA current over the life cycle of the plant and reallocating functions in an iterative manner in the FRA/FA process acceptable because the applicant has provided a structured method to conduct FRA and FA and provided a commitment for keeping the FRA and FA current over the life cycle of the plant in accordance with NUREG-0711.

Criterion 3

A description of the functions and systems should be provided along with a comparison to the reference plants/systems, i.e., the previous plants or plant systems on which the new system is based. This description should identify differences that exist between the proposed and reference plants/systems. Safety functions (e.g., reactivity control) include functions needed to prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. For each safety function, the set of plant system configurations or success paths that are responsible for or capable of carrying out the function should be clearly defined. Function decomposition should start at ‘top-level’ functions where a very general picture of major functions is described, and continue to lower levels until a specific critical

end-item requirement emerges (e.g., a piece of equipment, software, or HA).
The functional decomposition should address the following levels:

- high-level functions [e.g., maintain reactor coolant system (RCS) integrity] and critical safety functions (e.g., maintain RCS pressure control)
- specific plant systems and components

Staff Evaluation of Criterion 3

FSAR Tier 2, Section 18.3.2 provides a high-level summary description of the functional requirements analysis methodology that the applicant proposes to use for designing the HSI for the U.S. EPR. The applicant describes (in the HFEPM IP) the U.S. EPR as an evolutionary PWR design based on years of operation and design experience from the precursor PWR plants (i.e., based on European N4 and Konvoi plants which are in turn based upon Westinghouse-designed PWR currently operating in the U.S.). As stated in FSAR Tier 2, Section 18.1.1.2, the U.S. EPR also uses similar control of system functions and I&C concepts as the predecessor PWRs.

FRA/FA IP, Section 3.1, "Functional Requirements Implementation," provides a more detailed description of the FRA process.

The applicant explains that the FRA process begins early in the design process and starts with identifying top-level plant goals. Critical safety functions are allocated to systems. Plant system configurations or success paths that are responsible for or capable of carrying out the specified functions are defined for all Technical Specification (TS) modes. A hierarchy of functions and accompanying functional decomposition is described which consists of:

- Plant safety functions (e.g., maintain RCS integrity)
- Critical safety functions (e.g., maintain reactor coolant inventory)
- System functions (e.g., control reactivity with boron)
- Specific plant subsystems, structures, and components (e.g., in-containment refueling water storage tank (IRWST))

FRA/FA IP, Figure 3-1 graphically outlines the decomposition process. Additional details concerning the assessment of this criterion can be found below in the staff's evaluation of Criterion 10.

The staff finds the FSAR and FRA/FA IP treatment of the criterion for providing a description of the functions and systems along with a comparison to the reference plants/systems, and functional decomposition, in the FRA/FA process acceptable because the applicant, using both a summary description and graphical representation, has provided a process of functional decomposition that addresses this NUREG-0711 criterion.

Criterion 4

A description should be provided for each high-level function which includes:

- purpose of the high-level function

- conditions that indicate that the high-level function is needed
- parameters that indicate that the high-level function is available
- parameters that indicate the high-level function is operating (e.g., flow indication)
- parameters that indicate the high-level function is achieving its purpose (e.g., reactor vessel (RV) level returning to normal)
- parameters that indicate that operation of the high-level function can or should be terminated

Note that parameters may be described qualitatively (e.g., high or low). Specific data values or setpoints are not necessary at this stage.

Staff Evaluation of Criterion 4

FRA/FA IP, Sections 3.1 and 4.1 address this criterion. FRA/FA IP, Section 3.1.1, explains that FRA analyses are conducted early in the design process and address defense-in-depth, system interdependence, interaction, and diversity. Plant-level FRA activities start with high-level goals of plant safety and economical power generation and progress to increasingly detailed layers of analysis performed to support these top-level goals. Nuclear safety goals are based on defense-in-depth, which employs multiple fission product barriers maintained by critical safety functions. Critical safety functions are allocated to systems, guided by generic design criteria. Plant system configurations, or success paths that are responsible for or capable of carrying out the functions, are defined for all technical specification modes.

As explained in FRA/FA IP, Section 3.1.1, to ensure that all functions that are necessary to safely operate the plant under normal, abnormal, and emergency conditions are identified and important functional considerations are defined, analysts combine the inputs from sources such as: applicable parts of the *Code of Federal Regulations*; regulatory requirements for specific functionality such as defense-in-depth and diversity; post-accident monitoring instrumentation (PAMI); transient and accident mitigation, etc.; industry guidance documents; PWR Owner's Group Emergency Response Guidelines and associated basis documents outlining the functions, functional considerations, and parameter monitoring capabilities necessary to mitigate accidents; PRA/HRA assumptions and results as they relate to the functions and functional considerations that are specified to mitigate transients and accidents that are analyzed by the PRA/HRA; the FSAR and the normal, abnormal, and emergency functions and functional considerations it documents; system design documents and the normal, abnormal, and emergency functions and functional considerations they document; and predecessor plant design functionality and functional considerations. The applicant stated the following in the FRA/FA IP:

These inputs provide multiple, 'overlapping', avenues for analysis of plant and system level functional requirements analysis and determination of applicable requirements. These diverse and detailed analysis inputs provide analytical defense in depth. This analytical depth provides assurance that all functions required for safe operation and all requirements for each function are identified.

FRA/FA IP, Section 3.1.2 explains how plant-level functions are defined hierarchically using inputs from the various source materials. FRA/FA IP Figure 3-1 graphically depicts the process

of defining plant functions, processes, and systems with increasing levels of detail while maintaining the context and relationship of this information to other plant functions, processes, and systems; and explains how this relational context and linkage is maintained and “mapped” within the functional branch tree (FBT) database for all the aspects of each high-level function addressed by this criterion.

FRA/FA IP, Section 4.1, “Functional Requirements Analysis,” provides additional detail on developing the high-level function descriptions.

The staff finds the FSAR and FRA/FA IP treatment of the criterion for describing high-level functions in the FRA/FA process addresses this NUREG-0711 criterion and acceptable because the applicant has provided a detailed description for how high-level FRA/FA functions are developed, with an accompanying graphical representation which, together describe a process for developing the purpose of the of each high level function; conditions that indicate that the high-level function is needed; parameters that indicate the high-level function is available; parameters that indicate that the high-level function is operating; parameters that indicate the high-level function is achieving its purpose; and parameters that indicate that operation of the high-level function can or should be terminated.

Criterion 5

The technical basis for modifications to high-level functions in the new design (compared to the predecessor design) should be documented.

Staff Evaluation of Criterion 5

FRA/FA IP, Section 3.1.5 describes the process and considerations for making modifications to high-level functions of the U.S. EPR compared to the predecessor design. The IP explains that functional requirements analysis is done for all functions of the U.S. EPR design. When a modification is being entertained, the applicant considers the original design to be the only predecessor, by definition, for modifications. The applicant considers the following as bases for modifications to the design:

- Functional requirements analyses for modifications that are likely to change existing safety functions, introduce new functions for systems supporting safety functions, or involve unclear functional requirements that may be important to safety.
- A change in an operator’s role due to a modification is examined within the context of its effects on the operator’s overall responsibilities. Increases in certain task demands may affect the ability of the operator to carry out others that are risk-significant.
- The technical bases for all modifications to high level functions are documented.
- Applicable operational experience is considered.
- Modifications are analyzed again to:
 - Justify the original analysis of the function
 - Justify the original human-machine allocation

Modifications to the functional requirements data structure are made during:

- SFGA when functions are added, deleted, or modified.
- Task analysis (sequencing) when indications, controls elements, components, and/or subsystems are added, deleted, or modified to support effective and efficient performance of tasks.
- Task analysis (workload analysis) when functions are reallocated to optimize operating crew performance and situational awareness.
- Task analysis (design evaluation) when functions or tasks are modified based on evaluation during design of HSI, procedures, or training material.
- Task analysis (operating experience evaluation) when functions or tasks are modified based on industry operating experience, HFE V&V, Design Implementation or Human Performance Monitoring.

The staff finds the FSAR and FRA/FA IP treatment of this criterion acceptable because it provides for documenting the technical basis for modifications to high-level functions in the new design compared to predecessor design in accordance with NUREG-0711.

Criterion 6

The technical basis for all function allocations should be documented; including the allocation criteria, rationale, and analyses method. The technical basis for functional allocation can be any one or combination of the evaluation factors (see [NUREG-0711] Fig 4.1). For example, the performance demands to successfully achieve the function, such as degree of sensitivity needed, precision, time, or frequency of response, may be so stringent that it would be difficult or error prone for personnel to accomplish. This would establish a basis for automation (assuming acceptability of other factors, such as technical feasibility or cost).

Staff Evaluation of Criterion 6

In partial fulfillment of this criterion for documenting a technical basis for all function allocations, FSAR Tier 2, Section 18.3.3, "Functional Allocation Methodology and Results Summary," states:

Generally, functions automated in predecessor PWR and in the OL3 EPR design are automated in the U.S. EPR design. Functions that are not automated are assigned to operators, either in the MCR or at LCS. Any changes in automation are weighed against the total responsibilities of the operator to monitor automatic functions and to assume manual control during an automation system failure.

FRA/FA IP states, "Functions are allocated to systems, control stations, and levels of automation to provide defense-in-depth and operational flexibility." The FRA/FA IP continues by stating that allocation of functions considers all available information for the specified function. The initial allocation is compared to the actual FRA output. Consideration is given to available plant structures, initial FA, vendor constraints, and operating experience. Resolution of all differences between the initial FA and review of the output of FRA are resolved at this point. FRA/FA IP, Table 4-1, "Functional Allocation Considerations," which is a type of decision matrix,

gives many of the considerations that must be finalized at this point in the process such as: Is automation mandatory or preferred? Is FRA/FA IP automation technically feasible and cost effective? Is redesign possible? Can humans perform the tasks? These considerations are relevant contributions for establishing a technical basis for function allocations.

The staff finds the FSAR and FRA/FA IP treatment of the criterion for documenting the technical basis for all function allocations in the FRA/FA process acceptable because the applicant has provided and developed a technical basis for all function allocations in a description and matrix.

Criterion 7

The OER should be used to identify modifications to function allocations, if necessary. If problematic OER issues are identified, then an analysis should be performed to (a) justify the original analysis of the function, (b) justify the original human-machine allocation, and (c) identify solutions such as training, personnel selection, and procedure design that will be implemented to address the OER issues.

Staff Evaluation of Criterion 7

FSAR Tier 2, Section 18.3.4, "Changes to Functional Analysis or Allocation," states, "As the U.S. EPR design evolves, functions may be re-allocated in an iterative manner in response to developing design specifics, operating experience, and the outcome of analyses and industry research."

FSAR Tier 2, Section 18.12, "Human Performance Monitoring," which addresses V&V, indicates that "changes and modifications to the initial HSI configuration are required to be evaluated for impact to FRA or FA design documentation." Also, the FRA/FA IP, Section 3.0 states that the OER is "input to the FRA/FA process," and in FRA/FA, Section 3.3.2, OER is cited as an input to function allocation.

The staff finds the FSAR and FRA/FA IP treatment of the criterion for use of OER in the FRA/FA process acceptable because the applicant has explained how the OER will be used, in an iterative manner, to identify modifications to function allocations should they become necessary, in a manner consistent with this NUREG-0711 criterion.

Criterion 8

The allocation analysis should consider not only the primary allocations to personnel, but also their responsibilities to monitor automatic functions and to assume manual control in the event of an automatic system failure.

Staff Evaluation of Criterion 8

Although FSAR Tier 2, Section 18.3 does not address this criterion, the FRA/FA IP states that the FA not only details the primary allocations to personnel, but also operator responsibilities to monitor automatic functions. In addition, the allocation considers the role operators will take during automation failure.

The staff finds the FRA/FA IP treatment of the criterion for considering not only the primary allocations to personnel but also their responsibilities to monitor automatic functions and to assume manual control in the event of automatic system failure in the FRA/FA process

acceptable because, as described above, the applicant provided a commitment that the allocation analysis considers primary allocations to personnel and considers the role operators would take during automation failure.

Criterion 9

A description of the integrated personnel role across functions and systems should be provided in terms of personnel responsibility and level of automation.

Staff Evaluation of Criterion 9

FSAR Tier 2, Section 18.3.3, states, "A description of the personnel role with respect to functions and interfacing with automation" is provided in FSAR Tier 2, Section 18.7.2, "Concept of Operations." FSAR Tier 2, Section 18.7.2 provides a description of the concept of operations and assumptions for staffing, personnel characteristics, division of team responsibilities, and other related issues that form the basis for the main control room and related HSI design.

The FRA/FA IP references the applicant's document, "Concept of Operations: Design of the U.S. EPR Control Rooms," April 13, 2009, as another source for a description of the personnel role with respect to functions and interfacing with automation. Section 5.0 of the above referenced document, describes that the integrated personnel role across functions and systems should be provided in terms of personnel responsibility and level of automation in accordance with this NUREG-0711 criterion.

The staff finds the FSAR and the FRA/FA IP treatment of the criterion for providing a description of the integrated personnel role across functions and systems in terms of personnel responsibility and level of automation in the FRA/FA process acceptable because the applicant's FSAR and FRA/FA IP provided a description of the integrated role of personnel, which includes relating this description to the applicant's overall concept of operations for the U.S. EPR design in accordance with this NUREG-0711 criterion.

Criterion 10

The functional requirements analysis and function allocation should be verified:

- all the high-level functions necessary for the achievement of safe operation are identified.
- all requirements of each high-level function are identified.
- the allocations of functions result in a coherent role for plant personnel

Staff Evaluation of Criterion 10

FRA/FA IP, Section 3.1 describes a method to implement FRA, beginning with identifying top-level plant goals, plant-level safety functions, critical safety functions, system functions, and specific plant subsystems. FRA/FA IP, Figure 3-1 provides an overall structure of the FRA in the form of a "functional branch tree" which shows the FRA hierarchy and the relationships of the various plant, system, and component level functions. This hierarchy depicts how high-level functions necessary to achieve safe operation are identified.

In addition, FRA/FA IP, Section 3.1.1 provides a description of the applicant's FRA analysis process that uses "multiple, overlapping avenues for analysis of plant and system level functional requirements...that provide analytical defense-in-depth. This defense-in-depth provides assurance that all functions required for safe operation and all requirements for each function are identified."

In FSAR Tier 2, Section 18.3.3, the applicant states:

A specific objective of the V&V is to verify that the automation design decisions have resulted in an interface that permits accomplishment of the safety functions within human capabilities and identifies as human engineering discrepancies (HEDs) any ineffective function allocation observed. This V&V approach verifies that the FA uses human strengths and avoids human limitations.

The applicant describes this concept in further detail in FRA/FA IP, Section 3.0, "Method," and FRA/FA IP, Section 4.3.3, "Evaluate Operator Performance."

The staff finds that the FSAR description and supporting details provided in the FRA/FA IP address the criterion's point that function allocation will result in coherent roles for plant personnel, ultimately by using the V&V process.

Accordingly, the staff finds the FSAR and the FRA/FA IP treatment of the criterion for verifying functional requirements and functional allocation for the U.S. EPR design acceptable because the applicant has provided a method for verifying functional requirements analysis and function allocation to ensure that all the high-level functions necessary for the achievement of safe operation are identified; all requirements of each high-level function are identified; and the allocations of functions result in a coherent role for plant personnel that conforms to this NUREG-0711 criterion.

18.3.4 Other Documents Subject to Review

18.3.4.1 *FSAR Tier 1 Section 3.4, "Human Factors Engineering"*

FSAR Tier 1, Table 3.4-1, "Human Factors Engineering ITAAC," contains the ITAAC that are proposed for HFE. The staff's evaluation of these ITAAC is provided in Section 14.3.9 of this report.

18.3.5 Combined License Information Items

There are no combined license information items related to this area of review. The staff determined that no COL information items need to be included in FSAR Tier 2, Table 1.8-2, "U.S. EPR Combined License Information Items," for HFE functional requirements analysis and functional allocation.

18.3.6 Conclusions

The staff evaluated FRA and FA with respect to HFE, at an IP level using the review criteria in NUREG-0711, Section 4.4. Section 18.0.4 of this report provides a discussion of review levels. The staff determined that the FRA/FA IP that is proposed for the U.S. EPR will ensure that no significant safety degradation will occur due to plant changes that are made and the IP provides adequate assurance that the conclusions that are reached from the applicant's evaluation

remain valid over time. As discussed in Section 18.0.5 of this report, the FRA/FA IP is designated as Tier 2*, which ensures that the IP will be implemented by the COL applicant. Furthermore, because the FRA/FA IP is designated as Tier 2*, the COL applicant cannot make changes to the IP without obtaining prior NRC approval. Therefore, the staff concludes that HFE considerations with respect to FRA and FA have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.

18.4 Task Analysis

18.4.1 Regulatory Criteria

HFE task analysis is evaluated based on the criteria provided in NUREG-0711, Chapter 5, "Task Analysis," Section 5.4, "Review Criteria," and SRP Section 18.II.A.4. NUREG-0711, Section 5.4 specifies the review criteria that pertain to the staff's evaluation of TA. Specifically, the staff verifies whether the applicant's TA identifies the specific tasks that are needed for function accomplishment and its information, control, and task support considerations (e.g., job aids, specified clothing, tools, etc., that support implementing the task).

18.4.2 Summary of Technical Information

The applicant describes HFE TA in FSAR Tier 2, Section 18.4, "Task Analysis." FSAR Tier 2, section 18.4.2, "Task Analysis Methodology," incorporates by reference, "U.S. EPR Task Analysis Implementation Plan," February 23, 2011 (referred to as the TA IP). The staff reviewed the TA IP along with other documents that pertain to the staff's review of HFE TA as discussed in the subsections that follow. The staff focused its review on evaluating the information provided based on the review criteria in NUREG-0711, Chapter 5 and SRP Section 18.II.A.4.

18.4.3 Staff Evaluation

The staff performed an implementation plan level of review as described in NUREG-0711 and Section 18.0.4 of this report. This section presents the applicable review criteria from NUREG-0711 (reproduced below) followed by an evaluation of each. Note that the seventh criterion related to this area of review pertains to plant modifications and is not applicable to new reactor design certifications. Thus, this criterion is not included in the staff's evaluation.

Criterion 1

The scope of the task analysis should include:

- selected representative and important tasks from the areas of operations, maintenance, test, inspection, and surveillance
- full range of plant operating modes, including startup, normal operations, abnormal and emergency operations, transient conditions, and low-power and shutdown conditions
- HAs that have been found to affect plant risk by means of PRA importance and sensitivity analyses should also be considered risk-important. Internal and external initiating events and actions affecting the PRA Level I and II analyses should be considered when identifying risk-important actions

- where critical functions are automated, the analyses should consider all human tasks including monitoring of the automated system and execution of backup actions if the system fails.

Staff Evaluation of Criterion 1

TA IP, Section 1.5, "Objectives and Scope," identifies the following scope for TA: full range of plant conditions; selected representative and important tasks for operations, maintenance, test, inspection, and surveillance; all risk-significant human actions [the terms "risk-significant" human actions and "risk-important" human actions are synonymous in accordance with "U.S. EPR Implementation Plan for the Integration of Human Reliability Analysis (HRA) with the Human Factors Engineering (HFE) Program," November 18, 2010]; and automated task supporting critical safety functions that involve human interaction including backup of automation. The applicant's methodology also addresses staffing and qualifications levels. The overall scope of tasks to be included in the applicant's TA meets the task analysis scope encompassed in the staff's review criteria.

TA will not be performed on all possible tasks; rather, selected tasks will be analyzed. Thus, the methodology employed by the applicant to select which tasks within the overall scope will be analyzed is an important consideration. The TA IP states that a screening process will be used to select tasks. The process is described in TA IP, Section 3.0. The screening methodology uses objective and subjective criteria to screen in tasks. Objective criteria include tasks that support critical safety functions such as emergency operating procedure (EOP)-related tasks, risk-significant human actions as determined by the PRA/HRA analysis, tasks credited in the plant's defense-in-depth and diversity (D3) analysis, automated tasks supporting critical safety-related functions with human interactions (including monitoring the automated system and executing backup actions if the system fails), tasks that industry operating experience indicates have historically been plant or turbine trip hazards (high risk tasks), tasks that are associated with high workload tasks, and tasks related to systems and functions unique to the U.S. EPR design. Subjective criteria include judgment of the design team that a task is high-risk or high workload, and tasks needing additional analysis in support of HSI design.

The use of both objective and subjective criteria will address a broad range of tasks that include those that are risk-important, emergency operations, and tasks associated with human responsibilities related to automation. Tasks that are not screened into the formal task analysis process are still evaluated using systems engineering evaluations. The evaluations make use of existing industry and regulatory procedures. Examples are provided in TA IP, Section 3.0, and include NUREG-3371, "Task Analysis of Nuclear Power Plant Control Room Crews," 1983, and Institute of Electrical and Electronics Engineers (IEEE) Std 1023, "IEEE Guide to the Application of HFE to Systems, Equipment, and Facilities of Nuclear Power Generating Stations." Thus all tasks are subject to the analysis of personnel task requirements.

The staff finds the FSAR and TA IP treatment of the criterion for TA scope acceptable because the applicant has described a task analysis process that is consistent with the scope of this NUREG-0711 criterion.

Criterion 2

Tasks should be linked using a technique such as operational sequence diagrams. Task analyses should begin on a gross level and involve the development of detailed narrative descriptions of what personnel have to do. The analyses should define the nature of the input, process, and output needed

by and of personnel. Detailed task descriptions should address (as appropriate) the topics listed in [NUREG-0711] Table 5.1.

Staff Evaluation of Criterion 2

This criterion addresses the methodology to conduct task analysis. TA IP, Section 3.2, "Tools, Instruments, and Methods," indicates that the applicant will use two approaches to perform their TA:

- Task sequence analysis (TSA), and
- Hierarchical task analysis (HTA)

Each is briefly described in TA IP, Section 3.2. TSA provides for task descriptions and linkages between and among tasks, similar to the OSD analysis identified in the review criterion. Additional information is provided in TA IP Appendices C, D, and E. Appendix C describes a general approach to TSA, including: (1) Identifying the type of information needed, such as system functional requirements functional branch trees for systems involved in the task; (2) identifying the configuration changes; and (3) developing the task. "Develop the task" refers to a task description and references Appendix D which provides a sample work sheet. The sheet is filled out by the analyst and includes extensive task information, such as the task's purpose, precondition, sequence, information requirements, hazard identification, and situational factors. Appendix E describes the use of timeline analysis as part of workload and task analysis. The range of information is thorough and comprehensive.

The second method is HTA. HTA is another standard method. HTA divides high-level functions into detailed task steps. As noted in the applicant's TA IP, tasks are described at the high-level as overall goals of the task. Sub-goals are then identified that are needed to accomplish the high-level goal. The analysis continues until HSI requirements for tasks are identified.

The TA IP states that the analysis is performed at the "detailed level task analysis phase" (plant level), after tasks are selected in the "gross level task analysis" (system level tasks).

The TA implementation approach is described in TA IP, Section 4.0. TA IP, Section 4.2, "Analyze Selected Tasks," addresses how tasks are analyzed.

The staff finds the FSAR and TA IP treatment of the criterion for TA techniques acceptable because the applicant has described a process for applying task sequence analysis and a hierarchal task analysis that define the nature of the input, process, and output needed by and of personnel, and address the topics in NUREG-0711, Table 5.1.

Criterion 3

The task analysis should be iterative and become progressively more detailed over the design cycle. It should be detailed enough to identify information and control requirements to enable specification of detailed requirements for alarms, displays, data processing, and controls for human task accomplishment.

Staff Evaluation of Criterion 3

TA IP, Section 4.0 states that the analysis is performed iteratively for in-scope normal, abnormal, and emergency tasks. The iterations address (1) identification of operating

conditions and alarm boundaries; (2) identification of task details such as component manipulation, communication requirements, and feedback requirements; and (3) identification of maintenance, test, inspection, and surveillance activities.

TA IP, Section 4.2.4 gives the HSI task support requirements resulting from TA. These include requirements in the areas of:

- Information
- Decision-making
- Response
- Communication
- Task support

A list of the specific items within each area is provided. In addition, TA IP, Section 4.2.1 and TA IP, Appendix D, illustrate the types of detailed information to be derived from the TA process (as elaborated in the discussion of Criterion 2 above). Thus, the applicant's TA IP provides task requirements that conform to the information presented in NUREG-0711, Table 5.1, "Task Considerations."

The staff finds the FSAR and TA IP treatment of the criterion for using an iterative TA process acceptable because the applicant has described how the task analysis is iterative and becomes progressively more detailed over the design cycle in the TA IP and examples of more detailed information in an appendix to the IP, consistent with this NUREG-0711 criterion.

Criterion 4

The task analysis should address issues such as:

- the number of crew members
- crew member skills
- allocation of monitoring and control tasks to the (a) formation of a meaningful job and (b) management of crew member's physical and cognitive workload.

Staff Evaluation of Criterion 4

TA IP, Section 3.0 states that staffing and qualification needs for task performance are systematically analyzed and the initial staffing assumptions are adjusted based on the results. TA IP, Section 4.6, states that the applicant uses the results of the TA workload analysis to determine the personnel staffing and qualifications for each task and do consider physical and cognitive workload. Staffing and qualifications are identified in TA IP, Appendix D, "Sample TA Worksheet." The assessments are made qualitatively by analyst judgment.

As stated in TA IP, Section 4.0, the allocation of functions is assessed using the workload results and reallocation or redesign is suggested where necessary. Using the results of the analysis, monitoring and control tasks are allocated to crewmembers to ensure that workload is

balanced and the collection of tasks to be performed form an integrated meaningful job for each crewmember.

Using workload assessment in the context of overall task characteristics and requirements, as explained in the above evaluation, is an acceptable means to evaluate staffing levels, skills, and formation of responsibilities for crewmembers because it determines the skills and numbers of crew members needed to accomplish the tasks identified by the TA, and considers crew member skills and numbers to allocate tasks.

The staff finds the FSAR and TA IP treatment of the criterion for addressing crew member numbers, skills, and task allocation acceptable because the applicant has described a task analysis process, using the workload analysis method, which conforms to this NUREG-0711 criterion.

Criterion 5

The task analysis results should be used to define a minimum inventory of alarms, displays, and controls necessary to perform crew tasks based on both task and instrumentation and control requirements.

Staff Evaluation of Criterion 5

The minimum inventory of alarms, displays, and controls is not addressed in the applicant's task analysis. In RAI 374, Question 18-74, the staff requested that the applicant provide information clarifying how the minimum inventory is identified. In a March 4, 2010, response to RAI 374, Question 18-74, the applicant indicated that the purpose of TA is to define the full inventory of task requirements, such as alarms, displays, and controls. The specification of a "minimum" inventory is addressed as part of the HSI design process. In accordance with the staff's review of Criterion 3 above, the applicant's methodology will produce an inventory of task requirements. The selection of the minimum subset of that inventory involves other considerations that are addressed by the applicant in FSAR Tier 2, Section 18.7 and in the HSID IP, and addressed by the staff in Section 18.7 of this report. As described in section 18.7 of this report, the staff finds the applicant's March 4, 2010, response to RAI 374, Question 18-74, acceptable and, therefore, considers RAI 374, Question 18-74 resolved.

The staff finds the FSAR and TA IP treatment of the criterion for using task analysis to define a minimum inventory of alarms, controls, and displays necessary to perform crew tasks acceptable because the applicant has provided a methodology for defining an overall inventory of alarms, controls, and displays that includes, as a subset, the minimum inventory of alarms, controls and displays needed to perform the crew tasks identified in the TA that conforms to this NUREG-0711 criterion.

Criterion 6

The task analysis results should provide input to the design of HSIs, procedures, and personnel training programs.

Staff Evaluation of Criterion 6

The role of TA in HSIs, procedures, and training is summarized in TA IP Table 1-2, "TA interfaces with the Other HFE Elements:"

- HSI design – the results of TA are used as (1) the basis for detailed HSI design to ensure elements such as detailed displays and controls and their organization support operators task performance, and (2) support the coordination of crewmembers.
- Procedure development – the results of TA are used (1) as the basis for procedure development, and (2) for assessing staffing and qualification demands associated with procedure use.
- Training program development – the result of TA (1) form the basis for refining the skills and training needed by personnel to perform their tasks, and (2) are used to assess crew coordination concerns.
- The uses identified by the applicant encompass the application of task analysis results in later design activities and evaluation activities.

The staff finds the FSAR and TA IP treatment of this criterion for using the task analysis as input to the design of HSIs, procedures, and personnel training programs acceptable because the applicant provided a description of how task analysis provides input to other applicable HFE program elements that conforms to this NUREG-0711 criterion.

18.4.4 Other Documents Subject to Review

18.4.4.1 *FSAR Tier 1, Section 3.4, “Human Factors Engineering”*

FSAR Tier 1, Table 3.4-1, “Human Factors Engineering ITAAC,” contains the ITAAC that are proposed for HFE. The staff’s evaluation of these ITAAC is provided in Section 14.3.9 of this report.

18.4.5 Combined License Information Items

There are no combined license information items related to this area of review. The staff determined that no COL information items need to be included in FSAR Tier 2, Table 1.8-2, “U.S. EPR Combined License Information Items,” for HFE task analysis.

18.4.6 Conclusions

The staff evaluated TA with respect to HFE, at an IP level using the review criteria in NUREG-0711, Section 5.4. The staff determined that the TA IP proposed for the U.S. EPR will ensure that no significant safety degradation will occur due to plant changes that are made and the IP provides adequate assurance that the conclusions that are reached from the evaluation remain valid over time. As discussed in Section 18.0.5 of this report, the TA IP is designated as Tier 2*, which ensures that the IP will be implemented by the COL applicant. Furthermore, because the TA IP is designated as Tier 2*, the COL applicant cannot make changes to the IP without obtaining prior NRC approval. Therefore, the staff concludes that TA considerations with respect to HFE have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.

18.5 Staffing and Qualifications

18.5.1 Regulatory Criteria

HFE staffing and qualifications (S&Q) are evaluated based on the criteria provided in NUREG-0711, Chapter 6, "Staffing and Qualifications," Section 6.4, "Review Criteria," and SRP Section 18.II.A.5. NUREG-0711, Section 6.4 specifies the review criteria pertaining to the staff's evaluation of HFE S&Q. Specifically, the staff confirms that the applicant has analyzed the number and qualifications of needed personnel in a systematic manner that includes a thorough understanding of task requirements and applicable regulatory requirements.

18.5.2 Summary of Technical Information

HFE S&Q are described in FSAR Tier 2, Section 18.5, "Staffing and Qualifications." This section incorporates by reference, "U.S. EPR HFE Program Management Plan," December 16, 2010 (referred to as the HFEPM IP), and "U.S. EPR Task Analysis Implementation Plan," February 23, 2001 (referred to as the TA IP). The TA IP incorporates by reference, "Initial Staffing Assumptions for the U.S. EPR," December 16, 2010 (referred to as the ISA Document). The staff reviewed the TA IP and ISA Document along with other documents that pertain to the staff's review of HFE S&Q as discussed in the sections that follow. The staff focused its review on evaluating the information provided based on the review criteria in NUREG-0711, Chapter 6 and SRP Section 18.II.A.5.

18.5.3 Staff Evaluation

The staff performed an implementation plan level of review as described in NUREG-0711 and Section 18.0.4 of this report. This section presents the applicable review criteria from NUREG 0711 followed by an evaluation of each.

Criterion 1

Staffing and qualifications should address applicable guidance in NUREG-0800 Section 13.1, and 10 CFR 50.54.

Staff Evaluation of Criterion 1

Section 13.1 of this report evaluates management, organization, and shift crews for the U.S. EPR using the guidance in SRP Section 13.1. In addition, FSAR Tier 2, Section 13.1, "Organizational Structure of Applicant," includes COL Information Item No. 13.1-1, which is also evaluated in Section 13.1 of this report. COL Information Item No. 13.1-1 states:

A COL applicant that references the U.S. EPR design certification will provide site-specific information for management, technical support, and operating organizations.

The requirements in 10 CFR 50.54, "Conditions of licenses," that relate to staffing are contained in 10 CFR 50.54(i) through (m). Most of these requirements relate to aspects of reactor control by licensed reactor operators (ROs) and senior reactor operators (SROs) that go beyond simple staffing levels and are not pertinent to address in this staffing review. FSAR Tier 2, Section 18.5.1, "Objectives and Scope of Analysis," states that there will be two ROs, two SROs, and a number of non-licensed operators on shift. The staffing levels in the control

room are addressed in both the HFEPM IP and the ISA Document. Initial qualification assumptions are also provided in the ISA Document. These documents state that the U.S. EPR design goal is to design the plant and the HSIs such that the plant can be safely monitored and controlled by an operating crew of two licensed ROs, one licensed SRO as a control room supervisor, an SRO shift supervisor, a shift technical advisor (STA), and non-licensed auxiliary operators. Of these, one RO and one SRO are in the control room. This is the initial staffing assumption for the U.S. EPR design and for the applicant's staffing analysis. This initial staffing assumption also satisfies the staffing requirements of 10 CFR 50.54 since it specifies the minimum staffing stated in 10 CFR 50.54(m)(2)(iii). The assumed staffing levels will be further evaluated and confirmed through the HFE program as described under the other staffing criteria that follow.

Since the FSAR, ISA Document, HFEPM IP, and the TA IP meet the requirements in 10 CFR 50.54 and comply with the applicable guidance specified in SRP Section 13.1.1 the staff finds the applicant's treatment of this NUREG-0711 criterion acceptable.

Criterion 2

The staffing analysis should determine the number and background of personnel for the full range of plant conditions and tasks including operational tasks (normal, abnormal, and emergency), plant maintenance, and plant surveillance and testing. The scope of personnel that should be considered is identified in the HFE Program Management element (see [NUREG-0711] Section 2.4.1, Criterion 5).

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.5 states that staffing analyses will be performed in accordance with the TA IP. FSAR Tier 2, Section 18.5.1 notes that the objective of the workload analyses in the TA IP is to demonstrate that the number, roles, and responsibilities of the plant operating staff can satisfy plant demands and processes. The ISA Document includes Table 3-1, "Initial Minimum Baseline Staffing," which provides the initial minimum, on-shift staff complement for all categories of personnel within the scope of the HFE program. This includes all those categories of personnel given in 10 CFR 50.54(m) and 10 CFR 50.120; namely, non-licensed operator, shift supervisor, shift technical advisor, I&C technician, electrical maintenance personnel, mechanical maintenance personnel, radiological protection technician, chemistry technician, and engineering support personnel. ISA Document, Section 3.1, "Qualification Assumptions," also provides the initial qualification assumptions for these shift staff members.

TA IP, Section 1.5, "Objectives and Scope," states that the task analysis addresses changes to the initial staffing assumptions during the workload analysis portion of the TA. The TA IP further notes that the results summary of the TA will include all staffing and qualification levels needed to perform each task. The scope of the TA includes the full range of plant operating modes (Modes 1 – 6 of the Technical Specifications, transients, abnormal operations, and emergency operations). The TA also includes plant maintenance, testing, inspection, and surveillance. The scope of personnel to be addressed by the staffing analysis, as described in the TA IP, is the full scope of personnel addressed in the ISA Document noted above.

TA IP, Section 3.0, "Method," notes that S&Q needs are systematically analyzed with respect to both the TA and regulatory requirements, and initial staffing assumptions are adjusted as necessary. The workload analysis may lead to changes to functional allocation, staffing, and qualifications.

In addition, FSAR Tier 2, Section 1.8, "Interfaces with Standard Designs and Early Site Permits," Table 1.8-2 contains COL Information Item No. 18.5-1 states:

A COL applicant that references the U.S. EPR design will confirm that actual staffing levels and qualifications of plant personnel specified in COL application, Section 13.1 remain bounded by regulatory requirements and results of the staffing and qualifications analysis.

The staff finds the FSAR, TA IP, and ISA Document treatment of this criterion with respect to the number and qualifications of personnel that are necessary for the full range of plant conditions acceptable because the applicant has provided a description of a staffing analysis methodology that is consistent with this NUREG-0711 criterion.

Criterion 3

The staffing analysis should be iterative; that is, initial staffing goals should be reviewed and modified as the analyses associated with other elements are completed.

Staff Evaluation of Criterion 3

FSAR Tier 2, Section 18.5.2, "Staffing and Qualifications Analysis Methodology," states that the initial staffing assumptions are iterated as a result of TA in order to obtain an optimum staffing level. Initially, tasks are assigned to crew members based on assignments from operating experience and established roles and responsibilities, and then the process builds on these assumptions. Changes in team roles, responsibilities, and individual qualifications result from adjustments to individual crew member responsibilities.

The ISA Document states that in cases where the workload analysis identifies a task with high operator workload values or insufficient time available for performance, then changes are evaluated to the staffing assumptions, HSI design, or function allocation that are necessary to reduce operator workload.

TA IP, Section 4.0, "TA Implementation Approach," states that TA is performed iteratively and is represented in TA IP Appendix A, "TA Process." Appendix A illustrates the multiple inputs to TA and the details of the TA process. TA IP, Appendix B, "HFE Process Integration," illustrates the interplay and iteration that take place among the various HFE elements. These appendices illustrate the complexities involved and iterative nature of the TA process as other HFE elements are being addressed.

The staff finds the FSAR, ISA Document, and TA IP treatment of this criterion with respect to establishing an iterative process for performing staffing analysis acceptable because the applicant has provided a description of an iterative staffing analysis methodology that conforms to this NUREG-0711 criterion.

Criterion 4

The basis for staffing and qualifications should be modified to address these issues:

- Operating Experience Review

- operational problems and strengths that resulted from staffing levels in predecessor systems
- initial staffing goals and their bases including staffing levels of predecessor systems and a description of significant similarities and differences between predecessor and current systems
- staffing considerations described in NRC Information Notice 95-48, “Results of Shift Staffing Study”
- staffing considerations described in NRC Information Notice 97-78, “Crediting of Operator Actions in Place of Automatic Actions and Modifications of Operator Actions, Including Response Times”
- Functional Requirements Analysis and Function Allocation
 - mismatches between functions allocated to personnel and their qualifications
 - changes in the roles of personnel due to plant system and HFE modifications
- Task Analysis
 - the knowledge, skills, and abilities needed for personnel tasks addressed by the task analysis
 - personnel response time and workload
 - personnel communication and coordination, including interactions between them for diagnosis, planning, and control activities, and interactions between personnel for administrative, communications, and reporting activities
 - the job requirements that result from the sum of all tasks allocated to each individual both inside and outside the control room
 - decreases in the ability of personnel to coordinate their work due to plant and HFE modifications
 - availability of personnel considering other activities that may be ongoing and for which operators may take on responsibilities outside the control room (e.g., fire brigade)
 - actions identified in 10 CFR 50.47, NUREG-0654 [“Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants (FEMA-REP-1)”] and procedures to meet an initial accident response in key functional areas as identified in the emergency plan

- staffing considerations described by the application of ANSI/ANS 58.8-1994, “Time Response Design Criteria for Safety-Related Operator Actions”
- Human Reliability Analysis
 - the effect of overall staffing levels on plant safety and reliability
 - the effect of overall staffing levels and crew coordination for risk-important HAs
 - the effect of overall staffing levels and the coordination of personnel on human errors associated with the use of advanced technology
- HSI Design
 - staffing demands resulting from the locations and use (especially concurrent use) of controls and displays
 - coordinated actions between individuals
 - decreases in the availability or accessibility of information needed by personnel due to plant system and HFE modifications
 - the physical configuration of the control room and control consoles
 - the availability of plant information from individual workstations and group-view interfaces
- Procedure Development
 - staffing demands resulting from requirements for concurrent use of multiple procedures
 - personnel skills, knowledge, abilities, and authority identified in procedures
- Training Program Development
 - crew coordination concerns that are identified during the development of training

Staff Evaluation of Criterion 4

FSAR Tier 2, Section 18.5.1 states that to obtain an optimum staffing level for the U.S. EPR, factors associated with other elements of the HFE program are considered. FSAR Tier 2, Section 18.5.1 discusses in sequence how the following HFE elements interact with the staffing analyses: OER, function allocation, TA, HRA integration, and HSI design.

TA IP, Section 3.1.1.1, “TA Inputs from Operating Experience Review,” discusses how OER identifies issues, initial staffing assumptions, and operational problems and strengths that resulted from staffing levels in predecessor systems. The TA IP also addresses NRC

Information Notices 95-48, “Results of Shift Staffing Study,” and 97-78, “Crediting of Operator Actions in Place of Automatic Actions and Modifications of Operator Actions, including Response Times,” with respect to staffing issues.

ISA Document, Section 3.2.1, “Operating Experience Review (OER),” also explains how the OER is used as input to staffing goals.

TA IP, Section 3.1.1.2, “TA Inputs from Function Requirements Analysis/Function Allocation,” describes how staffing is considered during the function allocation process. During the TA, assumptions made during the FRA/FA process are either confirmed or, if the assumptions are invalidated during task analysis, then the earlier determined assumptions are re-examined for validity and if invalid, are revised.

ISA Document, Section 3.2.2, “Functional Requirements Analysis and Function Allocation (FRA/FA),” also explains how the FRA/FA provides input to staffing goals.

Since staffing is specifically addressed throughout the TA IP, it is well integrated with the TA. The various items noted in the TA portion of the criterion are specifically addressed in TA IP, including crew coordination, use of operators for the fire brigade, and emergency plan activities.

ISA Document, Section 3.2.3, “Task Analysis (TA),” also explains how TA provides input to staffing assumptions.

The HRA/PRA identifies the risk-significant human actions that need to be addressed in the TA. The staff’s evaluation of the integration of HRA/PRA with the HFE program is discussed in Section 18.6 of this report. TA IP, Section 3.1.1.3, “TA Inputs from HRA,” also discusses the process for addressing these risk-significant actions in the TA. TA IP, Section 4.1, “Identify Tasks to be Analyzed,” states that risk-significant HAs identified by the PRA Levels I and II analyses will be analyzed in the TA.

ISA Document, Section 3.2.4, “Human Reliability Analysis (HRA),” also explains how HRA provides input into staffing assumptions.

As part of the discussion of the TA process, TA IP, Section 4.2, “Analyze Selected Tasks,” includes the following subsections which contain more detailed discussions: “Develop Task Descriptions,” “Sequence Tasks,” “Assign Workload Values,” “Develop HSI Task Support Interface Requirements,” “Associate HSI Interfaces and Evaluate,” “Workload Analysis,” “Confirm FA Allocations,” and “Confirm Staffing and Qualification Needs.”

ISA Document, Section 3.2.5, “Human System Interface (HSI) Design,” and Section 3.2.6, “Verification and Validation (V&V),” explain respectively, how HSI design and V&V contribute to the development of staffing assumptions used for the U.S. EPR design. For example, the applicant cites how the use of mock-ups and walkthroughs, both tools used in the HSI design process, are also used to examine issues related to staffing levels and operator performance. As well, V&V serves as an integrating activity that contributes to determining appropriate MCR and plant support personnel staffing levels.

TA IP, Section 1.5 states that the sequencing of tasks provides the steps for the plant operating procedures and defines the activities that plant personnel are trained to execute. Tasks that are more complex requiring multiple procedures will be analyzed like other tasks to identify workload and staffing requirements.

The staff finds the FSAR, ISA Document, and TA IP treatment of this criterion with respect to the basis for staffing and qualifications acceptable because the applicant has provided a basis for modifying staffing assumptions to address inputs from the OER, FRA/FA, TA, HRA, HSI design, procedures development, and training development that is consistent with this NUREG-0711 criterion.

18.5.4 Other Documents Subject to Review

18.5.4.1 FSAR Tier 1, Section 3.4, “Human Factors Engineering”

FSAR Tier 1, Table 3.4.1, “Human Factors Engineering ITAAC,” contains the ITAAC that are proposed for HFE. The staff’s review of these ITAAC is provided in Section 14.3.9 of this report.

18.5.5 Combined License Information Items

Table 18.5-1 provides HFE S&Q-related COL information item numbers and descriptions from FSAR Tier 2, Table 1.8-2, “U.S. EPR Combined License Information Items”:

Table 18.5-1 U.S. EPR Combined License Information Items

Item No.	Description	FSAR Tier 2 Section
18.5-1	A COL applicant that references the U.S. EPR design will confirm that actual staffing levels and qualifications of plant personnel specified in COL application, Section 13.1 remain bounded by regulatory requirements and results of the staffing and qualifications analysis.	18.5

The staff finds the above description complete. Also, the description adequately describes actions necessary for the COL applicant or holder. No additional COL information items need to be included in FSAR Tier 2, Table 1.8-2 for HFE staffing and qualifications considerations.

18.5.6 Conclusions

The staff evaluated S&Q with respect to HFE, at an IP level using the review criteria in NUREG-0711, Section 6.4. Section 18.0.4 of this report provides a discussion of review levels. The staff determined that the TA IP that is proposed for the U.S. EPR will ensure that no significant safety degradation will occur due to S&Q considerations and the IP provides adequate assurance that the conclusions that were reached from the TA and S&Q evaluations remain valid over time. As discussed in Section 18.0.5 of this report, the TA IP is designated as Tier 2*, which ensures that the IP will be implemented by the COL applicant. Furthermore, because the TA IP is designated as Tier 2*, the COL applicant cannot make changes to this IP without obtaining prior NRC approval. Therefore, the staff concludes that S&Q considerations with respect to HFE have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.

18.6 Human Reliability Analysis

18.6.1 Regulatory Criteria

HFE human reliability analysis as it relates to HFE is evaluated based on the criteria provided in NUREG-0711, Chapter 7, "Human Reliability Analysis," Section 7.4, "Review Criteria," and SRP Section 18.II.A.6. NUREG-0711, Section 7.4 specifies the review criteria pertaining to the staff's evaluation of this HFE area of consideration. Specifically, the staff confirms that (1) the applicant has addressed human-error mechanisms in the design of the HFE aspects of the plant in order to minimize the likelihood of personnel error and to verify that errors are detected and recovered; and (2) the HRA activity effectively integrates the HFE program and probabilistic risk analysis (PRA).

18.6.2 Summary of Technical Information

HRA is described in FSAR Tier 2, Section 18.6, "Human Reliability Analysis." FSAR Tier 2, Section 18.6.2, incorporates by reference, "U.S. EPR Implementation Plan for the Integration of Human Reliability Analysis (HRA) into the Human Factors Engineering (HFE) Program," November 18, 2010 (referred to as HRA IP). The staff reviewed the HRA IP along with other documents, discussed in Section 18.6.4 of this report, that pertain to the staff's review of HFE functional requirements analysis and functional allocation as discussed in the subsections that follow. The staff focused its review on evaluating the information provided based on the review criteria in NUREG-0711, Chapter 7 and SRP Section 18.II.A.6.

18.6.3 Staff Evaluation

The staff performed an implementation plan level of review as described in NUREG-0711 and Section 18.0.4 of this report. This section presents the applicable review criteria from NUREG-0711 followed by an evaluation of each.

Criterion 1

(Only the first bulleted item in this NUREG-0711 criterion is applicable to new reactor designs. Therefore, the second bullet is not provided below.)

Risk-important human actions should be identified from the PRA/HRA and used as input to the HFE design effort.

- These actions should be developed from the Level 1 (core damage) PRA and Level 2 (release from containment) PRA including both internal and external events. They should be developed using selected (more than one) importance measures and HRA sensitivity analyses to provide reasonable assurance that an important action is not overlooked because of the selection of the measure or the use of a particular assumption in the analysis.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.6.1, provides the objectives and scope for HRA/HFE integration activities. FSAR Tier 2, Section 18.6.1 notes that the PRA is described in Chapter 19, "Probabilistic Risk Assessment and Severe Accident Evaluation," and risk-significant human

actions (HAs) are identified in the HRA portion of the PRA and are considered in the HFE design. Risk-significant HAs are identified by using selected importance measures, HRA sensitivity analyses, and threshold criteria.

The HRA IP provides a methodology for the integration of HRA with the design of the U.S. EPR and the HFE program. The HRA IP provides the purpose and scope of the plan and its high-level elements or aspects. It explains how the HRA is performed iteratively and how the analysis interacts with the various aspects of the HFE program.

HRA IP, Sections 1.5, "Definition of Terms," and 3.1.1, "Risk-Significant Human Actions," state that risk-significant HAs are defined using the risk-importance measures of Risk Achievement Worth (RAW) and Fussell-Vesely (FV). Human actions that have an FV value greater than or equal to 0.005 or a RAW value greater than or equal to 2.0 will be considered risk-significant. These will be determined using both the Level 1 and Level 2 PRA. For Level 1, core damage frequency (CDF) is used; and for Level 2, large release frequency (LRF) is used in computing the RAW and FV measures. This method of combining the importance measures is not typically used, but is a reasonable approach and, when considered together with suitably low threshold values for RAW and FV, provides a reasonable number of risk-significant HAs to focus the HFE program in important areas. HRA IP, Section 1.5 also notes that the term and definition, "Risk-important," as used in NUREG-0711 and the term and definition, "Risk-significant," as used in the HRA IP are synonymous.

The list of risk-significant HAs is developed using the FV and RAW risk importance measures derived from the human actions modeled in the Level 1 and Level 2 analyses of the PRA for different modes of operation. The FV and RAW values are calculated relative to the overall risk from both the PRA for operations at-power and the PRA for low power and shutdown (LPSD) operations. The importance measures are the sum of the at-power and LPSD values weighted according to their respective contribution to overall risk.

The list of risk-significant HAs is derived from the HAs modeled in both the Level 1 CDF and Level 2 LRF analyses of the PRA, and includes both internal and external events. The PRA results for the individual hazard groups (e.g., internal events, flooding, fires) are combined to yield and risk importance measures relative to the overall CDF and LRF risks. The PRA includes external events that are treated explicitly (internal fires and floods) and others that have been screened as negligible (e.g., airplane crash, tornado). No unique risk-significant HAs were identified by the Seismic Margins Analysis (SMA). The important SMA operator actions are the same as those in the internal events PRA. Thus, separate HAs for seismic hazards are not given.

In addition, HRA IP, Section 1.2.1.9, "Human Factors Verification & Validation," notes that the HRA integration will consider other aspects related to risk importance determination including:

- Dominant human actions (selected via risk-importance measures and/or sensitivity analyses).
- Dominant accident sequences.
- Dominant systems (selected via PRA importance measures and/or sensitivity analysis).

HRA IP, Appendix A, "U.S. EPR HRA Risk-Significant Human Actions," contains Table A-1, "U.S. EPR HRA Risk-Significant Human Actions (FV \geq 0.005 or RAW \geq 2)." Table A-1 contains

those actions determined to be risk-significant in accordance with the criteria in the HRA IP. The human error probability (HEP), and RAW and FV values for both CDF and LRF are provided in the table. The staff reviewed the table for reasonableness and completeness by comparing it with other reactor lists of HAs and by reviewing related information in FSAR Tier 2, Chapter 19, "Probabilistic Risk Assessment and Severe Accident Evaluation." The staff reviewed the following areas:

- Various CDF and LRF values
- Tables of risk-significant HAs by RAW and FV for the various internal and external PRA and for the at-power and shutdown PRA
- Tables of dominant cutsets

In its review, the staff noted an apparent discrepancy. In FSAR Tier 2, Table 19.1-33, "U.S. EPR Risk-Significant Human Actions based on RAW Importance – Level 2 Internal Events," the human action (OPF-SGTR-4H), "Operator fails to isolate blowdown line for SGTR," is listed with a RAW value of 41.3, but the action is not provided in HRA IP Table A-1, "U.S. EPR Risk-Significant Human Actions (FV \geq 0.005 or RAW \geq 2)." In a November 23, 2010, response to RAI 440, Question 18-234, the applicant agreed to add this HA to HRA IP Table A-1. This update was made and submitted to the staff for review in Revision 4 to the HRA IP. The staff also recognizes that the list of risk-significant human actions may change as the detailed design progresses and the PRA/HRA is updated. The staff finds the applicant's November 23, 2010, response to RAI 440, Question 18-234 acceptable and therefore resolved because the applicant included in the table the previously missing human action.

The staff finds FSAR Tier 2, Section 18.6.1 and HRA IP treatment of Criterion 1 for identifying risk important human actions acceptable because the applicant has provided a description for how risk important human actions that are identified from the U.S. EPR PRA/HRA are used as input to the HFE design of the U.S. EPR that is consistent with this NUREG-0711 criterion.

Criterion 2

Risk-important HAs and their associated tasks and scenarios should be specifically addressed during function allocation analyses, task analyses, HSI design, procedure development, and training. This will help verify that these tasks are well supported by the design and within acceptable human performance capabilities (e.g. within time and workload requirements).

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.6.2 states that the HRA IP describes how the PRA and HRA results along with the risk-significant HAs are addressed in other aspects of the HFE program with a goal of minimizing the likelihood for operator error and ensuring the ability to detect and recover from errors. FSAR Tier 2, Section 18.6.2 further states that risk-significant HAs and their associated tasks are specifically addressed during the HFE program elements of function allocation, task analyses, and HSI design. The applicant further states that risk-significant HAs will also be addressed as prime sources for assessment in Integrated System Validation (ISV) using the operational conditions sampling process. This program helps ensure that human tasks are well supported by the U.S. EPR HSI design and that required actions match human performance capabilities, such as time to perform actions and ensuring that a workload is reasonable.

HRA IP, Section 1.2.1 outlines that the HRA/PRA and risk-significant HAs are addressed in the various HFE program elements, including HFEPM, OER, Functional Requirements Analysis, Function Allocation, Task Analysis, Staffing and Qualifications, HSI Design, Procedure Development, Training, and Human Factors V&V. TA IP, Section 1.5 notes that the scope of TA includes all risk-significant HAs.

HRA IP, Section 3.1, "General Requirements," states that new items analyzed during the design process that exceed the human action risk thresholds noted above, are sent back through the HFE design process as candidates for design change to lower their risk.

In a May 10, 2010, response to RAI 328, Question 18-56(7), the applicant clarified that all risk-significant HAs will be examined as part of the U.S. EPR V&V process including scenarios tested during integrated V&V. The requested changes regarding making FSAR Tier 2, Section 18.6.2 and HRA IP, Section 1.2.1.9, consistent with related references in the application were also made by the applicant in response to RAI 328, Question 18-56(7). The staff finds the applicant's May 10, 2010, response to RAI 328, Question 18-56(7) acceptable because the V&V activities will ensure that risk-significant HAs are adequately addressed and, therefore, considers RAI 328, Question 18-56(7) resolved.

The staff finds FSAR Tier 2, Section 18.6.2 and HRA IP treatment of this NUREG-0711 criterion for addressing risk-important human actions acceptable because the applicant has described how risk-important human actions (and their associated tasks and scenarios) will be addressed in conducting functional allocation analysis, task analysis, HSI design, and procedures and training development in a manner consistent with NUREG-0711.

Criterion 3

The use of PRA/HRA results by the HFE design team should be specifically addressed; that is, how are risk-important HAs addressed (through HSI design, procedural development, and training) under the HFE program to minimize the likelihood of operator error and provide for error detection and recovery capability.

Staff Evaluation of Criterion 3

HRA IP, Section 1.2.1 describes how the HRA/PRA are used in the various HFE elements. HRA IP, Section 1.2.1.6, "Human System Interface Design," states that the initial HRA will consider the conceptual HSI designs and that the HRA results will then be used to consider design modifications when risk-significant HAs, along with their performance shaping factors, are identified that can be mitigated with interface design modifications. HRA IP, Section 1.2.1.7, "Procedure Development," states that the initial HRA will consider conceptual plant procedure guidelines. HRA results will then be used to revise procedures when further mitigation of risk-significant HA (beyond HSI improvements) is judged necessary. HRA IP, Section 1.2.1.8 "Training Program Development," states that HRA results will be used to identify risk-significant HAs that should be subject to specific personnel training.

HRA IP, Section 3.2.6, "Procedure Development," states that procedure developers provide emergency procedure guidelines (EPG) to the HFE design team for input in designing the HSI. The EPG are also used to complete the HRA analysis. The procedure writers receive input from the HRA analysts on risk-significant HAs that may require more detailed procedure steps.

HRA IP, Section 3.2.7, Personnel Training Development,” states that training personnel receive input from the HRA analysts that identifies risk-significant HAs that may require more detailed training and which may require specific knowledge and skills for personnel performing those tasks.

HRA IP, Section 3.3, Methodology,” notes that the HFE design is refined to improve the HEP value by adjusting the operator interface design, the sequence of actions in procedures, the plant systems design, or the training provided to operational and maintenance personnel.

HRA IP, Section 3.4, “HRA-HFE Integration Implementation,” explains that, as part of the HRA-HFE integration process, an initial step is developing a display and control philosophy. This includes using preliminary sets of risk-important HAs to perform various human engineering design activities, including procedure and training development and subsequent modifications if determined needed as the design progresses.

Accordingly, the staff finds the applicant’s treatment of the criterion for specifying how risk-important human actions will be addressed in the HFE program acceptable because the applicant has provided a description for how the HFE design team will use results from the PRA/HRA in the U.S. EPR HFE design that is consistent with this NUREG-0711 criterion.

Criterion 4

HRA assumptions such as decision making and diagnosis strategies for dominant sequences should be validated by walkthrough analyses with personnel with operational experience using a plant-specific control room mockup or simulator. Reviews should be conducted before the final quantification stage of the PRA.

Staff Evaluation of Criterion 4

FSAR Tier 2, Section 18.6.2 states that the HRA IP describes how HRA assumptions are validated during the design process using walkthrough analyses with operationally experienced personnel. This will be done using a plant-specific control room mockup or simulator. FSAR Tier 2, Section 18.6.2 also states that these reviews will be incorporated into the final quantification stage of the PRA.

HRA IP, Section 3.3 states that during V&V, HRA assumptions are assessed and validated. HRA IP, Section 3.4 states that during the V&V process, the HFE, HRA, and operations personnel will integrate efforts to finalize the HSI design, including the development of test scenarios for assessing each risk-significant HAs and associated HSI. The V&V test plan will validate HEP calculation assumptions. Also, before finalizing the design effort, the HRA and operations personnel will verify that the HRA and the EPG approaches are consistent. The staff verified that the HRA assumptions regarding operator time frames are consistent with the EPGs.

Accordingly, the staff finds the applicant’s treatment of the criterion for validating HRA assumptions acceptable because the applicant has provided a methodology description of how HRA assumptions are validated using walkthrough analysis with personnel having operational experience and a plant-specific control room mock-up or simulator which conforms to this NUREG-0711 criterion.

18.6.4 Other Documents Subject to Review

18.6.4.1 *FSAR Tier 1, Section 3.4, “Human Factors Engineering”*

FSAR Tier 1, Table 3.4-1, “Human Factors Engineering ITAAC,” contains the ITAAC that are proposed for HFE. The staff’s evaluation of these ITAAC is provided in Section 14.3.9 of this report.

18.6.5 Combined License Information Items

There are no COL information items related to this area of review. The staff determined that no COL information items need to be included in FSAR Tier 2, Table 1.8-2, “U.S. EPR Combined License Information Items,” for HFE human reliability analysis consideration.

18.6.6 Conclusions

The staff evaluated HRA with respect to HFE, at an IP level using the review criteria in NUREG-0711, Section 7.4. Section 18.0.4 of this report provides a discussion of review levels. The staff determined that the HRA IP that is proposed for the U.S. EPR will ensure that: (1) Human-error mechanisms are adequately addressed in the design of HFE aspects of the plant in order to minimize the likelihood of personnel error and to verify errors are detected and recovered; and (2) the HRA activity will effectively integrate the HFE program to include PRA/HRA considerations. As discussed in Section 18.0.5 of this report, the HRA IP is designated as Tier 2*, which ensures that the IP will be implemented by the COL applicant. Furthermore, because the HRA IP is designated as Tier 2*, the COL applicant cannot make changes to the IP without obtaining prior NRC approval. Therefore, the staff concludes that HRA considerations with respect to HFE have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.

18.7 Human-System Interface Design

18.7.1 Regulatory Criteria

HFE human-system interface design (HSID) is evaluated based on the review criteria provided in NUREG-0711, Section 8.4, “Review Criteria,” and SRP Section 18.II.A.7. NUREG-0711, Section 8.4 specifies the review criteria pertaining to the staff’s evaluation of HSID. Specifically, the staff confirms that the applicant has appropriately translated functional and task requirements into the detailed design of alarms, controls, and displays, and other aspects of the human-system interface through the systematic application of HFE principles and criteria.

HSID with respect to HFE, is also evaluated based on the review criteria provided by Digital Instrumentation and Controls (DI&C) Interim Staff Guidance (ISG) 05 (DI&C-ISG-05), “Task Working Group No. 5: Highly-Integrated Control Rooms – Human Factors Issues,” Revision 1, November 3, 2008, and guidance in Branch Technical Position (BTP) 18-1, “Guidance for Evaluating Minimum Inventory of Alarms, Controls, and Displays for New Light Water Reactor Plant Designs,” September 11, 2009. In particular, the staff confirms that the applicant has appropriately specified the minimum inventory of HSIs for the MCR and the remote shutdown facility (RSF). The staff’s focus for this part of the review is on the inventory of alarms, controls, and displays (minimum inventory) that is provided for the operators. This part of the staff’s

evaluation is based on the guidance provided in DI&C-ISG-05, Chapter 2, “Minimum Inventory” and BTP 18-1.

18.7.2 Summary of Technical Information

HSID is described in FSAR Tier 2, Section 18.7, “Human System Interface Design.” FSAR Tier 2, Section 18.7.4, “HSI Concept Design,” incorporates by reference, “U.S. EPR Human System Interface Design Implementation Plan,” December 16, 2010 (referred to as HSID IP). The staff reviewed the HSID IP along with other documents that pertain to the staff’s review of HFE HSID as discussed in the sections that follow. The staff’s focus for this part of the review is on the review criteria and topics of NUREG-0711, Chapter 8 and SRP Section 18.II.A.7.

18.7.3 Staff Evaluation

The staff’s evaluation of HSID consists of three parts. The first part, in Section 18.7.3.1 of this report, addresses the review criteria that are specified for HSID in NUREG-0711, Section 8.4. The second part, in Section 18.7.3.2 of this report, focuses on the minimum inventory of alarms, controls, and displays. The third part, in Section 18.7.3.3 of this report, is the staff’s evaluation of the applicant’s use of computer-based procedures.

18.7.3.1 NUREG-0711 Review Considerations

The staff performed an implementation plan level of review as described in NUREG-0711 and Section 18.0.4 of this report. This section presents the applicable review criteria from NUREG-0711, Section 8.4, “Review Criteria” (reproduced below), followed by an evaluation of each. Note that because the 11th criterion that is presented in NUREG-0711, Section 8.4, for this review topic relates to plant modifications and does not apply to new plant designs, it was not included in the staff’s evaluation.

18.7.3.1.1 HSI Design Inputs

Criterion 1

Analysis of Personnel Task Requirements - The analyses performed in earlier stages of the design process should be used to identify requirements for the HSIs. These analyses include:

- Operational experience review—Lessons learned from other complex human-machine systems, especially predecessor designs and designs involving similar HSI technology should be used as an input to HSI design.
- Functional requirement analysis and function allocation - The HSIs should support the operator’s role in the plant, e.g., appropriate levels of automation and manual control.
- Task analysis - The set of requirements to support the role of personnel is provided by task analysis. The task analysis should identify:
 - tasks that are necessary to control the plant in a range of operating conditions for normal through accident conditions;

- detailed information and control requirements (e.g., requirements for display range, precision, accuracy, and units of measurement);
 - task support requirements (e.g., special lighting and ventilation requirements); and
 - risk-important HAs and their associated performance shaping factors, as identified through HRA should be given special attention in the HSI design process.
- Staffing/qualifications and job analyses - The results of staffing/qualifications analyses should provide input for the layout of the overall control room and the allocation of controls and displays to individual consoles, panels, and workstations. They establish the basis for the minimum and maximum number of personnel to be accommodated and requirements for coordinating activities between personnel.

Staff Evaluation of Criterion 1

FSAR Tier 2 description states in several places (e.g., FSAR Tier 2, Section 18.1.1.2, “Assumptions and Constraints,” and FSAR Tier 2, Section 18.7.1, “Human System Interface Design Inputs”) that these different types of analyses are used to develop the design of HSIs. The HSID IP explains how these analyses provide design input to HSIs. For example, HSID IP, Section 2.1.1, “Analysis of Personnel Task Requirements,” explains that using the results from operating experience review during HSID helps to prevent the use of HSI options previously found to be undesirable. OER results also help to select acceptable HSID options from other HFE designs. While this explanation provides a sufficient level of detail to understand how the applicant uses OER in HSID, the applicant’s explanations for the other analyses (i.e., FRA/FA, task analysis, HRA, and staffing and qualifications (S&Q)) did not provide comparable detail. For example, HSID IP, Section 2.1.5, “Staffing and Qualifications Analysis,” states that S&Q analysis considers the allocation of assigned operational activities, the impact of those activities on crewmember roles and responsibilities, and the impact of changes on operational requirements for the operating crew as a whole. How the results of S&Q analysis provide input for the layout of the overall control room and the allocation of controls and displays to individual consoles, panels, and workstations was not explained. HSID IP, Section 2.1.5 also did not explain how these analyses establish the basis to accommodate the minimum and maximum number of personnel and requirements for coordinating activities among personnel. Therefore, in addition to the concerns stated above, in RAI 350, Question 18-113, the staff requested that the applicant provide further explanation of how FRA/FA, TA, HRA, and S&Q contribute to the analysis of personnel task requirements and also provide examples of how the FRA/FA, TA, HRA, and S&Q will satisfy the applicable criteria stated above in Criterion 1.

In a March 4, 2010, response to RAI 350, Question 18-113, the applicant explained how the results of S&Q analyses provide input for the control room layout and the allocation of controls and displays to individual consoles, panels, and workstations; and how these analyses establish the basis to accommodate the minimum and maximum number of personnel and requirements for coordinating activities among personnel. The staff has confirmed that the applicant has incorporated the response into the HSID IP. The staff finds that the applicant’s response and information incorporated into the HSID IP adequately describes how FRA/FA, TA, HRA, and S&Q are included in the overall HFE program for the U.S. EPR. Therefore, the staff considers RAI 350, Question 18-113 resolved.

Accordingly, the staff finds the FSAR and HSID IP treatment of Criterion 1 related to the analysis of personnel task requirements acceptable.

Criterion 2

System Requirements - Constraints imposed by the overall instrumentation and control (I&C) system should be considered throughout the HSI design process.

Staff Evaluation of Criterion 2

HSID IP, Section 2.2, "System Requirements," states that the HSIs are designed to meet several system requirements. I&C functional requirements are specified for each of the plant systems using AREVA Procedure, "Development of I&C Interface Requirements." System description documents identify limitations for the plant systems, and additionally, computer hardware and software limitations provide HSID constraints.

FSAR Tier 2, Section 18.7.1.2, "System Requirements," provides details concerning I&C constraints that are imposed throughout the HSID. FSAR Tier 2, Section 18.7.1.2 continues by explaining that most plant and system functions are monitored and controlled by the automation system, but some system and functional requirements require manual operator actions and associated monitoring activities. Additionally, FSAR Tier 2, Section 18.7.1.2, states that further details of HSI system requirements and HSI functions including power requirements, interactions between HSIs (e.g., the alarm system with the plant overview display system; the computerized procedure system with the workstation display system), and interaction between HSIs and I&C systems are addressed in FSAR Tier 2, Section 7.1, "Introduction."

Consideration is also provided in FSAR Tier 2, Section 18.7.1.2, "System Requirements," as to how various performance aspects of the I&C system are addressed such as management of alarm prioritization, the loss of non-safety computerized HSIs, and the loss of plant automation during a design-basis event with appropriate references to I&C-related sections of the FSAR for system details.

Accordingly, the staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to system requirements acceptable because the applicant has provided an explanation of how system requirements (e.g., I&C constraints) are considered in the design of U.S. EPR HSIs in a manner that is consistent with NUREG-0711.

Criterion 3

Regulatory Requirements - Applicable regulatory requirements should be identified as inputs to the HSI design process.

Staff Evaluation of Criterion 3

FSAR Tier 2, Section 18.7.1.3, "Regulatory Requirements," provides a comprehensive listing and description of the applicable regulatory requirements that are used as inputs to the HSID process (e.g., 10 CFR 50.34(f)(2)(i) (regarding the simulator) and 10 CFR 50.34(f)(2)(iv) (regarding the plant safety parameter display console)).

Accordingly, the staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to use of regulatory requirements in the HSID process acceptable because the applicant

has identified applicable regulatory requirements as inputs to the HSI design process consistent with NUREG-0711.

Criterion 4

Other Requirements - The applicant should identify other requirements that are inputs to the HSI design.

Staff Evaluation of Criterion 4

In addition to the requirements that are referred to above in the staff's evaluation of Criterion 3, FSAR Tier 2, Section 18.7.1.4, "Other Requirements," references other HSI-related documents that are applicable to HSID (e.g., HSID IP is referenced and provides supplemental references to additional guidance documents that are related to the subject matter such as NUREG/CR-6634, "Computer-Based Procedure Systems: Technical Basis and Human Factors Review Guidance," NUREG/CR-6636, "Maintainability of Digital Systems: Technical Basis and Human Factors Review Guidance").

HSID IP, Section 2.4, "Other Requirements," also cites numerous additional industry-related and customer-related requirements and guidance that the applicant used in preparing the HSID IP that are applied to HSID.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the use of other regulatory requirements in the HSID process acceptable because the applicant has identified other applicable requirements (standard practices, industry-related guidance and good practices) as inputs to the HSI design process consistent with NUREG-0711.

18.7.3.1.2 Concept of Operations

Criterion 1

A concept of operations should be developed indicating crew composition and the roles and responsibilities of individual crew members based on anticipated staffing levels. The concept of operations should:

- Identify the relationship between personnel and plant automation by specifying the responsibilities of the crew for monitoring, interacting, and overriding automatic systems and for interacting with computerized procedures systems and other computerized operator support systems.
- Provide a high-level description of how personnel will work with HSI resources. Examples of the types of information that should be identified is [sic] the allocation of task to the main control room or local control stations, whether personnel will work at a single large workstation or individual workstations, what types of information each crew member will have access to, and what types of information should be displayed to the entire crew.
- Address the coordination of crewmember activities, such as the interaction with auxiliary operators and coordination of maintenance and operations should be addressed.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.7.2, "Concept of Operations," provides a comprehensive summary of how the U.S. EPR design addresses a concept of operations that incorporates crew composition and the roles and responsibilities of individual crewmembers based on anticipated staffing levels. Topic areas such as crew composition, roles and responsibilities of MCR crewmembers and support staff are detailed. FSAR Tier 2, Section 18.7.2, provides a description of how personnel will work with HSI resources. Examples include describing how the RO is specifically tasked with monitoring and controlling portions of the plant in accordance with the operating procedures and as directed by the control room supervisor (CRS), with the RO normally seated at a workstation controlling the plant; and how I&C technicians perform modifications of plant I&C systems using applicable procedures from the Instrumentation and Control Services Center adjacent to the MCR. FSAR Tier 2, Section 18.7.2 also describes roles of crewmembers and explains the functions of additional licensed operators, non-licensed operators and support staff, detailing various forms of communication that are used to facilitate coordination. HSID IP, Section 3.0, "Concept of Operations," references AREVA Document, "Concept of Operations: Design of the U.S. EPR Control Rooms," April 13, 2009. The staff found that the referenced document provides a high-level, thorough description of plant operational strategies for dealing with normal and abnormal situations. The referenced document also provides a description and explanation of the design of HSIs to support operators and their functions.

The HSID IP also includes a description of the applicant's proposed application of computer-based procedures (CBPs) as an integral part of the U.S. EPR HSID to reduce human error and improve the operator's ability for rapidly tracking plant status. The applicant provides general design features for consideration during HSID and acknowledges that the final CBP system design and implementation are part of the iterative HSID process. Overall procedure development is considered an operational program and is the responsibility of the COL applicant. Plant procedures are evaluated by the staff in Section 13.5, "Plant Procedures," of this report.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to concept of operations development in the HSID process acceptable because the applicant has developed a concept of operations that conforms to NUREG-0711.

18.7.3.1.3 Functional Requirement Specification

Criterion 1

Functional requirements for the HSIs should be developed to address:

- the concept of operations
- personnel functions and tasks that support their role in the plant as derived from function, task, and staffing/qualifications analyses
- personnel requirements for a safe, comfortable working environment

Staff Evaluation of Criterion 1

HSID IP, Section 4.0, "Functional Requirements Specification," states that functional requirements for the HSIs are developed to address: The concept of operations, personnel

functions, and tasks that support their role in the plant as derived from function, task, and staffing/qualifications analyses, and personnel requirements for a safe, comfortable working environment. The applicant incorporated these functional requirements as part of the systems design requirements documents (SDRDs) for each of the U.S. EPR operation and control centers (i.e., MCR, technical support center, remote-shutdown station, and instrumentation and control service center), and HSIs (i.e., process information and control system and safety information and control system). SDRDs specify design inputs for systems, structures, and components which have been composed from plant level inputs. SDRDs document and convey design inputs for review and approval by the responsible design organization. SDRDs are released before issuing subsequent design output documents to provide reasonable assurance that inputs are specified to a level of detail necessary to permit further design activity. SDRDs include the reason and design basis for each design input to ensure that the basis for design decisions, changes to the configuration, and verification measures are consistently applied. SDRDs adequately define design inputs to ensure that the hierarchy of their application is clear.

The HSID IP further specifies that the functional requirements for the operation and control centers address aspects such as the monitoring and control responsibilities for each room, the number of people expected to perform/monitor plant operations, and other aspects of the concept of operations for normal, abnormal, and emergency operation, refueling, low power operation, shift turnover, shift briefings, communication, emergency plan implementation, safety tagging, maintenance, and surveillances.

The SDRDs provide requirements for personnel functions and tasks that support their role in the plant and habitability. They also provide functional requirements for HSI systems including human interface requirements, functions that need to be performed by the HSI system, as well as the display, control, and alarm requirements. The display and control requirements include aspects such as the need for any synthetic or calculated variables. These requirements ultimately become the display elements.

The HSID IP also explains that functional requirements for the HSIs are developed using several U.S. EPR-specific technical documents including the Plant Technical Requirements Document (PTRD), and plant and I&C systems documentation (i.e., SDRD and SDD). The SDD describes the system in sufficient detail to permit verification of the system design requirements. The SDD identifies interfaces with other systems so that the design input requirements for each system can be understood. The Concept of Operations, and display and control requirements derived from the U.S. EPR Display Design Desktop Guide are also used to develop functional requirements for HSIs.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to specification of functional requirements in the HSID process acceptable because the applicant has developed functional requirements for the U.S. EPR HSI design that conform to NUREG-0711.

Criterion 2

Requirements should be established for various types of HSIs, e.g., alarms, displays, and controls.

Staff Evaluation of Criterion 2

HSID IP, Section 4.0, "Functional Requirements Specification," explains that functional requirements are translated into lower level design inputs and the functional requirements for

plant systems are documented in the SDD for the system. This is accomplished using AREVA Procedure, "Development of I&C Interface Requirements." The applicant explained the process used to translate functional requirements into lower level design inputs. For example, the PTRD contains plant requirements (including high-level HSI requirements). SDRDs are created for plant systems, each operation and control center (i.e., MCR, TSC, RSS, and I&CSC, and for each HSI (the PICS and the SICS). These documents specify the design requirements for each of these systems/control centers. HSID IP, Section 4.0, further details the process by describing the preparation and use of SDDs, detailed work plans, and how plant requirements (including high-level HSI requirements) are identified from the SDRDs and SDDs and are documented in the requirements management tool (RMT). The applicant further explains how functions are subsequently divided into tasks and how outputs from the task analysis process are used as inputs to designing HSIs. The applicant also states that the U.S. EPR HSI Design Work Plan, which replaced an earlier version of the Display Desktop Guide, provides the detailed steps for designing HSI, including displays, conventional panels, and workstations. The HSI Design Work Plan provides instructions for collecting the requirements from the inputs for HSID, including SDRDs, SDDs, and the outputs of TA.

Accordingly, the staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to HSI requirements acceptable because the applicant has established requirements for various types of HSIs in a manner consistent with NUREG-0711.

18.7.3.1.4 HSI Concept Design

Criterion 1

The functional requirement specification should serve as the initial source of input to the HSI design effort. If the design is a direct evolution from a predecessor, rather than a new design concept, the criteria in this section should be considered relative to operating experience of the predecessor and the design features (e.g., aspects of the process, equipment, or operations) of the new design that may be different from the predecessor. Human performance issues identified from operating experience with the predecessor design should be resolved.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.7.4, and HSID IP, Section 5.0, "HSI Conceptual Design," indicate that the U.S. EPR implements a modern I&C design based on experience gained internationally in new plant designs and retrofits in existing plants with digital I&C equipment. The applicant further bases the U.S. EPR HSI concepts on predecessor designs and utilizes similar control of system functions and I&C concepts as used in predecessor designs.

HSID IP, Section 5.0 states that the conceptual design for the U.S. EPR begins with the predecessor HSID. Modifications are made to the predecessor design to comply with U.S. and HFE requirements that are specified in the applicant's compliance document "U.S. EPR HFE Requirements and Compliance Document." HSID IP, Section 5.0, also states that HSIs designed using preliminary inputs from predecessor designs are verified as accurate once final input information from the predecessor design is available and any identified changes are subsequently made. The staff found that FSAR Tier 2, Section 18.7.4, and the HSID IP descriptions comparing predecessor design inputs with U.S. HFE design requirements adequately addressed Criterion 1 related to HSI Concept Design.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to use of functional requirement specifications in the HSID effort acceptable because the applicant has used the concept of a functional requirement specification for HSIs as an initial source of input to the HSI design in a manner that conforms to NUREG-0711.

Criterion 2

Alternative approaches for addressing HSI functional requirements should be considered. A survey of the state-of-the-art in HSI technologies should be conducted to:

- support the development of concept designs that incorporate advanced HSI technologies
- provide assurance that proposed designs are technically feasible
- support the identification of human performance concerns and tradeoffs associated with various HSI technologies

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.7.1 describes a variety of inputs (e.g., OER, task analysis, staffing analysis, etc.) that the applicant uses to design the U.S. EPR HSIs. HSID IP, Section 5.3, "Develop Conceptual Alternative Designs," states that throughout the design process, the applicant proposes alternative designs to meet the requirements defined in the SDRDs. These alternative designs may include aspects such as a different MCR layout or identifying multiple HSI solutions such as trackball or touch display as an input device. Additionally, feedback given on the conceptual HSID may result in varying styles of display or conventional I&C layout. The HSID methodology analyzes and evaluates alternative designs to determine which leads to a better, more efficient design.

HSID IP, Section 5.3, provides a detailed explanation of how the evaluations are conducted throughout the design process and in conjunction with the HFE verification and validation effort using various technologies and techniques such as mock-ups, simulators, trade-off evaluations, user feedback, etc. HSID IP, Section 5.3 explains the application of these techniques and their strengths and limits. The staff determined that the FSAR and the HSID IP descriptions adequately addressed Criterion 2 related to HSI Concept Design.

Although the applicant identified alternative approaches addressing HSI functional requirements, neither the FSAR nor HSID IP, Section 5.3 specified using a survey of state-of-the-art HSI technologies to identify any new or unique advances for this type of evaluation. For example, it does not appear that the applicant has considered using task network modeling or virtual reality as possible evaluation techniques in the design of the U.S. EPR HSIs. Therefore, in RAI 350, Question 18-115, the staff requested that the applicant explain how surveys were used to support the development of concept designs that incorporate advanced HSI technologies, provide assurance that proposed designs are technically feasible, and support identification of human performance concerns and tradeoffs associated with various HSI technologies.

In a March 4, 2010, response to RAI 350, Question 18-115, the applicant explained that the U.S. EPR OER Implementation Plan, Section 3.2.3, "HFE Related Technologies," includes a survey of advanced HFE technology for nuclear and non-nuclear industries as part of the OER

process. HFE-related technology is not restricted to HSI hardware/software and includes HSI evaluation tools. The applicant uses the results of the OER survey for evaluating alternative designs as described in the U.S. EPR HSID IP, Appendix A, "OER Overview Process." These evaluations include trade-off studies and performance-based tests. HSID IP, Section 7.2.1, "Virtual Mock-up," provides an example of the use of advanced technology through virtual mockups, which includes evaluating the control rooms using a 3-D virtual model. The staff finds the applicant's March 4, 2010, response acceptable and, therefore, considers RAI 350, Question 18-115 resolved.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to conducting a survey of state-of-the art alternative approaches acceptable because the applicant has described the use of alternative approaches to the design of U.S. EPR HSIs in a manner that conforms to NUREG-0711.

Criterion 3

Alternative approaches for addressing HSI functional requirements should be considered. Evaluation methods can include operating experience and literature analyses, tradeoff studies, engineering evaluations and experiments.

Staff Evaluation of Criterion 3

The applicant's treatment of the use of alternative evaluation approaches is described in the staff's evaluation of criterion 2 immediately above. As explained there, the staff finds that the applicant's treatment of this criterion acceptable.

The staff finds the FSAR and HSID IP treatment of Criterion 3 related to using alternative approaches for addressing HSI functional requirements, as described in the applicant's response to Criterion 2 above, such as operating experience and literature analysis, tradeoff studies, engineering evaluations and experiments acceptable.

Criterion 4

Alternative concept designs should be evaluated so that one can be selected for further development. The evaluation should provide reasonable assurance that the selection process is based on a thorough review of design characteristics and a systematic application of selection criteria. Tradeoff analyses, based on the selection criteria, should provide a rational basis for the selection of concept designs.

Staff Evaluation of Criterion 4

FSAR Tier 2, Section 18.7, and HSID IP, Section 7.0, "HSI Evaluations," discuss evaluating HSID throughout the design process to optimize the HSID before performing verification and validation. The applicant uses activities such as concept evaluations, mock-up activities, trade-off evaluations, and performance-based evaluations at various stages of the design process to accomplish optimizing the HSID. The HSID IP describes the application of these activities. Specifically, the applicant's HSID IP uses tradeoff evaluations to ensure that the best design is chosen from alternative designs. These evaluations compare alternative display layouts, as well as alternative HSI input devices. To ensure the best HSI design is achieved, positive and negative features of each alternative design are identified as part of the applicant's trade-off evaluation process. The applicant considers factors such as personnel task

requirements (workload analysis), human performance capabilities and limitations, use of proven technology, and operating experience of predecessor designs in performing the trade-off evaluations. This approach provides assurance that a rational basis is used to select the HSI concept design.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to evaluation and use of alternative concept designs acceptable because the applicant has provided a process to evaluate alternative concept designs that conforms to NUREG-0711.

Criterion 5

HSI design performance requirements should be identified for components of the selected HSI concept design. These requirements should be based on the functional requirement specifications but should be refined to reflect HSI technology considerations identified in the survey of the state of the art in HSI technologies and human performance considerations identified in the human performance research.

Staff Evaluation of Criterion 5

As discussed in Criterion 2 related to HSI Concept Design, the applicant uses alternative approaches to address HSI functional requirements that are based on functional requirement specifications. The applicant's OER survey of state-of-the-art HSI technologies is the process used to identify any new or unique advances during the HSID process. The HSID is refined based on the HSI evaluations described in the U.S. EPR HSID IP. The survey yields alternate design options that are evaluated and considered for HSI integration. Alternative designs that are considered during the evaluations may result from the survey.

The applicant emphasizes that the HSID process is iterative. Design changes identified during the HSID evaluation phase follow the design change control process as described in the HFEPM IP, Section 4.5.1, "U.S. EPR Design Control." HSID IP, Appendix A, shows the HSID process.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to identifying HSID performance requirements acceptable because the applicant has provided a methodology, including a survey, to identify HSI design performance requirements that conform to NUREG-0711.

18.7.3.1.5 HSI Detailed Design and Integration

Criterion 1

Design-specific HFE design guidance (style guide) should be developed. HFE guidelines should be utilized in the design of the HSI features, layout, and environment.

- The content of the Style Guide should be derived from (1) the application of generic HFE guidance to the specific application, and (2) the development of the applicant's own guidelines based upon design-related analyses and experience. Guidelines that are not derived from generic HFE guidelines may be justified by the applicant based on an analysis of recent literature, analysis of current industry practices and operational

experience, tradeoff studies and analyses, and the results of design engineering experiments and evaluations. The guidance should be tailored to reflect design decisions by the applicant to address specific goals and needs of the HSI design.

- The topics in the Style Guide should address the scope of HSIs included in the design and address the form, function, and operation of the HSIs as well as environmental characteristics relevant to human performance.
- The individual guidelines should be expressed in concrete, easily observable terms. In general, generic HFE guidelines should not be used in their abstract form. Such generic guidance should be translated into more specific design guidelines that can, as much as possible, provide unambiguous guidance to designers and evaluators. They should be detailed enough to permit their use by design personnel to achieve a consistent and verifiable design that meets the applicant's guideline.
- The Style Guide should provide procedures for determining where and how HFE guidance is to be used in the overall design process. The Style Guide should be written so it can be readily understood by designers. The Style Guide should support the interpretation and comprehension of design guidance by supplementing text with graphical examples, figures, and tables.
- The guidance should be maintained in a form that is readily accessible and usable by designers and that facilitates modification when the contents require updating as the design matures. Each guideline included in the guidance documentation should include a reference to the source upon which it is based.
- The Style Guide should address HSI modifications. This guidance should specifically address consistency in design across the HSIs.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.7.5, "Human Factors Design for the Non-Human System Interface Portion of the Plant," and HSID IP, Section 6.2, "HSI Style Guide," both provide a discussion of the development and application of AREVA Document, "U.S. EPR Human System Interface Style Guide." The HSI Style Guide is written to conform to the characteristics specified in HSI Detailed Design and Integration Criterion 1 above. For example, the HSID IP states that the guide is written to be understood by designers and addresses the overall design process. It contains graphical examples, specific rules for information arrangement and is written to maintain consistency in designing HSIs for the U.S. EPR design. The guide contains basic principles that affect the design of HSIs such as guidance related to the basic display design, use of alarm systems, display formats and elements, user interface interaction and management. The staff reviewed the HSI Style Guide during an August 28 and 29, 2009, onsite audit and determined that the guide was both useful and usable.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to development of an HSI style guide acceptable because the applicant has provided

design-specific HFE design guidance for use in the design of U.S. EPR-specific HSIs that is consistent with NUREG-0711.

Criterion 2

The HSI detailed design should support personnel in their primary role of monitoring and controlling the plant while minimizing personnel demands associated with use of the HSIs (e.g., window manipulation, display selection, display system navigation). NUREG-0700 ["Human-System Interface Design Review Guidelines," Revision 2] describes high-level HSI design review principles that the detailed design should reflect.

Staff Evaluation of Criterion 2

HSID IP, Section 1.1, "Purpose," states the U.S. EPR HSIs are designed such that "The HSI design supports the personnel in their role of monitoring and controlling the plant. In addition, the demands upon personnel using the HSI are optimized." The applicant discusses the role of personnel in monitoring and controlling the plant in the document, "Concept of Operations: Design of the U.S. EPR Control Rooms," April 13, 2009. Both the FSAR and the HSID IP discuss the U.S. EPR HSI Style Guide and how the design guidance supports personnel roles and tasks.

As part of the staff's review of the HSI detailed design, the staff reviewed the information provided by the applicant pertaining to the SPDS with respect to the requirements of 10 CFR 50.34(f)(2)(iv), which apply to design certification applications by virtue of 10 CFR 52.47(a)(8). 10 CFR 50.34(f)(2)(iv) requires that the design provide a plant safety parameter display console that will (1) display to operators a minimum set of parameters defining the safety status of the plant, (2) be capable of displaying a full range of important plant parameters and data trends on demand, and (3) be capable of indicating when process limits are being approached or exceeded.

FSAR Tier 2, Section 18.7.4.1, "Safety Parameter Display System," states, "The parameters required to be displayed as part of the SPDS are made available on the PICS and SICs...." More detail regarding the integration of the SPDS function into the U.S. EPR digital protection and control systems is provided in FSAR Tier 2, Section 7.5, and evaluated by the staff as part of the I&C review contained in Chapter 7, "Instrumentation and Controls," of this report.

In HSID IP, Section 5.1.2.1, "Safety Parameter Display System," the applicant states that the "required safety parameter display system (SPDS) parameters are available on the HSIs. These parameters, as well as transmission criteria, are in accordance with NUREG-0696, NUREG-0654, and NUREG-0737. During the conceptual design phase, these parameters are defined and documented through the SDDs."

In a June 22, 2011, response to RAI 47, Question 18-29, the applicant provided additional information on the U.S. EPR SPDS design. The applicant stated that SPDS parameters and trends defining plant safety status are provided as a specifically designed display on the PICS and the SICs. The SPDS display can be viewed on the PICS and SICs workstations as well as on the plant overview panel (POP) (driven by the PICS) in the MCR. Additionally, the SPDS display can be viewed on the PICS workstations in the Technical Support Center and the Remote Shutdown Station. The display navigation and hierarchy is designed such that the operator does not have to search through plant operating displays to find the SPDS display. By integrating the SPDS display into the PICS and SICs workstations, as well as the POP, a

convenient location is provided for personnel to readily view the SPDS display. Having the SPDS implemented in this manner makes it an integral part of day to day plant safety oversight and operations.

The applicant's response also explains that the U.S. EPR human system interface provides the status of the SPDS functions. The SPDS functions include:

- Reactivity control
- Reactor core cooling and heat removal from the primary system
- Reactor coolant system integrity
- Radioactivity control
- Containment conditions

The integrated U.S. EPR alarm system provides overview alarms addressing the five safety functions providing a direct indication of when process limits are being approached or exceeded.

In the MCR, the SPDS display is provided on both the PICS and SICS workstations, which provides redundancy and equal accuracy in both systems. The response time of both the PICS and the SICS are equal to or better than the response times recommended in NUREG-1342. The response times will be verified during equipment Factory Acceptance Testing, initial, and final Integrated System Validation.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to personnel support provided by HSID acceptable because the applicant has provided a commitment to design HSIs that support personnel in their primary roles while minimizing demands placed on personnel using guidance in the "Concept of Operations" document and "HSI Style Guide," which conforms to NUREG-0711. In particular, the staff finds that the applicant has proposed an integrated SPDS design that achieves the underlying purpose for an SPDS, which is to provide a CR improvement that enhances operator ability to comprehend plant conditions and interact in situations that call for human intervention. The applicant's proposed SPDS design provides a concise display of critical plant variables and safety function status, along with their trends and alarm condition to CR operators to aid them in rapidly and reliably determining the safety status of the plant. In this respect, the design is adequate to satisfy Criterion 2.

Criterion 3

For risk-important HAs, the design should seek to minimize the probability that errors will occur and maximize the probability that an error will be detected if one should be made.

Staff Evaluation of Criterion 3

HSID IP, Section 1.1, states that for risk-important HAs, the U.S. EPR HSID seeks to minimize the probability that errors will occur and maximize the probability that errors are detected prior to a negative safety impact. The HSID IP provides additional information by explaining that a human reliability analysis is conducted to evaluate the potential for human error that may affect

plant safety. The results of the HRA provide a list of risk-important human actions and scenarios. The HSIs used to perform those risk-important HAs are specifically addressed to provide a design that minimizes the probability of human error. The applicant gives further details to address this criterion in the HRA IP which are addressed in Section 18.6, "Human Reliability Analysis," of this report.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to error considerations for risk-important HAs acceptable because the applicant has provided an explanation, acceptable to the staff, of how the HFE design will minimize the probability that errors will occur for risk-important tasks that conforms to this NUREG-0711 criterion.

Criterion 4

When developing functional requirements for monitoring and control capabilities that may be provided either in the control room or locally in the plant, the following factors should be considered:

- communication, coordination, and workload
- feedback
- local environment
- inspection, test, and maintenance
- importance to safety

Staff Evaluation of Criterion 4

FSAR Tier 2, Section 18.7.2.5.1, "Forms of Communication and Expected Use," provides a general level discussion of the contributions the factors of communication, coordination, workload feedback, local environment, inspection, test, and maintenance make and their importance to safety on developing functional requirements for monitoring and control capabilities. For example, regarding communication, the FSAR emphasizes that MCR operator communication is essential for the safe operation of the plant and explains how MCR operators communicate with operations and support staff inside and outside the MCR.

FSAR Tier 2, Section 18.7.2.5.1, states that to reduce the burden on the operator and validate the minimum staffing requirement assumptions, training the operators to communicate efficiently, effective layout of the control rooms, and a well-designed HSI are required. Furthermore, U.S. EPR flexibility in the layout of the control rooms and design of the HSI allows for ease of change as communication methods improve with new technology.

FSAR Tier 2, Section 18.7.2.5.1, identifies that environmental conditions such as temperature, humidity, adequate lighting, and noise levels, etc., are addressed using appropriate HFE guidance. The HSID process considers risk-important actions through the application of an HRA to evaluate the potential for human error that may affect plant safety. The results provide a list of risk-important HAs and scenarios. The HSIs used to perform those risk-important HAs are specifically addressed to provide a design that minimizes the probability of human error.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the development of functional requirements for monitoring and control capabilities acceptable

because the applicant has provided a methodology to develop functional requirements for monitoring and control capabilities that conforms to this NUREG-0711 criterion.

Criterion 5

The layout of HSIs within consoles, panels, and workstations should be based upon (1) analyses of operator roles (job analysis) and (2) systematic strategies for organization such as arrangement by importance, frequency of use, and sequence of use.

Staff Evaluation of Criterion 5

FSAR Tier 2, Section 18.7.4, "HSI Design Concept," states that the U.S. EPR implements a modern I&C design based on experience gained internationally in new plant designs and retrofits in existing plants with digital I&C equipment. The HSI concepts are further based on predecessor designs and utilize similar control of system functions and I&C concepts. HSI layout is based on input from the FRA/FA, task analysis activities, and activities such as concept evaluations, mock-up activities, trade-off evaluations, and performance-based evaluations.

The HSID IP indicates that details concerning placement of operator sit-down workstations, stand-up consoles, and plant overview panels for the MCR are also defined. The layout of these components in the MCR is modified from the predecessor layout to incorporate guidance from NUREG-0700, Revision 2, such as visibility, reach and grasp requirements, and anthropometric dimensions for the intended user population. Additionally, the layout is modified to accommodate operator roles and responsibilities provided in the applicant's initial staffing assumptions and concept of operations documents which were reviewed by the staff in report in Sections 18.5, "Staffing and Qualifications," and 18.1, "Human Factors Engineering Program Management," of this report. Continued modifications to the layout are made depending on feedback from lessons learned or from the review of operating experience.

The staff finds the FSAR and HSID IP treatment this NUREG-0711 criterion related to the layout of HSIs acceptable because the applicant has provided a methodology to develop to layout HSIs within consoles, panels, and workstations that conforms to this NUREG-0711 criterion.

Criterion 6

Personnel and task performance should be supported during minimal, nominal, and high-level staffing.

Staff Evaluation of Criterion 6

FSAR Tier 2, Section 18.7.2.5.1, indicates that activities such as training the operators to communicate efficiently, establishing an effective layout for the control rooms, and providing a well-designed HSI are personnel and task performance considerations that reduce the burden on plant operators and validate the minimum staffing requirement assumptions. In addressing staffing qualifications and job analysis, FSAR Tier 2, Section 18.7.2.5.1 considers the influence of factors such as crewmember roles and responsibilities, workload, and the impact of a loss of HSIs on personnel and task performance. The applicant's concept of operations document explains how personnel and task performance are supported by the role procedures play in guiding operators to take appropriate actions and how the control room facilitates interaction with other plant personnel to perform their required functions. The V&V IP provides additional support for addressing this criterion in the discussion of various testing and evaluation methods

that the U.S. EPR HFE method uses to validate HSID using minimal, nominal, and maximum staffing levels.

Accordingly, the staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the accommodation of varying staffing levels acceptable because the applicant has provided an explanation of how personnel and task performance will be supported during minimal, nominal, and high-level staffing that conforms to NUREG-0711.

Criterion 7

The design process should take into account the use of the HSIs over the duration of a shift where decrements in performance due to fatigue may be a concern.

Staff Evaluation of Criterion 7

FSAR Tier 2, Section 18.7.6.2, "HSI Considerations and Demands on Operators," states the HSI design takes into account the use of HSIs over the duration of a shift where decrements in human performance due to fatigue may occur. The applicant's HFE design uses attributes such as physical layout of the control room and workstations that consider the distances operators are required to move to initiate manual actions. Excessive amounts of movement, including arm and hand movement, for long durations can impact the performance of the operator and are considered by the applicant in the HSI design. FSAR Tier 2, Section 18.7.6.2, explains that the HSID supports operators in their primary role of monitoring and controlling the plant while minimizing physical and mental demands associated with use of HSIs and that NUREG-0700 principles affecting the design of HSIs are incorporated into the HSI Style Guide. The applicant's methodology also evaluates, as part of the staffing analysis and during V&V, the influence of factors such as situational awareness and workload on personnel performance.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the use of HSIs to mitigate the effects of operator fatigue over extended shifts acceptable because the applicant has provided a explanation of how the design process accounts for the use of the HSIs over the duration of a shift where decrements in performance due to fatigue may be a concern that is in conformance to this NUREG-0711 criterion.

Criterion 8

HSI characteristics should support human performance under the full range of environmental conditions, e.g., normal as well as credible extreme conditions. For the main control room, requirements should address conditions such as loss of lighting, loss of ventilation, and main control room evacuation. For the remote-shutdown facility and local control stations, requirements should address constraints imposed by the ambient environment (e.g., noise, temperature, contamination) and by protective clothing (if necessary).

Staff Evaluation of Criterion 8

FSAR Tier 2, Section 18.7 did not address this consideration. The HSID IP states that the HSIs are designed for all modes of operation; normal, abnormal, and emergency, during refueling, startup, and low power operation. The HSID IP further explains that the MCR provides the capability for achieving safe shutdown, even assuming a safe-shutdown earthquake (SSE), a loss of offsite power, and the most limiting single failure; and that if evacuation of the MCR is

required, the operators can establish and maintain safe shutdown conditions from outside the MCR through the use of the PICS and SICS in the RSS. The applicant's concept of operations document also specifies that diagnosing equipment failures is enhanced through the use of equipment self-diagnosis and self-monitoring systems. However, FSAR Tier 2, Section 18.7, the HSID IP, and other referenced documents such as the HSI Style Guide did not address handling a loss of lighting, loss of ventilation, and main control room evacuation for the main control room. In addition, FSAR Tier 2, Section 18.7, HSID IP, and other referenced documents did not explain how the remote shutdown facility and local control stations address constraints imposed by the ambient environment (e.g., noise, temperature, contamination), and the use of protective clothing (if needed) has not been addressed. Therefore, in RAI 350, Question 18-117, the staff requested that the applicant explain how the HSI design will handle the loss of lighting, loss of ventilation, and main control room evacuation. The staff also requested that the applicant explain how requirements for the remote shutdown facility and local control stations address constraints imposed by the ambient environment (e.g., noise, temperature, contamination) and by protective clothing, if needed.

In a March 4, 2010, response to RAI 350, Question 18-117, the applicant indicated that the U.S. EPR HFE Program Management IP, Section 2.2.2.2.9, "Loss of MCR," states that, "If the main control room (MCR) becomes uninhabitable, the plant is tripped as the operators leave the MCR. Operators will conduct further shutdown activities from the RSS." The applicant further explains that the TA process evaluates extreme workplace conditions (e.g., lighting/glare, heat, temperature, noise, humidity, radiation/contamination, unsafe floors (oily, wet, and icy), pressure differentials between zones, confined spaces, and working at heights) during the development of task requirements.

Regulatory requirements related to extreme environmental conditions are considered during HSID and are documented in SDRDs using the standard design control process described in the HFE Plan. These requirements are incorporated into the HSID. In a March 4, 2010, response to RAI 350, Question 18-117, the applicant stated that the design of HSIs for LCSs addresses environmental and lighting considerations in the U.S. EPR LCS Style Guide, Sections 13.0 and 14.0. These considerations include normal and emergency situations. Factors addressed by the U.S. EPR LCS Style Guide include the workstation envelope (e.g., access, reach, and so forth), radiation, heat, cold, noise, and lighting.

In the applicant's March 4, 2010, response to RAI 350, Question 18-117, the applicant explained how the EPR HSI design will handle the loss of lighting, loss of ventilation, and main control room evacuation and how the remote shutdown facility and local control stations address constraints imposed by the ambient environment (e.g., noise, temperature, contamination) and by protective clothing. Since this explanation addresses developing HSIs to support human performance under the full range of environmental conditions, the staff finds this RAI resolved. The staff finds the FSAR and HSID IP treatment of Criterion 8 related to the accommodation of environmental conditions acceptable because the applicant's FSAR, HSID IP, together with the March 4, 2010, response to RAI 350, Question 18-117, provide a process for developing HSIs that should support human performance under the full range of environmental conditions that conforms to this NUREG-0711 criterion.

Criterion 9

The HSIs should be designed to support inspection, maintenance, test, and repair of (1) plant equipment and (2) the HSIs. The HSIs should be designed so that inspection, maintenance, test, and repair of the HSIs do not interfere with

other plant control activities (e.g., maintenance tags should not block the operators' views of plant indications).

Staff Evaluation of Criterion 9

FSAR Tier 2, Section 18.7.7, "HSI Verification and Validation (Tests and Evaluations)," and HSID IP, Section 7.0, "HSI Evaluations," indicate that trade-off evaluations are performed to ensure that the best design is selected from the alternative designs that are available. Factors that the applicant considers in performing the trade-off evaluations of HSIs include how inspection, testing, and maintenance requirements affect the HSIs. The applicant uses testing and evaluation throughout the HSID process at various stages of HSI development to ensure that HSIs support inspection, testing, maintenance, and repair activities without interference with plant control activities.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the accommodation of test, inspection, and maintenance activities acceptable because the applicant provided a methodology to ensure that HSIs support inspection, maintenance, and repair activities without interference with plant control activities that conforms to this NUREG-0711 criterion.

Criterion 10

Criterion 10 relates to design modifications and, therefore, is not applicable to this review.

18.7.3.1.6 HSI Tests and Evaluations

Testing and evaluation of HSI designs should be conducted throughout the HSI development process and evaluations should be conducted iteratively. The methodology used for testing should be reviewed using the appropriate criteria provided below. The types of tests and evaluations performed will vary depending on the specific applicant's design process.

18.7.3.1.6.1 Trade-Off Evaluations

Criterion 1

Aspects of human performance that are important to task performance should be carefully selected and defined so that the differential effects of design options on human performance can be adequately considered in the selection of design approaches. The following factors should be considered when developing selection criteria:

- personnel task requirements
- human performance capabilities and limitations
- HSI system performance requirements
- inspection and testing requirements
- maintenance requirements

- use of proven technology and the operating experience of predecessor designs.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.7.7 and HSID IP, Section 7.0 indicate that trade-off evaluations are performed to ensure that the best design is selected from the alternative designs that are available. These evaluations compare alternative display layouts as well as alternative HSI input devices. Positive and negative features of each alternative design are identified to ensure an accurate determination of the optimum design. The applicant considers factors such as personnel task requirements, workload analysis, human performance capabilities and limitations, HSI system performance requirements, inspection and testing requirements, maintenance requirements, and use of proven technology and operating experience of predecessor designs in performing trade-off evaluations. Performance-based evaluation is another method the applicant uses to help determine the best HSI design. In this type of evaluation, users are requested to perform pre-defined scenarios. Performance of the user or the HSI is then measured. These measurements may include items such as the time required to operate a trackball and a touch screen during a specific task. The performance measurements are used in trade-off evaluations to determine whether the trackball or touch screen is the best design for that scenario.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to human performance trade-off evaluations acceptable because the applicant has described a method to select and define aspects of human performance that are important to task performance in a manner that conforms to this NUREG-0711 criterion.

Criterion 2

The selection process should make explicit the relative benefits of design alternatives and the basis for their selection.

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.7 and HSID IP, Section 7.0, did not address Criterion 2. Therefore, in RAI 350, Question 18-118, the staff requested that the applicant explain the process that will be used to determine the relative benefits of design alternatives derived from trade-off studies, the basis for their selection, and relative schedule for when the selection of design alternatives will be completed.

In a March 4, 2010, response to RAI 350, Question 18-118, the applicant indicated that the V&V IP explains that HSI evaluations, including trade-off evaluations, are performed as part of the iterative HSID process described in the HSID IP. The HSI evaluations are completed independent of and before the human factors V&V. HSID IP, Section 7.4, "Trade-Off Evaluations," was revised with the following representative information to address Criterion 2:

The results of trade-off studies are recorded to document the advantages and disadvantages of available options. The basis for the selection of the optimized design is provided. Results of the evaluations are used to determine HSI selection decisions. For example, the choice of a trackball or a touch screen is determined for certain applications based on evaluation results. The HSI design process is iterative, and if a design change is required due to the results of a

trade-off evaluation, then the output is reintroduced into the HSI detailed design phase as shown in Appendix A.

Based on the applicant's March 4, 2010, response, which explained the process that will be used to determine the relative benefits of design alternatives derived from trade-off studies, the basis for their selection, and relative schedule for when the selection of design alternatives will be completed, the staff finds RAI 350, Question 18-118 resolved. The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to addressing the relative benefits of design alternatives acceptable because the applicant has described a process that addresses the relative benefits of design alternatives that is consistent with NUREG-0711.

18.7.3.1.6.2 Performance-Based Tests

Criterion 1

Performance-based tests can have many different purposes; therefore, the hypotheses should be structured to address the specific questions being addressed.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.7.7, "HSI Verification and Validation (Tests and Evaluations)," states that the criteria used to decide which type of testing or evaluation technique is appropriate to use for HSID are described in the applicant's V&V IP. The staff considers use of the V&V IP acceptable for addressing Criterion 1. The staff's evaluation of the V&V IP in this regard is provided in Section 18.10.3, of this report.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the structuring of hypotheses acceptable because the applicant has provided a process to structure performance-based test hypotheses, described in Section 18.10.3 of this report, that the staff has determined conforms to this NUREG-0711 criterion.

Criterion 2

The general approach to testing should be based on the test objective. The design of performance-based tests should be driven by the purpose of the evaluation and the maturity of the design.

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.7.7 and HSID IP, Section 7.0, did not address Criterion 2. Therefore, in RAI 350, Question 18-119, the staff requested that the applicant explain how the general approach to testing is based on the test objective and how the design of performance-based tests is driven by the purpose of the evaluation and the maturity of the design.

In a March 4, 2010, response to RAI 350, Question 18-119, the applicant indicated that the U.S. EPR HSID IP would be revised to address this NUREG-0711 consideration. The applicant also stated that information on performance measures, scenario selection, and performance evaluation is provided in the March 4, 2010, response to RAI 328, Question 18-62. RAI 328, Question 18-62, is related to the applicant's V&V process, the details of which are evaluated in Section 18.10, "Human Factors Engineering Verification and Validation," of this report.

On December 16, 2010, the applicant submitted a final HSID IP. The HSID IP included changes to HSID IP, Section 7.5, "Performance-Based Evaluations," consistent with the March 4, 2010, response to RAI 350, Question 18-119. HSID IP indicated that performance-based testing is part of the HSI evaluation process. The pre-defined scenarios, test participants, and test beds that are used are designed based on the test objectives and on the maturity of the HSID being tested. The applicant also stated that once performance-based evaluations are complete, the HSID process is used to analyze the results and to make design modifications if problems are identified in the test results. The results of performance-based tests also can be used as input to trade-off studies. The staff finds that the applicant's explanation of using test objectives to determine and design test scenarios, select test participants, and test beds adequately addressed the provisions of Criterion 2. HSID IP contains these changes. Based on the applicant's December 16, 2010, response, the staff finds RAI 350, Question 18-119 resolved.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the general approach to testing acceptable because the applicant has described a process for using a general approach to testing that is based on the test objective and a process using performance-based tests that are driven by the purpose of the evaluation and the maturity of the design, that conforms to this NUREG-0711 criterion.

Criterion 3

The specific design features or characteristics of design features should be carefully defined. If the characteristics are to be manipulated in the test, i.e., systematically varied, the differences between test conditions should be specified in detail.

Staff Evaluation of Criterion 3

FSAR Tier 2, Section 18.7.7 and HSID IP, Section 7.0, did not address Criterion 3. Therefore, in RAI 350, Question 18-120, the staff requested that the applicant explain how the specific design features or characteristics of design features are carefully defined. If the characteristics are to be manipulated in the test, that is systematically varied, the differences between test conditions should be specified in detail.

In a March 4, 2010, response to RAI 350, Question 18-120, the applicant indicated that the response to this question was contained in the March 4, 2010, response to RAI 350, Question 18-119. As stated in the staff's evaluation of the March 4, 2010, response to RAI 350, Question 18-119, the applicant provided the final HSID IP on December 16, 2010. The applicant's response and HSID IP addressed Criterion 3 by explaining that performance of the user and the HSI interactions are measured using, for example, timed responses employing a trackball and touch screen operations. The applicant indicated that for any manipulated characteristics, each distinct test condition is documented. The selection of performance measurements is based on test objectives, the parameters measured, and the criteria they are measured against. The applicant also stated that information on performance measures, scenario selection, and performance evaluation is provided in the March 4, 2010, response to RAI 328, Question 18-62. RAI 328, Question 18-62 is related to the applicant's V&V process, the details of which are evaluated in Section 18.10.3 of this report. The applicant's response and the staff's question discuss aspects of measurement characteristics of performance-based tests but not characteristics or specific design features of the HSIs that will be tested using the performance-based tests. To address Criterion 3 and RAI 328, Question 18-62, the applicant needed to explain, or provide a specific reference to where this explanation exists, how specific

HSID features will be tested and systematically varied during testing. As an example, two HSID features that might be tested, which may vary under different conditions, are font size and visual display unit (VDU) screen background color. In RAI 433, Question 18-215, the staff requested that the applicant explain how these design features are determined and systematically tested under varying conditions of expected usage.

In a December 16, 2010, response to RAI 433, Question 18-215, the applicant expanded the discussion of HSID IP, Section 7.5, "Performance-Based Evaluations," to explain how HSID features are determined and systematically tested under varying conditions of usage. The applicant explained that HSID features to be tested are determined using sources such as OER data, input from PRA/HRA (i.e., risk-important HAs), and surveys of advanced HSI technologies. The selected HSIs and features are exercised under varying test conditions (e.g., environments, time limitations, etc.) in accordance with test objectives, and the results are documented. The HSID IP contains these changes. Based on the applicant's December 16, 2010, response, which explained how the specific design features or characteristics of design features are defined under varying test conditions, the staff finds RAI 433, Question 18-215 resolved.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the specific definition of design features acceptable because the applicant defined specific design features or characteristics of design features and, explained the differences in test conditions that would exist if these features or characteristics were to be manipulated during performance testing, in manner that conforms to this NUREG-0711 criterion.

Criterion 4

The selection of test beds for the conduct of performance-based tests should be based upon the requirements imposed by the test hypotheses and the maturity of the design.

Staff Evaluation of Criterion 4

FSAR Tier 2, Section 18.7.7 and HSID IP, Section 7.0, did not address Criterion 3. Therefore, in RAI 350, Question 18-121, the staff requested that the applicant explain how the selection of test beds for the conduct of performance-based tests is based upon the requirements imposed by the test hypotheses and the maturity of the design.

In a March 4, 2010, response to RAI 350, Question 18-121, the applicant indicated that the response to this question was contained in the March 4, 2010, response to RAI 350, Question 18-119. In its response, the applicant indicated that the criteria that are used to decide which type of testing or evaluation technique is appropriate to use for HSID are described in the V&V IP. V&V IP, Section 3.5.4.1, "Validation Testbed," provides a detailed explanation of selecting testbeds that are appropriate for the hypotheses being examined. The staff considers use of the V&V IP acceptable for addressing Criterion 4. The staff's evaluation of the V&V IP in this regard is provided in Section 18.10.3 of this report. The staff finds the applicant's March 4, 2010, response to RAI 350, Question 18-121 acceptable, and therefore resolved.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the selection of test-beds for performance-based testing acceptable because the applicant has provided a methodology for selecting testbeds that conforms to this NUREG-0711 criterion.

Criterion 5

The selection of performance measures should be based on a consideration of:

- measurement characteristics
- identification and selection of variables to represent measures of the aspects of performance under investigation
- development of performance criteria

Staff Evaluation of Criterion 5:

FSAR Tier 2, Section 18.7.7 and the HSID IP, Section 7.0, did not address Criterion 5. Therefore, in RAI 350, Question 18-122, the staff requested that the applicant explain how the selection of performance measures is based on a consideration of: Measurement characteristics; identification and selection of variables to represent measures of the aspects of performance under investigation; and development of performance criteria.

In a March 4, 2010, response to RAI 350, Question 18-122, the applicant indicated that the response to this question was contained in the March 4, 2010, response to RAI 350, Question 18-119. In its response, the applicant indicated that the criteria that are used to decide which type of testing or evaluation technique is appropriate to use for HSID are described in the V&V IP. V&V IP, Section 3.5.4.4, "Performance Measurement," provides a detailed explanation of selecting performance measures that are based on the characteristics identified in this NUREG-0711 criterion. As explained in the V&V section of this report, the staff finds the applicant's processes for deciding which type of testing or evaluation technique is appropriate to use for HSID and for selecting performance measures, to be an acceptable means to meet this NUREG-0711 criterion. The staff's evaluation of the V&V IP process for selecting performance measures is provided in Section 18.10.3 of this report. Accordingly, the staff finds the applicant's March 4, 2010, response to RAI 350, Question 18-122 resolved.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the selection of performance measures acceptable because the applicant provided a methodology for selecting HSI design test performance measures that conforms to this NUREG-0711 criterion.

Criterion 6

The selection of participants for HSI design tests should be based on the nature of the questions being addressed in test objectives and the level of design maturity.

Staff Evaluation of Criterion 6

FSAR Tier 2, Section 18.7.7 and HSID IP, Section 7.0, did not address Criterion 6. Therefore, in RAI 350, Question 18-123, the staff requested that the applicant explain how the selection of participants for HSID tests is based on the nature of the questions being addressed in test objectives and the level of design maturity.

In a March 4, 2010, response to RAI 350-4185, Question 18-123, the applicant indicated that the response to this question was contained in the March 4, 2010, response to RAI 350,

Question 18-119. In its response, the applicant indicated that the criteria that are used to decide which type of testing or evaluation technique is appropriate to use for HSID are described in the V&V IP. V&V IP, Section 3.5.4.2, "HFE Integrated System Validation Team and Participant Population," provides a detailed explanation for selecting participant personnel for the integrated testing process that are based on the characteristics identified in this NUREG-0711 criterion. The staff considers use of the V&V IP acceptable for addressing Criterion 6 because the process used for test participant selection, as described in the V&V section, is acceptable to the staff and also applicable to this NUREG-0711 criterion 6 for test participant selection. The staff's evaluation of the V&V IP process for selecting HSI design test participants is provided in Section 18.10.3 of this report. Accordingly, the staff finds the applicant's March 4, 2010, response to RAI 350, Question 18-123 resolved.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the selection of participants for HSI design tests acceptable because the applicant provided a methodology for selecting participants for HSI design tests that conforms to this NUREG-0711 criterion.

Criterion 7

The test design should permit the observation of performance in a manner that avoids or minimizes bias, confounds, and error variance (noise).

Staff Evaluation of Criterion 7

FSAR Tier 2, Section 18.7.7 and HSID IP, Section 7.0, did not address Criterion 7. Therefore, in RAI 350, Question 18-124, the staff requested that the applicant explain how the test design should permit the observation of performance in a manner that avoids or minimizes bias, confounds, and error variance (noise).

In a March 4, 2010, response to RAI 350, Question 18-124, the applicant indicated that the response to this question was contained in the March 4, 2010, response to RAI 350, Question 18-119. The applicant provided Revision 3 to the HSID IP by letter dated May 7, 2010. The applicant explained in the March 4, 2010, response to RAI 350, Question 18-119, and in HSID IP, Revision 3, that the goal of performance-based tests is to exclude confounding variables so that cause and effect can be established. The effects of confounding are controlled by changing certain conditions (experimental variables). This is done by keeping controllable variables not being studied constant, such as time of day or ambient noise level, including a control group in the evaluation such as a group that is not subjected to the studied variable, and through the random assignment of participants to groups. Using matched pairs and/or exposing the participants to experimental conditions is another technique considered by the applicant to avoid testing bias. The applicant further stated that error variance (noise) is variability among results that cannot be attributed to the effects of the independent variable and may obscure the independent variable. Error variance may be the result of individual differences such as age, skill level, or motivation. The applicant's testing protocol attempts to keep potential nuisance variables, such as time of day and day of the week, constant throughout the evaluation to minimize their effects. Evaluations are designed to permit the identification of nuisance variables so that their effect (error variance) can be removed. Based on the applicant's March 4, 2010, response, which explains how test design will allow observation of performance without introducing bias, the staff finds RAI 350, Question 18-124 resolved.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to test design provisions for minimizing bias, confounding, or error variance (noise) acceptable

because the applicant provided a methodology for minimizing testing bias, confounding, or error variance (noise) that conforms to this NUREG-0711 criterion.

Criterion 8

Test data should be analyzed using established analysis techniques.

Staff Evaluation of Criterion 8

FSAR Tier 2, Section 18.7.7 and the HSID IP, Section 7.0, did not address Criterion 8. Therefore, in RAI 350-4185, Question 18-125, the staff requested that the applicant explain how the test data is analyzed using established analysis techniques.

In a March 4, 2010, response to RAI 350, Question 18-125, the applicant indicated that the response to this question was contained in the March 4, 2010, response to RAI 350, Question 18-119. In its response, the applicant indicated that the criteria that are used to decide which type of testing or evaluation technique is appropriate to use for HSID are described in the V&V IP. V&V IP, Section 3.5.4.6, "Data Analysis and Interpretation," provides a detailed explanation for the process the applicant proposes to use to evaluate test results obtained from conducting the verification and validation process for the U.S. EPR HFE design. The staff considers use of the V&V IP acceptable for addressing Criterion 8 because the process analyzing test data that the applicant describes as part of its V&V activity is acceptable to the staff and is applicable to this NUREG-0711 criterion 8 for HSID. The staff's evaluation of the V&V IP for test data analysis is provided in Section 18.10.3 of this report. Based on the applicant's March 4, 2010, response, the staff finds RAI 350, Question 18-125 resolved.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to analysis of test data acceptable because the applicant provided a methodology for analyzing test data that conforms to this NUREG-0711 criterion.

Criterion 9

Design solutions, such as modifications of the HSIs or user training requirements, should be developed to address problems that are identified during the testing and evaluation of the HSI detailed design.

Staff Evaluation of Criterion 9

FSAR Tier 2, Section 18.7.7 and HSID IP, Section 7.0, did not address Criterion 9. Therefore, in RAI 350, Question 18-126, the staff requested that the applicant explain how design solutions, such as modifications of the HSIs or user training requirements, are developed to address problems that are identified during the testing and evaluation of the HSI detailed design.

In a March 4, 2010, response to RAI 350, Question 18-126, the applicant indicated that the response to this question was contained in the March 4, 2010, response to RAI 350, Question 18-119. In its response, the applicant indicated that the criteria that are used to decide which type of testing or evaluation technique is appropriate to use for HSID are described in the V&V IP. The staff considers use of the V&V IP acceptable for addressing Criterion 9 because the criteria that are used to decide which type of testing or evaluation technique is appropriate to use for HSID, as described in the applicant's V&V IP, are acceptable. These criteria are also applicable to this NUREG-077 criterion. The staff's

evaluation of the V&V IP process for deciding which type of testing or evaluation technique is appropriate to use for HSID is provided in Section 18.10.3 of this report. Based on the applicant's March 4, 2010, response, the staff finds RAI 350, Question 18-126 resolved.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the development of design solutions for addressing problems that are identified during HSID testing acceptable because the applicant provided a methodology for developing design solutions for addressing problems that are identified during HSID testing that conforms to this NUREG-0711 criterion.

18.7.3.1.7 HSI Design Documentation

Criterion 1

The HSI design should be documented to include:

- the detailed HSI description including its form, function and performance characteristics
- the basis for the HSI requirements and design characteristics with respect to operating experience and literature analyses, tradeoff studies, engineering evaluations and experiments, and benchmark evaluations
- records of the basis of the design changes

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.7.8, "HSI Design Results and Documentation," indicates that the HSID is documented using specific design control process requirements. The various configuration management, design change controls, design verification, and design quality control tools are described in AREVA's Quality Assurance Plan. The staff finds that the design quality control tools described in the QAP contribute to satisfying the considerations of Criterion 1. The HSID IP provides more specific information indicating that the HSID documentation includes a detailed HSI description, including its form, function and performance requirements and characteristics, the basis for the HSI requirements and design characteristics, and required documentation of the bases for design changes. The SDRD and SDD for each HSI (e.g., PICS, SICS, MCR, etc.) also serve as documentation for the HSI design.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to HSI design documentation acceptable because the applicant has provided a process for documenting HSI design results that conforms to this NUREG-0711 criterion.

Criterion 2

The outcomes of tests and evaluations performed in support of HSI design should be documented.

Staff Evaluation of Criterion 2

HSID IP, Section 9.0, "HSI Design Documentation," states that HSID documentation is developed during the design process. The documentation includes the outcomes of tests and

evaluations, with separate reports being generated to document the results of tests and evaluations that are performed to support HSID.

The staff finds the FSAR and HSID IP treatment of this NUREG-0711 criterion related to the documentation of tests and evaluations for HSID acceptable because the applicant has provided a method to document outcomes from HSI test and evaluations that conforms to this NUREG-0711 criterion.

18.7.3.2 *Minimum Inventory of Alarms, Controls, and Displays*

The staff performed an implementation plan level of review of the minimum inventory of alarms, controls, and displays for the MCR and RSF as described in NUREG-0711 and Section 18.0.4 of this report. The staff's evaluation in this section is based on using guidance provided from several sources that include SECY 92-053, SRP Chapter 18.0, and SRP Chapter 14.0, Section 14.3.9. The staff also used the review criteria for minimum inventory (MI) published as Interim Staff Guidance DI&C-ISG-05, Revision 1, Section 2, "Minimum Inventory," November 3, 2008.

During the time the staff was reviewing the FSAR, DI&C-ISG-05, Revision 1, was updated and the revised guidance was published for public comment in BTP 18-1. As of the preparation of this report, the staff is in the process of reviewing the public comments and anticipates publishing a final version of the guidance in the near term. A significant change from the previous staff guidance for addressing the minimum inventory is that listings of the alarms, controls, and displays that comprise the Main Control Room and Remote Shutdown Facility minimum inventories have been deferred from being part of the design certification application. For the design certification applicant, the staff emphasizes assessing the process the applicant proposes using to develop the listings; the lists are developed as part of the detailed human system interface design process and addressed by ITAAC.

The principal guidance sources the staff used to review the applicant's MI were the DI&C-ISG-05, Revision 1, Section 2, and BTP 18-1.

As stated in BTP 18-1, the staff reviews the applicant's implementation plan for developing the MI of HSIs for the MCR and RSF and the applicant's proposed ITAAC to verify and validate acceptable implementation of the MCR and RSF minimum inventories.

BTP 18-1 defines minimum inventory as follows:

The MCR minimum inventory is that set of MCR HSIs needed by operators to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition.

The RSF minimum inventory is that set of remote shutdown HSIs needed by operators, upon MCR evacuation, to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition.

HSID IP, Section 6.1, "Minimum Inventory Development," states that:

The minimum inventory (MI) for the U.S. EPR MCR and RSS [the applicant refers to the RSF as the Remote Shutdown Station or, "RSS." For purposes of this review, RSS and RSF are synonymous] is developed as a part of the HSI design process. The MCR minimum inventory for the U.S. EPR design is the set

of alarms, displays, and controls required for the operator to perform the manual actions that are credited in the emergency operating procedures (EOPs) and that are determined critical by PRA to bring the reactor to a safe shutdown condition and maintain it in the safe shutdown condition. This includes the plant process parameters (indications, controls, and alarms) that support the identified operator actions.

In FSAR Tier 2, Section 18.7.4.5, "Remote Shutdown Station Alarms, Displays, and Controls," the applicant further indicates:

The minimum inventory of alarms, displays, and controls in the RSS consists of only those functions necessary to attain safe shutdown following an MCR evacuation. The RSS minimum inventory includes the readily accessible HSIs that the operator needs to:

- Perform and confirm a reactor trip.
- Place and maintain the reactor in a safe condition using the normal or preferred safety means.

The definitions that the applicant uses for the MCR and RSS minimum inventories differ from, but are consistent with, the definitions used by the staff.

BTP 18-1, Section 4, "Acceptance Criteria," identifies two broad criteria the staff uses to evaluate an applicant's proposed MI for the MCR and RSS; Criterion 1, which the staff has divided into three parts for the purpose of this safety evaluation, focuses on the applicant's Tier 2* implementation plan to develop the MI for the MCR and RSS, and Criterion 2 focuses on the FSAR Tier 1 ITAAC for the MCR and RSS minimum inventories. Both criteria are evaluated below.

18.7.3.2.1 Criteria Evaluation

Criterion 1

Part 1:

Applicants for new plant DC should include with the FSAR, Chapter 18, "Human Factors Engineering" Tier 2* information, an implementation plan to develop the minimum inventory for the MCR and RSF of those HSIs that the operator needs to:

- a. perform manual actions credited in the plant's EOPs that are necessary to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition
- b. perform manual actions determined to be critical by the applicant's PRA and that are needed by operators to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition.

Part 2:

The implementation plan should provide the applicant's proposed methodology for meeting the acceptance criteria. It should contain a level of detail sufficient for

individuals experienced in the technical disciplines needed to develop a minimum inventory to satisfactorily execute the plan. At a minimum, the implementation plan should include a description of the methodology, and identify the source documents and applicable guidance that the applicant will use to:

- identify those manual actions credited in the plant's EOPs that are necessary to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition
- identify those manual actions determined to be critical by the applicant's PRA and that are needed by operators to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition
- determine the plant process parameter(s) (e.g., containment pressure, feedwater flow) associated with initiating and carrying out each manual action
- apply the HSI design process (i.e., NUREG-0711, Chapter 8, "Human System Interface Design," NUREG-0700, etc.) to developing the MCR and RSF minimum inventory HSIs
- ensure adequate availability and reliability of the MCR and RSF minimum inventories to support safe shutdown and the ability to maintain safe shutdown.

Part 3:

The implementation plan also should identify the technical qualifications of the individuals responsible for developing the MCR and RSF minimum inventories.

Staff Evaluation of Criterion 1

The staff's evaluation of the three parts of Criterion 1, which emphasizes developing an implementation plan for the MCR and RSS minimum inventories, is provided below.

FSAR, Tier 2, Section 18.7.4.4, "Minimum Inventory of Main Control Room Alarms, Displays, and Controls," discusses the concept of MI of alarms, controls, and displays. FSAR Tier 2, Section 18.7.4.5, "Remote-Shutdown Station Alarms, Displays, and Controls," discusses the RSS MI.

FSAR Tier 2, Section 18.7.4.4, further states that the HSID IP describes the methodology for selecting the MI. HSID IP, Section 6.1, "Minimum Inventory Development," provides the applicant's MI implementation plan, which the staff evaluated using Criterion 1 above.

Criterion 1 (Part 1) specifies that the applicant for a new plant design certification should provide an implementation plan to develop the minimum inventory for the MCR and RSF of those HSIs that the operator needs to:

- a. perform manual actions credited in the plant's EOPs that are necessary to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition

- b. perform manual actions determined to be critical by the applicant's PRA and that are needed by operators to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition.

Staff Evaluation of Criterion 1 (Part 1)

HSID IP, Section 6.1, "Minimum Inventory Development," states that the MI is the set of HSI in the MCR as well as the HSI inventory in the RSS. The RSS MI is a smaller set of the parameters that are required to perform and confirm a reactor trip and then to maintain the reactor in a safe condition using the normal or preferred safety means.

HSID IP, Section 6.1, explains that the MI for the MCR and RSS is developed as a part of the HSI design process. The MCR MI is the set of alarms, displays, and controls that allow the operator to perform the manual actions that are credited in the emergency operating procedures and that are determined critical by PRA to bring the reactor to a safe shutdown condition and maintain it in the safe shutdown condition. This includes the plant process parameters (indications, controls, and alarms) that support the identified operator actions.

To identify those manual actions credited in the plant's EOPs that are necessary to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition, HSID IP, Section 6.1.4.1, "Identify MI Tasks," states that the Emergency Procedures Guidelines (EPGs) are analyzed to determine the manual actions that are performed to bring the reactor to a safe shutdown condition, and maintain it in that condition. The EPGs are an input to the MI identification process and are complete before this process is started. The applicant's commitments address the HSID IP aspect of developing an MI of HSIs needed for operators to perform these manual actions as credited in the plant's EOPs.

In HSID, Section 6.1.4.1, the applicant states that, as a part of the PRA, risk-significant HAs are identified. The list of these actions is updated each time the PRA is revised. The applicant further states that the HRA IP provides additional detail on how the PRA is used in the HFE program. This acceptably addresses the implementation plan aspect of identifying those manual actions determined to be critical by the applicant's PRA and that are needed by operators to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition. The applicant's proposed method commits to meet this PRA-related aspect of the criterion, and is therefore acceptable.

The staff finds the FSAR and the HSID IP treatment of Criterion 1, Part 1, related to providing an implementation plan that addresses manual operator actions from EOPs and critical operator actions from the plant's PRA acceptable because the applicant has provided a process that addresses manual operator actions from EOPs and critical operator actions from the plant's PRA that is consistent with the staff's review of this regulatory criterion and related staff guidance.

Criterion 1 (Part 2) states:

The implementation plan should provide the applicant's proposed methodology for meeting the acceptance criteria. It should contain a level of detail sufficient for individuals experienced in the technical disciplines needed to develop a minimum inventory to satisfactorily execute the plan. At a minimum, the implementation plan should include a description of the methodology, and identify the source documents and applicable guidance that the applicant will use to:

- identify those manual actions credited in the plant's EOPs that are necessary to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition
- identify those manual actions determined to be critical by the applicant's PRA and that are needed by operators to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition
- determine the plant process parameter(s) (e.g., containment pressure, feedwater flow) associated with initiating and carrying out each manual action
- apply the HSI design process (i.e., NUREG-0711, Chapter 8, "Human System Interface Design," NUREG-0700, etc.) to developing the MCR and RSF minimum inventory HSIs
- ensure adequate availability and reliability of the MCR and RSF minimum inventories to support safe shutdown and the ability to maintain safe shutdown

Staff Evaluation of Criterion 1 (Part 2)

HSID IP, Section 6.1, provides an overall description of the process the applicant proposes to use to develop an MI of alarms, controls, and displays for the MCR and RSF. This section of the HSID IP addresses the Criterion 1, Part 1, aspect of including a description of the methodology used to develop the minimum inventory as part of the minimum inventory implementation plan.

In HSID IP, Section 6.1.1, "Applicable Minimum Inventory Guidance," the applicant provided a list and description of the source documents and guidance for developing the minimum inventory. Documents include RG 1.97, Revision 4, "Criteria for Accident Monitoring Instrumentation for Nuclear Power Plants," which focuses on post-accident monitoring (PAM) variables, NUREG-0800, and the applicable staff guidance documents such as ISG-05, Revision 1. This explanation adequately addresses the Criterion 1, Part 2, aspect of identifying minimum inventory source documents, and is therefore acceptable.

HSID IP, Section 6.1.4, "MCR Methodology," provides a description of how the applicant's methodology will develop an MI for the MCR. The methodology analyzes EPG, PRA/HRA, and PAM variables. This analysis is followed by a task analysis on the identified tasks which will determine the task support requirements needed for the operator to successfully perform the actions. Any additional parameters determined from the output of the analyses are added to the MI list. Once all MI parameters are identified, the accessibility of the parameters is then determined. The outputs of the MI methodology are inputs into the overall HSI design process such as control room layout, display/panel design, and HSI evaluations. Once the HSI design is complete, the MI is addressed during the HFE verification and validation activities. This explanation contained in HSID IP, Section 6.1.4, acceptably addresses the first two bulleted items of Criterion 1, Part 2.

In HSID IP, Section 6.1.4.1, "Identify MI Tasks," the applicant states that the methodology used to identify accident monitoring variables that contribute to defining HSIs for the MI is described in AREVA Document, "U.S. EPR Accident Monitoring Variables." In addition, the applicant indicates in HSID IP, Section 6.1.1.4, "NRC Regulatory Guide 1.97, Rev. 4 – Criteria for

Accident Monitoring Instrumentation for Nuclear Power Plants,” that this Regulatory Guide references IEEE Std 497-2002, which focuses on PAM variables. This guidance is used to verify the appropriate PAM variables are included as a part of the minimum inventory. The results of the PAM variable identification process are used as input to the minimum inventory identification process. More specifically, PAM variable types A, B, and C are considered for MI in accordance with NUREG-0800. This explanation contained in HSID IP, Section 6.1.4.1 together with the commitment to use RG 1.97 as specified in HSID Section 6.1.1.4, satisfactorily addresses the third bulleted item of Criterion 1, Part 2 with respect to the PAM variables.

To further address the third bulleted item in Criterion 1, Part 2, the applicant states in HSID IP, Section 6.1.3, that the manual actions in the EOPs and the risk-significant HAs required to bring the reactor to a safe shutdown condition and maintain it in that condition are included in MCR MI HSIs that the operator uses to:

- monitor the status of fission product barriers; perform and confirm a reactor trip
- perform and confirm a controlled shutdown of the reactor using the normal or preferred safety means
- actuate safety-related systems that have the critical safety function of protecting the fission product barriers
- analyze failure conditions of the HSI while maintaining the current plant operating condition and power level until the HSI can be restored in accordance with applicable regulatory requirements
- maintain the plant in a safe condition (hot standby, hot shutdown, or cold shutdown depending on the event)

This detail contained in HSID IP, Section 6.1.3, also satisfactorily addresses the third bulleted item of Criterion 1, Part 2, in part, by providing an additional data source (i.e., EOPs) for determining plant process parameters.

In the applicant’s description of the methodology for determining the MCR MI in HSID IP, Section 6.1.1.2, “NUREG-0711, Rev. 2 – Human Factors Engineering Program Review Model,” the applicant states:

The development of minimum inventory is a part of the HSI design element of the HFE program described in NUREG-0711. Task analysis is the primary input into HSI design because it defines the task support requirements for the operators. These tasks include normal and emergency operations. The task analysis process is used for the development of minimum inventory. The parameters required to support the identified manual operator actions are determined.

This explanation contained in HSID IP, Section 6.1.1.2, satisfactorily addresses the fourth bulleted item of Criterion 1, Part 2.

Regarding the last bulleted item of Criterion 1, Part 2, (ensuring adequate availability and reliability of the MCR and RSF minimum inventories to support safe shutdown and the ability to maintain safe shutdown), in HSID IP, Section 6.1.5, “RSS Methodology,” the applicant states:

The RSS contains the equipment necessary to bring the plant to a safe shutdown state during an event requiring evacuation of the MCR, in addition to:

- A simultaneous single failure of a system, structure, or component (SSC) required to bring the plant to safe shutdown (not required to accommodate a single failure in addition to equipment damage caused by a fire)
- A sustained loss of either onsite or offsite AC power.

This explanation contained in HSID IP, Section 6.1.5, adequately addresses the fifth bulleted item of Criterion 1, Part 2.

The staff finds the FSAR and the HSID IP treatment of Criterion 1, Part 2, related to providing an implementation plan with a description of a methodology and identification of source documents used to prepare the plan and methodology acceptable because the applicant has provided a description of a methodology and identification of source documents used to prepare the implementation plan and methodology that is consistent with the staff's review of this regulatory criterion and related staff guidance.

Criterion 1 (Part 3) states:

The implementation plan also should identify the technical qualifications of the individuals responsible for developing the MCR and RSF minimum inventories.

Staff Evaluation of Criterion 1 (Part 3)

HSID IP, Section 6.1.2, "Personnel Qualification," states that the team members and their qualifications are defined within the "U.S. EPR HFE Program Management Plan," December 16, 2010, which the staff has reviewed and accepted in Section 18.1 of this report. The applicant indicates that team members participating in the minimum inventory development include: Human Factors Engineering; System Engineering; I&C Engineering; and Plant Operations. Additional team members that contribute to developing the minimum inventory on an as-needed basis include: Nuclear Engineering; Architect Engineering; Computer System Engineering; Plant Procedure Development; Personnel Training; Systems Safety Engineering; Maintainability and Inspectability Engineering; and Reliability and Availability Engineering. This explanation contained in HSID IP, Section 6.1.2, addresses Criterion 1, Part 3 because the HSID IP identifies the technical qualifications of personnel responsible for developing the minimum inventories that conform to this regulatory criterion and related staff guidance.

Accordingly, the staff finds the FSAR and the HSI IP treatment of Criterion 1, Part 3, related to providing the technical qualifications of the individuals responsible for developing the MCR and RSS inventories acceptable.

Criterion 2

Applicants for new plant DC should include with the FSAR Tier 1 information, ITAAC for both the MCR and RSF minimum inventories. The ITAAC should:

- a. verify that the implementation plan methodology contained in the approved DC was correctly used to develop the MCR and RSF minimum inventories

- b. verify that the as-built MCR and RSF contain, as a minimum, the HSIs identified through the use of the implementation plan methodology in the approved DC
- c. validate that the as-built MCR and RSF minimum inventories support operator performance of those EOP actions and PRA critical operator actions necessary to bring the reactor to a safe shutdown condition and maintain it in a safe shutdown condition

Staff Evaluation of Criterion 2

FSAR Tier 1, Table 3.4-1, "Human Factors Engineering Inspections, Tests, Analyses, and Acceptance Criteria," contains the FSAR Tier 1, ITAAC developed by the applicant for HFE. The staff's review of the FSAR Tier 1, HFE ITAAC is documented in Section 14.3.9 of this report.

18.7.3.3 *Computer-Based Procedures*

In FSAR Tier 2, Section 18.7.4.6, "Computer-Based Procedures," the applicant references the HFPEM IP. HFPEM IP, Section 6.2.9, "Plant Operating Procedures," states that, "Where technically feasible, operating procedures for the U.S. EPR design may use computer based procedures on the PICS." Since the applicant indicated that CBPs may be used as a platform for presenting operating procedures, the staff assessed the applicant's proposed use of CBPs.

To evaluate the applicant's proposed use of CBPs, the staff used guidance in NUREG-0711, Section 9.4, "Review Criteria," and DI&C-ISG-05, Chapter 1, "Computer Based Procedures." Specifically, NUREG-0711, Section 9.4, Criterion 7 states:

Criterion 7

An analysis should be conducted to determine the impact of providing computer-based procedures (CBPs) and to specify where such an approach would improve procedure utilization and reduce operating crew errors related to procedure use. The justifiable use of CBPs over paper procedures should be documented. An analysis of alternatives in the event of loss of CBPs should be performed and documented.

Staff Evaluation of Criterion 7

The HSID IP describes the applicant's approach to using CBPs and paper backup procedures for operating the plant. FSAR Tier 2, Section 18.7.4.6, references the HFPEM IP, which states "where technically feasible, operating procedures for the U.S. EPR design may use computer-based procedures (CBPs)..." Duplicate paper based procedures (PBP) will provide backup in the event CBPs are not available. CBPs and paper based procedures are created, revised, and validated using the processes described in the "U.S. EPR Human Factors Verification and Validation Implementation Plan," February 23, 2011.

It was not necessary for the applicant to address the first two sentences of this criterion. Based on ongoing technology development, the use of CBPs with paper back-up procedures is a generally accepted approach in the staff's experience. The advantages and disadvantages of using computer procedures are well documented. As discussed in the following paragraph, and

in accordance with this NUREG-0711 criterion, the applicant also accounts for the disadvantages by providing alternatives to CBPs.

The staff did expect the applicant to address the last sentence of Criterion 7. This portion of the criterion discusses providing an analysis of alternatives in the event of loss of CBPs, and that this should be performed and documented. To address this consideration, the staff used current staff guidance contained in DI&C-ISG-05, Chapter 1. Specifically, the six criteria in the section titled "Backup Procedures Review Criteria," provide expanded guidance that adds additional clarity to what should be provided as alternatives in the event of a loss of CBPs. In response to the consideration of providing a backup to CBPs, HSID IP, Section 6.8, "Computer Based Procedures," states that hard copy procedures are provided in the MCR for use in the event that the CBP system is unavailable. These PBPs contain the same information in the same format as the CBPs. In addition to providing PBPs as a backup, the CBP system has other features that alert the operators in the event of a CBP system failure. Some of the features described in the HSI IP are alarms that annunciate CBP failure, and a system heartbeat that alerts the operators to the CBPs data quality. Also, the status of all open procedures is continuously recorded. This will provide for a smooth transition between the two mediums in the event there is a problem accessing the CBPs. The items mentioned above provide an acceptable representation of the applicant's alternatives for the loss of CBPs.

The staff finds the FSAR and HSID IP, Section 6.8, treatment of this NUREG-0711 criterion related to analyzing the impact and justifying the use of CBPs acceptable because the applicant provided a process to analyze the impact and justify using CBPs in designing the U.S. EPR procedures system that conforms to this NUREG-0711 criterion.

18.7.4 Other Documents Subject to Review

18.7.4.1 *FSAR Tier 1, Section 3.4, "Human Factors Engineering"*

FSAR Tier 1, Table 3.4-1, "Human Factors Engineering ITAAC," contains the ITAAC that are proposed for HFE. The staff's evaluation of these ITAAC is provided in Section 14.3.9 of this report.

18.7.5 Combined License Information Items

There are no COL information items related to this area of review. The staff determined that no COL information items need to be included in FSAR Tier 2, Table 1.8-2, "U.S. EPR Combined License Information Items," for HSID consideration.

18.7.6 Conclusions

The staff evaluated HSID with respect to HFE, at an IP level using the review criteria in NUREG-0711, Section 8.4, DI&C-ISG-05, Chapter 2, "Minimum Inventory," and staff guidance contained in BTP 18-1. Section 18.0.4 of this report provides a discussion of review levels. The staff finds that HSID provides a satisfactory process by which HSID requirements are developed, and HSI designs are identified and refined. The staff also finds that HSID adequately addresses minimum inventory for the main control room and the remote shutdown facility. The staff determined that the HSID IP that is proposed for the U.S. EPR will ensure that functional and task requirements will be appropriately translated into the detailed design of alarms, controls, and displays, and other aspects of the HSI through the systematic application of HFE principles and criteria. The HSID IP will also ensure that the minimum inventory of HSIs

for the main control room and the remote shutdown station are properly established and specified. The HSID IP will also ensure that the use of computer-based procedures will be analyzed to determine the impact of their use and will justify using CBPs for the U.S. EPR design. As discussed in Section 18.0.5 of this report, the HSID IP is designated as Tier 2*, which ensures that the IP will be implemented by the COL applicant. Furthermore, because the HSID IP is designated as Tier 2*, the COL applicant cannot make changes to the IP without obtaining prior NRC approval. Therefore, the staff concludes that HSID considerations with respect to HFE have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.

18.8 Procedure Development

18.8.1 Regulatory Criteria

The staff's review of procedure development with respect to HFE is evaluated using the guidance provided in NUREG-0711, Chapter 9, "Procedure Development," Section 9.4, "Review Criteria," and SRP Section 18.II.A.8. The staff considers procedure development to be an operational program and, therefore, a COL applicant's responsibility rather than a design certification applicant's responsibility. Therefore, the staff's evaluation of the applicant's overall procedure development program is provided in Section 13.5 of this report. As procedure development is an operational program, in FSAR Tier 2, Section 18.8, "Procedure Development," the applicant states that their procedure development is discussed in FSAR Tier 2, Section 13.5, "Plant Procedures."

18.8.2 Summary of Technical Information

Although overall procedure development is an operational program, in HFEPM IP, Section 6.2.9, the applicant states, "Where technically feasible, operating procedures for the U.S. EPR design may use computer-based procedures (CBPs)..." In FSAR Tier 2, Section 18.7.4.6, "Computer Based Procedures," the applicant indicates that "operating procedures can be implemented in a screen-based format that provides access to information by direct links" (i.e., electronic procedures or CBPs). FSAR Tier 2, Section 18.7.4.6 incorporates by reference the "U.S. EPR Human System Interface Design Implementation Plan," December 16, 2010 (referred to as the HSID IP). The HSID IP includes Section 6.8, "Computer Based Procedures," that describes the applicant's CBP methodology. The staff reviewed the HSID IP along with other documents (e.g., Conduct of Operations Document) that pertain to the applicant's CBP development as described in Section 18.8.3 of this report.

18.8.3 Staff Evaluation

The staff's evaluation of the HFE design for CBP interface is provided in Section 18.7.3.3, "Computer Based Procedures," of this report. The staff's evaluation of the applicant's overall procedure development is provided in Section 13.5 of this report.

18.8.4 Other Documents Subject to Review

18.8.4.1 *FSAR Tier 1, Section 3.4, "Human Factors Engineering"*

FSAR Tier 1, Table 3.4-1, "Human Factors Engineering ITAAC," contains the ITAAC that are proposed for HFE. The staff's evaluation of these ITAAC is provided in Section 14.3.9 of this report.

18.8.5 Combined License Information Items

Table 18.8-1 provides an HFE procedure development-related COL information item from FSAR Tier 2, Revision 2, Table 1.8-2, "U.S. EPR Combined License Information Items." In a March 21, 2011, letter, the applicant stated that this COL item remains although overall procedure development for the U.S. EPR is an operational program.

Table 18.8-1 U.S. EPR Combined License Information Items

Item No.	Description	FSAR Tier 2 Section
18.8-1	A COL applicant that references the U.S. EPR design certification will describe how HFE principles and criteria are incorporated into the development program for site procedures.	18.8

The staff finds the above description to be complete. The description provides actions necessary to ensure that the COL applicant will consider HFE principles and practices in the design of plant-specific procedures.

18.8.6 Conclusions

The staff evaluated the applicant's CBPs with respect to HFE in Section 18.7.3.2 of this report and the applicant's overall procedure development in Section 13.5 of this report. The staff determined that the HSID IP treatment of CBPs proposed for the U.S. EPR will ensure that CBP development and implementation satisfies recent staff guidance that has been prepared for this purpose. The staff's guidance includes provisions to ensure that paper-based procedures are fully maintained and readily available in the event that there is a problem accessing the CBPs. As discussed in Section 18.0.5 of this report, the HSID IP is designated as Tier 2*, which ensures that the IP will be implemented by the COL applicant. Furthermore, because the HSID IP is designated as Tier 2*, the COL applicant cannot make changes to the IP without obtaining prior NRC approval. Therefore, the staff concludes that CBP considerations with respect to HFE development and implementation have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.

18.9 Training Program Development

18.9.1 Regulatory Criteria

The staff's review of the applicant's training program development is addressed in Section 13.2 of this report. The staff considers training development as an operational program and, therefore, a COL applicant's responsibility rather than a design certification applicant's responsibility. NUREG-0711, Section 10.4 and SRP Section 18.II.A.9 criteria addressing training, are a subset of the review criteria contained in the regulatory guidance associated with SRP Section 13.2 which provides guidance on the description and scheduling of the training program for reactor operators and senior reactor operators.

18.9.2 Summary of Technical Information

FSAR Tier 2, Section 18.9, "Training Development," indicates that a COL applicant referencing the U.S. EPR design will describe how HFE principles and criteria are incorporated into developing training programs.

18.9.3 Staff Evaluation

The staff's evaluation of the applicant's training program is provided in Section 13.2 of this report.

18.9.4 Other Documents Subject to Review

18.9.4.1 *FSAR Tier 1, Section 3.4, "Human Factors Engineering"*

FSAR Tier 1, Table 3.4-1, "Human Factors Engineering ITAAC," contains the ITAAC that are proposed for HFE. The staff's evaluation of these ITAAC is provided in Section 14.3.9 of this report.

18.9.5 Combined License Information Items

Table 18.9-1 provides an HFE training development-related COL information item from FSAR Tier 2, Table 1.8-2, "U.S. EPR Combined License Information Items." In a March 21, 2011, letter, the applicant stated that this COL Item remains although training is an operational program.

Table 18.9-1 U.S. EPR Combined License Information Items

Item No.	Description	FSAR Tier 2 Section
18.9-1	A COL applicant that references the U.S. EPR design certification will describe how HFE principles and criteria are incorporated into the development of training program scope, structure, and methodology.	18.9

18.9.6 Conclusions

The staff's conclusions on the applicant's training program are documented in accordance with the evaluation performed as part of Section 13.2 of this report.

18.10 Human Factors Engineering Verification and Validation

18.10.1 Regulatory Criteria

HFE verification and validation is evaluated based on the review criteria provided in NUREG-0711, Chapter 11, "Human Factors Verification and Validation," Section 11.4, "Review Criteria," and SRP Section 18.II.A.10. NUREG-0711, Section 11.4 specifies the review criteria that pertain to the staff's evaluation of HFE V&V. Specifically, the staff confirms that:

- The applicant has identified a sample of operational conditions that: (1) includes conditions that are representative of the range of events that could be encountered during operation of the plant, (2) reflects the characteristics that are expected to contribute to system performance variation, and (3) considers the safety significance of HSI components. These sample characteristics are best identified through the use of a multi-dimensional sampling strategy to provide reasonable assurance that V&V evaluations include variation along important dimensions.
- The applicant's HSI inventory and characterization accurately describe all HSI displays, controls, and related equipment that are within the defined scope of the HSI design review.
- The applicant has verified that the HSI provides all alarms, information, and control capabilities needed for personnel tasks.
- The applicant has verified that the characteristics of the HSI and the environment in which it is used conform to HFE guidelines.
- The applicant has validated the integrated system design (i.e., hardware, software, and personnel elements) using performance-based tests to determine whether it supports safe operation of the plant.
- The applicant's HED evaluation acceptably prioritizes HEDs in terms of their need for improvement, and the applicant develops design solutions and a

realistic schedule for implementation to address those HEDs selected for correction.

One element of V&V, integrated system validation, interfaces with operating programs. Various types of operating procedures (e.g., normal, abnormal, emergency, maintenance) are used by the operators to respond to scenarios that are run on a full scope simulator. By running these scenarios, the HSIs are tested under a variety of conditions. Deficiencies and potential improvements are identified, documented, and resolved with the end result being a complete HFE design capable of supporting safe plant operation. While the primary purpose of the ISV is not to test the procedures, the opportunity is used to assess whether procedure improvements can resolve validation deficiencies better than HFE design modifications. Similarly, operator training is relied on to provide the operators participating in the validation test with knowledge of plant control and control board layout. While the primary purpose of the ISV is not to test the operators' ability, the opportunity is used to assess whether training improvements can resolve validation deficiencies better than HFE design modifications. To review the applicant's V&V plan, the staff used the criteria in NUREG-0711, Chapter 11, "Human Factors Validation and Verification," Section 11.4, "Review Criteria," and SRP Section 18.II.A.10.

18.10.2 Summary of Technical Information

V&V is described in FSAR Tier 2, Section 18.10, "Verification & Validation." FSAR Tier 2, Section 18.10 incorporates by reference "U.S. EPR Human Factors Human Factors Verification and Validation Implementation Plan," February 23, 2011 (referred to as the V&V IP). The staff focused its review on evaluating the information provided based on the criteria and topics of NUREG-0711, Chapter 11, "Human Factors Validation and Verification," and SRP Section 18.II.A.10.

18.10.3 Staff Evaluation

The staff performed an implementation plan level review as described in NUREG-0711 and Section 18.0.4 of this report. This section presents the applicable review criteria from NUREG-0711 followed by an evaluation of each. V&V IP, Section 1.2, "Purpose," explains that the V&V will provide the processes, methods, and criteria for performing the HFE design and task support verification, the integrated system validation, operational conditions sampling, and HED identification and resolution.

V&V review sections and topics include the following:

- Operation condition sampling (three review topics)
 - Sampling Dimensions (three review criteria)
 - Identification of Scenarios (two review criteria)
 - Special Considerations for Plant Modernization Programs (four review criteria – zero applicable)
- Design verification (three review topics)
 - Inventory and Characterization (three review criteria)

- HSI Task Support Verification (six review criteria – five applicable)
- HFE Design Verification (four review criteria – three applicable)
- Integrated system validation (three review topics)
 - Test Objectives (one review criterion)
 - Validation Testbeds (nine review criteria)
 - Plant Personnel (four review criteria)
 - Scenario Definition (three review criteria)
 - Performance Measurement (five review criteria)
 - Test Design (nine review criteria)
 - Data Analysis and Interpretation (five review criteria)
 - Validation Conclusions (two review criteria)
 - HED resolution (seven review criteria – six applicable)

The criteria that do not apply to the U.S. EPR safety review are those addressing V&V of plant modifications (i.e., those criteria that apply only to changes to HFE features of operating plants).

18.10.3.1 *Operational Conditions Sampling Acceptance Criteria*

The sampling methodology will identify a range of operational conditions to guide V&V activities. The review of operational conditions sampling considers the dimensions to be used to identify and select conditions and their integration into scenarios.

V&V IP, Section 3.1, “Operational Condition Sampling,” discusses operational conditions sampling.

18.10.3.1.1 Sampling Dimensions

The sampling dimensions addressed in NUREG-0711, Section 11.4.1.2, “Operational Conditions Sampling Review Criteria,” (reproduced below) include plant conditions, personnel tasks, and situational factors known to challenge personnel performance.

Criterion 1

The following plant conditions should be included:

- normal operational events including plant startup, plant shutdown or refueling, and significant changes in operating power
- failure events, e.g.,
 - instrument failures [e.g., safety-related system logic and control unit, fault tolerant controller, local “field unit” for multiplexer (MUX)]

- system, MUX controller, and break in MUX line] including I&C failures that exceed the design basis, such as a common mode I&C failure during an accident
 - HSI failures (e.g., loss of processing and/or display capabilities for alarms, displays, controls, and computer-based procedures)
- transients and accidents, e.g.,
 - 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 main control room (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, and various-sized loss-of-coolant accidents)
 - reactor shutdown and cooldown using the remote shutdown system
- reasonable, risk-significant, beyond-design-basis events, which should be determined from the plant specific PRA
- consideration of the role of the equipment in achieving plant safety functions [as described in the plant safety analysis report (SAR)] and the degree of interconnection with other plant systems. A system that is interconnected with other systems could cause the failure of other systems because the initial failure could propagate over the connections. This consideration is especially important when assessing non-class 1E electrical systems.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.10.3.4.2, "Plant Conditions," provides a list of plant conditions that will be included in the operation conditions sampling that repeats the list provided in Criterion 1. V&V IP, Section 3.1.4.1, "Representative Population of Operational Conditions and Tasks," provides a similar list divided into plant control elements and plant conditions. Since these lists correspond to the plant conditions set forth above, they satisfactorily address the range of plant conditions given in the criterion. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for plant condition sampling acceptable.

Criterion 2

The following types of personnel tasks should be included:

- *Risk-significant HAs, systems, and accident sequences* - All risk-important HAs should be included in the sample. These include [those] identified in the PRA and those identified as risk-important in the SAR and NRC's safety evaluation report (SER) should be considered. Situations where human monitoring of an automatic system [that] is risk-important should be considered. Additional factors

should be sampled that contribute highly to risk, as defined by the PRA, including:

- dominant human actions (selected via sensitivity analyses)
- dominant accident sequences
- dominant systems (selected via PRA importance measures such as Risk Achievement Worth or Risk Reduction Worth)
- *OER-identified difficult tasks* - The sample should include all personnel tasks identified as problematic during the applicant's review of operating experience.
- *Range of procedure guided tasks* - These are tasks that are well defined by normal, abnormal, emergency, alarm response, and test procedures. The operator should be able to, as part of rule-based decision-making, understand and execute the specified steps. Regulatory Guide 1.33, Appendix A, contains several categories of "typical safety-related activities that should be covered by written procedures." The sample should include appropriate procedures in each relevant category:
 - administrative procedures
 - general plant operating procedures
 - procedures for startup, operation, and shutdown of safety-related systems
 - procedures for abnormal, off normal, and alarm conditions
 - procedures for combating emergencies and other significant events
 - procedures for control of radioactivity
 - procedures for control of measuring and test equipment and for surveillance tests, procedures, and calibration
 - procedures for performing maintenance
 - chemistry and radiochemical control procedures
- *Range of knowledge-based tasks* -these are tasks that are not as well defined by detailed procedures. Knowledge-based decision-making involves greater reasoning about 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 [an] appropriate rule is not clear. An example in a pressurized water reactor plant may be the difficulty in diagnosing a steam generator tube rupture (SGTR) with a failure of radiation monitors on the secondary side of the plant because (1) there is no main indication of the rupture (the presence of radiation in secondary side), and (2) the

other effects of the rupture (i.e., slight changes in pressures and levels on the primary and secondary sides) may be attributed to other causes. While the operators may use procedures to treat the symptoms of the event, the determination that the cause is a[n] SGTR may require situation assessment based on an understanding of the plant's design and the possible combinations of failures that could result in the observed symptoms. Errors in rule-based decision-making result from selecting the wrong rule or incorrectly applying a rule. Errors in knowledge-based decision-making result from mistakes in higher-level cognitive functions such as judgment, planning, and analysis. The latter are more likely to occur in complex failure events where the symptoms do not resemble the typical case, and thus, are not amenable to pre-established rules.

- *Range of human cognitive activities* - The sample should include the range of cognitive activities performed by personnel, including:
 - detection and monitoring (e.g., of critical safety-function threats)
 - situation assessment (e.g., interpretation of alarms and displays for diagnosis of faults in plant processes and automated control and safety systems)
 - response planning (e.g., evaluating alternatives for recovery from plant failures)
 - response implementation (e.g., in-the-loop control of plant systems, assuming manual control from automatic control systems, and carrying out complicated control actions)
 - obtaining feedback (e.g., of the success of actions taken)
- *Range of human interactions* - The sample should reflect the range of 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. These interactions among plant personnel should include interactions between:
 - main control room operators (e.g., operations, shift turnover walkdowns)
 - main control room operators and auxiliary operators
 - main control room operators and support centers (e.g., the technical support center and the emergency offsite facility)
 - main control room operators with plant management, NRC, and other outside organizations
- Tasks that are performed with high frequency.

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.10.3.4.1, "Personnel Tasks," states that personnel tasks from the following sources will be included in the operational conditions sampling:

- Activities identified related to EOP development
- Risk-significant HAs
- Tasks that are "particularly difficult" to design into the HSI
- Tasks which require significant compromise during the HSI design
- Tasks which have the potential to cause error because of complexity
- Tasks that use design features retained or modified because of the OER analysis
- Knowledge based tasks as identified in the criterion
- Human cognitive activities including detection and monitoring, situation assessment, response planning, and obtaining feedback
- The range of human interactions defined by the criterion
- Tasks that are performed with high frequency, in accordance with the criterion

V&V IP, Section 3.1.4.1, "Representative Population of Operational Conditions and Tasks," contains a similar list which adds detail to what is provided in the design certification as follows:

- Human actions identified in the HRA/PRA and design certification as being risk-significant.
- Historically problematic tasks as identified in the operating experience reports generated using the HFE operating experience review process.
- Plant operation procedures that involve MCR, RSS, or risk-significant LCS activities. This includes administrative, emergency, abnormal, alarm response, general operating, system operating, surveillance and testing, and maintenance procedures. Tasks represent a broad range of human cognitive activities. Tasks in this population contain activities associated with:
 - Detection and monitoring
 - Diagnosis and situational assessment
 - Decision making and planning
 - Plant manipulation
 - Monitoring plant response
- Tasks involving a range of human interactions and communications as identified in the HFE task analysis. Tasks in this population are those that analysts

identified as containing communication interactions among the primary task performer and other personnel.

- Tasks performed with high frequency as identified in the HFE task analysis.

These sections cumulatively address the six types of personnel tasks identified in Criterion 2. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for types of personnel tasks acceptable.

Criterion 3

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.

Staff Evaluation of Criterion 3

FSAR Tier 2, Section 18.10.3.4.3, "Situational Related Performance Shaping Factors," discusses the incorporation of situational related performance factors in the operational conditions sampling. In this section, the applicant commits to incorporating operationally difficult tasks, high workload conditions, varying workload conditions, fatigue, and environmental factors, all as defined in Criterion 3. FSAR Tier 2, Section 18.10.3.4.3 also states that error

forcing context situations designed to create human errors to assess the tolerance of the system to human error and the capability of operators to recover from errors will be included in the sample.

V&V IP, Section 3.1.4.4, "Selecting the Risk-Informed Representative Sample," explains how a proprietary risk weighting factor and the situational performance shaping factors are incorporated into the operational conditions sample. In summary, each of the plant conditions and tasks (or task sequences) identified in the operational conditions sample receives a weighting factor that, for each item in the sample, identifies the item's relationship to PRA/HRA, Diverse Actuation System manual actions, the Knowledge and Abilities Catalogue importance ranking and task analysis results indicating high work load, high stress, or the presence of critical tasks. This weighting provides a method for ensuring the most relevant and significant operating conditions are addressed during scenario development. Similarly, each item in the operating conditions sample is evaluated for its sensitivity to the six situational factors given in Criterion 3. This information is documented in a scenario selection matrix illustrated in V&V IP, Table 3-1, "Example Scenario Selection Matrix."

The applicant has identified a complete set of situational factors that challenge human performance and has added a prioritization system that ensures the most significant factors will receive appropriate attention. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for range of situational factors acceptable.

18.10.3.1.2 Identification of Scenarios

Criterion 1

The results of the sampling should be combined to identify a set of scenarios to guide subsequent analyses. A given scenario may combine many of the characteristics identified by the operational event sampling.

Staff Evaluation of Criterion 1

V&V IP, Section 3.5.4.3, "Scenario Definition," states that the scenarios used in the ISV are crafted to incorporate the tasks and scenarios selected in the operational conditions sampling process. V&V IP, Section 3.1.4.4 explains the method used to make this selection. A scenario selection matrix, as shown in V&V IP, Table 3-1, "Example Scenario Selection Matrix," provides a structure within which all the identified operating conditions are related to risk significance and situational factors that address degree of difficulty. The HFE V&V team members identify a selection of tasks and plant conditions from each category of the matrix using the risk rankings to set selection priority. All risk-significant human actions are represented within the group of tasks and plant conditions selected. Additionally, the selection process ensures that situational factors known to challenge human performance are included in at least one task. Based upon their analysis of the material in the scenario selection matrix, the HFE V&V team members select a number of tasks and plant conditions sufficient to ensure a broad and representative sample of the highest significance.

The staff concludes that the applicant has provided a structured and well documented method for combining various operational event sample conditions into a set of scenarios. This method will ensure diversity between scenarios so that a sufficient number of plant conditions are tested. The addition of a prioritization system ensures the most significant plant conditions are included in the scenarios. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for scenario identification acceptable.

Criterion 2

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)

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.10.3.4.4, “Identification of Scenarios,” contains the criteria to be used to identify the scenarios. It commits that the scenario sample will not be biased toward positive outcomes, administratively easy to conduct scenarios, or familiar and well-structured scenarios (e.g., textbook design basis accidents).

V&V IP, Section 3.5.4.5.5, “Controlling Bias,” describes how bias is controlled throughout the ISV. Procedures are used to provide specific direction of scenario development. After scenario development is complete, the scenarios are examined to verify that no bias is evident in any of the three areas listed in this criterion. If development bias, is detected, scenarios are analyzed for alternatives to create a more fair and representative range of events. Any occurrences of significant sampling bias are logged as HEDs in the HFE issue tracking system for tracking and resolution.

Stratified random sampling techniques are employed to ensure that the populations of selected scenarios are bias free. Stratified random sampling is a sampling procedure in which a population is separated into subgroups (strata), and then samples are selected from each subgroup.

The staff concludes that procedure controls for the scenario development process is an effective method for minimizing the potential of scenarios being too positive, too easy, or too familiar as described in this criterion. By consolidating the various plant conditions used to create a scenario within a selection matrix (see Criterion 1 above for additional detail) and then prioritizing each condition, choosing scenario components is restricted to a set of rules as opposed to individual analyst opinion. The use of stratified random sampling techniques verifies that all subgroups (types of scenarios) are represented and that bias is controlled. Accordingly, the staff finds the V&V IP treatment of this NUREG -0711 criterion for avoiding bias in scenario development and selection acceptable.

18.10.3.2 *Design Verification*

This section contains three elements: Inventory and Control, HSI Task Support Verification, and HFE Design Verification. The objective of the Inventory and Control element is to verify that the applicant’s HSI inventory and the design characteristics of the inventory accurately describes all HSI displays, controls, and related equipment that are within the defined scope of the HSI design review. The objective of the HSI Task Support Verification element is to verify the HSI

provides all alarms, information, and control capabilities relied upon for personnel tasks. The objective of the HFE Design Verification is to verify the characteristics of the HSI and the environment in which it is used conform to HFE guidelines.

18.10.3.2.1 Inventory and Characterization

FSAR Tier 2, Section 18.10.3.1, "HSI Inventory and Characterization," and V&V IP, Section 3.2, "HSI Inventory and Characterization," discuss HSI inventory and characterization.

Criteria 1

Scope - The applicant should develop an inventory of all HSI components associated with the personnel tasks based on the identified operational conditions. The inventory should include aspects of the HSI that are used for interface management such as navigation and display retrieval in addition to those that control the plant.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.10.3.1 states that the HSI inventory and characterization activity describes HSI components and related equipment associated with personnel tasks within the scope of the HSI design that are to be verified. The complete inventory is created by compiling data from the I&C database which receives input from sources such as system description documents, design specifications, equipment lists, and process and instrumentation drawings. 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. V&V IP, Section 3.2 provides additional detail on the process used to identify and document the characteristics associated with the inventory. Since the inventory is based on the identified operational conditions and includes aspects of the HSI used for interface management, the staff finds the V&V IP treatment of this NUREG-0711 criterion for scenario identification acceptable.

In RAI 433, Question 18-222, the staff requested that the applicant clarify how the I&C database is used. In a December 16, 2010, response to RAI 433, Question 18-222, the applicant committed to modify the FSAR by providing an additional paragraph that has been added to FSAR Tier 2, Revision 3-Interim, Section 18.10.3.2. The content of this paragraph is reflected in the evaluation above. The staff has reviewed the applicant's response to RAI 433, Question 18-222 and finds it acceptable. **RAI 433, Question 18-222 is being tracked as a confirmatory item** to ensure that the FSAR is revised accordingly.

Criterion 2

HSI Characterization - The inventory should describe the characteristics of each HSI component within the scope of the review. The following is a minimal set of information for the characterization:

- a unique identification code number or name
- associated plant system and subsystem
- associated personnel functions/subfunction
- type of HSI component

- computer-based control (e.g., touch screen or cursor-operated button and keyboard input)
- hardwired control (e.g., J-handle controller, button, and automatic controller)
- computer-based display (e.g., digital value and analog representation)
- hardwired display (e.g., dial, gauge, and strip chart recorder)
- display characteristics and functionality [e.g., plant variables/parameters, units of measure, accuracy of variable/parameter, precision of display, dynamic response, and display format (bar chart, and trend plot)]
- control characteristics and functionality [e.g., continuous versus discrete settings, number and type of control modes, accuracy, precision, dynamic response, and control format (method of input)]
- user-system interaction and dialog types (e.g., navigation aids and menus)
- location in data management system (e.g., identification code for information display screen)
- physical location in the HSI (e.g., control panel section), if applicable

Photographs, copies of VDU screens, and similar samples of HSI components should be included in the HSI inventory and characterization.

Staff Evaluation of Criterion 2

V&V IP, Section 3.2.4, "Process," provides a general procedure for identifying the HSI inventory and sources for obtaining the inventory characterization. The direction provided for characterization includes all the information given in the criterion. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for inventory characterization acceptable.

Criterion 3

Information Sources - The inventory should be based on the best available information sources. Equipment lists, design specifications, and drawings describe HSI components. These descriptions should be compared by directly observing the components, both hardwired and computer-generated, to verify that the inventory accurately reflects their current state.

Staff Evaluation of Criterion 3

V&V IP, Section 3.2 states that the accuracy of the inventory is confirmed by comparing it to plant design documents such as system description documents, design specifications, equipment lists, and process and instrumentation drawings. V&V IP, Section 3.2.3, "Inputs," adds Panel drawing, Room layout/arrangement drawings, and Computer-generated displays as additional inputs to the HSI characterization. V&V IP, Section 3.2.4 states that the HSI

inventory will be based on the most recent system documents. This inventory will be compared to the available hardware and software generated screens for accuracy verification.

These sections of the V&V IP cumulatively address this criterion by providing a complete list of information sources needed for inventory characterization. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for the information sources supporting inventory characterization acceptable.

18.10.3.2.2 Human-System Interface Task Support Verification

Criterion 1

Criteria Identification - The criteria for Task Support Verification come from task analyses of HSI requirements for performance of personnel tasks that are selected from operational conditions should be defined.

Staff Evaluation of Criterion 1

The task analysis identifies HSI design specifications. Task support verification confirms that these specifications are incorporated in the HSI design. This criterion is designed to ensure a sample of design specifications derived from the task analysis is identified.

V&V IP, Section 3.3.1, "Purpose," states that the HSI inventory and characterization list derived from the operational condition sampling process is compared to requirements contained in HFE task analysis results. The HSI task support verification process ensures that in-scope HSIs:

- Are designed with capabilities and features consistent with the HFE task analyses
- Collectively support the safe and efficient performance of in-scope operator tasks
- Provide all alarms, information, and control capabilities required for the safe and efficient performance of operator tasks

The applicant identified the task analysis as the source of specifications to be verified within the task support verification. Additional information is provided that shows the task support verifications activity tests the acceptability of these specifications to appropriate objectives that ensure the HSI design supports safe and efficient operation. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for task support verification criteria identification acceptable.

Criterion 2

General Methodology - The HSIs and their characteristics (as defined in the HSI inventory and characterization) should be compared to the personnel task requirements identified in the task analysis.

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.10.3.2, "HSI Task Support Verification," outlines a two-step task support verification. Initial task support verification is performed early in the HSI design process to provide information for the HSI screen and panel layouts. The initial task support verification confirms that the inventory of HSI elements will support personnel tasks as defined by the

procedures, design goals, and analysis. The initial task support verification verifies completeness of the HSI inventory. The second step, which involves dynamic task support verification, is performed when the HSI and simulator designs have developed to the point that the simulator represents the complete HSI inventory. A set of performance measures derived from the applicable hardware and software design specifications, the style guide, and task analysis specifications is defined prior to starting the dynamic task support verification. Then the dynamic task support verification confirms that HSI components meet these performance measures.

V&V IP, Section 3.3.4, "Process," provides additional description of the interfaces included in the task verification process. Included within this verification are:

- HSIs that indicate that the task objective is needed
- HSIs that indicate that the end state of the task has been achieved
- HSIs that indicate that the end state of the task has achieved the desired results
- HSIs that indicate that the end state of the task is no longer needed and can be terminated
- HSIs identified as part of the task prerequisites
- HSIs supporting decisions imbedded in the task
- HSIs needed to accomplish each step
- HSIs monitoring automation sequences
- HSIs monitoring success criteria
- HSIs supporting communication requirements

This methodology provides a thorough comparison of the U.S. EPR HSIs to the personnel task specifications identified in task analysis. The simulators being used are appropriate for modeling of the two step process described. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for the methodology for task support verification acceptable.

Criterion 3

Task Requirements Deficiencies - HEDs should be identified when:

- an HSI needed for task performance (e.g., a [needed] control or display) is not available
- HSI characteristics do not match the personnel task requirements, e.g., a display shows the necessary plant parameter but not the range or precision needed for the task.

Staff Evaluation of Criterion 3

V&V IP, Section 3.3.4.2, "Evaluation," indicates that HEDs are written for any of the following conditions:

- The aggregate HSI does not provide the alarms, controls, or indications relied upon by HFE task analysis
- HSI task support verification activities identify alarms, controls, or indications that do not appear to support any operator task (the HED analysis and resolution process will determine if the HSIs support other tasks unknown to the evaluators performing the HSI task support verification or if they are, in fact, extraneous)
- Alarms, controls, or indications are present but do not function adequately to support task or scenario performance measures.
- Alarms, controls, or indications are present but their design attributes, capabilities, or presentation to operators do not support task or scenario performance measures.
- Alarms, controls, or indications are present but are not human engineered or grouped to support task or scenario performance measures.

These conditions satisfy all elements of the regulatory guidance. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for task requirement HED identification acceptable.

Criterion 4

Unnecessary HSI Components - An HED should be identified for HSIs that are available in the HSI but are not needed for any task. Unnecessary HSIs introduce clutter and can distract personnel for the selection of appropriate HSIs. It is important to verify that the HSI is actually unnecessary. Appropriate HSI components may not appear to be associated with personnel tasks for the following reasons:

- The HSI component is needed for a task that was not addressed by the task analysis (e.g., it was not within the scope of the design review.)
- The task analysis was incomplete, and thus overlooked the need for the HSI component.
- The HSI component only partially meets the personnel task requirements that were established.

If an HSI component has no associated personnel tasks because the function and task analysis was incomplete, then the applicant should identify and resolve any shortcomings in that analysis.

Staff Evaluation of Criterion 4

V&V IP, Section 3.3.4.2 states that an HED will be identified for any HSIs that are available but are not needed for any task, or when HSI characteristics do not match what is needed to perform the tasks. This conforms to Criterion 4. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for HED identification of unnecessary HSI Components acceptable.

Criterion 5

Criterion 5 describes additional methodology considerations for plant modifications. Therefore, this NUREG-0711 criterion is not applicable to new construction.

Criterion 6

HED Documentation - HEDs should be documented to identify the HSI, the relevant task criterion, and basis for the deficiency (what aspect of the HSI has been identified as not meeting task requirements.)

Staff Evaluation of Criterion 6

FSAR Tier 2, Section 18.10.3.6, "Human Engineering Discrepancy Resolution," calls for documentation of the three elements given above in Criterion 6 plus additional information including a recommendation for correcting the problem, possible impact of similar areas of design, and impact on plant design. This information is tracked in the HFE Issues Tracking Database. These three elements along with the others given in the FSAR represent a broad set of information needed to fully resolve the HED.

Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for HED documentation acceptable.

18.10.3.2.3 Human Factors Engineering Design Verification

Criterion 1

Criteria Identification - The criteria for this verification are the HFE guidelines. The selection of guidelines used in the review depends upon the characteristics of the HSI components included in the scope of the review, as defined in the HSI characterization. It also depends upon whether the applicant has developed a style guide (design-specific HFE guideline document). When a style guide is used by the applicant, its acceptability should be reviewed by the staff. The procedures involved are described in [NUREG-0711] Section 8.4.5. The HFE guidelines contained in NUREG-0700 may be used to support the staff's review of the guidance contained in an applicant's style guide. When an NRC reviewed style guide has been used, it can provide the criteria for HFE design verification.

When no style guide is available, the guidelines in NUREG-0700 can be used for the HFE design verification. However, since not all of these guidelines will be applicable to each review, the selection of guidelines should be based on the characteristics of the HSI components being evaluated. A subset of guidelines appropriate to the specific design implementation should be identified based on the HSI characterization.

Staff Evaluation of Criterion 1

In FSAR Tier 2, Section 18.10.3.3, "Design Verification," the applicant states the HFE design verification will evaluate the final design against the design specifications. Design specifications are derived from a style guide.

In RAI 433, Question 18-230, the staff requested that the applicant provide an explanation of how NUREG/CR-6393 will be applied to determine design requirements. In a December 16, 2010, response to RAI 433, Question 18-230, the applicant stated the NUREG was not applicable and deleted it from FSAR Tier 2, Revision 3-Interim. The NUREG deals with integrated system validation and contains no information on design verification. The staff has reviewed the applicant's response to RAI 433, Question 18-230 and finds it acceptable.

RAI 433, Question 18-230 is being tracked as a confirmatory item to ensure that the FSAR is revised accordingly.

V&V IP, Section 3.4 adds additional details stating that HFE design verification verifies that each HSI component design meets HFE guidelines, standards, and principles reflected in the HSI design style guide, and the local control station style guide HFE design verification covers design aspects including:

- HSI characteristics (e.g., coding, conventions, input devices, dialog, and display navigation)
- Inter-personnel communication systems that support users of the HSI (e.g., functional capabilities, equipment performance, and ease of use)
- Room layouts and panel configurations (e.g., anthropometrics, ergonomics, grouping, and labeling)
- Work environment (e.g., lighting, space, air conditions, floor design, and noise mitigation)

Designs are compared to HFE guidelines to determine whether they account for human characteristics and capabilities. Deviations from accepted HFE guidelines, standards, and principles are documented as HEDs for resolution in accordance with the HED resolution process presented in V&V IP, Section 3.6, "Human Factors Issue Resolution Verification/HED Resolution."

The applicant has included design specification and HSI style guides as sources for the standards used to verify the final design. The staff determined that this represents a complete and satisfactory set of standards to compare the final HSI design against during design verification activities because the style guides include HFE regulatory guidance and industry good practices. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for criteria identification acceptable.

Criterion 2

General Methodology - The characteristics of the HSI components should be compared with HFE guidelines. These guidelines are applicable to different aspects of the design: task-independent features (e.g., font size), task-specific features (e.g., scale units), and task-integration features (e.g., proximity of control-display).

A single guideline may apply to many identical HSI components, especially in the case of significant HSI modifications and HSIs for new plants. In addition, some environmental considerations (e.g., lighting) may be applicable. To simplify the application of guidelines and reduce redundancy when reporting findings, the guidelines may be applied to features of the HSI as follows:

- *Global features* - global HSI features are those relating to the configurational and environmental aspects of the HSI, such as MCR layout, general workstation configuration, lighting, noise, heating, and ventilation. These aspects of the review, e.g., MCR lighting, tend to be evaluated only once.
- *Standardized features* - standardized features are those that were designed using HFE guidelines applied across individual controls and displays (e.g., display screen organization, display format conventions, and coding conventions). Therefore, their implementation should be more consistent across the interface than features that were not designed with guidelines. Thus, for example, if display labeling is standardized by the applicant's HFE guidelines (style guide), which have been accepted by the NRC, then display labels can be spot-checked rather than being verified individually.
- *Detailed features* - detailed features are the aspects of individual HSIs that are not addressed by general HFE guidelines. The latter can be expected to be more variable than the standardized design features.

For each guideline, it should be determined whether the HSI is 'acceptable' or 'discrepant' from the guideline (therefore, potentially unacceptable) [, i.e.,] an HED. 'Acceptable' should be indicated only if there is total compliance, i.e., only if every instance of the item is fully consistent with the criteria established by the HFE guidelines. If there is any instance of noncompliance, full or partial, then an evaluation of discrepant [conditions] should be given, and a notation made as to where noncompliance occurs.

Discrepancies should be evaluated as potential indicators of additional issues. For example, identifying an inappropriate format for presenting data on an individual display should be considered a potential sign that other display formats could be incorrectly used or that the observed format is inappropriately used elsewhere. As a result, the sampling strategy could be modified to encompass other display formats. In some cases, discovering these discrepancies could warrant further review in the identified areas of concern.

Staff Evaluation of Criterion 2

In FSAR Tier 2, Section 18.10.3.3, the applicant outlines the methodology for design verification. This methodology includes the following attributes:

- Design requirements are derived from the style guide and cover the following aspects of HSI design: Global features, standardization features, and detailed features. V&V IP, Section 3.4.4 provides specific direction on the types of HSIs that fall into each of these categories. The definitions and examples used to describe these areas comply with the guidance included with this in NUREG-0711 criterion.
- Checklists are used to collect relevant style guide requirements, final design documentation, panel drawings, mockups, and screen shots.
- Designers justify and document instances where the design deviates from the specifications or established practices.
- An HED is generated when an HSI component does not conform to the operation requirements as defined in the validated procedure guidelines, HEDs are also identified for crew-identified functionality issues, poor integration with the rest of the HSI, and poor integration with procedures and training, HFE design specification or the style guide. These HEDs are evaluated for extent of condition.

This method contains a complete set of steps for conducting design verification. The first step contains specific definitions and examples of each type of design feature identified in this criterion that will facilitate thorough design verification. Together, these steps provide reasonable assurance that the design verification process will determine whether the HSI is acceptable or discrepant from the design guideline. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for HFE design verification methodology acceptable.

Criterion 3

Criterion 3 describes additional methodology considerations for plant modifications. Therefore, this NUREG-0711 criterion is not applicable to new construction.

Criterion 4

HED Documentation - HEDs should be documented by the applicant in terms of the HSI component involved and how its characteristics depart from a particular guideline.

Staff Evaluation of Criterion 4:

In FSAR Tier 2, Section 18.10.3.6, the applicant states that HED documentation will include, among other items, the relevant task criterion, and explanation of the basis of the deficiency, a recommended fix, justification of discrepancy, and impact on schedule.

Since the explanation of the basis of the HED will identify the HSI component involved and how its characteristics depart from an HSI guideline, the staff finds the V&V IP treatment of this NUREG-0711 criterion for HED documentation acceptable.

18.10.3.3 *Integrated System Validation*

ISV is the process by which an integrated system design (i.e., hardware, software, and personnel elements) is evaluated using performance-based tests to determine whether it supports plant personnel in the safe operation of the plant. It is intended to evaluate the acceptability of those aspects of the design that cannot be determined through such analytical means as HSI task-support verification and HFE design verification.

18.10.3.3.1 Test Objectives

Criterion 1

Detailed objectives should be developed to provide evidence that the integrated system adequately supports plant personnel in the safe operation of the plant. The test objectives and scenarios should be developed to address aspects of performance that are affected by the modification [of the] design, including personnel functions and tasks affected by the modification. The objectives should be to:

- Validate the role of plant personnel.
- 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 should include validation of the nominal shift levels, minimal shift levels, and shift turnover.
- Validate that for each human function, the design provides adequate alerting, information, control, and feedback capability for human functions to be performed under normal plant evolutions, transients, design-basis accidents, and selected, risk-significant events that are beyond-design basis.
- 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 crew can make effective transitions between the HSIs and procedures in the accomplishment of their tasks and that interface management tasks such as display configuration and navigation are not a distraction or undue burden.
- Validate that the integrated system performance is tolerant of failures of individual HSI features.
- Identify aspects of the integrated system that may negatively affect integrated system performance.

- For modifications that change plant systems but do not modify the HSI, validation can provide evidence about the adequacy of the existing HSIs, procedures, and training for supporting personnel performance.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.10.3.5.4, "ISV Test Objectives," repeats the ISV objectives contained in the criterion. V&V IP, Section 5.5.1, "Purpose," provides additional complimentary objectives. Accordingly, the staff finds the V&V Plan treatment of the criterion for ISV objectives acceptable.

18.10.3.3.2 Validation Testbeds

NUREG-0711, Section 11.4.3.2.2, "Validation Testbeds," Criteria 1 through 7 provide for the review of simulation testbed fidelity. This section states that one approach to identifying a testbed that meets the staff's fidelity criteria is to ensure its compatibility with ANSI/ANS Standard (Std) 3.5 - 1988. V&V IP, Section 3.5.4.1, "Validation Testbed," states that the ISV will be performed on a high fidelity full scope simulator that meets the criteria of ANSI/ANS Std 3.5 and RG 1.149, Revision 3, "Nuclear Power Plant Simulation Facilities for Use in Operator Training and License Examinations," 2001. Accordingly, the staff finds the V&V IP treatment of NUREG-0711, Section 11.4.3.2.2, Criteria 1 through 7 pertaining to simulator fidelity acceptable. For consistency, the individual criteria are provided below.

Criterion 1

Interface Completeness - The testbed should completely represent the integrated system. This should include HSIs and procedures not specifically required in the test scenarios. For example, adjacent controls and displays may affect the ways in which personnel use those that are addressed by a particular validation scenario.

Staff Evaluation of Criterion 1

The applicant's testbed meets this criterion by reference to ANS 3.5 and RG 1.149.

Criterion 2

Interface Physical Fidelity - A high degree of physical fidelity in the HSIs and procedures should be represented, including presentation of alarms, displays, controls, job aids, procedures, communications, interface management tools, layout and spatial relationships.

Staff Evaluation of Criterion 2

The applicant's testbed meets this criterion by reference to ANS 3.5 and RG 1.149.

Criterion 3

Interface Functional Fidelity - A high degree of functional fidelity in the HSIs and procedures should be represented. All HSI functions should be available. High functional fidelity includes HSI component modes of operation, i.e., the changes in functionality that can be invoked on the basis of personnel selection and/or plant states.

Staff Evaluation of Criterion 3

The applicant's testbed meets this criterion by reference to ANS 3.5 and RG 1.149.

Criterion 4

Environment Fidelity - A high degree of environment fidelity should be represented. The lighting, noise, temperature, and humidity characteristics should reasonably reflect that expected. Thus, noise contributed by equipment, such as air handling units and computers should be represented in validation tests.

Staff Evaluation of Criterion 4

The applicant's testbed meets this criterion by reference to ANS 3.5 and RG 1.149.

Criterion 5

Data Completeness Fidelity - Information and data provided to personnel should completely represent the plant systems monitored and controlled from that facility.

Staff Evaluation of Criterion 5

The applicant's testbed meets this criterion by reference to ANS 3.5 and RG 1.149.

Criterion 6

Data Content Fidelity - A high degree of data content fidelity should be represented. The information and controls presented should be based on an underlying model that accurately reflects the reference plant. The model should provide input to the HSI in a manner such that information accurately matches that which will actually be presented.

Staff Evaluation of Criterion 6

The applicant's testbed meets this criterion by reference to ANS 3.5 and RG 1.149.

Criterion 7

Data Dynamics Fidelity - A high degree of data dynamics fidelity should be represented. The process model should be capable of providing input to the HSI in a manner such that information flow and control responses occur accurately and in a correct response time; e.g., information should be provided to personnel with the same delays as would occur in the plant.

Staff Evaluation of Criterion 7

The applicant's testbed meets this criterion by reference to ANS 3.5 and RG 1.149.

Criterion 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.)

Staff Evaluation of Criterion 8

V&V IP, Section 3.5.4.1 states that the full scope simulator contains the full functionality of the MCR and RSS HSIs and is used as the testbed for these two operator stations.

Human actions performed at LCSs are specifically addressed in V&V IP, Section 3.5.4.5. Detailed data associated with LCS actions are collected using the following analysis techniques:

- Procedure walk-through
- Table-top analyses
- Task performance analysis using mockups
- Task performance analysis using part task simulators

The analysis methodology is selected by analysts based upon the complexity and significance of the local control station task with particular emphasis placed upon risk-significance actions. Analysts document all observations associated with task performance to support both accurate portrayal of the task in HFE ISV scenarios and establish the basis for the information included in the scenario documentation. Local control station task performance information documented includes:

- Analysis technique used to capture the performance data
- Basis for selecting the analysis technique
- Plant, system, component, or procedural cue that initiates the local control station task
- Communications that take place between the local control station and the control room during task performance
- Plant, system and component control room indication changes that take place during performance of the local control station task
- Time delays and overall timeline information associated with the task including sequencing of all of the information gathered above. The timing and time delay information gathered supports replication of local tasks during HFE ISV scenarios. Activities such as the time to gather task materials, don protective attire, complete long tasks, and any other time-consuming aspect of task performance are included.

This local control station task performance information is then incorporated into HFE ISV scenario documentation packages along with the rest of scenario details.

This method provides a thorough approach to validating LCS HSIs. Using complexity and significance with emphasis on risk-significant actions ensures the most important local action will be subject to this methodology. Accordingly, the staff finds the V&V Plan treatment of this NUREG-0711 criterion for evaluating important local actions acceptable.

Criterion 9

The testbeds should be verified for conformance to the testbed characteristics identified [in Criteria 1-8] above before validations are conducted.

Staff Evaluation of Criterion 9

V&V IP, Section 3.5.4.1 states that a documented basis for determining when the U.S. EPR full scope simulator is of sufficiently high fidelity is prepared prior to validation. This fidelity review includes the following areas:

- Interface completeness – the full scope simulator accurately represents the integrated system and includes but is not limited to controls, displays, or other control room features adjacent to the HSIs being evaluated.
- Interface physical fidelity – the full scope simulator accurately represents the physical layout and content of the integrated control room including, but not limited to room, panel, and HSI layouts, shapes, colors, and contents as well as other control room features such as job aids, communications equipment, etc.
- Interface functional fidelity – The full scope simulator hard and soft control functionality accurately represents the functionality of control room HSIs including, but not limited to modes of operation, feedback, design capabilities, and limitations.
- Environmental fidelity – The environment in which the full scope simulator is housed accurately represents the plant control room environment including but not limited to lighting, noise, humidity, and temperature.
- Data completeness fidelity – The simulated plant and HSI data presented by the full scope simulator accurately represents the data designed to be available in the control room and its associated HSI including but not limited to plant and system parameters, control feature feedback, and soft control capabilities built into the HSI.
- Data content fidelity – The full scope simulator underlying plant modeling (computer coding driving simulation computer responses) accurately represents plant responses to stimuli as observed through the HSI including but not limited to plant and system responses to simulated transients, accidents, and system perturbations or control device input.
- Data dynamics fidelity – The full scope simulator underlying plant modeling (discussed above) and the simulation computers “driving” the simulated hard and soft HSIs are of sufficient capability to accurately represent the manner in which control room hard and soft HSIs provide information to operators. Data dynamics fidelity includes but is not limited to information flow, responses to control commands, and response timing.

The testbed fidelity review against plant design is an acceptable method to verify the simulator reflects the plant design and will provide an acceptable level of detail. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for testbed fidelity acceptable.

18.10.3.3.3 Plant Personnel

Criterion 1

Participants in the validation tests should be representative of actual plant personnel who will interact with the HSI, e.g., licensed operators rather than training or engineering personnel.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.10.3.5.5, "Strategy," states that test participants will be qualified operators currently licensed on similar plant designs.

V&V IP, Section 3.5.4.2, "Integrated System Validation Team and Participant Population," states that the participant staffing for the performance of integrated system validation testing uses licensed personnel for crew members or participants from the training program described below.

V&V IP, Section 3.5.4.5.6 indicates that all participant personnel receive both periodic and comprehensive final tests (similar to the tests plant personnel will receive in actual plant qualification and licensing training) prior to participating in HFE ISV. Test participant training continues until testing indicates both:

- Satisfactory knowledge, skills, and abilities
- Stable testing results that do not significantly vary from test to test

The training classes provide the test participants with a comprehensive knowledge of U.S. EPR systems training, procedure training and simulator training for familiarization with the controls for the specific U.S. EPR systems. This training is similar to existing PWR license training in content.

Test participants with no previous PWR operating experience will receive additional training for PWR general fundamentals. The systems and procedure training required for these personnel is similar to existing PWR initial license training. The formerly licensed personnel attend integrated plant simulator training with the new trainees to promote teamwork and allow the new trainees to benefit from their experience.

For both new and experienced ISV participants, training programs are modeled after existing operating plant training programs whose effectiveness has been demonstrated. Therefore, the staff concludes that test participants will be representative of actual plant personnel and able to perform the ISV at a level comparable to actual plant personnel. The testing method used will ensure that the applicant's understand and retain the information presented in the program. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for participant representation acceptable.

Criterion 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.

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.10.3.5.5 states that participants in the validation studies will be qualified operators who are not chosen on the basis of operator license and qualification, skill or experience, age, or general demographics.

V&V IP, Section 3.5.4.2 states that crews are selected to ensure that they are representative of actual plant personnel including both experienced and new operators, a range of ages, and a range of general demographics. Information on the crew characteristics is gathered. A prepared form, suitable for data base entry, is completed on each of the validation participants. The form documents operator age, experience, license held, and biometric information.

The data base provides an acceptable way to effectively manage operating crew diversity. It ensures a complete set of information is available during crew selection as well as documentation of operator characteristics useful in the ISV data analysis. Accordingly, the staff finds the V&V Plan treatment of the criterion for accounting for human variability acceptable.

Criterion 3

In selection of personnel, consideration should be given to the assembly of minimum and normal crew configurations, including shift supervisors, reactor operators, shift technical advisors, etc., that will participate in the tests.

Staff Evaluation of Criterion 3

V&V IP, Section 3.5.1 states that one purpose of ISV is to verify the adequacy of both minimum and normal staffing levels. V&V IP, Section 3.5.4.2 states that ISV participant personnel are selected to support the formulation of both minimum and normal crew configurations including Shift Supervisors, Unit Supervisors, Shift Technical Advisors, and Unit Operators. Minimum crew size will consist of two reactor operators and one SRO. Normal crew configuration consists of two reactor operators, the Shift Supervisor, Unit Supervisor, and Shift Technical Advisor in the control room. This provides a reasonable and acceptable variation in crew configurations. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for crew configuration size acceptable.

Criterion 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.

Staff Evaluation of Criterion 4

V&V IP, Section 3.5.4.2 states that participant sample bias is minimized by the following selection restrictions:

- Members of the HSI design team are not allowed to act as crew members.
- Test participants are not allowed to act as a crew member in a given scenario more than once.
- Selection criteria specifically targeting individual characteristics such as skill are not used in the participant selection process.

These three participant selection restrictions conform to the NUREG-0711 guidance. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for the participant sampling bias acceptable.

18.10.3.3.4 Scenario Definition

Criterion 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, questionnaire, and rating scale administrations)
- specific criteria for terminating the scenario.

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.10.3.4.4 includes scenario description standards that encompass all the elements given above. V&V IP, Section 3.5.4.3, "Scenario Definition," restates the list presented in this criterion. Three scenarios were provided as a sample of how this information is developed and communicated. The staff concludes that the scenarios were developed in accordance with the appropriate sections of the V&V IP and provide reasonable assurance that the complete set of ISV scenarios developed as part of ITAAC will adequately support the ISV.

Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for scenario performance dimensions acceptable.

Criterion 2

Scenarios should have appropriate task fidelity so that realistic task performance will be observed in the tests and so that test results can be generalized to actual operation of the real plant.

Staff Evaluation of Criterion 2

V&V IP, Section 3.5.4.3 states that scenarios are realistic in the sense that they represent what could actually happen, making it reasonable to expect that integrated HSI and crew performance observed during evaluation scenarios is substantially similar to performance that would be seen in the plant control room were operating crews faced with a similar scenario.

Realism, feasibility, complexity, and ambiguity, are four elements discussed in V&V IP, Section 3.5.4.3 that are balanced within the scenario development process to provide challenging but realistic scenarios. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for scenario task fidelity acceptable.

Criterion 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).

Staff Evaluation of Criterion 3

V&V IP, Section 3.5.4.3 states that when evaluating performance associated with operations remote from the main control room, the effects on crew performance due to potentially harsh environments (e.g., high radiation) are realistically simulated (e.g., additional time to don protective clothing and access radiologically controlled areas). Scenario developers include appropriate time delays, feedback indications within the HSI, and verbal feedback cues in the scenario package by providing specific time delays and remote HSI indications within the scenario directions. These validation elements ensure a realistic simulation of remote

operations. Accordingly, the staff finds the V&V Plan treatment of this NUREG-0711 criterion for evaluating remote operations acceptable.

18.10.3.3.5 Performance Measurement

The performance measurement review covers measurement characteristics, performance measure selection, and performance criteria.

18.10.3.3.5.1 Measurement Characteristics

Criterion 1

Performance Measurement Characteristics - Performance measures should acceptably exhibit the following measurement characteristics to provide reasonable assurance that the measures are of good quality (it should be noted that some of the characteristics identified below may not apply to every performance measure):

- *Construct Validity* - A measure should accurately represent the aspect of performance to be measured.
- *Diagnosticity* - A measure should provide information that can be used to identify the cause of acceptable or unacceptable performance.
- *Impartiality* - A measure should be equally capable of reflecting good as well as bad performance.
- *Objectivity* - A measure should be based on phenomena that are easily observed.
- *Reliability* - A measure should be repeatable; i.e., if the same behavior is measured in exactly the same way under identical circumstances, the same measurement result should be obtained.
- *Resolution* - A measure should reflect the performance at an appropriate level of resolution, i.e., with sufficient detail to permit a meaningful analysis.
- *Sensitivity* - A measure's range (scale) and the frequency of measurement (how often data are collected) should be appropriate to the aspect of performance being assessed.
- *Simplicity* - A measure should be simple both from the standpoint of executing the tests and from the standpoint of communicating and comprehending the meaning of the measures.
- *Unintrusiveness* - A measure should not significantly alter the psychological or physical processes that are being investigated.

Staff Evaluation of Criterion 1

V&V IP, Section 3.5.4.4, "Performance Measurement," states that the performance measures will be evaluated in terms of the characteristics defined in the criterion above. Each

characteristic is defined, and the concepts of reliability and construct validity are discussed. In later sections, applicable characteristics are applied to the four tiers of performance measures. For example, for plant core thermal-hydraulic measures, V&V IP, Section 3.5.4.4.1 provides the following assessment:

- Construct Validity – Plant design is driven by the ability to control and determine core thermal hydraulic condition. The selected performance measures represent the ability of the plant to complete that function, and thus demonstrate construct validity.
- Impartiality – Achieved by using a performance measure that provides a measurement of successful or unsuccessful performance.
- Objectivity – Participant actions can easily be observed and timed; likewise, the outcome of a scenario is easily observed through the use of simulator technology.
- Reliability – This measure is repeatable, because any event resulting in the core thermal-hydraulic parameters exceeding defined limits produces the same result.
- Unintrusiveness – Achieved by using a performance measure that is monitored with no input required from the test personnel or participants.

The staff concludes that the measurement characteristics applied to the plant core thermal-hydraulic measure provide reasonable assurance that the performance measure itself will be of good quality. Similarly, measurement characteristics are identified for each measure and the staff finds them to be appropriate for each measure.

Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for measurement characteristics acceptable.

18.10.3.3.5.2 Performance Measure Selection

Criterion 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.

Staff Evaluation of Criterion 1

V&V IP, Section 3.5.4.4 discusses the performance measure hierarchy. There are four levels of performance measures, which include two sets of plant level measures (core thermal hydraulic conditions and PRA/HRA performance criteria), task measures, and personnel measures (called supplemental measures).

The applicant presents a hierarchy of performance measures in which ability to maintain plant thermal-hydraulic conditions is the most critical, and personnel criteria are the lowest tier. Plant

level indicators derived from core thermal hydraulic and PRA/HRA calculations are pass/fail acceptance criteria. If credited actions are not initiated within the accepted times or critical plant parameters are exceeded, the scenario subject to the performance measure fails.

Task indicators are developed for critical tasks identified in the HFE task analysis process. A task is classified as a critical task if failure of a crew to perform that task leads to the inability to:

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

If a validation scenario contains a critical task identified in HFE task analysis within its sequence of events, the limits documented in the HFE task analysis for the critical task are included in the V&V scenario package as scenario pass/fail criteria applied to crew/system performance during the specific event being analyzed.

Supplemental criteria include personnel measures of crew coordination and communication; situation awareness; workload; and anthropometrics. Normative (comparison with historical norms) and expert judgment observations and observer judgments are made and documented to assess these areas. These observations and judgments are used to better understand the results of V&V scenarios and are not “Pass/Fail” criteria. V&V IP, Section 3.5.4.4.2 describes proprietary questionnaires used to support observers in assessing the supplemental criteria. The applicant has established specific criteria to measure validation effectiveness and has provided appropriate prioritization of these measures to clearly distinguish which ones are pass/fail and which ones are used for general performance improvement. The measures are applied to both plant and personnel performance, thus, ensuring that a holistic approach is maintained while evaluating the ISV activities. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for hierarchal measurement acceptable.

Criterion 2

Plant Performance Measurement - Plant performance measures representing functions, systems, components, and HSI use should be obtained.

Staff Evaluation of Criterion 2

V&V IP, Section 3.5.4.4 describes how plant performance related functions are incorporated into all levels of performance measurement described above. At the plant level measures, examples of plant performance measurement include:

- Prevention or mitigation of transients and accidents, as described in FSAR Tier 2, Chapter 15, “Transient and Accident Analyses” as demonstrated by maintaining the plant within plant and core thermo-hydraulic limitations

- HSI software and hardware failures
- Plant, system, or component performance limits and criteria contained in U.S. EPR design basis documents such as thermo-hydraulic analyses, PHR/HRA analyses, Technical Specifications, and task analysis results
- Challenges to safety limits such as:
 - Degradation of a fission product barrier
 - Degradation to a safety system, main control room, or emergency power capacity
 - Violation of a safety limit
 - Incorrect reactivity control (e.g., failure to initiate standby liquid control)
 - A significant reduction of safety margin beyond that which is irreparably introduced by a scenario
- Crew understanding of Plant and System Responses
- Operator interfaces with the control boards

The approach described by the applicant is comprehensive and addresses key aspects of plant performance and the operator's interface with HSIs. The measures selected have a fundamental and immediate connection back to the ability to maintain reactor safety. Some plant performance measures are scenario-specific. The applicant has provided direction that performance measures will be developed specifically for each scenario. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for plant performance measurement acceptable.

Criterion 3

Personnel Task Measurement - For each specific scenario, the tasks that personnel perform should be identified and assessed. Two types of personnel tasks should be measured: primary (e.g., start a pump), and secondary (e.g., access the pump status display). Primary tasks are those involved in performing the functional role of the operator to supervise the plant; i.e., monitoring, detection, situation assessment, response planning, and response implementation. Secondary tasks are those personnel perform when interfacing with the plant, but which are not directed to the primary task, such as navigation and HSI configuration. This analysis should be used for the identification of potential errors of omission.

- Primary tasks should be assessed at a level of detail appropriate to the task demands. For example, for some simple scenarios, measuring the time to complete a task may be sufficient. For more complicated tasks, especially those that may be described as knowledge-based, it may be appropriate to perform a more fine-grained analysis such as identifying task components: seeking specific data, making decisions, taking actions, and obtaining feedback. Tasks that are important to successful

integrated system performance and are knowledge-based should be measured in a more fine-grained approach.

- The measurement of secondary tasks should reflect the demands of the detailed HSI implementation, e.g., time to configure a workstation, navigate between displays, and manipulate displays (e.g., changing display type and setting scale).
- The tasks that are actually performed by personnel during simulated scenarios should be identified and quantified. (Note that the actual tasks may be somewhat different from those that should be performed). Analysis of tasks performed should be used for the identification of errors of commission.
- The measures used to quantify tasks should be chosen to reflect the important aspects of the task with respect to system performance, such as:
 - time
 - accuracy
 - frequency
 - errors (omission and commission)
 - amount achieved or accomplished
 - consumption or quantity used
 - subjective reports of participants
 - behavior categorization by observers

Staff Evaluation of Criterion 3

V&V IP, Section 3.5.4.4.2 states that for each ISV scenario, the tasks that personnel perform during the scenario are identified. These tasks are assessed during scenario performance to validate that the integrated HSI adequately supports task performance. Task performance measures include detection time (from the occurrence of the first alarm until detection of the alarm), decision making time, time to find and access the correct procedures, response time (from the first significant alarm until the first manual action related to safety of the plant), and task completion time.

Tasks are also measured using a subjective rating scale. For example, the measure of “Understanding of Plant and System Responses” is assessed using a series of questions that are answered by the ISV observers using a 1-3 point rating scale, where 1 = Poor, 2 = Average, and 3 = Good). For this measure, the following questions are assessed:

- Did the crew locate and interpret control room indicators correctly and efficiently to ascertain and verify the status/operation of plant systems?

3 = Each crew member located and interpreted instruments accurately and efficiently.

2 = Some crew members committed minor errors in locating or interpreting instruments or displays. Some crew members required assistance.

1 = The crew members made serious omissions, delays, or errors in interpreting safety-related parameters.

- Did the crew demonstrate an understanding of the manner in which the plant, systems, and components operate, including set points, interlocks, and automatic actions?

3 = Crew members demonstrated thorough understanding of how systems and components operate.

2 = The crew committed minor errors because of incomplete knowledge of the operation of the system or component. Some crew members required assistance.

1 = Inadequate knowledge of safety system or component operation resulted in serious mistakes or plant degradation.

- Did the crew demonstrate an understanding of how their actions (or inaction) affected systems and plant conditions?

3 = All members understood the effect that actions or directives had on the plant and systems.

2 = Actions or directives indicated minor inaccuracies in individuals' understanding, but the crew corrected the actions.

1 = The crew appeared to act without knowledge of or with disregard for the effects on plant safety.

Similarly, the following measurements are applied to tasks:

- Understanding of plant and system responses
- Diagnosis of events and conditions based on signals or readings
- Control board operations
- Operating crew communications and coordination
- Situation awareness
- Physical and cognitive workload
- Anthropometric and physiological factors

This approach to personnel task measurement provides a comprehensive method for assessing both scenario-specific and general task performance and includes both primary and secondary tasks. Quantitative and qualitative measurements are appropriately mixed providing reasonable assurance that personnel performance will be evaluated for potential improvements as well as specific problems. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for measurement of personnel tasks acceptable.

Criterion 4

Situation Awareness - Personnel situation awareness should be assessed. The approach to situation awareness measurement should reflect the current state-of-the-art.

Staff Evaluation of Criterion 4

FSAR Tier 2, Section 18.10.3.5, "Integrated System Validation," indicates that situation awareness will be assessed in ISV. In a follow on section, validation of a high level of situation awareness is given as an objective of ISV.

V&V IP, Section 3.5.4.4.2 states that situation awareness will be assessed during the ISV via the Situation Awareness Control Room Inventory (SACRI), a situation awareness assessment technique. SACRI was developed by Halden Reactor Project and is based upon the Situation Awareness Global Assessment Technique (SAGAT), a well known, accepted measure of situational awareness that was originally developed for aviation but modified for the nuclear power industry. The general procedure used is at various points during scenarios the simulator is frozen, the test subjects turn away from the displays, and a series of questions is asked which relate to the current plant state. The questions asked relate to key process parameters that the operator must monitor to maintain situation awareness. The operator's ability to correctly answer indicates the degree of situation awareness. In addition, it can indicate if the operators are reluctant to act, because they expect automatic system actuation.

Situation awareness data using freeze points is not used during significant events because of its impact on the scenario. During these events, more subjective supplemental situational awareness data is gathered by test personnel using behavioral measures. Observers infer situational awareness from the actions that operators chose to take, based on the assumption that good actions (following the correct procedure) follow from good situational awareness and vice-versa. During scenario events, test personnel observe and rate operator behaviors during task performance. Ratings are conducted using a five point behaviorally anchored rating scale (1 = very poor, 5 = very good) to rate the degree to which individuals are carrying out actions and exhibiting behaviors that would be expected to promote the achievement of higher levels of situational awareness. The list of situational awareness indicative behaviors is developed using information from HFE task analysis, training, and operating procedures. To establish reliability, each participant is rated by more than one observer, and test personnel observations are compared. Observed ratings can also be compared to videotapes of the test session, to confirm accuracy of observations. Observations are recorded from locations that are unobtrusive.

By combining a measurement technique with observations as described above, the applicant achieves a complete assessment of the situational awareness with minimum intrusiveness on scenario implementation. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for measurement of situational awareness acceptable.

Criterion 5

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

Staff Evaluation of Criterion 5

V&V IP, Section 3.5.4.4.2 states that the NASA task load index (TLX) will be used to assess cognitive workload. The TLX is based on operator assessment of workload along six dimensions. To obtain a workload assessment, at the end of selected tasks, a screen in a central location at each operator workstation displays the TLX dimensions, and operators rate their perception of the workload associated with each. Weighting dimensions will be obtained for each scale by having operators do pair-wise comparisons between each of the dimensions. The TLX is an accepted and widely used measure and is appropriate for use in validation tests. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for measurement of workload acceptable.

Criterion 6

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

Staff Evaluation of Criterion 6

V&V IP, Section 3.5.4.4.2 addresses the measurement of anthropometric and physiological factors. The plan states that the primary evaluation of these factors is a part of the design verification. Validation tests also verify these factors have no significant negative impact on crew performance and that no problems arise during HSI use that may not have been evident when HSI components were verified without reference to specific tasks. The applicant will use a combination of observations by test personnel and post-scenario questions to assess the acceptability of anthropometric and physiological parameters. These include reach and accessibility of control devices, ease of control, ease of device manipulation, physical movements, workspaces, and posture data. Operator debriefing comments will also be obtained concerning these aspects of the design. The applicant provides a number of example questions to be included on the anthropometrics questionnaire. The questions provide subjective operator assessment of whether the operator can reach and manipulate appropriate controls for manipulation or to make repairs. These measures will provide a comprehensive assessment of these factors.

Based on the above evaluation, the staff finds the V&V IP treatment of this NUREG-0711 criterion for measurement of anthropometric and physiological factors acceptable.

18.10.3.3.5.3 Performance Criteria

Criterion 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.

Staff Evaluation of Criterion 1

V&V IP, Section 3.5.4.4 describes performance measures containing both pass/fail and subjective acceptance criteria. Tested attributes that do not meet pass/fail criteria constitute a failure of the scenario being validated. This includes plant level measures whose acceptance criteria are identified through thermal-hydraulic analyses and PRA/HRA calculations. The bases for the criteria identified are “requirements referenced” (i.e., operating specifications for system, subsystem, and operator performance defined through engineering analysis). Task measures that verify critical tasks identified during the task analysis process are also pass/fail performance measures. Specific parameter values are determined based on scenario-specific considerations. They are derived from the task analysis and are, therefore, referenced based measures.

The supplemental measures described in V&V IP, Section 3.5.4.4.2 (Understanding of plant and system responses, diagnosis of events and conditions based on signals or readings, control board operations, operating crew communications and coordination) are assessed using a three point ranking system to grade performance. A score of “3” constitutes good performance. A score of “1” is unacceptable; corrective actions are needed, and the design needs to be revalidated. A score of “2” warrants follow-up during operator interviews to determine if performance is justifiable. If not, an HED is initiated. The basis for these task measures is normative (compared to expected responses [actions, times, results] as defined by previous observations of the same or similar responses to comparable cues) and expert-judgment referenced. Situational awareness is a supplemental measure. The acceptance criteria are expert-judgment referenced. V&V IP, Section 3.5.4.4.2 indicates the acceptance criteria will include:

- An average score on the 5 point rating system of greater than 3.5
- Operators can provide a minimum of half the data requested
- The absence of large discrepancies between the perceived state of the plant or plant systems and the actual state of the plant or plant systems

HEDs are generated when any of these criteria are not met.

Workload is a supplemental measure. V&V IP, Section 3.5.4.4.2 provides acceptance criteria for interpreting NASA TLX scores and the basis is normative referenced (the performance criteria are established through use in many system evaluations rather than a single benchmark system). A zone of acceptability exists at the center of the spectrum along a figurative line with conditions of unacceptable levels of mental workload being at either end of the spectrum (high and low). The zone calculated as acceptable is based on the overall data collected within a specific scenario. It includes the following criteria:

- Workload does not create stress for the operators.
- Actions do not take more than 75 percent of the allotted time to perform and operators do not exhibit failures, confusion, or misunderstanding.
- Actions can be completed.

These criteria were developed for published studies of TLX use and will be reevaluated based on test and evaluations to be performed during validation.

Anthropometric and physiological factors are a supplemental measure. The criteria identified are expert-judgment referenced. HEDs are generated when anthropometric and physiological factors negatively impact task performance or represent a risk to operator safety or well-being.

The staff concludes that the V&V IP outlines an acceptable approach for identifying acceptance criteria. Specific, measurable acceptance criteria are developed, the bases for the criteria are appropriate, and the bases are captured in the ISV documentation. The use of pass/fail criteria as opposed to supplemental measures provides for a clear distinction between measurements that validate the design and those which are used to better understand the results. The acceptance criteria identified for the supplemental measures is more subjective but the applicant is using a combination of expert judgment, industry data, and follow-up HEDs to ensure a complete evaluation of the ISV activities. All acceptance criteria are scenario-specific and are identified as part of scenario development. Three scenarios were provided as a sample of how this information would be developed and communicated. The staff concludes that the acceptance criteria are appropriate for the sample scenarios and are communicated in a manner that supported a timely, accurate assessment of ISV activities.

Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for identification of acceptance criteria for performance measures and their bases acceptable.

Criterion 2

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

Staff Evaluation of Criterion 2

The evaluation for Criterion 1 also addresses Criterion 2. Since the staff finds Criterion 1 satisfied, as discussed above, the staff finds the V&V IP treatment of this NUREG-0711 criterion for criteria bases acceptable.

18.10.3.3.6 Test Design

The review criteria for test design are divided into five sections: (1) Coupling crews and scenarios; (2) test procedures; (3) training of test conductors; (4) training of test participants, and (5) the conduct of pilot studies.

18.10.3.3.6.1 *Coupling Crews and Scenarios*

Criterion 1

Scenario Assignment - Important characteristics of scenarios should be balanced across crews. Random assignment of scenarios to crews is not recommended. The value of using random assignment to control bias is only effective when the number of crews is quite large. Instead, the validation team should attempt to provide each crew with a similar and representative range of scenarios.

Staff Evaluation of Criterion 1

V&V IP, Section 3.5.4.5.2 states that scenario assignment to crews is made prior to starting the first HFE ISV integrated system validation scenario. Depending upon the number of available crews, some crews may not participate in all scenarios. The set of scenarios, selected by test personnel and presented to a crew, is carefully balanced to ensure that each crew receives a similar and representative range of scenarios (difficult scenarios are assigned to all crews and not just above average crews). To establish adequate test data reliability, each validation scenario is run on a minimum of three crews.

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

The standards the applicant has identified conform to the guidance in the criterion and the checklist provides an effective way to administer those standards. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for scenario assignments acceptable.

Criterion 2

Scenario Sequencing -The order of presentation of scenario types to crews should be carefully balanced to provide reasonable assurance that the same types of scenarios are not always being presented in the same linear position, e.g., the easy scenarios are not always presented first.

Staff Evaluation of Criterion 2

V&V IP, Section 3.5.4.5.2 states that test personnel balance the order in which scenarios are presented to crews. The same types of scenarios are not always presented in the same order (avoiding always presenting the easy scenarios first), and the scenario sets do not always occur in the same sequence. The checklist described above which sorts the scenarios by complexity, operating conditions, and expectations during the scenario is used to ensure scenarios are balanced across crews. This ensures more complex scenarios are equally likely to be given to any crew, and provides for tracking and inspection of assignments, as well as assurance that a variety of scenarios are assigned to each crew. Control of scenario sequencing also serves to minimize any bias resulting from crew expectations of scenario type. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for scenario sequencing acceptable.

18.10.3.3.6.2 Test Procedures

Criterion 1

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

- The identification of which crews receive which scenarios and the order that the scenarios should be presented.
- Detailed and standardized instructions for briefing the participants. The type of instructions given to participants can affect their performance on a

task. This source of bias can be minimized by developing standard instructions.

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

Staff Evaluation of Criterion 1

V&V IP, Section 3.5.4.5.3 discusses test design. ISV is governed by a two tier system of administrative control documents. One set is specific to individual HFE ISV scenarios. The second set of documents, the ISV process administration documents, applies to the planning, execution, evaluation, and documentation of the HFE ISV as a whole including

administration of all test scenarios. These documents provide working level details that comply with and amplify the processes and requirements presented in the V&V IP.

Scenario documentation is described in the V&V IP, Section 3.5.4.1 and includes:

- A coversheet and revision log
- An administrative information sheet
- Console operator instructions
- Test personnel information sheet
- One or more event guides
- Scripting for communications with outside personnel expected to take place during the scenario
- A critical task summary
- Shift briefing/ transfer of authority information (plant turnover sheets may be used)
- Questionnaires for determining where and when HFE aspects of the HSI contribute to problems with response to the various tasks/events during the scenario (provided to test personnel and participants)
- Termination criteria for completion of the scenario

The specific content of each of these elements is explained in the V&V IP.

The administrative documents are described in V&V IP, Section 3.5.4.3, and call for information that conforms to all the elements in the Criterion 1 above. The IP also calls for the documentation of the identity of test personnel and the qualification, experience, and skill sets of these scenario developers, administrators, and evaluators. Similar information is recorded for the test participants.

Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for test procedures acceptable.

Criterion 2

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

Staff Evaluation of Criterion 2

In regard to minimizing bias, V&V IP, Section 3.5.4.5.5 states that the HFE design team members conducting ISV integrated system validation activities minimize bias through the following:

- Procedurally controlled scenario development and validation process

- Ensuring validation tests are performed using scenarios that are developed by selecting from the full range of operational conditions and that cover a representative range of conditions
- Pilot studies to detect and eliminate possible bias
- Selection of subjects to balance evaluation groups
- Appropriate statistical analysis
- Appropriate selection of tests and measures for evaluation
- Controls for the effects of data collection and measurement
- Optimization of study (interview and questionnaire) elements
- Control of variables
- Identification of possible validity problems and subsequent control of them
- Carefully designed evaluations that are both qualitative (explicit acknowledgement of bias) and quantitative (attempts to eliminate bias)
- Inclusion of both subjective and objective measures
- Balanced subject pool and diverse subject matter experts

The applicant has taken a holistic approach in describing bias control. The controls start as part of the initial scenario development and continue through the completion of data analysis. This provides a robust barrier against any impact from bias. For example, there are controls to prevent bias and then additional controls to detect it should it exist. This strategy significantly minimizes the potential for bias in general, as well as tester expectancy bias and participant response bias. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for minimizing test bias acceptable.

18.10.3.3.6.3 *Test Personnel Training*

Criterion 1

Test administration personnel should receive training on:

- the use and importance of test procedures
- experimenter bias and the types of errors that may be introduced into test data through the failure of test conductors to accurately follow test procedures or interact properly with participants
- the importance of accurately documenting problems that arise in the course of testing, even if due to test conductor oversight or error.

Staff Evaluation of Criterion 1

V&V IP, Section 3.5.4.5.6 states that test personnel will receive training on the following topics:

- Planning and coordinating simulator sessions
- Observing operator performance
- Evaluating operator performance
- The use and importance of test procedures
- Experimenter bias and the types of errors that are introduced into test data through the failure of test personnel to accurately follow test procedures or interact properly with participants
- The importance of accurately documenting problems that arise in the course of testing, even if due to test personnel oversight or error
- Protocols such as when and how to interact with the crew during the simulation, nonintrusive locations, use of recording devices, development and use of observation tools for taking notes during the scenario, and focus on the HSI, procedure or tasks of importance for the specific scenario

This list encompasses all areas addressed in the criterion. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for test personnel training acceptable.

18.10.3.3.6.4 *Participant Training*

Criterion 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.

Staff Evaluation of Criteria 1

V&V IP, Section 3.5.4.5.6 states that test participants who will participate in HFE ISV scenarios are trained as follows:

- Test participants that were licensed on previous generation PWRs are required to receive U.S. EPR systems training, procedure training, and simulator training for familiarization with the controls for the specific U.S. EPR systems. This training is similar to existing PWR license training in content.
- Test participants with no previous PWR operating experience are required to receive additional training for PWR general fundamentals. The systems and procedure training required for these personnel is similar to existing PWR initial license training. The formerly licensed personnel attend integrated plant

simulator training with the new trainees to promote teamwork and allow the new trainees to benefit from their experience.

For both new and experienced ISV participants, training programs are modeled after existing operating plant training programs whose effectiveness has been demonstrated. Therefore, the staff concludes that, for the ISV, test participants will be able to perform at a level comparable to actual plant personnel. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for high-fidelity training of participants acceptable.

Criterion 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.

Staff Evaluation of Criteria 2

V&V IP, Section 3.5.4.5.6 states that test participants who will participate in HFE ISV scenarios receive both periodic and comprehensive final tests (similar to the tests plant personnel will receive in actual plant qualification and licensing training) prior to participating in HFE ISV scenarios. Test participant training continues until testing indicates both:

- Satisfactory knowledge, skills, and abilities
- Stable testing results that do not significantly vary from test to test

The testing method used provides reasonable assurance that applicants will understand and retain the information presented in the program. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for stable participant performance acceptable.

18.10.3.3.6.5 Pilot Testing

Criterion 1

A pilot study should be conducted prior to conducting the integrated validation tests to provide an opportunity to assess the adequacy of the test design, performance measures, and data collection methods.

Staff Evaluation of Criterion 1

In FSAR Tier 2, Section 18.10.3.5.3, "Pilot Study," the applicant states 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. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for conducting pilot tests before validation acceptable.

Criterion 2

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 taken to provide reasonable assurance that the participants do not become so familiar with the data collection process that it may result in response bias.

Staff Evaluation of Criterion 2

In FSAR Tier 2, Section 18.10.3.5.3, the applicant states that personnel used during pilot testing are not to be the same personnel to be used as test participants during ISV tests. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for participant selection acceptable.

18.10.3.3.6.6 *Data Analysis and Interpretation*

Criterion 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.

Staff Evaluation of Criterion 1

V&V IP, Section 3.5.4.6, "Data Analysis and Interpretation," discusses data analysis and interpretation. It identifies four levels of data: plant level 1; plant level 2; task level; and supplemental criteria. Plant levels 1 and 2 and task level performance measures use quantitative methods to compare ISV activities to accident analysis, PRA/HRA, and task analysis based acceptance criteria. The supplemental measures use qualitative methods to assess operator performance such as situation awareness and workload. Data analysis is conducted in accordance with the established hierarchical set of performance measures, with the greatest weight being placed on data coming from the highest performance measure tiers. Analysis is dependent on the type and quality of data that has been acquired but generally follows a four step process which includes the following:

- The transformation step translates the raw data into dependent measures of interest.
- The organization step puts the data into a form suitable for statistical analysis.
- The identification step identifies significant main effects and interactions, and determines if the system does or does not meet the objective criteria defined during the evaluation process.
- The interpretation step identifies insights into the practical significance of the results. This step is performed by someone with knowledge of the context and situations to which the evaluation is relevant.

The applicant has combined quantitative and qualitative data analysis methods to maximize the effectiveness of the ISV process. The four step analysis process provides an effective way to collect and organize the data so the analysis methods can be effectively applied and so that the

relationship between performance data and the acceptance criteria is understood and properly justified. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for data analysis acceptable.

Criterion 2

For performance measures used as pass/fail indicators, failed indicators must be resolved before the design can be validated. Where performance does not meet criteria for the other performance measures, the results should be evaluated using the HED evaluation process.

Staff Evaluation of Criterion 2

V&V IP, Section 3.5.4.6 states that for performance measures used as pass/fail indicators, failed indicators are resolved using the HED resolution process before the design can be validated. Where performance does not meet criteria for supplemental performance measures, the results are evaluated using the HED resolution process. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for treatment of pass/fail criteria and other measures acceptable.

Criterion 3

The degree of convergent validity should be evaluated, i.e., the convergence or consistency of the measures of performance.

Staff Evaluation of Criterion 3

FSAR Tier 2, Section 18.10.3.5.7, "Data Analysis, Interpretation and Validation Conclusions," states that converging performance measures will be independently evaluated. V&V IP, Section 3.5.4.6.2 specifically addresses data convergence. In this section, the applicant states that convergence is established by comparing data from measures that are intended to measure the same or closely related aspects of performance. For example, the participant's subjective reports of high situation awareness should correlate to measures of situation awareness as indicated by SACRI. If there is a no correlation between related measures, an HED is created.

The applicant's plan to compare data associated with similar aspects of performance is an effective way of demonstrating consistency across associated performance measures and is consistent with industry practices. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for convergent validity acceptable.

Criterion 4

The data analyses should be independently verified for correctness of analysis.

Staff Evaluation of Criterion 4

FSAR Tier 2, Section 18.10.3.5.7 states that data analysis and validation of converging performance measures are verified independently in accordance with the AREVA Design Control QA Program. V&V IP, Section 3.5.4.6.5 indicates that the HFE ISV process provides that the results and conclusions reached for each scenario, as well as the aggregate HFE integrated system analysis be independently verified with regards to the correctness of analysis and resulting conclusions. HFE design team members not involved in the administration or

evaluation of HFE ISV scenarios are selected to perform these independent reviews. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for analysis verification acceptable.

Criterion 5

The inference from observed performance to estimated real-world performance should allow for margin of error; i.e., some allowance should be made to reflect the fact that actual performance may be slightly more variable than observed validation test performance.

Staff Evaluation of Criterion 5

As stated in FSAR Tier 2, Section 18.10.3.5.7, a margin of error is built into testing to ensure conservative analysis of the results. V&V IP, Section 3.5.4.6.3 states that the limitations of validation testing are documented, along with considerations regarding the potential effects of these limitations on validation conclusions and design implementation. These include problems such as:

- Aspects of the tests that were not well controlled
- Potential differences between the test situation and actual operations
- Potential differences between the validated design and plant as built

If an item cannot be fully validated during HFE ISV due to testing limitations or other complications, a HED is written to ensure associated validation activities are completed during design implementation. Also, the applicant's use of a full scope simulator for ISV will minimize differences between testing and real-world performance.

The staff concludes that the applicant's use of bias controls, conservative analysis methods, and a full scope simulator substantiate their statement that the margin of error is built into the testing. Plan variability is addressed through the three criteria above and provides reasonable assurance that the variances will be thoroughly evaluated. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for error margins acceptable.

18.10.3.3.7 Validation Conclusions

Criterion 1

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

Staff Evaluation of Criterion 1

FSAR Tier 2, Section 18.10.3.5.7 states that the logical bases for performance measures and associated testing is provided in engineering documentation, and conclusions will be documented in validation reports throughout the design process. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for validation conclusions acceptable.

Criterion 2

Validation limitations should be considered in terms of identifying their possible effects on validation conclusions and impact on design implementation. These include:

- aspects of the tests that were not well controlled
- potential differences between the test situation and actual operations, such as absence of productivity-safety conflicts
- potential differences between the validated design and plant as built (if validation is directed to an actual plant under construction where such information is available or a new design using validation results of a predecessor)

Staff Evaluation of Criterion 2

V&V IP, Section 3.5.4.6.3 indicates that the limitations of validation testing will be addressed and will include considerations noted in the staff's review criterion. In instances where validation limitations impact the conclusions, the validation process will be extended to the plant itself and will be addressed by the "U.S. EPR Human Factors Engineering Design Implementation Plan," December 16, 2010. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for validation limitations acceptable.

18.10.3.4 *Human Engineering Discrepancy Resolution Review Criteria*

Criterion 1

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

Staff Evaluation of Criterion 1

V&V IP, Section 3.6.4.3 provides the methodology for HED justification. Justification is acceptable when HFE designers determine from recent industry literature, tradeoff studies, or HFE analyses that the benefits of the deviant design feature outweigh potential drawbacks. This section states that HEDs that constitute safety concerns or performance problems cannot be justified. The basis for acceptance of an as-is justification is documented by the HFE design team member assigned to resolve the HED and reviewed by HFE design team leader. The

method used and the technical basis for the justification are documented and tracked in the applicant's documentation system.

The conditions applied to HED justifications ensure that an appropriate basis is captured by documenting the justification rationale within the corrective action program and that there is a review and approval of that basis by the HFE Team Leader. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for HED justification acceptable.

Criterion 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 they generally have to be assessed.
 - Other - this subcategory specifically pertains to HEDs identified from integrated system validation that cannot be easily assigned to any of the three preceding categories.
- Individual HSI or procedure - HEDs should be analyzed with respect to individual HSIs and procedures. The potential effects of these HEDs on plant safety and personnel performance are determined, in part, by the safety significance of the plant system(s) that are related to the particular component.
- Personnel function - HEDs should be analyzed with respect to individual personnel functions. The potential effects of these HEDs are 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 warrant 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.

Staff Evaluation of Criterion 2

V&V IP, Section 3.6.4.4 describes the HED analysis methodology. The scope and impact of each HED are analyzed in the context of other open HEDs. When an HED reflects a global or standard design feature, the broader impact of the HED is assessed. This approach enables the analyst to identify crosscutting or programmatic concerns. When such concerns are found they are documented on an HED for resolution.

Specific information considered during analysis includes system or systems affected; whether the HED affects global, standardized, or detailed design features; the HSIs affected; the personnel functions or tasks affected; and the procedures or training affected.

The methodology also considers the cumulative impact of HED in the context of other open HEDs affecting the same design features, functions, or processes.

The applicant's HED analysis plan, by virtue of the cross referencing between HEDs and the scope of the evaluations performed, provides reasonable assurance that the generic implications of an HED issue will be fully evaluated. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for HED analysis acceptable.

Criterion 3

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

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

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

Priority 2 HEDs should be those that do not have significant safety consequences, but do have potential consequences to plant performance/operability, non-safety-related personnel performance/efficiency, or other factors affecting overall plant operability. These include deviations from credited personnel information 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.

Staff Evaluation of Criterion 3

V&V IP, Section 3.6.4.5 describes the HED prioritization. The HED analysis process provides criteria for sorting HEDs into three categories. The first category contains safety issues, the second contains plant or personnel performance issues, and the third contains all remaining HEDs that do not fit in the Priority 1 or Priority 2 category. These HEDs have no impact on plant safety, plant performance, or personnel performance. These criteria for prioritizing HEDs conforms to the acceptance criterion and provides reasonable assurance that important issues will be identified for timely evaluation. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for HED prioritization acceptable.

Criterion 4

HED Evaluation Documentation - Each HED should be fully documented including assessment category (priority for correction), associated plant system, associated personnel function, and associated HSI or procedure. The documentation should clearly show whether the HED was dismissed or identified as needing design modification, and the basis for this determination in terms of consequence to plant safety or operation should be clearly described.

Staff Evaluation of Criterion 4

V&V IP, Section 3.6.4.6 describes the HED documentation. All HEDs are entered into the HED issues tracking system database. This provides an auditable system that fully describes the HED and its resolution. It includes identifying information; any justification for accepting the

condition (if applicable); the results of the HED analysis (including systems, HSIs, personnel functions, procedures, training, and other plant design features that are impacted by the HED); the HED's priority and its basis; and the HED resolution. This documentation provides all the documentation recommended in the criterion. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for HED documentation acceptable.

Criterion 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.

Staff Evaluation of Criterion 5

V&V IP, Section 3.6.4.7 indicates that when an HED warrants a design solution, an entry is made in the Quality Assurance Corrective Action Program. A cause analysis is conducted, and the most appropriate corrective actions are identified. Any design change identified follows the Quality Assurance Design Control Process. This process includes a rigorous cross disciplinary review to ensure the HFE design process is followed. The V&V IP makes specific note that any changes to the detailed design must not cause deviations from design requirements or unintentionally distract the plant operators.

When the item is entered into the HFE issue tracking system, it is coded by type of defect, system impacted, and stage of design. An extent of condition review is performed upon entry of a new HED to see if other similar items were already discovered; so that trends or common design issues can be identified and resolved in a consistent manner.

The Corrective Action Program and the Design Control Process have been approved by the staff as part of the Quality Assurance Plan. This approval is based on the program/process providing sound solutions to problems, including design solutions, as described in Section 17.5, "Quality Assurance Program Description," of this report. As applied to HFE design solutions, the CAP provides for the consideration of design solutions for multiple HEDs together, and the coordination of multiple design solutions affecting a single system such that the solutions' combined effect enhances rather than detracts from the system's performance. Since the V&V IP commits to applying the CAP to the HFE design, including portions of the HFE design that are not safety-related, the staff finds the V&V IP treatment of this NUREG-0711 criterion for design solution development acceptable.

Criterion 6

Design Solution Evaluation - Designs should be evaluated by repeating the appropriate analyses of the verification and validation. 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.

Staff Evaluation of Criterion 6

FSAR Tier 2, Section 18.10.3.6.3, "HED Design Solution Evaluation," indicates that a solution is evaluated to determine if it:

- Adequately corrects the HED
- Does not adversely impact other areas of the design
- Is consistent with the HFE guidelines, and that ISV can be conducted to evaluate its usability

The V&V process is then reapplied to the new design.

This guidance provides reasonable assurance that design changes will be effective. The criteria that the applicant proposes to use to judge acceptability of HED resolution ensure these changes are screened using similar methods to those used to accept the initial design. In particular, ISV (limited in scope to the change being made) is used to prove the effectiveness of the change. Accordingly, the staff finds the V&V IP treatment of this NUREG-0711 criterion for design solution evaluation acceptable.

18.10.4 Other Documents Subject to Review

18.10.4.1.1 FSAR Tier 1, Section 3.3, "Human Factors Engineering"

FSAR Tier 1, Table 3.4-1, "Human Factors Engineering ITAAC," contains the ITAAC that are proposed for HFE. The staff's evaluation of these ITAAC is provided in Section 14.3.9 of this report.

18.10.5 Combined License Information Items

There are no combined license information items related to this area of review. The staff determined that no COL information items need to be included in FSAR Tier 2, Table 1.8-2, "U.S. EPR Combined License Information Items," for validation and verification.

18.10.6 Conclusions

The staff reviewed the applicant's HFE V&V, at an IP level using the review criteria in NUREG-0711, Section 11.4. Section 18.0.4 of this report provides a discussion of review levels. For the reasons set forth above, the staff concludes that the V&V Program, as described in the V&V IP, provides an acceptable methodology for the following:

- Identifying a sample of operational conditions that (1) includes conditions that are representative of the range of events that could be encountered during operation of the plant, (2) reflects the characteristics that are expected to contribute to

system performance variation, and (3) considers the safety significance of HSI components

- Developing an HSI inventory and characterization that accurately describes all HSI displays, controls, and related equipment that are within the defined scope of the HSI design review
- Verifying that the HSI provides all alarms, information, and control capabilities needed for personnel tasks
- Verifying that the characteristics of the HSI and the environment in which it is used conform to HFE guidelines
- Validating the integrated system design (i.e., hardware, software, and personnel elements) using performance-based tests to determine whether it acceptably supports safe operation of the plant
- Developing an HED evaluation process that acceptably prioritizes HEDs in terms of their need for improvement and developing design solutions and a realistic schedule for implementation to address those HEDs selected for correction

As discussed in Section 18.0.5 of this report, the V&V IP is designated as Tier 2*, which ensures that the IP will be implemented by the COL applicant. Furthermore, because the V&V IP is designated as Tier 2*, the COL applicant cannot make changes to the IP without obtaining prior NRC approval. Therefore, the staff concludes that V&V considerations with respect to HFE have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.

18.11 Design Implementation

18.11.1 Regulatory Criteria

HFE design implementation (DI) is evaluated based on the review criteria provided in NUREG-0711, Chapter 12, "Design Implementation," Section 12.4.6, "Final Plant HFE Design Verification," and SRP Section 18.II.A.11. NUREG-0711, Section 12.4.6 specifies the review criteria that pertain to the staff's evaluation of DI. Specifically, the staff confirms that the applicant has an acceptable process to verify that the as-built design conforms to the verified and validated design that resulted from the HFE design process.

18.11.2 Summary of Technical Information

DI is described in FSAR Tier 2, Section 18.11, "Design Implementation." FSAR Tier 2, Section 18.11.2, "Methodology," incorporates by reference, "Human Factors Engineering (HFE) Design Implementation Plan," December 16, 2010 (referred to as the DI IP). The staff reviewed the DI IP, along with other documents that pertain to the staff's review of DI, as discussed in the subsections that follow. The staff focused its review on evaluating the information provided based on the review criteria in NUREG-0711, Chapter 12 and SRP Section 18.II.A.11.

18.11.3 Staff Evaluation

The staff performed an implementation plan level of review as described in NUREG-0711 and Section 18.0.4 of this report. This section presents the applicable review criteria from NUREG-0711 (reproduced below) followed by the staff's evaluation of each.

Criterion 1

Aspects of the design that were not addressed in V&V should be evaluated using an appropriate V&V method. Aspects of the design addressed by this criterion may include design characteristics such as new or modified displays for plant-specific design features and features that cannot be evaluated in a simulator such as CR lighting and noise.

Staff Evaluation of Criterion 1

As discussed in the DI IP, Section 1.3, "Purpose," one purpose of DI is to verify aspects of the design that may not have been evaluated previously in the V&V process. Another purpose is to show that all issues in the HITS were adequately addressed. The DI IP also ensures that the as-built design conforms to the standard U.S. EPR design that results from the V&V process. These high-level purposes stated by the applicant provide the scope of the DI process which is acceptable to the staff.

DI IP, Section 3.3, "Verification of Features that cannot be evaluated with a Simulator," describes the methodology and implementation of the applicant's DI process to verify HSIs that are not addressed by V&V through the simulator. Some of the aspects mentioned are control room lighting, background noise, communication system, accessibility of instrumentation, and control room climate. DI IP, Section 3.3 outlines an acceptable scope of those aspects of the design included in this verification.

Since the DI IP provides a method to address the aspects of the U.S. EPR HFE design that are not examined by V&V through the simulator and the method is appropriate to accomplish V&V for such aspects of the design, the staff finds the FSAR and the DI IP treatment of this NUREG-0711 criterion acceptable.

Criterion 2

The final (as-built in the plant) HSIs, procedures, and training should be compared with the detailed design description to verify that they conform to the design that resulted from the HFE design process and V&V activities. Any identified discrepancies should be corrected or justified.

Staff Evaluation of Criterion 2

FSAR Tier 2, Section 18.11 describes the purposes, scope, and methodology for HFE DI for the U.S. EPR. A more detailed description of the process is described in DI IP, Sections 3.4 through 3.6. In particular, these sections of the DI IP describe the applicant's methodology for satisfying this criterion.

To address the first part of this criterion, related to comparing the final HSIs to the design that resulted from V&V, the staff evaluated the applicant's process described in DI IP, Sections 3.4 through 3.6. The staff first evaluated the applicant's process for comparing vendor design

documents to the as-built documents. Next, the staff evaluated the applicant's process for comparing the HSIs that resulted from V&V to the as-built HSIs.

The staff did not evaluate the second portion of this criterion related to the applicant's process for comparing the final procedures and training to the verified and validated design. This is because the applicant revised FSAR Tier 2, Section 18.11 and the DI IP by deleting information related to the verification of as-built procedures and training. This deletion is consistent with the approach taken in a February 21, 2011, response to RAI 472, Question 18-238, in which the staff informed the applicant that procedures and training are being addressed by SRP Chapter 13, "Conduct of Operations." Therefore, the applicant deleted information that was previously submitted for review in FSAR Tier 2, Chapter 18, "Human Factors Engineering." The deleted information related to procedures and training and was deleted because it is now being addressed in FSAR Tier 2, Chapter 13. In both cases, the applicant complied with the staff's request by providing an acceptable response. The staff finds RAI 472, Question 18-238 resolved.

In the DI IP, the applicant indicates that "Final 'as-built' Documents" and "Standard EPR Detailed Design Documents," are the types of documentation that are used in design implementation to help determine that the as-built design conforms to the design that resulted from the HFE design process. "Final 'as-built' Documents" consist of HSI-related documentation such as AREVA Design Specification Documents, the COL applicant's procurement and fabrication documents, manufacturer specifications and drawings, and equipment lists. If design changes have been made from the standard U.S. EPR plant design, they are documented in, "Design Change Documentation."

FSAR Tier 2, Section 18.11.1, "Objectives and Scope," states that the DI process will verify that the as-built HSIs conform to the design that resulted from V&V process. DI IP, Section 3.5.1 states that "a physical verification using the as-built HSI" is conducted. Later in DI IP, Section 3.5.1, one of the steps instructs the HFE engineer to conduct the physical verification of the as-built HSIs, making sure they conform to the design. The HFE Engineer creates an HED, if any discrepancy is found, and enters it into the HFE issues tracking system. The discrepancy is then resolved using the resolution process described in the V&V IP. After the design verification process has been completed, the results are entered into a Final Summary Report.

The applicant has identified the standard design documentation and as-built documentation. These documents are used in a clear step-by-step methodology that compares the as-built design to the standard design. The DI methodology also ensures that HEDs are entered into the HITS.

Accordingly, the staff finds the FSAR and the DI IP treatment of this NUREG-0711 criterion related to verifying that the final (as-built in the plant) HSIs have been compared with the detailed design description to ensure that they conform to the design that resulted from the HFE design process and V&V activities acceptable.

Criterion 3

All HFE-related issues documented in the issue tracking system should be verified as adequately addressed.

Staff Evaluation of Criterion 3

DI IP, Section 1.3, "Purpose," indicates that one purpose of DI is for the final verification to show that all issues identified in the HITS have been adequately addressed and that the "as-built" design conforms to the standard U.S. EPR design that resulted from the V&V process. DI IP, Section 3.6, "HFE-related issues documented in the HFE Issue Tracking Database," describes the methodology and acceptance criteria for addressing all issues in the HITS. Following completion of HFE Design Verification for the standard plant design, the responsibility for tracking the remaining issues that could not be resolved will be turned over to the COL holder for future resolution. DI IP, Section 3.6.1 provides guidance for evaluating the remaining HEDs and open issues in the HITS.

For this criterion, the DI IP provides guidance to ensure that all of the HFE-related issues documented in the issue tracking system will be adequately addressed. The stated purpose complies with the objectives stated in NUREG-0711 for this criterion. The step-by-step methodology described in DI IP, Section 3.6.1 guides the HFE Engineer to use the HITS to compile those items that have been closed out and those that remain open. For those items that are open, guidance is provided to re-verify the HED. Guidance is also provided to verify that all of the design requirements are being fulfilled, and to verify that issues identified in the HSI documentation were implemented and reflected in the final documentation. The output of the process is the Final Summary Report which will be provided to the COL holder. The DI IP specifies that the Final Summary Report will include all HEDs (open and closed). This is acceptable to the staff, because the DI IP identifies inputs, process, and outputs, and ensures that the methodology will be conducted reliably by the design organization. Therefore, based on the above considerations, the staff has reasonable assurance that the documented process for HFE DI will provide results that satisfy the above stated criterion.

Accordingly, the staff finds acceptable the FSAR and the DI IP treatment of this NUREG-0711 criterion related to verifying that all HFE-related issues documented in the issues tracking system have been adequately addressed.

18.11.4 Other Documents Subject to Review

18.11.4.1 *FSAR Tier 1, Section 3.4, "Human Factors Engineering"*

FSAR Tier 1, Table 3.4-1, "Human Factors Engineering ITAAC," contains the ITAAC that are proposed for HFE. The staff's evaluation of these ITAAC is provided in Section 14.3.9 of this report.

18.11.5 Combined License Information Items

There are no COL information items related to this area of review. The staff determined that no COL information items need to be included in FSAR Tier 2, Table 1.8-2, "U.S. EPR Combined License Information Items," for HFE design implementation consideration.

18.11.6 Conclusions

The staff evaluated design implementation, with respect to HFE, at an IP level using the review criteria in NUREG-0711, Section 12.4. Section 18.0.4 of this report provides a discussion of review levels. The staff determined that the DI IP that is proposed for the U.S. EPR will ensure that no significant safety degradation will occur due to changes that are made in the plant and

provides adequate assurance that the conclusions that have been reached from the evaluation of the DI IP will remain valid over time. As discussed in Section 18.0.5 of this report, the DI IP is designated as Tier 2* which ensures that the IP will be implemented by the COL applicant. Furthermore, because the DI IP is designated as Tier 2*, the COL applicant cannot make changes to the DI IP without obtaining prior NRC approval. Therefore, the staff concludes that DI considerations with respect to HFE have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.

18.12 Human Performance Monitoring

18.12.1 Regulatory Criteria

HFE human performance monitoring (HPM) is evaluated based on the review criteria provided in NUREG-0711, Chapter 13, "Human Performance Monitoring," Section 13.4, "Review Criteria," and SRP Section 18.II.A.12. NUREG-0711, Section 13.4 specifies the review criteria that pertain to the staff's evaluation of HFE HPM. Specifically, the staff confirms that the applicant has prepared a human performance monitoring strategy for ensuring that no significant safety degradation occurs due to changes that are made in the plant and that conclusions from the applicant's analysis with respect to HPM remain valid over time.

18.12.2 Summary of Technical Information

HPM is described in FSAR Tier 2, Section 18.12, "Human Performance Monitoring." This section incorporates by reference, "U.S. EPR Human Performance Monitoring Implementation Plan," December 16, 2010 (referred to as the HPM IP). The staff reviewed the HPM IP along with other documents that pertain to the staff's review of HPM as discussed in the subsections that follow. The staff focused its review on evaluating the information provided based on the review criteria in NUREG-0711, Chapter 13 and SRP Section 18.II.A.12.

18.12.3 Staff Evaluation

The staff performed an implementation plan level of review as described in NUREG-0711 and Section 18.0.4 of this report. This section presents the applicable review criteria from NUREG-0711 (reproduced below) followed by the staff's evaluation of each.

Criterion 1

The scope of the performance monitoring strategy should provide reasonable assurance that:

- The design can be effectively used by personnel, including within the control room and between the control room and local control stations and support centers.
- Changes made to the HSIs, procedures, and training do not have adverse effects on personnel performance, e.g., a change interferes with previously trained skills.
- Human actions can be accomplished within time and performance criteria.

- The acceptable level of performance established during the integrated system validation is maintained.

Staff Evaluation of Criterion 1

The first bullet of NUREG-0711 Criterion 1 for the HPM element in states that the performance monitoring strategy should provide reasonable assurance that the design can be effectively used by personnel, including within the control room and between the control room and local control stations and support centers. FSAR Tier 2, Section 18.12 and HPM IP, Section 1.4, "Objectives and Scope," address this criterion.

HPM IP, Section 1.4 includes the main control room, technical support center, remote shutdown station, operational support center, and the emergency operations facility. In addition, HPM IP, Section 1.4 states that the HPM program provides reasonable assurance of the following:

- Changes made to the initial HSI, procedures, and training do not have adverse effects on personnel performance.
- Acceptable performance levels established during the integrated HSI validation are maintained, using evaluation and trending methods established by Institute of Nuclear Power Operations (INPO) as part of the Human Performance Enhancement System.

FSAR Tier 2, Section 18.12 states that an objective of the HPM IP is to confirm that the acceptable level of performance established during the ISV is maintained. HPM IP, Section 1.5, "Responsibilities," states that the applicant provides the baseline V&V portion of the design phase. HPM IP, Section 3.2.2, "Design Change Process," describes the effective use of various HSI by personnel through the design change process. Additionally, HPM IP, Section 3.2, "HPM Tracking and Trending," states that the operational phase of the HPM program provides reasonable assurance of the following:

- Changes made to the standard U.S. EPR HSIs, procedures, staffing, and training are evaluated for design impact and consistently applied at all U.S. EPR in a timely manner.
- Changes made to the HSI are tested in the full scope simulator (FSS) before implementation in the plant.

HPM IP, Section 3.2 also describes the periodic evaluation and trending of operator performance. The performance indicators described in the HPM IP are used to trend operator performance. The trends are tracked and any adverse trends that are discovered are entered into the CAP, or analyzed further to identify the necessary corrective actions. This ensures that operator performance is consistent with that developed during the various analyses that support the design.

The staff finds the FSAR and HPM IP treatment of this criterion related to the scope of the performance monitoring strategy acceptable because the scope of the applicant's performance monitoring strategy includes each of the four items identified in this NUREG-0711 criterion.

Criterion 2

A human performance monitoring strategy should be developed and documented. The strategy should be capable of trending human performance after the changes have been implemented to demonstrate that performance is consistent with that assumed in the various analyses that were conducted to justify the change. Applicants may integrate, or coordinate, their performance monitoring for risk-informed changes with existing programs for monitoring personnel performance, such as the licensed operator training program and the corrective action program. If a plant change requires monitoring of actions that are not included in existing training programs, it may be advantageous to adjust the existing training program rather than to develop additional monitoring programs for risk-informed purposes.

Staff Evaluation of Criterion 2

The HPM IP and FSAR Tier 2, Section 18.12, provide the overview of a detailed plan for HPM during the design, V&V, and operational phases of the U.S. EPR. The plan includes activities for the system designer (AREVA) and the COL applicant. The HPM IP outlines the use of various existing programs in the overall scheme, including HFE V&V, CAP, Maintenance Rule program, PRA and HRA activities, in-service inspection and in-service testing programs, operator training program, HITS, and operating experience reports.

The staff finds that the applicant has described a plan for trending human performance that provides a sufficient scope of HPM programs and a description of responsibility to carry out HPM. This will ensure that when changes are made, human performance is considered and will remain consistent with the analyses that were used to justify those changes. Accordingly, the staff finds the FSAR and HPM IP treatment of this NUREG-0711 criterion related to development and documentation of the HPM strategy acceptable.

Criterion 3

The program should be structured such that:

- human actions are monitored commensurate with their safety importance
- feedback of information and corrective actions are accomplished in a timely manner
- degradation in performance can be detected and corrected before plant safety is compromised (e.g., by use of the plant simulator during periodic training exercises).

Staff Evaluation of Criterion 3

An objective stated in the HPM IP the applicant states is to ensure that no safety degradation occurs due to changes in design, procedures, training, or staffing. HPM IP, Section 3.2 describes the HFE tracking and trending methodology for HPM. HPM IP, Section 3.2.3, "Performance Indicators," describes a performance indicator process whereby the performance of day to day activities by operators is assigned a color for tracking purposes. HPM IP, Section 3.1, "Monitoring," states that risk-important HAs are monitored commensurate with their importance, and discusses use of the simulator during training and operation for monitoring

human performance. In addition, HPM IP, Section 3.2.2, mentions that before a significant design change is made, the change is modeled on the engineering part task simulator. After the change has been implemented, performance is observed and follow-up interviews are conducted. The HPM IP also discusses the use of trending and root cause analysis to understand the impact of an issue on plant operation and safety. The HPM Program includes data collection, screening for importance, analyzing events to determine the cause and to trend the events, and developing corrective actions.

The staff has determined that together, these actions provide a program that detects and corrects issues before plant safety is compromised. In this regard, HPM IP, Section 1.5 outlines the responsibilities of the design certification applicant and the COL applicants referencing the U.S. EPR design.

Accordingly, the staff finds that the FSAR and HPM IP treatment of this criterion related to the structure of the human performance monitoring strategy that conforms to this NUREG-0711 criterion and is acceptable.

Criterion 4

Plant or personnel performance under actual design conditions may not be readily measurable. When actual conditions cannot be simulated, monitored, or measured, the available information that most closely approximates performance data in actual conditions should be used.

Staff Evaluation of Criterion 4

The HPM IP provides for the use of operating experience data, full scope simulator, HRA and PRA analysis data, and involvement of licensee and the design certification applicant. The combination of probabilistic data, HFE expert input, and industry human performance issues most closely approximates performance data for actual conditions of the design, and will be used if performance data under actual design conditions is not readily measurable.

Accordingly, the staff finds the FSAR and HPM IP treatment of this NUREG-0711 criterion related to measuring plant or personnel performance acceptable.

Criterion 5

As part of the monitoring program, it is important that provisions for specific cause determination, trending of performance degradation and failures, and corrective actions be included. The cause determination should identify the cause of the failure or degraded performance to the extent that corrective action can be identified that would preclude the problem or provide adequate assurance that it is anticipated prior to becoming a safety concern. The program should address failure significance, the circumstances surrounding the failure or degraded performance, the characteristics of the failure, and whether the failure is isolated or has generic or common cause implications. The monitoring program should identify and establish any corrective actions necessary to preclude the recurrence of unacceptable failures or degraded performance.

Staff Evaluation of Criterion 5

By virtue of CAPs that are implemented by licensees, the HPM program has a built-in method for identifying causes of human performance issues or degradation, trending, and correcting identified issues. HPM IP, Section 3.2.1, "CAP and HFE Issues Tracking System," notes that licensees evaluate conditions and trends for potential adverse impact on the standard plant design under CAPs. HPM IP, Section 3.2, states that the CAP and HITS address the safety significance of failures through analysis.

The staff has determined that, a CAP program that meets 10 CFR Appendix B is a long standing practice of documenting human performance issues. CAPs have features to address significant human failures and to prevent the recurrence of such failures. Additionally, the HPM IP states that HFE issues will be documented in the CAPs via the HITS.

Accordingly, the staff finds the FSAR and HPM IP treatment of this criterion related to establishing provisions for determining the causes of poor human performance degradation and failures, and for implementing corrective actions to conform to this NUREG-0711 criterion and is acceptable.

18.12.4 Other Documents Subject to Review

18.12.4.1 *FSAR Tier 1, Section 3.4, "Human Factors Engineering"*

FSAR Tier 1, Table 3.4-1, "Human Factors Engineering ITAAC," contains the ITAAC that are proposed for HFE. The staff's evaluation of these ITAAC is provided in Section 14.3.9 of this report. HPM, however, does not have associated ITAAC because the activity is a COL applicant's responsibility.

18.12.5 Combined License Information Items

There are no COL information items related to this area of review. The staff determined that no COL information items need to be included in FSAR Tier 2, Table 1.8-2, "U.S. EPR Combined License Information Items," for HPM consideration.

18.12.6 Conclusions

The staff evaluated HPM with respect to HFE, at an IP level using the review criteria in NUREG-0711, Section 13.4. Section 18.0.4 of this report provides a discussion of review levels. The staff determined that the HPM IP that is proposed for the U.S. EPR will ensure that no significant safety degradation will occur due to changes that are made in the plant and that conclusions that have been reached from the applicant's evaluation of the human performance for the U.S. EPR will remain valid over time. As discussed in Section 18.0.5 of this report, the HPM IP is designated as Tier 2* which ensures that the IP will be implemented by the COL applicant. Furthermore, because the HPM IP is designated as Tier 2*, the COL applicant cannot make changes to the HPM IP without obtaining prior NRC approval. Therefore, the staff concludes that HPM considerations with respect to HFE have been adequately addressed, and that the requirements in 10 CFR 50.34(f) and 10 CFR 52.47 related to this technical area are satisfied.