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No tables were included in this chapter.

18 HUMAN FACTORS ENGINEERING

The Human Factors Engineering (HFE) program plan describes the human-system interface (HSI) design development, the HSI design goals and bases, the standard HSI design features, and the detailed HSI design and implementation process, with embedded design acceptance criteria, for the U.S. EPR design. The incorporation of human factors engineering principles into all phases of the design of these interfaces is also discussed. The state-of-the-art HFE principles are incorporated into (1) the planning and management of HFE activities; (2) the plant design process; (3) the characteristics, features, and functions of the HSIs, procedures, and training; (4) the implementation of the design; and (5) monitoring of performance at the site. The HFE program plan describes how human characteristics and capabilities are successfully integrated into the nuclear power plant design in such a way that results in a state-of-the-art design and supports successful performance of the required job tasks by plant personnel. Calvert Cliffs Nuclear Power Plant (CCNPP) Unit 3 Final Safety Analysis Report (FSAR), Chapter 18 incorporates by reference U.S. EPR FSAR, Tier 2, Chapter 18, with a departure as addressed in Section 18.12.4 of this report.

18.1 Human Factors Engineering Program Management

The HFE program management section describes the program for applying human factors principles to the design and engineering of the U.S. EPR human system interfaces. The objective of the staff's review is to confirm that the combined license (COL) applicant has adequately considered the role of HFE and the means by which HFE activities will be accomplished.

18.1.1 HFE Program Goals, Assumptions and Constraints, and Scope

18.1.1.1 *Introduction*

HFE program goals and scope describe the role of HFE and the means by which HFE activities are accomplished in plant design and operation defining the assumptions and constraints involved. The HFE program goals support a plant design that will enable personnel to accomplish their tasks within time and performance criteria. The goals also facilitate development of HSIs that support a high degree of operating crew situational awareness.

All plant facilities that are designed using the HFE program plan are identified. These include the main control room, remote shutdown room, Technical Support Center (TSC), emergency operations facility (EOF), and local control stations (LCSs). All plant personnel who perform tasks that are directly related to safety are identified (e.g., management, engineering, maintenance, health physics, and chemistry personnel).

18.1.1.2 *Summary of Application*

COL FSAR Section 18.1 incorporates by reference U.S. EPR FSAR, Tier 2, Section 18.1 with no departures. In addition, in COL FSAR Section 18.1, the COL applicant provided the following:

COL Information Items

The COL applicant provided additional information in COL FSAR Section 18.1 to address COL Information Item 18.1-1 which states:

A COL applicant that references the U.S. EPR design will execute the NRC-approved HFE program as described in this section.

In response to this COL Information Item, the COL applicant indicated that it would execute the NRC-approved HFE program described in the U.S. EPR FSAR Tier 2, Section 18.1.

The COL applicant provided additional information in COL FSAR Section 18.1.1.3 to address COL Information Item 18.1-2 which states:

A COL applicant that references the U.S. EPR design will be responsible for HFE design implementation for a new emergency operations facility (EOF) or changes resulting from the addition of the U.S. EPR to an existing EOF.

In response to this COL Information Item, the COL applicant indicated that the existing EOF supporting CCNPP Units 1 and 2 will be modified to accommodate an interface with CCNPP Unit 3. A description of the modified EOF is provided in the CCNPP Unit 3 Emergency Plan (Part 5 of the CCNPP Unit 3 COL application). Modifications to the existing EOF will be consistent with the U.S. EPR HFE program described in U.S. EPR FSAR Tier 2, Chapter 18 and NUREG-0696, "Functional Criteria for Emergency Response Facilities," February 1981 (hereafter referred to as NUREG-0696). The COL applicant will verify that the design changes to the existing EOF consider the effects on personnel performance and that the changes will provide the necessary support to provide reasonable assurance of effective implementation of the CCNPP Unit 3 Emergency Plan. Also, the modified EOF as-built design will be verified to conform to the design that results from the HFE design process. This verification will be addressed through site-specific inspections, tests, analyses, and acceptance criteria (ITAAC).

ITAAC

Part 10 of the COL application, Item 5.2.2, Table 2.3-1, "Emergency Planning ITAAC," indicates that an inspection of the implementation of the HFE program EOF design requirements will be performed.

18.1.1.3 *Regulatory Basis*

The regulatory basis of the information incorporated by reference is addressed within the Final Safety Evaluation Report (FSER) related to the U.S. EPR FSAR. Relevant requirements for the HFE program goal, scope, assumptions, and constraints, and the associated acceptance criteria are given in NUREG-0800, "Standard Review Plan [SRP] for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 18 (hereafter referred to as NUREG-0800 or the SRP).

The applicable regulatory requirement for COL Information Items 18.1-1 and 18.1-2 is as follows:

- Title 10 of the *Code of Federal Regulations* (10 CFR) 52.79, "Contents of Applications; Technical Information in Final Safety Analysis Report," Section 52.79(a)(1), as it relates to the HFE program and design implementation.

The related HFE acceptance criteria are contained in the following regulatory guidance documents:

1. NUREG-0711, Revision 2, "Human Factors Engineering Program Review Model"
2. NUREG-0696, February, 1981, "Functional Criteria for Emergency Response Facilities"
3. NUREG-0737 Supplement 1, Section 8, "Clarification of TMI Action Items – Emergency Response Facilities"

18.1.1.4 *Technical Evaluation*

The staff reviewed COL FSAR Section 18.1.1 and verified the referenced U.S. EPR FSAR to ensure that the information in these documents represents the complete scope of information relating to this review topic. The staff's review confirmed that the information contained in the COL application and incorporated by reference addresses the required information relating to this section. U.S. EPR FSAR Tier 2, Section 18.1.1 is being reviewed by the staff under Docket No. 52-020. The staff's technical evaluation of the information incorporated by reference related to HFE program goals, assumptions and constraints, and scope will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR.

COL Information Items

The staff reviewed COL Information Item 18.1-1 and 18.1-2 from U.S. EPR FSAR Tier 2, Table 1.8-2 included under COL FSAR Section 18.1.

- Item 18.1-1: A COL applicant that references the U.S. EPR design will execute the NRC-approved HFE program as described in this section.
- Item 18.1-2: A COL applicant that references the U.S. EPR design will be responsible for HFE design implementation for a new emergency operations facility or changes resulting from the addition of the U.S. EPR to an existing EOF.

COL Information Item 18.1-1

In COL FSAR Section 18.1, the COL applicant commits to execute the NRC-approved HFE program as described in the U.S. EPR FSAR. U.S. EPR FSAR Tier 1, Table 3.4-1, "Human Factors Engineering ITAAC," verify that the HFE design is satisfactorily implemented. Therefore, the staff finds that the COL applicant's commitment to implement the HFE program described in the U.S. EPR FSAR is satisfactorily tracked via ITAAC. The staff considers this COL information item closed.

COL Information Item 18.1-2

In COL FSAR Section 18.1.1.3, the COL applicant states that an existing EOF will be modified to accommodate an interface from CCNPP Unit 3. The COL applicant addressed this COL information item by stating that the following procedures will be adhered to when modifications to the existing EOF are made:

- Modifications to the existing EOF will be consistent with the U.S. EPR HFE Program described in U.S. EPR FSAR Tier 2, Chapter 18 and NUREG-0696.

- Modifications will be evaluated using the U.S. EPR HFE design implementation process described in U.S. EPR FSAR Tier 2, Chapter 18.
- The design implementation process will verify the operability of the EOF features for CCNPP Unit 3 and ensure no degradation has occurred to the CCNPP Unit 1 and 2 features in the EOF. Specifically, the plan will verify that the design changes to the existing EOF consider the effects on personnel performance and that the changes provide the necessary support to provide reasonable assurance of effective implementation of the CCNPP Unit 3 Emergency Plan.

The modified EOF as-built design will be verified to conform to the verified and validated design that results from the HFE design process. This verification will be addressed through site-specific ITAAC provided in the COL application, Part 10 (Table 2.3-1, "Emergency Preparedness ITAAC," EP program element 5.2). Unlike the specific regulatory guidance for the Control Room HFE design, regulatory guidance for the EOF and TSC is general. The Control Room guidance addresses the HFE design process while the EOF/TSC guidance addresses final design attributes. Since NUREG-0696 is an accepted standard for EOF functional standards and the staff identified no safety case for making the EOF HFE design more prescriptive, the staff finds the commitment to complete the EOF HFE design in accordance with NUREG-0696 acceptable. In addition, the staff notes that similar to the control room HFE design, the EOF HFE design is subject to an "integrated system validation" test. This integrated system validation test for the EOF is a full-participation emergency plan exercise which is included in the Emergency Planning ITAAC. This exercise demonstrates EOF functionality which, in turn, demonstrates that the human-system interfaces are acceptable. Accordingly, the staff concludes the EOF HFE design plan is consistent with program guidance and requirements. The ITAAC provides appropriate tracking of program implementation. The staff considers this COL information item closed.

18.1.1.5 *Post Combined License Activities*

There are no post COL activities related to this section.

18.1.1.6 *Conclusions*

The staff reviewed the COL application and verified the referenced U.S. EPR FSAR. The staff's review confirmed that the COL applicant addressed the required information relating to HFE Program Management, and there is no outstanding information expected to be addressed in the COL FSAR related to this section. The staff is reviewing the information in U.S. EPR FSAR on Docket No. 52-020. The results of the staff's technical evaluation of the information related to HFE Program Management incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER of the U.S. EPR is not yet complete. The staff issued Request for Additional Information (RAI) 222, Question 01-5 to track the ongoing review of the U.S. EPR design certification application. **RAI 222, Question 01-5 is being tracked as an open item.** The staff will update Section 18.1.1 of this report to reflect the final disposition of the design certification application.

The staff concludes that the information presented in this COL FSAR section, except for the open item associated with RAI 222, Question 01-5, is complete, meets the requirements in 10 CFR 52.79(a), and conforms to the criteria defined in NUREG-0711, Section 2.4.1 and NUREG-0737, Section 8.

18.1.2 HFE and Control Room Design Team Organization

COL FSAR Section 18.1.2 incorporates by reference, U.S. EPR FSAR Tier 2, Section 18.1.2, "Human Factors Engineering and Control Room Design Team Organization." The staff reviewed the COL application and verified the referenced U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR, Tier 2, Section 18.1.2 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to the HFE and Control Room Design Team Organization incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER of the U.S. EPR FSAR is not yet complete. The staff will update Section 18.1.2 of this report to reflect the final disposition of the design certification application.

18.1.3 HFE Processes and Procedures

COL FSAR Section 18.1.3 incorporates by reference, U.S. EPR FSAR Tier 2, Section 18.1.3, "Human Factors Engineering Processes and Procedures." The staff reviewed the COL application and verified the referenced U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR Tier 2, Section 18.1.3 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to the HFE and Processes and Procedures incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR FSAR is not yet complete. The staff will update Section 18.1.3 of this report to reflect the final disposition of the design certification application.

18.1.4 HFE Issues Tracking

COL FSAR Section 18.1.4 incorporates by reference U.S. EPR FSAR Tier 2, Section 18.1.4, "Human Factors Engineering Issues Tracking." The staff reviewed the COL application and verified the referenced U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR Tier 2, Section 18.1.4 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to the HFE Issues Tracking incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR FSAR is not yet complete. The staff will update Section 18.1.4 of this report to reflect the final disposition of the design certification application.

18.1.5 Technical Program

COL FSAR Section 18.1.5 incorporates by reference, U.S. EPR FSAR Tier 2, Section 18.1.5, "Technical Program." The staff reviewed the COL application and verified the referenced

U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR Tier 2, Section 18.1.5 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to the Technical Program incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR FSAR is not yet complete. The staff will update Section 18.1.5 of this report to reflect the final disposition of the design certification application.

18.2 Operating Experience Review

COL FSAR Section 18.2 incorporates by reference, U.S. EPR Tier 2, Section 18.2, "Operating Experience Review." The staff reviewed the COL application and verified the referenced U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR Tier 2, Section 18.1.3 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to Operating Experience Review incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR FSAR is not yet complete. The staff will update Section 18.2 of this report to reflect the final disposition of the design certification application.

18.3 Functional Requirements Analysis and Function Allocation

COL FSAR Section 18.3 incorporates by reference, U.S. EPR FSAR Tier 2, Section 18.3, "Functional Requirements Analysis and Allocation." The staff reviewed the COL application and verified the referenced U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR Tier 2, Section 18.3 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to the Functional Requirements Analysis and Function Allocation incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR FSAR is not yet complete. The staff will update Section 18.3 of this report to reflect the final disposition of the design certification application.

18.4 Task Analysis

COL FSAR Section 18.4 incorporates by reference, U.S. EPR FSAR Tier 2, Section 18.4, "Task Analysis," with no departures or supplements. The staff reviewed the COL application and verified the referenced U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR Tier 2, Section 18.4 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to this section to be incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER for the U.S. EPR is not yet complete. The staff will update Section 18.4 of this report to reflect the final disposition of the design certification application for the U.S. EPR.

18.5 Staffing and Qualifications

18.5.1 Introduction

The staffing and qualification part of the HFE program analyzes the requirements for the number and qualifications of personnel in a systematic manner that includes a thorough understanding of task requirements and applicable regulatory requirements. The scope includes the number and, following the guidance in Regulatory Guide (RG) 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," qualifications of personnel for the full range of plant conditions and tasks, including operational tasks (normal, abnormal, and emergency) and plant maintenance and testing (including surveillance testing). The personnel that are considered include licensed control room operators as defined in 10 CFR Part 55, as well as the categories of personnel defined by 10 CFR 50.120, including non-licensed operator, 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 directly relate to plant safety are addressed.

This section is coordinated with U.S. EPR FSAR Tier 2, Section 13.1, which also relates to organization and staffing. The staffing analysis is iterative in nature, and the plan discusses how the initial staffing goals are/have been reviewed and modified as the analyses associated with other HFE elements are/were completed. Staffing and qualifications commitments are also shown to comply with 10 CFR 50.54(m).

18.5.2 Summary of Application

COL FSAR Section 18.5 incorporates by reference U.S. EPR FSAR Tier 2, Section 18.5.

In addition, in COL FSAR Section 18.5, the COL applicant provided the following:

COL Information Items

The COL applicant provided additional information in COL FSAR Section 18.5 to address COL Information Item 18.5-1 which states:

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

In response to this COL Information Item, the COL applicant indicated that the COL FSAR incorporates by reference U.S. EPR FSAR Tier 1, Table 3.4-1, No. 5. This ITAAC requires that a staffing and qualification analysis be performed which includes an evaluation of the number and qualifications of personnel needed to operate, maintain, and test the U.S. EPR based on

HSI design features. This analysis will confirm that actual staffing levels and qualifications of plant personnel, as specified in COL FSAR Section 13.1, remain bounded by NRC regulation.

18.5.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is addressed within the FSER related to the U.S. EPR FSAR. Relevant requirements for the HFE program goal, scope, assumptions, and constraints, and the associated acceptance criteria are given in NUREG-0800, Section 18.

The applicable regulatory requirement for COL Information Item 18.5-1 is as follows:

- 10 CFR 50.54, “Conditions of Licenses,” Section 50.54(m), as it relates to staffing levels and qualifications of plant personnel

The related HFE acceptance criteria are contained in the following regulatory guidance document:

- NUREG-0711, Section 6, “Staffing and Qualifications”

18.5.4 Technical Evaluation

The staff reviewed COL FSAR Section 18.5 and verified the referenced U.S. EPR FSAR to ensure that the information in these documents represents the complete scope of information relating to this review topic. The staff’s review confirmed that the information contained in the COL application and incorporated by reference addresses the required information relating to this section. U.S. EPR FSAR Tier 2, Section 18.5 is being reviewed by the staff under Docket No. 52-020. The staff’s technical evaluation of the information incorporated by reference related to Staffing and Qualifications will be documented in the staff’s final safety evaluation report on the design certification application for the U.S. EPR.

COL Information Item

The staff reviewed COL Information Item 18.5-1 from U.S. EPR FSAR Tier 2, Table 1.8-2 included under COL FSAR Section 18.5.

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

COL FSAR Section 18.5 states:

Confirmation that actual staffing levels and qualifications of plant personnel specified in Section 13.1 remain bounded by regulatory requirements and results of staffing and qualification analysis shall be verified by the implementation of ITAAC 5 of FSAR Tier 1 Table 3.4-1 of the U.S. EPR FSAR. Tier 1 Table 3.4-1 of the U.S. EPR FSAR is incorporated by reference in Part 10 of the COL application.

ITAAC Commitment 5 specifically validates that the staffing and qualification analysis includes an evaluation of the number and qualification of personnel needed to operate, maintain, and test

the U.S. EPR design. The staff concludes that the ITAAC is an acceptable way to verify that actual staffing levels and qualifications of plant personnel specified in COL FSAR Section 13.1 remain bounded by regulatory requirements and results of the HFE staffing and qualification analysis. The staff considers COL Information Item 18.5-1 closed.

18.5.5 Post Combined License Activities

There are no post COL activities related to this section.

18.5.6 Conclusions

The staff reviewed the COL application and verified the referenced U.S. EPR FSAR. The staff's review confirmed that the COL applicant addressed the required information relating to Staffing and Qualifications, and there is no outstanding information to be addressed in the COL FSAR related to this section.

The staff is reviewing the information in the U.S. EPR FSAR on Docket No. 52-020. The results of the staff's technical evaluation of the information related to Staffing and Qualifications incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR is not yet complete. The staff will update Section 18.5 of this report to reflect the final disposition of the design certification application.

The staff concludes that the information presented in this COL FSAR section is complete, meets the NRC requirements in 10 CFR 50.54(m), and conforms to the criteria defined in NUREG-0711, Section 6.4.

18.6 Human Reliability Analysis

COL FSAR Section 18.6 incorporates by reference U.S. EPR FSAR Tier 2, Section 18.6. The staff reviewed the COL application and verified the U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR Tier 2, Section 18.6 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to Human Reliability Analysis incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR FSAR is not yet complete. The staff will update Section 18.6 of this report to reflect the final disposition of the design certification application.

18.7 Human System Interface Design

COL FSAR Section 18.7 incorporates by reference, U.S. EPR FSAR Tier 2, Section 18.7, "Human System Interface Design." The staff reviewed the COL application and verified the referenced U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR Tier 2, Section 18.7 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to the

Human System Design Interface incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR FSAR is not yet complete. The staff will update Section 18.6 of this report to reflect the final disposition of the design certification application.

18.8 Procedure Development

18.8.1 Introduction

Procedure development is an operational program that is evaluated in Section 13.5, "Plant Procedures," of this report.

HFE principles, as described in the procedure writer's guide, are incorporated during procedure development to help ensure procedures are technically accurate, comprehensive, explicit, easy to use, and validated. The writer's guide is part of the Procedures Generation Package which is reviewed in accordance with NUREG-0800, Section 13.5.2.1, "Operating and Emergency Operating Procedures."

18.8.2 Summary of Application

COL FSAR Section 18.8 incorporates by reference U.S. EPR FSAR Tier 2, Section 18.8. In addition, in COL FSAR Section 18.8, the COL applicant provided the following:

COL Information Items

COL Information Item 18.8-1 from U.S. EPR FSAR Tier 2, Table 1.8-2 states:

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.

In response to this COL Information Item, the COL applicant indicated that plant-specific procedures are developed consistent with the operational guidelines in COL FSAR Section 13.5.

18.8.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is addressed within the FSER related to the U.S. EPR FSAR. Relevant requirements for procedures and the associated acceptance criteria are given in NUREG-0800, Chapter 13.

18.8.4 Technical Evaluation

The staff reviewed COL FSAR Section 18.8 and verified the referenced U.S. EPR FSAR to ensure that the information in these documents represents the complete scope of information relating to this review topic. The staff's review confirmed that the information contained in the COL application and incorporated by reference addresses the required information relating to this section. U.S. EPR FSAR Tier 2, Section 18.8 is being reviewed by the staff under Docket No. 52-020. The staff's technical evaluation of the information incorporated by reference related

to Procedure Development will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR.

The staff reviewed the information contained in the COL FSAR.

COL Information Item

The staff reviewed COL Information Item 18.8-1 from U.S. EPR FSAR Tier 2, Table 1.8-2 included in COL FSAR Section 18.8 which states:

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.

COL FSAR, Revision 7, Section 18.8, does not reflect the changes made in the U.S. EPR FSAR, Revision 3. This created an incorrect reference and did not account for the management of procedure development as an operational program. Therefore, in RAI 319, Question 18-2, the staff requested that the COL applicant update the COL FSAR to reflect changes in the U.S. EPR FSAR. In an October 18, 2011, response to RAI 319, Question 18-2, the COL applicant stated that the procedures would be developed consistent with the operational guidance in COL FSAR Section 13.5. The COL applicant provided a proposed revision to the FSAR. The staff finds the proposed changes acceptable. **RAI 319, Question 18-2 is being tracked as a confirmatory item** to ensure that the COL FSAR is revised accordingly.

COL FSAR Section 13.5 contains COL Information Item 13.5-1 from U.S. EPR FSAR Tier 2, Table 1.8-2 which states:

A COL applicant that references the U.S. EPR design certification will provide site-specific information for administrative, operating, emergency, maintenance, and other operating procedures.

HFE principles are described in a procedure writer's guide. The writer's guide is part of the Procedures Generation Package which is reviewed in accordance with the NUREG-0800, Section 13.5.2.1, "Operating and Emergency Operating Procedures." Therefore, the staff concludes that COL Information Item 13.5-1 encompasses the material addressed within COL Information Item 18.8-1 and, therefore, considers COL information Item 18.8-1 closed.

18.8.5 Post Combined License Activities

There are no post COL activities related to this section.

18.8.6 Conclusions

The staff reviewed the COL application and verified the referenced U.S. EPR FSAR. The staff's review confirmed that the COL applicant addressed the required information relating to Procedure Development, and except for the confirmatory item related to RAI 319, Question 18-2, there is no outstanding information to be addressed in the COL FSAR related to this section.

The staff is reviewing the information in the U.S. EPR FSAR on Docket No. 52-020. The results of the staff's technical evaluation of the information related to Staffing and Qualifications incorporated by reference in the COL FSAR will be documented in the staff' final safety

evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR is not yet complete. The staff will update Section 18.8 of this report to reflect the final disposition of the design certification application.

18.9 Training Program Development

18.9.1 Introduction

The training program is an operational program and is evaluated in Section 13.2, "Training," of this report.

18.9.2 Summary of Application

COL FSAR Section 18.9 incorporates by reference U.S. EPR FSAR Tier 2, Section 18.9.

In addition, in COL FSAR Section 18.9, the COL applicant provided the following:

COL Information Item

COL Information Item 18.9-1 from U.S. EPR FSAR Tier 2, Table 1.8-2 states:

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.

In response to this COL information item, the COL applicant indicated that the training program is addressed in COL FSAR Section 13.2.

18.9.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is addressed within the FSER related to the U.S. EPR FSAR. Relevant requirements for training and the associated acceptance criteria are given in NUREG-0800, Section 13.

18.9.4 Technical Evaluation

The staff reviewed COL FSAR and verified the referenced U.S. EPR FSAR to ensure that the information in these documents represents the complete scope of information relating to this review topic. The staff's review confirmed that the information contained in the COL application and incorporated by reference addresses the required information relating to this section. U.S. EPR FSAR Tier 2, Section 18.9 is being reviewed by the staff under Docket No. 52-020. The staff's technical evaluation of the information incorporated by reference related to Training Program Development will be documented in the staff final safety evaluation report on the design certification application for the U.S. EPR.

The staff reviewed the information contained in the COL FSAR.

COL Information Item

The staff reviewed COL Information Item 18.9-1 from U.S. EPR FSAR Tier 2, Table 1.8-2 included in COL FSAR Section 18.9.

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.

The COL applicant indicates this COL information item will be addressed in COL FSAR Section 13.2. COL FSAR Section 13.2 contains COL Information Item 13.2-1 from U.S. EPR FSAR Tier 2, Table 1.8-2 which states:

A COL applicant that references the U.S. EPR design certification will provide site-specific information for training programs for plant personnel.

The HFE principles and criteria identified in NUREG-0711 are a subset of those addressed in NUREG-0800, Section 13.2. Therefore, the staff concludes that COL information item 13.2-1 encompasses the material addressed within COL Information Item 18.9-1 and, therefore, considers COL information Item 18.9-1 closed.

18.9.5 Post Combined License Activities

There are no post-COL activities related to this section.

18.9.6 Conclusions

The staff reviewed the COL application and verified the referenced U.S. EPR FSAR. The staff's review confirmed that the COL applicant addressed the required information relating to Training Development, and there is no outstanding information expected to be addressed in the COL FSAR related to this section.

The staff is reviewing the information in the U.S. EPR FSAR on Docket No. 52-020. The results of the staff's technical evaluation of the information related to training incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR is not yet complete. The staff will update Section 18.9 of this report to reflect the final disposition of the design certification application.

18.10 Verification and Validation

COL FSAR Section 18.10 incorporates by reference U.S. EPR FSAR Tier 2, Section 18.10, "Verification and Validation." The staff reviewed the COL application and verified the referenced U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR Tier 2, Section 18.10 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to Verification and Validation incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR FSAR is not yet complete. The staff will update Section 18.10 of this report to reflect the final disposition of the design certification application.

18.11 Design Implementation

COL FSAR Section 18.11 incorporates by reference, U.S. EPR FSAR Tier 2, Section 18.11, "Design Implementation." The staff reviewed the COL application and verified the referenced U.S. EPR FSAR to ensure that no issue relating to this section remained for review. The staff's review confirmed that there is no outstanding issue related to this subsection.

The staff is reviewing the information in U.S. EPR FSAR, Tier 2, Section 18.11 on Docket No. 52-020. The results of the staff's technical evaluation of the information related to Design Implementation incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR FSAR is not yet complete. The staff will update Section 18.11 of this report to reflect the final disposition of the design certification application.

18.12 Human Performance Monitoring

18.12.1 Introduction

Human performance monitoring (HPM) is used to assure that no significant safety degradation occurs because of any changes that are made in the plant and to confirm that the conclusions that have been drawn from the integrated system validation remain valid over time. Human performance monitoring is a program that begins after plant operation commences. Therefore, the COL applicant describes the documentation to be maintained after the program is implemented. The objective of this review is to verify that the COL applicant has prepared a human performance monitoring strategy for ensuring that no significant safety degradation occurs because of any changes that are made in the plant.

The program describes: (1) A human performance monitoring strategy; (2) how it trends human performance relative to changes implemented in the plant after startup; and (3) how it demonstrates that performance is consistent with that assumed in the various analyses conducted to justify the changes.

The program provides for specific cause determination, trending of performance degradation and failures, and determination of appropriate corrective actions. Detailed implementation plans and procedures for human performance monitoring remain available for NRC review.

18.12.2 Summary of Application

COL FSAR Section 18.12 describes a plant-specific HPM program submitted as a departure from the HPM program described in U.S. EPR FSAR Tier 2, Section 18.12.

18.12.3 Regulatory Basis

The relevant NRC regulations for the human factors engineering program goal, scope, assumptions, and constraints, and the associated acceptance criteria are given in NUREG-0800, Chapter 18.

The related acceptance criteria for the proposed HPM program are contained in NUREG-0711, Section 13.4.

18.12.4 Technical Evaluation

The staff reviewed COL FSAR Section 18.12 and verified the referenced U.S. EPR FSAR to ensure that the information in these documents represents the complete scope of information relating to this review topic. The staff's review confirmed that the information contained in the COL application and incorporated by reference addresses the required information relating to this section. U.S. EPR FSAR Tier 2, Section 18.12 is being reviewed by the staff under Docket No. 52-020. The staff's technical evaluation of the information incorporated by reference related to HPM will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR.

COL Departure

COL FSAR, Revision 7, Section 18.12, did not reflect the changes made in the U.S. EPR FSAR, Revision 3. This resulted in a reference to a COL information item that had been deleted. Also, the COL applicant submitted a site-specific version of the HFP program contained in the U.S. EPR FSAR. The site-specific program version was submitted as supplementary information but contained some departures from the U.S. EPR FSAR versions. A basis for the differences was not included. Therefore, in RAI 319, Question 18-2, the staff requested that the COL applicant update the COL FSAR to reflect changes in the U.S. EPR FSAR. In an October 18, 2011, response to RAI 319, Question 18-2, the COL applicant submitted an updated site-specific HPM program as a departure. The updated HPM program removed all the significant differences between the U.S. EPR HPM program and the CCNPP HPM program. However, because the CCNPP HPM program was submitted as a departure, the staff has evaluated it against the relevant acceptance criteria in NUREG-0711. It should be noted that both the U.S. EPR HPM program and the CCNPP HPM program are more detailed than what is usually submitted and the variations are in the details, not in program fundamentals. The COL applicant provided a proposed revision to the FSAR. The staff finds the proposed changes acceptable. **RAI 319, Question 18-2 is being tracked as a confirmatory item** to ensure that the COL FSAR is revised accordingly.

The staff performed a complete element level of review as described in NUREG-0711. 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

COL FSAR Section 18.12.1, "Objectives and Scope," addresses all items in this criterion. Additional objectives include:

- monitoring is done commensurate with safety significance
- detecting degraded performance before plant safety is compromised
- confirming design errors are resolved in a timely manner

The HPM is conducted in all areas within the HFE program scope during all modes of plant operation.

The staff concludes that the HPM program scope is complete and conforms to this acceptance criterion. The program is being applied where human actions have significant impact on plant safety and plant safety is being used appropriately to prioritize monitoring activities.

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

COL FSAR Section 8.12.2, "Methodology," provides an overview of a detailed plan for HPM during plant operation. Performance monitoring is performed by observing personnel activities, interviews, self-initiated feedback, and walkthroughs. Subsequent sections describe how the corrective action program, the design change process, performance indicators, probabilistic risk assessment and plant maintenance and inspection programs are used to support these activities. COL FSAR Section 18.2.1, "Corrective Action Program and Issue Tracking," and COL FSAR Section 18.12.2.2, "Monitoring and Trending," both address human performance trending and include provisions for tracking corrective action effectiveness as well as proactively identifying both positive and negative changes in human performance.

The staff concludes that HPM is appropriately integrated into a wide scope of operating programs. These programs interface with the corrective action program which trends human performance data. This strategy provides reasonable assurance that when changes are made; human performance is considered and will remain consistent with the analyses assumptions that were used to justify those changes. Accordingly, the staff finds the COL FSAR 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

The COL applicant states these objectives in COL FSAR Section 18.12.1, "Objectives and Scope." Throughout the program description, proactive measures are outlined that provide more detail on how timely, safety relevant feedback is achieved. These measures include:

- application of human performance tools to the identification, evaluation and performance of risk-significant activities
- use of subordinate and peer coaching to reinforce desired behaviors
- providing feedback on improvement suggestions
- use of an operational focus index to trend performance of operator's day to day activities

The staff concludes that these actions, along with others not listed here, provide a program that detects and corrects issues before plant safety is compromised. Accordingly, the staff finds the COL FSAR treatment of this criterion related to the structure of the human performance monitoring strategy 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

COL FSAR Section 18.12, "Human Performance Monitoring," provides for the use of operating experience data, a full scope simulator, and the PRA analysis to provide data where performance under actual design conditions is not readily measurable. These elements are discussed in more detail within different sections of the HPM IP. Accordingly, the staff finds the COL 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

As explained in COL FSAR Section 18.12.2.1, "Corrective Action Program and Issue Tracking," the HPM program interfaces with the Corrective Action Program for identifying causes of human performance issues, trending, and correcting identified issues. A Corrective Action program by virtue of complying with 10 CFR Part 50, Appendix B, is an accepted method for addressing the guidance in the criterion. Accordingly, the staff considers the COL FSAR treatment of this criterion acceptable.

18.12.5 Post Combined License Activities

There are no post COL activities related to this section.

18.12.6 Conclusions

The staff reviewed the COL application and verified the referenced U.S. EPR FSAR. The staff confirmed that the COL applicant addressed the required information relating to the HPM program and, except for the confirmatory item associated with RAI 319, Question 18-2, the staff concludes there is no outstanding information to be addressed in the COL FSAR related to this section.

The staff is reviewing the information in the U.S. EPR FSAR on Docket No. 52-020. The results of the staff's technical evaluation of the information related to Staffing and Qualifications incorporated by reference in the COL FSAR will be documented in the staff's final safety evaluation report on the design certification application for the U.S. EPR. The staff notes that the final SER on the U.S. EPR is not yet complete. The staff will update Section 18.12 of this report to reflect the final disposition of the design certification application.

The staff concludes that the relevant information presented within the COL FSAR is acceptable and meet the acceptance criteria defined in NUREG-0711, Section 13; and, therefore, concludes that the COL applicant complies with NRC requirements.