18. Human Factors Engineering

18.1.1 Introduction

This chapter of the safety evaluation report (SER) provides the U.S. Nuclear Regulatory Commission (NRC) staff's review of the human factors engineering (HFE) of the General Electric Hitachi Nuclear America, LLC (GEH) economic simplified boiling-water reactor (ESBWR). The staff completed this review as part of the larger design certification review being conducted by the NRC under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The staff conducted this review in accordance with NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants" (hereafter referred to as the SRP), Chapter 18, "Human Factors Engineering." Consistent with SRP Chapter 18, the review used the detailed review criteria in NUREG-0711, Revision 2, "Human Factors Engineering Program Review Model," issued February 2004.

DCD Tier 2, Revision 8, Chapter 18 incorporates by reference 12 Licensing Topical Reports (LTRs) corresponding to the 12 areas of review discussed in Section 18.1.3 of this report. 5 of these LTRs have both proprietary and nonproprietary versions. The remaining 7 LTRS are nonproprietary. The staff determined that it had to rely on proprietary information in 3 of the LTRs to address the NUREG-0711, Revision 2 review criteria for the corresponding areas of review. These three LTRs address task analysis, HSI design, and human factors verification and validation. These areas of review are discussed in Sections 18.5, 18.8, and 18.11 of this report, respectively. Accordingly, the staff has prepared a proprietary safety evaluation report (SER) for chapter 18 which addresses the NUREG-0711, Revision 2 review criteria based on both proprietary and nonproprietary information. This SER discusses the nonproprietary information submitted by the applicant and references the Chapter 18 proprietary SER where necessary to address the NUREG-0711, Revision 2 review criteria.

18.1.2 Purpose of Review

The overall purpose of the HFE review is to verify the following:

- 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.

18.1.3 Areas of Review

SRP Chapter 18 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 and listed below.

- HFE program management
- operating experience review (OER)

- functional requirements analysis (FRA) and function allocation (FA)
- task analysis
- staffing and qualifications
- human reliability analysis (HRA)
- HSI design
- procedure development
- training program development
- human factors verification and validation (V&V)
- design implementation
- human performance monitoring

For these areas, the staff conducted and documented the ESBWR review using the review criteria from NUREG-0711. In addition, for a limited number of specific topics, the staff used criteria from other review guidance documents as identified in the appropriate sections. Sections 18.2 through 18.13 of this report detail the results of the review.

18.1.4 Regulatory Criteria Applicable to All Areas of Review

This section describes those regulatory criteria applicable to all 12 areas of review.

As required by 10 CFR 52.47, "Contents of Applications; Technical Information," applications for design certification of new reactor designs must meet the technically relevant portions of the Three Mile island (TMI) requirements contained in 10 CFR 50.34(f) (except for 10 CFR 50.34(f)(1)(xii), 10 CFR 50.34(f)(2)(ix), and 10 CFR 50.34(f)(3)(v)). The NRC bases its HFE review on current regulatory requirements established after TMI and contained in 10 CFR 50.34(f). The NRC reviews HFE aspects of new main control rooms (MCRs) 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," requires a safety parameter display system (SPDS), automatic indication of bypassed and operable status of safety systems, and monitoring capability in the MCR 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 practices are acceptable and that there is reasonable assurance that plant safety will not be compromised by human error or by deficiencies in HSIs, considering both hardware and software.

Sections 18.2 through 18.13 of this report each include a regulatory criteria section that is based on review objectives taken from the corresponding NUREG-0711 section. The objectives provide a high-level summary of the detailed review criteria used in the review.

18.1.5 Levels of Review

The staff in general 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 ESBWR, The applicant provided information for IP or complete element level reviews, so that the programmatic level review was not used.

A complete element level of review is performed when the applicant has completed the HFE activity and submitted a description of it for staff review. The review is completed when the applicant has acceptably met all of the NUREG-0711 criteria.

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

> An IP gives the applicant's proposed methodology for meeting the acceptance criteria of the element. An IP 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 18-1 summarizes the level of review performed by the staff for each of the twelve HFE areas of review related to the ESBWR design certification.

Table 18-1 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	Implementation Plan
Training Program Development	Implementation Plan
Human Factors Verification and Validation	Implementation Plan
Design Implementation	Implementation Plan
Human Performance Monitoring	Implementation Plan

18.1.6 Use of Design Acceptance Criteria for Human Factors Engineering

The NRC accepts the use of 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 inspection, test, analysis, and acceptance criteria (ITAAC), and they are used in lieu of detailed design information in the HFE area. The NRC allows the use of 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 this section and the remaining sections of this report, the use of the acronym ITAAC refers to all ITAAC including DAC.

The applicant has identified ITAAC for each HFE element that has an IP with the exception of the procedure and training elements which do not have ITAAC because they are operational programs. These ITAAC are contained in Design Control Document (DCD), Tier 1, Section 3.3, "Human Factors Engineering". The staff's evaluation of these ITAAC is in Section 14.3.9 of this

report. The acceptance criteria of the ITAAC are linked closely to the IPs. Because the key technical information for the HFE element is contained in the IP and the acceptance criteria of the ITAAC are linked to the IP, each IP is designated as Tier 2* with the exception of the IP for the procedure and training elements. This designation prohibits changes to the plan without prior NRC approval. The expiration date of the Tier 2* designation must be after completion of the IP and related ITAAC and is selected as first achievement of full-power following the finding required by 10CFR 52.103(g). In Request for Additional Information (RAI) 18.2-19, the staff requested that all IPs be designated as Tier 2*. RAI 18.2-19 was being tracked as an open item in the SER with open items. In its response, the applicant stated that all IPs would be designated as Tier 2*. Based on the applicant's response, RAI 18.2-19 was resolved. The staff confirmed that the applicant satisfactorily implemented this change in Revision 5 of the DCD. The applicant subsequently requested that the IP for the procedure and training elements not be designated as Tier 2*. The staff finds that the IP for the procedure and training elements not need to be Tier 2* because they are for operation programs addressed by DCD Tier 2, Chapter 13.

The staff will verify the final design was developed in accordance with the design process described in the ITAAC. This may occur via a design certification amendment, the combined license (COL) application review, or the ITAAC closure process. The staff identified two RAIs closely related to the implementation of the DAC approach described above. In RAI 14.3-211, the staff requested that the applicant revise the 11 design descriptions in DCD Tier 1, Table 3.3-1 to refer to the applicable IPs rather than the overall "MMIS and HFE Implementation Plan." RAI 14.3-211 was being tracked as an open item in the SER with open items. In its response, the applicant agreed to implement this change. Based on the applicant's response, RAI 14.3-211 was resolved. In RAI 14.3-271, the staff requested that the applicant revise DCD Tier 1, Table 3.3-1 for each design commitment to ensure that they accurately reflect the methodology described in the IPs. RAI 14.3-271 was being tracked as an open item in the SER with open items. In its response, the applicant revised the ITAAC in DCD Tier 1, Table 3.3-1 to include key output items from the IPs. Based on the applicant's response, RAI 14.3-271 was resolved. The staff confirmed that the applicant satisfactorily implemented changes from RAIs 14.3-211 and 14.3-271 in Revision 5 of the DCD.

18.1.7 Minimum Inventory

Section 18.14 of this report evaluates the applicant's minimum inventory. MCR designs incorporate, and are therefore influenced by, rapidly changing technologies. Accordingly, the NRC allows detailed MCR design to be deferred and evaluated after design certification under "DAC ITAAC" (see SECY- 92-053). The concept of Minimum Inventory originated as part of the Commission's general resolution of the limited MCR design detail that would be available at the time of design certification. The concept of Minimum Inventory was intended to ensure that design certification applicants provided, as a minimum, sufficient CR design information for the staff to make a safety determination at the time of design certification. However, as the HFE design process and the staff's evaluation of the process has matured, there has been increased recognition that the HFE design process, as outlined in NUREG-0711, can and should be the primary process used to identify all controls, displays, and alarms (CDAs)needed in the MCR design. The staff evaluated the Minimum Inventory using the direction provided in the SRP Section 14.3.9, recognizing that the NUREG-0711 process, as implemented by the applicant, will validate and continue to develop the design characteristics associated with the parameters that make up the minimum inventory. For clarity, "Minimum Inventory" is capitalized when referring to the inventory of CDAs specifically covered by the Staff Requirements Memorandum (SRM) on SECY-92-0053 and SRP Section 14.3.9.

18.1.8 Generic Issues Related to Human Factors Engineering

Section 18.15 of this report evaluates the generic issues related to HFE. A brief summary of each generic issue is provided followed by a description of how the technical issue is evaluated in an applicable section of this report. If open items are identified in the applicable sections, the generic issue is characterized as open for the ESBWR design.

18.2 Human Factors Engineering Program Management

18.2.1 Regulatory Criteria

The objective of reviewing HFE program management is to verify that the applicant 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. The team should also be guided by a plan to provide reasonable assurance that the HFE program is properly developed, executed, overseen, and documented. This plan should describe the technical program elements that verify that all aspects of the HSI, procedures, and training are developed, designed, and evaluated on the basis of accepted HFE principles.

To review the applicant's HFE program management, the staff used the review criteria in NUREG-0711, Section 2.4.

18.2.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.2, "MMIS and HFE Program Management," describes the ESBWR HFE program management. DCD Tier 2, Revision 6, Section 18.2 incorporates by reference NEDE-33217P (proprietary), Revision 6, "ESBWR Man-Machine Interface System and Human Factors Engineering Implementation Plan (or the MMIS-HFE Plan)." The nonproprietary version of NEDE-33217P is designated as NEDO-33217.

The staff also reviewed the following ESBWR documents:

- GEH responses to RAIs 18.2-1 through 18.2-20 (MFN 06-163, MFN 07-428, MFN 08-086, MFN 08-088, MFN 08-154, MFN 08-647, and MFN 08-943)
- ESBWR DCD Tier 2, Chapter 19, "PRA & Severe Accidents," Revision 6
- General Electric ESBWR Baseline Record Review (BRR), Draft 1A, January 2007
- GEH Quality Assurance Plan, NEDO-33181, "NP-2010 COL Demonstration Project Quality Assurance Plan," Revision 1
- GE Nuclear Energy Quality Assurance Program Description, NEDO-11209-04A, Revision 8, March 31, 1989

In addition to reviewing the applicant's design documents, the staff conducted regulatory audits in January 16-18, and July 25-27, 2007 (audit reports: ML101960241) to examine how the applicant initially applied the processes described in these documents to the ESBWR design and to evaluate the documentation of the results. Following design certification, the staff will

need to verify the final results of the design analyses for the other HFE elements, as part of the staff's COL application review or through the ITAAC process, to ensure that the design was completed in accordance with the process specified in the design certification, as reflected in the ITAAC.

18.2.3 Staff Evaluation

The staff performed a complete element level of review as described in NUREG-0711 and Section 18.1 of this report.

This section presents the applicable review criteria from NUREG-0711 (reproduced below) followed by an evaluation of each criterion. HFE program management 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)

The applicant has identified the MMIS-HFE Plan and each of the HFE element IPs as Tier 2* in DCD Chapter 18.

18.2.3.1 NUREG-0711 Review Criteria

18.2.3.1.1 General Human Factors Engineering 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.

(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 and 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

Evaluation of Criterion (1)

NEDE-33217P, Revision 6, Section 3.1.2, states that the goal of the MMIS implementation process is to ensure that the vital role personnel play in the plant operation is supported through human-centered design, development, and operational activities. Section 3.2.2, states the goals for the ESBWR HFE process in human-centered terms which include personnel task accomplishment, support for situation awareness, acceptable workload, and minimizing error and support for recovery when they occur. These are the four general directives in NUREG-0711. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for program goals acceptable.

(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.

Evaluation of Criterion (2)

NEDE-33217P, Revision 6, Section 1.2, Item 1, clearly identifies the assumptions and constraints of the ESBWR HFE design by listing them. These include predecessor advanced boiling-water reactor (ABWR) designs, standard design features, safety requirements, and staffing plans. The IP references appropriate DCD sections that further address these aspects of the design. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for assumptions and constraints acceptable.

(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).

Evaluation of Criterion (3)

NEDE-33217P, Revision 6, Section 1.2, Item 2, and DCD Tier 2, Section 18.2, specify the facilities to which the MMIS-HFE Plan applies. These include the facilities in NUREG-0711, namely: the MCR, remote shutdown control station, TSC, and the EOF. Also included are LCSs that have a safety function or have been identified by the ESBWR task analysis.

Accordingly, the staff finds the MMIS-HFE Plan treatment of the criterion for applicable facilities acceptable.

(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).

Evaluation of Criterion (4)

NEDE-33217P, Revision 6, Section 1.2, Item 3, notes the applicable HSIs, procedures, and training included in the program. These encompass operations, accident management, maintenance, test, inspection, and surveillance interfaces (including procedures) for those systems that have safety significance, which are the activities specified for inclusion in

NUREG-0711. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for applicable HSIs, procedures, and training acceptable.

(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: non-licensed 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.

Evaluation of Criterion (5)

NEDE-33217P, Revision 6, Section 1.2, Item 5, identifies applicable personnel, including the categories of personnel identified in the review criterion in NUREG-0711. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for applicable personnel acceptable.

18.2.3.1.2 Human Factors Engineering Team and Organization

(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.

Evaluation of Criterion (1)

NEDE-33217P, Revision 6, Section 3.1.4.1, describes the HFE design team's responsibilities. This section states that the HFE design team's specific duties are to guide and oversee the design implementation activity and to ensure that the execution and documentation of each step in the activity is carried out in accordance with the established program and procedures. In addition, this section addresses, each of the responsibilities identified in the review criterion in NUREG-0711. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for the HFE team's responsibility acceptable.

(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 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.

Evaluation of Criterion (2)

NEDE-33217P, Revision 6, Section 3.1.4.1, describes the project organization and the responsibilities of key functions in the organization. Figure 3.1.4-1, "Engineering, Quality, and Project Management Organization," provides an organization chart and lines of communication. The HFE team is situated within the software project engineering function. The team is fully responsible for the development of HFE IPs and for the use of these plans in designing the HFE aspects of the ESBWR. NEDE-33217P describes the overall guidance for HFE activities, with additional details provided in the individual HFE element IPs. The HFE team designs, controls, and manages the HFE activities and oversees the V&V of the design and implementation of the HFE aspects of the plan. Consistent with the responsibilities of the HFE team defined in NEDE-33217P, the team has the authority to ensure that all responsibilities are accomplished, to determine where their inputs are necessary, and to control overall use of its work products. This authority includes control over any nonconformance or deficiency within its areas of responsibility to ensure an acceptable solution. Furthermore, the team ensures that HFE work performed by outside organizations conforms to the applicant HFE plans, procedures, and guidelines. The organizational structure, responsibilities, and authorities defined in the plan provide reasonable assurance that the HFE activities will be successfully accomplished. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for the HFE team's organizational placement and authority responsibility acceptable.

(3) Composition—The HFE design team should include the expertise described in the Appendix to NUREG-0711.

Evaluation of Criterion (3)

NEDE-33217P, Revision 6, Section 3.1.4.1, describes the team's expertise and skills, which include the areas of expertise identified in NUREG-0711. In its response to RAIs 18.2-5 and 18.2-6 (MFN 06-163), the applicant provided an Attachment A, which outlined a skills matrix for HFE activities, and an Attachment B, which provided a qualification cross-matrix for ESBWR HFE participants. These matrices list each member of the HFE team and their pertinent skills. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for the HFE team's composition acceptable.

(4) Team Staffing—Team staffing should be described in terms of job descriptions and assignments of team personnel.

Evaluation of Criterion (4)

NEDE-33217P, Revision 6, Table 3.1.4-1 provides the assignment of necessary skills to the various HFE element activities. Further, in its response to RAIs 18.2-5 and 18.2-6 (MFN 06-163), the applicant provided Attachment A, which outlined a skills matrix for HFE activities, and Attachment B, which provided a qualification cross-matrix for ESBWR HFE participants. These matrices list each member of the HFE team and their pertinent skills. The combination of the two lists provides the job descriptions and assignments information for the entire team.

In addition, the staff evaluated the team composition in the January and July 2007 regulatory audits. the applicant provided detailed job descriptions and assignment information for the individual team members and their qualifications. The staff noted that additional personnel beyond those on the above attachments had been added to the team. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for the HFE team staffing acceptable.

18.2.3.1.3 Human Factors Engineering Process and Procedures

(1) General Process Procedures—The process through which the team will execute their 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

Evaluation of Criterion (1)

NEDE-33217P, Revision 6, Section 3.1.4.2, addresses general process procedures. The plan references the applicant's project quality assurance (QA) plan (NEDO-33181). This plan also refers to the GE nuclear QA program description, (NEDO-11209-04A). The staff reviewed these QA plans and found that they provided general overall QA for the HFE program aspects of the project. NEDO-33181 provides the overall scope of the QA program and describes how it relates to and incorporates aspects of other QA requirements and guidance, including Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and International Standardization Organization Standard 9001 issued in 2000. NEDO-33181 endorses NEDO-11209-04A and related detailed implementing procedures for use with the ESBWR design project. The NRC previously reviewed the NEDO-11209-04A QA program as part of the ABWR design certification and found it to be acceptable. As discussed under the previous two acceptance criteria, the applicant provided satisfactory information related to the assignment of HFE activities to team members and the overall structure and management of the team. Section 3 of NEDO-11209-04A addresses design control and design review.

The staff further evaluated general process procedures during the January and July 2007 regulatory audits at which the applicant explained the use of its procedures. The applicant provided lists of personnel on the human factors team and organization charts showing personnel. The applicant introduced team personnel to the NRC audit team and various responsible personnel on the team gave presentations on the progress in their respective areas. The NRC was able to interact with GEH personnel and obtained answers related to their processes and results to date. The staff determined that the procedures used to govern the HFE program are sufficient and are being satisfactorily implemented at the time of the audit. The staff acknowledges that QA plans and procedures may be updated periodically, but that they are always subject to NRC inspection and audit.

In view of the above, the staff finds the MMIS-HFE Plan's treatment of the criterion for general HFE process procedures acceptable.

(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.

Evaluation of Criterion (2)

In RAI 18.2-10, the staff requested that the applicant clarify the general process management tools included in the design certification to address this criterion. RAI 18.2-10 was being tracked as an open item in the SER with open items. The first two responses provided plans and schedules for addressing the RAI. The last response provided a satisfactory description of the process management tools and provided revisions to NEDE-33217P. These changes are described below.

Appendix E to NEDE-33217P, Revision 6, addresses process management tools. The applicant's process management for HFE is based on higher level engineering operating procedures which govern activities such as work planning and scheduling, design reviews, independent design verification, design record files, and document initiation and change. Appendix E describes the process as applied to the HFE program. It describes the development, execution, control, output reviews, and closure of all of the HFE activities within the scope of the HFE program and technically governed by the separate IPs for each. Appendix E also identifies specific management responsibilities for the management of the HFE program. For example, for each HFE task, a work plan is developed by a qualified process lead in accordance with higher level GEH engineering procedures. A functional lead reviews the work plan with respect to, among other things, ESBWR planning and scheduling needs. The responsible manager then approves the plan.

Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for process management tools acceptable. Based on the direction the applicant included in the plan, RAI 18.2-10 is resolved.

(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.

Evaluation of Criterion (3)

NEDE-33217P, Revision 6, Section 3.2.4.2, addresses the integration of HFE and other plant design activities. Figure 3.1.4-2, "Process Feedback and Issues Disposition," and Figure 3.2.4-1 of the plan depict the process that executes the integration of the engineering disciplines. It is iterative in structure and the process continues until handed over to the COL holder. Each of the IPs for the various NUREG-0711 elements describes the process further and provides more detail regarding the specific element. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for HFE integration acceptable.

(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.

Evaluation of Criterion (4)

NEDE-33217P, Revision 6, Section 3.1.4.2, describes HFE program milestones, thus enabling the effectiveness of the HFE effort to be evaluated at critical checkpoints. The milestones are to

be identified in terms of their relationship to HFE program activities. This is acceptable at the ESBWR design certification stage.

However, the staff expects the COL applicant to address the status of the milestones in a manner that will facilitate timely review by the staff at each milestone. In RAI 14.3-210, the staff requested that the applicant include a COL item concerning the schedule for ITAAC closure. RAI 14.3-210 was being tracked as an open item in the SER with open items. In response to RAI 14.3-210, the applicant provided Attachment 14.3A to Chapter 14 of the ITAAC. The attachment summarizes material found in 10 CFR 52.99(a) and Regulatory Guide (RG) 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," related to the closure of ITAAC. In response to RAI 14.3-210 Supplement 1, COL Information Item 14.3A-1-1 was included in the appendix to ensure that COL applicants provide an ITAAC closure schedule and identify the closure process to be used. Based on the applicant's response, RAI 14.3-210 is resolved. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for HFE program milestones acceptable.

(5) HFE Documentation—HFE documentation items should be identified and briefly described along with the procedures for retention and access.

Evaluation of Criterion (5)

NEDE-33217P, Revision 6, Section 3.1.4.2, addresses HFE and software documentation. This section states that the applicant's project QA plan includes retention and limited access provisions, and controls the HFE documentation and document management. The applicant's project QA plan, NEDO-33181, provides general overall QA for the HFE program aspects of the project.

In addition, NEDE-33217P, Revision 6 identifies the documentation associated with individual HFE activities discussed in subsequent sections of this report. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for HFE documentation acceptable.

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

Evaluation of Criterion (6)

NEDE-33217P, Revision 6, Section 3.1.4.2, addresses subcontractor HFE efforts. It specifies that each subcontract include requirements for HFE and that these requirements be verified in accordance with the applicant's project QA plan. The applicant's project QA plan, NEDO-33181, provides general overall QA for the HFE program aspects of the project. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for subcontractor HFE requirements acceptable.

18.2.3.1.4 Human Factors Engineering Issues Tracking

(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 18.3 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).

Evaluation of Criterion (1)

NEDE-33217P, Revision 6, Section 3.1.4.3 describes the HFE Issue Tracking System (HFEITS). This system ensures that HFE problems, issues and human engineering discrepancies (HEDs) identified throughout the development and evaluations of MMIS implementation are addressed. The tracking system includes the known industry issues and operating experience of the ESBWR predecessor plants that were identified in their OER and were determined to be appropriate for inclusion in the ESBWR design (see Section 18.3 of this report for the staff's review of operating experience). The plan specifies that the CR design team develops the project work instructions that address issue tracking. Appendix A to the MMIS-HFE Plan provides additional detail about the structure and functioning of the HFEITS. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for HFEITS availability acceptable.

(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.

Evaluation of Criterion (2)

NEDE-33217P, Revision 6, Section 3.1.4.3 and Appendix A, demonstrate that the proposed HFEITS documents and tracks HFE issues to a satisfactory resolution. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for HFEITS methodology acceptable.

(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.

Evaluation of Criterion (3)

NEDE-33217P, Revision 6, Section 3.1.4.3 and Appendix A, demonstrate that the proposed HFEITS appropriately documents and tracks issues. As discussed in Appendix A, the proposed HFEITS has 23 fields for inputting information, including fields to document each of the information items identified in the criterion (e.g., the issue description (field 6) and disposition (field 15)) set forth in NUREG-0711. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for HFEITS documentation acceptable.

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

Evaluation of Criterion (4)

NEDE-33217P, Revision 6, Section 3.1.4.3 and Appendix A, demonstrate that responsibilities are appropriately specified. The proposed HFEITS has 23 fields for inputting information, including fields to clearly identify issue priority, assignment of actions to responsible organizations and individual action owners, due dates, actual completion dates, and resolution verification. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for assignment of responsibility acceptable.

18.2.3.1.5 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.

(1) The general development of IPs, analyses, and evaluation of the following should be identified and described:

- OER
- FRA and FA
- task analysis
- staffing and qualifications
- HRA
- HSI design
- procedure design
- training design
- human factors V&V
- design implementation
- human performance monitoring

Evaluation of Criterion (1)

In RAI 18.2-18, the staff asked the applicant to clarify the description of the technical program in NEDE-33217P. NEDE-33217P, Revision 3, included summary descriptions of the IPs which could potentially conflict with the language in the IPs. RAI 18.2-18 was being tracked as an open item in the SER with open items. The applicant's responses provided a general plan for deleting duplicative material in the NEDE-33217P, but no markups. The applicant's responses also provided a schedule to address the RAI. NEDE-33217P, Revision 4, deleted the duplicative material as identified in the RAI responses. NEDE-33217P, Revision 4, retained necessary and sufficient material to address the technical program review criterion as described below (as implemented in NEDE-33127P, Revision 6). Based on the applicant's responses and NEDE-33217P revisions, RAI 18.2-18 is resolved.

NEDE-33217P, Revision 6, Section 2.1.2, references the individual HFE activity IPs for each HFE element noted in the criterion above. Sections 3.1.4, 3.2.4, and 3.2.6 describe the development and use of the various IPs. Table 3.1.4-1 links the project team expertise to the various HFE element IPs. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for HFE IPs acceptable.

(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.

Evaluation of Criterion (2)

Section 2 of NEDE-33217P, Revision 6, describes the HFE requirements used in the design process. A fairly extensive listing of nuclear industry documents is included that encompasses codes and standards, NRC documents, relevant GEH reports, and other industry documents, such as those from the Institute of Electrical and Electronics Engineers (IEEE) and the Electric Power Research Institute. The list includes all appropriate documents. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for HFE requirements acceptable.

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

Evaluation of Criterion (3)

NEDE-33217P, Revision 6, Section 3.2.1, describes HFE facilities, tools, equipment, and techniques used in the HFE program. The overall report presents the general approach and discusses the use of dynamic models, CR mockups, part-test simulators, and full-scope simulators. Moreover, in the January and July 2007 regulatory audits, the staff obtained additional information on the applicant's use of simulator-based engineering and the various tools and their applications, which provided additional details on the application of HFE techniques and tools in the ESBWR design. Accordingly, the staff finds the MMIS-HFE Plan's treatment of the criterion for identification of facilities and tools acceptable.

18.2.3.2 Relationship to Other Documents

18.2.3.2.1 DCD Tier 1, Section 3.3, "Human Factors Engineering"

DCD Tier 1, Section 3.3, provides a high-level discussion of the Human Factors Program Plan. Since HFE program management is reviewed at a completed element level, there are no ITAAC associated with this area. Section 14.3.9 of this report addresses the staff's review of the HFE ITAAC described in DCD Tier 1, section 3.3.

18.2.3.2.2 DCD Tier 2, Section 18.2, "MMIS and HFE Program Management"

In RAI 18.2-20, the staff requested that the applicant update the reference to the ESBWR MMIS and HFE IP in the DCD. RAI 18.2-20 was being tracked as an open item in the SER with open items. The applicant indicated that it would update the references to all HFE IPs in the DCD. The staff confirmed that the applicant included appropriate references in DCD Tier2, Revision 6. Based on the applicant's response, RAI 18.2-20 is resolved.

DCD Tier 2, Revision 6, Section 18.2 provides a high-level description of the MMIS and HFE program for the ESBWR, which includes an overview of the IP, the scope of the program, a description of the HFE design team, and a discussion of the HFE issue tracking system. NEDE-33217P, Revision 6, and NEDO-33217, Revision 5, which are reviewed throughout Chapter 18 of this report, provide more detail, are referenced by this DCD chapter, and are designated as Tier 2*. Thus, Tier 2, together with the referenced IP, provides an acceptable

description of the ESBWR HFE program management. The staff finds the DCD Tier 2, Chapter 18 treatment of HFE program management acceptable.

18.2.4 Conclusions

The staff reviewed the HFE program management at a complete element level (see Section 18.1.4 of this report for a discussion of review levels) using the review criteria in Section 2.4 of NUREG-0711. As discussed above, the staff concludes that the HFE program management for the ESBWR has identified general HFE program goals and scope, specified an acceptable HFE team and organization, implemented appropriate HFE process and procedures, developed an HFE issues tracking system, and established an acceptable HFE technical program. Accordingly, the staff concludes that the applicant's HFE program management is acceptable at the complete element level.

18.3 Operating Experience Review

18.3.1 Regulatory Criteria

The objective of reviewing the applicant's OER is to verify that it has identified and analyzed HFE-related problems and issues in 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 one while retaining positive features.

To review the applicant's OER, the staff used the review criteria in NUREG-0711, Section 3.4.

18.3.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.3, "Operating Experience Review," describes the ESBWR OER. DCD Tier 2, Section 18.3, incorporates by reference NEDE-33217P, Revision 6, and NEDO-33262, Revision 3, "ESBWR Human Factors Engineering Operating Experience Review Implementation Plan."

The staff also reviewed the following ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 6
- ESBWR DCD Tier 2, Chapter 19, "PRA & Severe Accident," Revision 6
- NEDO-33201, "ESBWR Probabilistic Risk Assessment," Revision 5
- GEH Response to RAIs 18.3-1 through 18.3-21 (MFN 06-192)
- GEH ABWR First-of-a-Kind Engineering (FOAKE) Program, "Operating Experience/Lessons Learned Evaluation," Revision 0, February 2, 1996, (audited material)
- GEH, "Standby Liquid Control Functional Requirements Analysis Report (Lungmen)," October 16, 1997, (audited material)

- GEH, “Reactor Water Clean-up Functional Requirements Analysis Report (Lungmen),” October 16, 1997, (audited material)

- General Electric ESBWR Baseline Record Review (BRR), Draft 1A, January 2007, (audited material)

In addition to reviewing the applicant’s design documents, the staff conducted a regulatory audit on July 14, 2007, to examine the initial application of the processes described in these documents to the ESBWR design and to evaluate the documentation of the results. The staff also notes that DCD Tier 1, Table 3.3-2, contains an ITAAC verification of the OER element.

18.3.3 Staff Evaluation

The staff performed an IP level of review as described in NUREG-0711 and Section 18.1 of this report.

This section presents the applicable review criteria from NUREG-0711 (reproduced below), followed by an evaluation of each criterion. OER review topics include the following:

- scope (five review criteria)
- issue analysis, tracking, and review (three review criteria)

In addition, this section addresses related documents (i.e., DCD Tier 1 and Tier 2 information).

18.3.3.1 NUREG-0711 Review Criteria

18.3.3.1.1 Scope

NUREG-0711 includes five scope-related criteria, as described below.

(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. 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.

Evaluation of Criterion (1)

NEDO-33262, Revision 3, discusses the review of human factors issues associated with predecessor plants in several ways. First, the applicant’s notes that a review of the industry experience with the operation of selected MMIS equipment technologies includes reviewing those designs similar to the proposed design. This process includes a review of the literature pertaining to the human factors issues related to similar system applications of such technologies and interviews with personnel experienced with the operation of these systems. The OER also classifies and evaluates events reported by boiling-water reactor (BWR) and ABWR predecessor systems upon which the design is based.

In RAI 18.3-1, the staff asked how experience with isolation condensers would be addressed if the OER focused on ABWR work instead of previous BWRs. Current BWR fleet experience

with isolation condenser systems would not have been applicable to the ABWR, since it does not have isolation condensers, but current BWR fleet experience would be pertinent to the ESBWR. In its response, the applicant stated that the ESBWR OER includes operational experience gained from previous BWRs with isolation condensers. The ESBWR OER includes experience from the ABWR and the current BWR fleet. The staff determined that the applicant's response was acceptable because the ESBWR OER includes BWRs with isolation condensers and the ABWR. Based on the applicant's response, RAI 18.3-1 is resolved.

NEDO-33262, Revision 3, Section 1.2, "Scope," notes that an OER was performed as part of the first-of-a-kind engineering (FOAKE) effort for the ABWR. The ABWR system functional requirements analysis (SFRA) reports for each system document the results. The staff reviewed two example SFRA reports for the Lungmen ABWR. These reports used the system functions from the system design descriptions. The reports were reasonably comprehensive and focused on operator actions. They included information from the OER performed for the system that was the subject of the report. Section 1.2 also discusses the baseline record review (BRR), which identifies significant differences between the ESBWR design and predecessor designs and establishes a process for evaluation and resolution of identified differences. The staff reviewed a draft of the BRR (issued January 2007) at the GEH facility that discussed, among other items, the sources and types of predecessor information and the transition to the ESBWR from earlier BWR designs. The applicant's approach appeared reasonable and thorough.

NEDO-33262, Revision 3, Section 3, states that the OER process includes both plant operations and HFE design topics. For the ESBWR, three predecessor ABWR plants have been operating for several years and three additional ABWRs are in the design and construction stages. There is also the entire U.S. and worldwide BWR fleet that preceded the ABWRs and from which the ABWR and ESBWR designs were developed.

NEDO-33262, Revision 3, Section 3.1.3, states that the HFE design team interviewed plant operations personnel and previous HFE team members and personnel from the ABWR predecessor plant and previous BWR plants, as well as operators who are involved with the full-scale simulator training. At a meeting at its facility in January 2007, the applicant discussed a trip to Japan made specifically to gather OER-type information from the operating Japanese ABWRs. NEDO-33262, Revision 3, specifies that the information and analysis results are included in the BRR/OER database, used for the ESBWR design as appropriate, and summarized in the OER results summary report.

The OER Plan considers predecessor and highly similar plant HFE issues. Accordingly, the staff finds the OER Plan's treatment of the criterion for predecessor/related plants and systems acceptable.

(2) Recognized Industry HFE Issues—NUREG/CR-6400 issues should be addressed. The issues are organized into the following categories:

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

Evaluation of Criterion (2)

NEDO-33262, Revision 3, Section 1.2, specifies that the OER addresses recognized industry HFE issues that are documented in NRC reports, such as NUREG-0933, "A Prioritization of Generic Safety Issues," and NUREG/CR-6400, "HFE Insights for Advanced Reactors Based upon Operating Experience." NEDO-33262, Revision 3, Section 1.2, also states that the OER analyzes experience summary documents in detail to integrate the insights that support enhancement of human actions (HAs) which affect the risk and reliability of both normal and outage operations (e.g., generic safety issues defined by the NRC). NEDO-33262, Revision 3, Section 3, "Methods," lists further areas and sources to be reviewed.

NEDO-33262, Revision 3, Appendix A, "Example Identification of Human Interactions from Event Experience Related to BWRs," provides a detailed example of an OER of current BWR plants related to shutdown operations. The applicant provided this as an example for conducting an OER for the ESBWR, specifically to illustrate how the ESBWR OER team reviews this experience as possible input to the ESBWR design.

In Section 3.2.3.5 of NEDO-33262, Revision 3, the applicant also noted that the ESBWR design is an extension of the ABWR design, which is an extension of the BWR design. Previous OERs were reviewed and actions were taken to minimize or eliminate identified human interaction deficiencies at BWR/ABWR plants. This philosophy continues with the ESBWR design. NEDO-33262, Revision 3, specifies that the ESBWR HFE design team review the lessons learned and recommendations from the shutdown study, along with other OER results, and enter applicable items into HFEITS for resolution. This process provides input into the ESBWR design, operator training, and procedure improvements.

The OER Plan addresses the categories of recognized industry HFE issues identified in the criterion as described in detail above. Accordingly, the staff finds the OER Plan's treatment of the criterion for recognized industry HFE issues acceptable.

(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.

Evaluation of Criterion (3)

NEDO-33262, Revision 3, Section 1.2, states that review of experience and identification of problems in prior MMIS implementations, including human factors problems, are addressed throughout the design process. The Scope section also notes that the review of the MMIS technologies includes both a review of literature pertaining to the human factors issues related to similar system applications of such technologies and interviews with personnel experienced with the operation of these systems. Sections 3 and 3.2 provide a list of the HFE design topics and technologies to be addressed. Section 3 states that HFE design topics include selection of alarm and annunciation elements; displays, control, and automation elements; information processing and job aids; real-time communications with plant personnel and other organizations; and procedures, training, staffing and qualifications, and job design. NEDO-33262, Revision 3, Section 5.1, specifies that the results summary report includes the review of HSI equipment and technologies.

The OER Plan considers related HFE technology as described in detail above. Accordingly, the staff finds the OER Plan's treatment of the criterion for related HFE technology acceptable.

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

Evaluation of Criterion (4)

NEDO-33262, Revision 3, Section 1.2, provides for obtaining and incorporating feedback from utility operators on the needs of operators, maintainers, testers, and outage planners. Section 3 states that the OER includes conducting personnel interviews to determine the operating experience related to predecessor plants or systems. At a minimum, interview topics include plant operations and HFE design topics. Sections 3 and 3.2 contain an acceptable list of HFE design topics to be addressed by personnel interviews. Section 3.1 addresses the area of plant operations and notes potential topics for the conduct of interviews with experienced operators. Section 3.1.4 contains an acceptable list of operational areas. The intent of this portion of the ESBWR OER is to receive candid input from plant staff that may not be provided in published reports. Design teams from predecessor designs also serve as potential contributors to OERs. The information gathered is intended to be based upon facts, such as the results of evaluations

or test results, rather than personal opinion. The applicant has completed some interviews and is planning to conduct further interviews of plant operations personnel and previous HFE team members or personnel from the ABWR Lungmen predecessor plant and previous BWR plants. The HFE design team interviews operators that are involved with the full-scale simulator training for additional OER input. Additionally, during the January 2007 meeting at its Wilmington, NC, facility, the applicant described a trip to Japan that included interviews with operations personnel from operating ABWRs to obtain OER-type information.

The OER Plan includes the conduct of personnel interviews on plant and HFE design topics to determine operating experience related to predecessor plants or systems, as described in detail above. Accordingly, the staff finds the OER Plan's treatment of the criterion for issues identified by plant personnel acceptable.

(5) Risk-Important Human Actions (HAs)—The OER should identify risk-important HAs that have been identified as different from predecessor plants or where errors have occurred in the execution of risk important HAs. These HAs should be identified as requiring special attention during the design process to lessen their probability of failure.

Evaluation of Criterion (5)

NEDO-33262, Revision 3, Section 1.2, specifies that the ESBWR system designers use the BRR database, in conjunction with an OER database, to analyze risk-important HAs. The scope of the OER plan includes analyzing experience summary documents and integrating insights to support enhancement of HAs affecting the risk and reliability of both normal and outage operations. Section 3.2.3.1 includes the use of shutdown probabilistic risk assessment (PRA) studies as part of the OER. Section 3.2.3.4 discusses a classification scheme that includes consideration of the critical tasks identified in the ESBWR Human Factors Engineering Human Reliability Analysis Plan and the Task Analysis Plan. The purpose of the classification is to place issues into categories that can facilitate their disposition.

Section 3.2.4, "Applications," discusses how the OER addresses risk-important HAs in predecessor and similar plant designs and how experience related to these actions is used to improve human performance and lower risk in the ESBWR.

Section 5.1 notes that the results summary report will describe the risk important HAs from predecessor plants and their resolution and risk important HAs from the OER that warrant special attention in the design process.

The OER Plan considers risk-important HAs that have been identified as different from predecessor plants, as well as cases in which errors have occurred in the execution of risk important HAs described in detail above. Accordingly, the staff finds the OER Plan's treatment of the criterion for risk-important HAs acceptable.

18.3.3.1.2 Issue Analysis, Tracking, and Review

NUREG-0711 includes three criteria for this topic as described below.

(1) Analysis Content—The 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

Evaluation of Criterion (1)

NEDO-33262, Revision 3, Section 3.2.3.4, “Classification,” states that individual OER information files are screened and classified for the human factors aspects of operating experience, according to a scheme or framework. The purpose of the classification is to place issues into categories to facilitate their disposition. Section 1.2 of the OER Plan discusses the framework.

NEDO-33262, Revision 3, Section 3.2.3.5, “Identification of Human Issues,” states that event data or analyzed reports are selected and considered for ESBWR design HFE support. These data and reports can be analyzed to identify problematic operations and tasks and to point to potential human factor enhancements for all aspects of human performance. This includes the HSI design, procedures, personnel training, and CR staffing and qualifications.

The OER Plan identifies issues and design elements related to human performance as described in detail above. Accordingly, the staff finds the OER Plan’s treatment of the criterion for analysis content acceptable.

(2) Documentation—The analysis of operating experience should be documented in an evaluation report.

Evaluation of Criterion (2)

NEDO-33262, Revision 3, Section 5.1, describes the proposed summary report. The report addresses the scope of Section 1.2 by summarizing the results of the OERs, including OERs of previous nuclear power plant HSI designs that identify human performance issues and the HFE solutions that support human performance improvements. the applicant provided a proposed outline for the report which addresses the specified areas of NUREG-0711.

The OER Plan describes an evaluation report called a results summary report that documents the analysis of operating experience as described in detail above. Accordingly, the staff finds the OER Plan’s treatment of the criterion for documentation acceptable.

(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.

Evaluation of Criterion (3)

NEDE-33217P, Revision 6, describes the overall methodology for the functioning of the HFEITS. In particular, Sections 3.1.4.2 and 3.1.4.3, Figure 3.1.4-2, and Appendix A all discuss the purpose and workings of the HFEITS. The methods and types of items to be entered into the system are described. In addition, NEDO-33262, Revision 3, describes the OER Plan and various operating experience issues that are input to the HFEITS.

The OER Plan includes an issue tracking system called HFEITS that documents appropriate operating experience issues for incorporation in the design as described in detail above. Accordingly, the staff finds the OER Plan’s treatment of the criterion for incorporation into the HFEITS acceptable

18.3.3.2 Relationship to Other Documents

18.3.3.2.1 DCD Tier 1, Section 3.3, “Human Factors Engineering”

DCD Tier 1, Revision 6, Table 3.3-2, contains the Tier 1 ITAAC developed by the applicant for HFE. Table 3.3-2 contains 10 items, one for each element of NUREG-0711 (except HFE program management, procedures and training) plus one item that addresses integrated system validation scenarios. Each item in Table 3.3-2 is linked to the corresponding ESBWR element IP. As described in Section 14.3.9 of this report, DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the OER is completed in accordance with the IP (NEDO-33262, Revision 3), which the staff has reviewed and approved.

18.3.3.2.2 DCD Tier 2, Section 18.3, “Operating Experience Review”

DCD Tier 2, Section 18.3 provides the primary description of OER activities, which summarizes the OER program, including the purpose, objectives and scope, and the OER methodology. This section of the DCD also references the detailed IP (NEDO-33262, Revision 3), which is designated as Tier 2*. As discussed above, NEDO-33262, Revision 3, describes an OER program which conforms to the NUREG-0711 criteria for OER. Thus, DCD Tier 2, Chapter 18, together with the referenced IP, provides an acceptable description of the ESBWR OER program.

18.3.4 Conclusions

The staff has reviewed the ESBWR OER at an IP level (see Section 18.1.4 of this report for a discussion of review levels) using the review criteria in Section 3.4 of NUREG-0711. The staff concludes that the ESBWR OER IP, as described in NEDO-33262, Revision 3, provides an acceptable methodology to identify and analyze HFE-related problems and issues in previous designs that are similar to the ESBWR design. This methodology provides a means to ensure that negative features associated with predecessor designs may be avoided in the ESBWR while retaining positive features. DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the OER is completed in accordance with the IP (NEDO-33262, Revision 3), which the staff has reviewed and approved. Accordingly, the staff concludes that the applicant’s OER is acceptable at the IP level.

18.4 Functional Requirements Analysis and Function Allocation

18.4.1 Regulatory Criteria

The objective of reviewing FRA and FA is to verify that the applicant has (1) defined the plant's functions that must be performed to satisfy plant safety objectives and (2) allocated those functions to human and system resources in a manner that takes advantage of human strengths and avoids human limitations.

To review the applicant’s FRA and FA plans, the staff used the review criteria in NUREG-0711, Section 4.4.

18.4.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.4, "Functional Requirements Analysis and Allocation of Functions," describes the ESBWR FRA and FA. DCD Tier 2, Revision 6, Section 18.4, incorporates by reference NEDE-33217P, Revision 6; NEDO-33219, Revision 4, "ESBWR System Functional Requirements Analysis Implementation Plan"; NEDO-33220, Revision 4, "ESBWR Allocation of Functions Implementation Plan"; and NEDE-33220P, Revision 4, a proprietary version of the Allocation of Functions IP.

The staff also reviewed the following ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 6
- ESBWR DCD Tier 2," Chapter 19, "PRA & Severe Accident," Revision 6
- NEDO-33201, "ESBWR Probabilistic Risk Assessment," Revision 3
- GEH responses to RAIs 18.4-1 through 18.4-26 (MFN 06-400, MFN 07-408, MFN 07-499, MFN 08-154, MFN 08-156, MFN 08-647, and MFN 09-246)
- GEH, "Standby Liquid Control Functional Requirements Analysis Report (Lungmen)," October 16, 1997 (audited material)
- GEH, "Reactor Water Clean-up Functional Requirements Analysis Report (Lungmen)," October 16, 1997 (audited material)

The applicant initially submitted NEDO-33219, Revision 0, "ESBWR System Functional Requirements Analysis Implementation Plan," and NEDO-33220, Revision 0, "ESBWR Allocation of Functions Implementation Plan," in January 2006. The NRC developed and issued RAIs on these documents. Revision 1 to these IPs reflected a significant revision, which led to several followup RAIs. The applicant issued Revision 2 in May 2008 to address the followup RAIs and changes in the methods. Revision 3, issued in April 2009, made only minor changes. The applicant issued Revision 4 in February 2010 to implement a minor modification to the references.

In addition to reviewing the GEH design documents, the staff conducted a regulatory audit in January and July, 2007, to examine the initial application of the processes described in these documents to the ESBWR design and to evaluate the documentation of the results. Following design certification, the staff will verify the final results of the design analyses, either in the COL application or through the ITAAC process, to ensure that the design was completed in accordance with the process specified in the design certification, as reflected in the DAC.

18.4.3 Staff Evaluation

The staff performed an IP level of review, as described in NUREG-0711 and Section 18.1 of this report. This section presents the applicable review criteria from NUREG-0711 (reproduced below) followed by an evaluation of each criterion. This section also addresses related documents (i.e., DCD Tier 1 and Tier 2 information).

18.4.3.1 NUREG-0711 Review Criteria

NUREG-0711 includes 11 criteria for this topic. However, the 11th criterion relates to plant modifications and is not applicable to new plant designs.

(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 are shown in Figure 4.1 of NUREG-0711. The functional requirements analysis and function allocation may be graded based on:

- the degree to which the 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.

Evaluation of Criterion (1)

In RAIs 18.4-16 and 18.4-21, the staff identified that (1) the FA decision making guidelines were incomplete, (2) the allocation criteria were too general to be consistently applied, (3) several criteria needed additional clarification, and (4) the appendix providing the criteria used for deciding the FA was inconsistently referenced. As documented through several supplemental RAIs, the staff determined that the necessary level of detail was in the applicant's internal work instructions and needed to be incorporated into the IP NEDE-33220P. RAIs 18.4-16 and 18.4-21 were being tracked as open items in the SER with open items. In response to these RAIs, the applicant provided the information at a level of detail sufficient for the staff to complete its review of the FRA and FA criteria. The applicant incorporated this information into the appropriate IPs. The staff's evaluation of the IPs, as updated through the RAI responses, is described below. Based on the applicant's responses and NEDE-33220P revisions, RAIs 18.4-16 and 18.4-21 are resolved.

NEDO-33219, Revision 4, describes the applicants approach to FRA, and NEDO-33220, Revision 4, describes the applicants approach to FA.

NEDO-33219, Revision 4, describes an overall operational analysis approach that includes FRA, allocation of function, and task analysis. This operational analysis is iterative, as shown in NEDO-33219, Revision 4, Figures 1 through 6. In accordance with NEDO-33219, Revision 4, Section 1, the FRA establishes methods to do the following:

- denote ESBWR mission and goals
- conduct the FRA consistent with accepted HFE methods
- identify critical safety functions
- validate system functions identified in the ESBWR system design specifications (SDS)
- define the relationships between high-level functions and plant systems
- reconcile any differences between plant-level analyses and the SDS

NEDO-33219, Revision 4, Section 1.2, specifies that plant-level and system-level goals and functions are systematically analyzed concurrently. In accordance with Section 3.2.4 of the plan, systems are analyzed with information taken from the SDS. The system-level FRA is linked to the plant-level FRA, which allows the eventual linking of the high level plant mission and functions to system components. The staff reviewed examples of this process during the

January 2007 regulatory audit at GEH, and the following was noted. As described in NEDO-33219, Revision 4, Section 3.1, and Figures 2 and 4, the functional relationships between plant functions and system functions are reconciled through a gap analysis that ensures that both plant-level and system-level goals are met. The plant-level FRA is conducted in three phases as the design proceeds: a high-level plant FRA, a design FRA, and a detailed FRA. Section 3.2 and Figure 3 describe the system-level FRA. These FRAs analyze each system and its functions to determine individual task requirements necessary to meet the high-level plant objectives. A gap analysis, described in Section 3.3 and Figure 6, is performed to link the plant and system FRAs and identify any gaps that must be addressed.

NEDO-33220, Revision 4, describes the applicant's structured methodology to allocating to personnel and automation the functions identified by the NEDO-33219, Revision 4, FRA methodology. The methodology is generally based on accepted approaches documented in publications such as NUREG/CR-3331, "A Methodology for Allocation of Nuclear Power Plant Control Functions to Human and Automated Control." As described in Section 3.1.4 of the FA Plan, the scope of the analysis is broad and includes all functions identified in the FA. Section 3 of the FA Plan describes the general methodology, and Section 4 describes the means of implementing the methodology.

NEDO-33220, Revision 4, Section 3.1.2, defines a set of goals for the allocation of function process that emphasizes human performance objectives. These goals include considerations such as minimizing errors and performance of normal, abnormal, and emergency functions.

NEDO-33220, Revision 4, Section 4, and a set of companion figures, especially Figures 3 and 4, present the details of the FA methodology. For safety functions, the methodology guides the analyst through a set of considerations to determine whether the function should be automated or not. Such considerations are at the core of FA methods. Section 4.1.3.1, Item 2, provides the criteria for this analysis, which include the following:

- regulatory requirement
- design requirement
- PRA basis assumption
- HRA/PRA risk significance
- OER/BRR significance
- human cognitive limitations
- human response time limitations
- human physical limitations
- hostile environment, including atmosphere, temperature, and radiation

The applicant provided detailed guidance for FA in Appendix B to NEDE-33220P, Revision 4. Analysts use the guidance to evaluate the factors employed to make allocation decisions. Where it is feasible to do so, quantitative guidance is provided, such as in the assessment of physical workload. The guidance is sufficiently detailed to enable a clear and consistent use of the FA methodology.

The methodology of the FRA Plan also appropriately considers the need for personnel backup of functions for which automation is indicated, as well as automatic backup of functions for which manual performance is indicated.

The allocation process results in functions being automatic, manual, or shared. Shared functions are accomplished by a combination of automation and personnel action. These functions are further analyzed using the considerations in NEDO-33220, Revision 4, Figure 4.

The FRA and FA Plans provide a structured, documented methodology reflecting HFE principles for performing these analyses as described in detail above. Accordingly, the staff finds the treatment of the criterion for a structured methodology in the FRA and FA Plans to be acceptable.

(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.

Evaluation of Criterion (2)

NEDO-33219, Revision 4 and NEDO-33220, Revision 4, describe the iterative nature of the operational analyses that include both FRA and FA. Figure 2 depicts these analyses, which are further described in Sections 3.1, 3.2, and 4 of NEDO-33219, Revision 4 and in Figure 1 of NEDO-33220, Revision 4. This methodology inherently ensures that the FRA is kept current over the life cycle of design development.

Additionally, NEDE-33217P, Revision 6, Section 3.1.4.2, "Management Process and Procedures," states the following:

> Each licensee is responsible to maintain as-built design bases and SQA [software quality assurance] records during the operating life of the related ESBWR license. A fleet-wide owners' group provides a means of coordination between GEH and the ESBWR licensees to facilitate and maintain uniformity of…Operational Analysis.

The ESBWR operational analysis includes FRA, allocation of function analysis, and task analysis.

The FRA and FA Plans provide for keeping the FRA and FA current and for allocating control functions in an iterative manner, as described in detail above. Accordingly, the staff finds the FRA and FA Plans treatment of the criterion for life-cycle currency acceptable.

(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 human action (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

Evaluation of Criterion (3)

NEDO-33219, Revision 4, Sections 3 and 4.1, describe the top-level or plant FRA to be performed. These analyses identify the major functions needed to achieve the plant goals and subgoals, both safety and economic, and high-level functions for safe operation. The analyses then proceed to a lower level to identify processes, critical safety functions (CSFs), subfunctions, indications, controls, and accident monitoring parameters. Section 4.1.3.7 describes the identification of the CSFs, which include reactivity control, reactor pressure vessel overpressure protection, core cooling, and containment heat removal. NEDO-33219, Revision 4, Figure 4, summarizes this process.

NEDO-33219, Revision 4, Section 4.2, describes the system-level FRA. This portion of the overall FRA describes and analyzes each system in the design, the majority of which were inherited from predecessor plants (i.e., the earlier BWR fleet and the ABWRs). The analyses identify the functions performed by each system, down to the division, channel, or train level. The analyses also identify the processes necessary for a system to accomplish its functions, support elements and components for each process, system alignments and configurations, and the details of transitions between configurations. NEDO-33219, Revision 4, Figure 5, depicts the system-level FRA.

NEDO-33219, Revision 4, Section 3.3, describes a gap analysis that is performed to address any discrepancies between the plant-level and system-level FRAs. Any discrepancies are addressed in the design or are added to the HFEITS for later correction. Figure 6 summarizes the system function gap analysis.

Moreover, in addition to reviewing the GEH design documents, the staff conducted a regulatory audit in January, 2007 during which the staff reviewed two examples of typical system FRAs performed by GEH for a new ABWR, specifically, the standby liquid control system and the reactor water cleanup system. The staff notes that the FRAs were generally performed in accordance with the IP and provided appropriate analyses of the system functions. They also included information from the OER performed for the system being evaluated.

The FRA Plan calls for descriptions of functions and systems and the identification of differences between proposed and reference plants. The FRA Plan includes performing a functional decomposition that addresses high-level functions and specific plant systems and components, as described in detail above. Accordingly, the staff finds the FRA Plan's treatment of the criterion for functional description and decomposition acceptable.

(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 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.

Evaluation of Criterion (4)

In RAI 18.4-26, the staff noted that the applicant had removed information addressing this criterion from NEDO-33219 Revision 1, and moved it to a work instruction. The staff determined that this information was needed in NEDO-33219 and requested that the applicant return the information. RAI 18.4-26 was being tracked as an open item in the SER with open items. In the RAI responses, the applicant indicated that it would move appropriate information addressing this criterion back into NEDO-33219. The staff determined that the applicant identified the information at a level of detail sufficient for the staff to complete its review of the criterion and had incorporated this information into NEDO-33219. The staff's evaluation of NEDO-33219 for this criterion, as updated through the RAI responses, is described below. Based on the applicant's responses and the NEDO-33219 revision, RAI 18.4-26 is resolved.

DCD Section 18.4.1.1 states that the FRA will provide methods and criteria for conducting both the plant-level FRA and the system-level FRA and will also provide descriptions for each identified function. NEDO 33219, Revision 4, Section 4.3.3.8, "Plant Function Operational Summary," states that the FRA will determine the following for each high-level plant function:

- purpose of the plant function
- the plant condition or conditions which require the plant function
- parameter or parameters that represent the availability of the plant system designated to support the plant function
- parameter or parameters that represent operation of the plant system in support of the plant function
- parameter or parameters that represent the success of the plant system in support of the function
- parameter or parameters that indicate when support of the function from the plant system can or should be terminated

Accordingly, the staff finds the FRA Plan's treatment of the criterion for the description of high-level functions acceptable.

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

Evaluation of Criterion (5)

The plant-level functional requirements analysis (PFRA) is used to determine the technical basis for each high-level function in the ESBWR. NEDO-33219, Revision 4, Section 3.1 states the following:

> The High-level PFRA is performed early in the design process and identifies critical safety functions...The Design PFRA includes plant goals and functions that support the ESBWR mission of generating safe economic electric power during all plant operating modes....

The functions from ESBWR predecessor designs are embedded in the system designs that were inherited from these earlier BWR plants. NEDO-33219, Revision 4, Section 3.2, discusses the SFRA. The SFRA is the second step of the "top-down" approach to FRA and analyzes each system and its functions. The system function gap analysis then determines and resolves any discrepancies between the high-level plant functions and the system functions. NEDO-33219, Revision 4, Section 3.3, describes this process, which is summarized above and which could result in engineering design changes if needed. The staff finds that this process provides a suitable documented method for modifying functions when needed.

The FRA Plan includes documenting the technical basis for modifications to high-level functions in the new design, as described in detail above. Accordingly, the staff finds the FRA Plan's treatment of the criterion for modifications to high-level functions acceptable.

(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 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).

Evaluation of Criterion (6)

NEDO-33220, Revision 4, Section 4.1.3, "Process," indicates that the FA process is documented in formal records that capture the criteria, rationale, and analysis method used. NEDO-33220, Revision 4, Section 5, Results, describes the results summary report that is generated.

As part of the January and July 2007 regulatory audits, the staff examined examples of the applicant approach to documenting FA results. The approach was complete and provided an auditable documentation of the findings. The approach provided a traceable path from high-level requirements analysis through task analysis. The regulatory audit confirmed that NEDO-33220, Revision 4, identifies appropriate documentation approaches. Accordingly, the staff finds the FA Plan's treatment of the criterion for the FA technical basis acceptable.

(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.

Evaluation of Criterion (7)

NEDO-33220, Revision 3, Section 4.1.2.1, "Inputs," discusses the process by which OER provides input to all operational analyses, which is illustrated in Figure 1. OER results, which are documented in the OER/BRR, provide input to the ESBWR analysis. OER is listed as one criterion for making allocation decisions in the various subsections of Section 4.1.3.1, Allocation of Function Flow Chart Process. NEDO-33219, Revision 4, provides that all FRA functions are to be analyzed. OER serves as one basis for making allocation decisions, but is not used to screen out any functions from being analyzed. The availability and use of the OER/BRR as a means to capture operating experience and lessons learned should help ensure the use of that information in the allocation process.

The FA Plan includes performing analyses on problematic OER issues and using the OER to identify modifications to FAs, as described in detail above. Accordingly, the staff finds the FA Plan's treatment of the criterion for use of OER in the FA process acceptable.

(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.

Evaluation of Criterion (8)

The process for allocating functions discussed above with respect to Criterion (1) explicitly incorporates the evaluation of personnel roles in automatic function performance. Similarly, the analysis considers the role of automation in backing up personnel performance. NEDO-33220, Revision 4, Figures 3 and 4, illustrate these considerations, which and are described in Section 4.1.3.2, "Shared Function Detailed Flowchart Process." Accordingly, the staff finds the FRA Plan's treatment of the criterion for allocation related to automation acceptable.

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

Evaluation of Criterion (9)

The applicant's FRA and FA methodologies incorporate both plant-level and system-level analyses (see NEDO-33220, Revision 4, Figure 2, and NEDO-33219, Revision 4, Figures 3 through 6). Plant-level analyses address the demands of allocations that cut across functions. Those analyses are carried through to the task analysis, where the detailed performance of functions assigned to plant personnel is further analyzed.

The FRA and FA Plans include providing a description of the integrated personnel role across functions and systems in terms of personnel responsibility and level of automation as described in detail above. Accordingly, the staff finds the treatment of the criterion for the integrated role of personnel in the FRA and FA Plans to be acceptable.

(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

Evaluation of Criterion (10)

NEDO-33219, Revision 4, describes the complete top-down FRA approach used to verify the functional requirements of this criterion. This method does not assume functions from prior designs, but searches for and ensures that all functions and related requirements are identified. The concurrent development of the PFRA and the SFRA provides another check in the method to help ensure completeness. NEDO-33220, Revision 4, Section 3.1.4, explains that the V&V (and other HFE processes) provides feedback that is evaluated to determine whether or not additional iterations of the operational analysis process are warranted in specific areas. These added iterations will be implemented should the V&V process identify any problems with the role of personnel versus automation. This provides reasonable assurance of a coherent role for plant personnel. Accordingly, the staff finds the treatment of the criterion for verification of analyses to be in the FRA and FA Plans acceptable.

18.4.3.2 Relationship to Other Documents

18.4.3.2.1 DCD Tier 1, Section 3.3, “Human Factors Engineering”

DCD Tier 1, Revision 6, Table 3.3-2, contains the Tier 1 ITAAC which the applicant developed for HFE. Table 3.3-2 contains 10 items, one for each element of NUREG-0711 (except HFE program management, procedures and training) plus one item that addresses the integrated system validation scenarios. Each item in Table 3.3-2 is linked to the corresponding ESBWR element IP. As described in Section 14.3.9 of this report, DCD Tier 1, Section 3.3 provides ITAAC sufficient to confirm that the FRA and FA are completed in accordance with their respective IPs (NEDO-33219, Revision 4, and NEDO-33220, Revision 4), which the staff has reviewed and approved.

18.4.3.2.2 DCD Tier 2, Section 18.4, “Functional Requirements Analysis and Allocation of Functions”

In RAI 18.4-25, the staff requested that the applicant address inconsistencies between DCD Tier 2, Section 18.4, Revision 3, and NEDO-33220, Revision 1. RAI 18.4-25 was being tracked as an open item in the SER with open items. In its response, the applicant agreed to remove extraneous information from DCD Tier 2. The staff confirmed that the applicant did remove extraneous information from DCD Tier 2, Section 18.4, Revision 5 and that this information was consistent with NEDO-33220, Revision 2. Based on the applicant’s response and DCD revisons, RAI 18.4-25 is resolved.

DCD Tier 2, Section 18.4.1 discusses the FRA IP. This provides a reasonable, high-level discussion of the FRA, which NEDO-33219, Revision 4, describes in more detail. DCD Tier 2, Section 18.4.2 discusses the FA IP. This provides a reasonable, high-level discussion of the FA, which NEDO-33220, Revision 4, describes in more detail.

DCD Tier 2, Section 18.4.4 references the detailed IPs (NEDO-33219, Revision 4; NEDE-33220P, Revision 4; and NEDO-33220, Revision 4), which are all designated as Tier 2*. As discussed above, NEDO-33219, Revision 4, and NEDO-33220, Revision 4, describe the FRA and FA program, which address the NUREG-0711 criteria for FRA and FA. Thus, Tier 2, together with the IPs, provides an acceptable description of the ESBWR FRA and FA programs.

18.4.4 Conclusions

The staff reviewed the FRA and FA at an IP level (see Section 18.4.1 of this report for a discussion of review levels) using the review criteria in Section 4.4 of NUREG-0711. For the reasons set forth above, the staff concludes that the FRA and FA programs for the ESBWR have: (1) defined the plant functions that are relied upon to satisfy plant safety objectives, and (2) allocated those functions to human and system resources in a way that takes advantage of human strengths and avoids human limitations. DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the FRA and FA are completed in accordance with the IPs (NEDO-33219, Revision 4, and NEDE-33220P, Revision 4), which the staff has reviewed and approved. Accordingly, the staff concludes that the applicant's FRA and FA are acceptable at the IP level.

18.5 Task Analysis

18.5.1 Regulatory Criteria

The objective of reviewing task analysis is to verify that the applicant's task analysis identifies the specific tasks that are needed for function accomplishment and their information, control, and task-support requirements.

To review the applicant's task analysis plan, the staff used the review criteria in NUREG-0711, Section 5.4.

18.5.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.5, "Task Analysis," describes the ESBWR task analysis. DCD Tier 2, Revision 6, Section 18.5, incorporates by reference NEDE-33217P, Revision 6, and NEDO-33221, Revision 4, "ESBWR HFE Task Analysis Implementation Plan."

The staff also reviewed the following ESBWR documents:

- GEH responses to RAIs 18.5-1 through 18.5-40 (MFN 07-624, MFN 08-662, MFN 09-024, MFN 09-087, MFN 09-246, and MFN 09-346)
- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 6
- ESBWR DCD Tier 2, Chapter 19, "PRA & Severe Accident," Revision 6
- NEDO-33201, "ESBWR Probabilistic Risk Assessment," Revision 5

In addition to reviewing the applicant's design documents, the staff conducted a regulatory audit in January and July 2007, to examine the initial application of the processes described in these documents to the ESBWR design and to evaluate the documentation of the results. Following

design certification, the staff will need to verify the final results of the design analyses, either in the COL application or through the ITAAC process, to ensure that the design was completed in accordance with the process specified in the design certification, as reflected in the DAC.

18.5.3 Staff Evaluation

The staff performed an IP level of review as described in NUREG-0711 and Section 18.1 of this report. This section presents the applicable review criteria from NUREG-0711 (reproduced below) followed by an evaluation of each criterion. In addition, this section also addresses related documents (i.e., DCD Tier 1 and Tier 2 information).

18.5.3.1 NUREG-0711 Review Criteria

NUREG-0711 includes seven criteria for this topic. However, the seventh criterion relates to plant modifications and is not applicable to new plant designs.

(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.

Evaluation of Criterion (1)

The applicant operational analyses include FRA, FA, and task analysis. These analyses are performed in an iterative, top-down fashion. NEDO-33221, Revision 4, establishes a scope for task analysis that includes a comprehensive range of tasks. Section 1.2 states that the analyses address the following:

- startup
- normal operations
- abnormal and emergency operations
- transient conditions
- low power operation
- shutdown conditions

In addition, the plan's scope includes:

- operation support during periods of maintenance and tests of plant systems and equipment, including HSI equipment

- evaluation of tasks that are risk important as determined by the HRA/PRA

- identification of minimum inventory HSIs

The Task Analysis Plan scope includes important tasks, the full range of plant operating modes, risk-important HAs, and critical automated functions, as described in detail above. Accordingly, the staff finds the Task Analysis Plan's treatment of the criterion for scope acceptable.

(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 Table 5.1 of NUREG-0711.

Evaluation of Criterion (2)

In RAIs 18.5-5 and 18.5-19, the staff identified that the applicant's proposed task analysis methodology needed to (1) provide step-by-step, specific guidance on how to perform the task analysis, (2) clarify that the methodology was an actual plan for performing a task analysis rather than a compilation of recommended practices, (3) clarify task analysis methods, and (4) define risk-important HAs. As documented through several supplemental RAIs, the staff determined that the necessary level of detail was in the applicant's internal work instructions and needed to be incorporated into the IPs, NEDO-33221 and NEDO-33217. RAIs 18.5-5 and 18.5-19 were being tracked as open items in the SER with open items. In response to these RAIs, the applicant provided the information at a level of detail sufficient for the staff to complete its review of the task analysis methodology and incorporated this information into the appropriate IPs. The staff evaluation of the IP, as updated through the RAI responses, is described below. Based on the applicant's responses and NEDE-33221P and NEDO-33217P revisions, RAIs 18.5-5 and 18.5-19 are resolved.

NEDO-33221, Revision 4, Sections 4.1 and 4.2, provide an overview of the ESBWR task analysis methodology for system-level analyses and plant-level analyses, respectively. Appendices B and C of NEDE-33221P, Revision 4, describes the methodology for each analysis in detail. Sections 4.1 and 4.2 identify the inputs to the task analyses and include the results of the FRA, FA, and identification of risk-important actions.

NEDO-33221, Revision 4, Sections 4.1.3 and 4.2.3, provide an overview of the process to be used by task analysts. Appendices B, and C of NEDE-33221P, Revision 4, describe the process in step-by-step detail. The process includes steps for identifying tasks, sequencing tasks in a logical order, identifying design elements required for task completion (discussed further below), and identifying operating instructions and procedures. While the specific processes differ slightly, depending on whether the analyses are conducted for plant-level or system-level tasks, the methodology is largely consistent. High-level task descriptions, or narratives, are developed and analyzed until task performance elements and task termination criteria are identified.

NEDO-33221, Revision 4, Sections 4.1.4 and 4.2.4, lists the outputs of the task analysis. The outputs include the types of considerations identified in NUREG-0711, Table 5.1. NEDE-

33221P, Revision 4, provides proprietary information describing the administrative controls and methodology for performing the task analysis, which are evaluated in the proprietary SER. In general, the task analysis methodology includes step by step direction for addressing the considerations identified in the NUREG-0711, Table 5.1.

Accordingly, the staff finds the Task Analysis Plan's treatment of the criterion for task analysis methods acceptable.

(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.

Evaluation of Criterion (3)

The methodology presented is an iterative analysis leading to task requirements for HSI design. NEDO-33221, Revision 4, page 1, states that the operations analyses, including FRA, allocation of function, and task analysis, "is an iterative integration of the three elements of functional requirements, FA, and task analysis to establish requirements for the Human-System Interface (HSI) design." NEDE-33221P, Revision 4, Appendices B and C, provide detailed steps for identifying task design elements, including alarms, displays, data processing, and controls, for system-level and plant-level task analysis, respectively. The staff evaluated the level of detail of the task analysis and the associated design elements identified during the July 2007 regulatory audit. The sample results examined provided a comprehensive decomposition of tasks to the point at which individual HSI requirements, including alarms, indications, controls, and communications, were identified. Moreover, the regulatory audit confirmed that NEDO-33221P, Revision 4 outlines the appropriate steps for identifying the task related design elements at an acceptable level of detail. Accordingly, the staff finds the Task Analysis Plan's treatment of the criterion for iterative analysis acceptable.

(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.

Evaluation of Criterion (4)

In RAI 18.5-26, the staff identified that the level of detail describing the workload analysis was insufficient in terms of (1) describing the integration of all tasks into a specific job; (2) providing information regarding workload assessments to list considerations such as workload, crew member skills, and work allocation; and (3) describing the means to evaluate workload. As documented through several supplemental RAIs, the staff determined that the necessary level of detail was in the applicant's internal work instructions and needed to be incorporated into the IP, NEDO-33221. RAI 18.5-26 was being tracked as open item in the SER with open items. In response to the RAI, the applicant provided the information at a level of detail sufficient for the staff to complete its review of the workload analysis methodology and incorporated this information into the appropriate IP, particularly in Appendix A to NEDE-33221P. The staff

evaluation of the IP, as updated through the RAI responses, is described below. Based on the applicant's responses and NEDE-33221P revisions, RAI 18.5-26 was resolved.

NEDE-33221P, Revision 4, Sections 4.1.3.6 and 4.2.3.6, address crew numbers, skills, and the allocation of tasks to form meaningful jobs for system-level analyses and plant-level analyses, respectively. Workload analyses, including both physical and cognitive workload, are used as the primary basis for work distribution. Appendix A, "Workload Analysis Process," to NEDE-33221P, Revision 4, describes the detailed, proprietary methodology. The proprietary SER provides additional detail on how the process used conforms to the NUREG criterion. In general the process is specific and has appropriate interfaces with other parts of the HFE design process. The workload analysis results are applied and the numbers of personnel needed for task performance and their requisite skills are specified during the detailed system-level and plant-level task analyses described in NEDE-33221P, Revision 4, Appendices B and C, respectively.

Accordingly, the staff finds the Task Analysis Plan's treatment of the criterion for task analysis issues acceptable.

(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.

Evaluation of Criterion (5)

In RAI 18.5-27, the staff requested that the applicant explain how Minimum Inventory is identified and what criteria are used in the selection process. As documented through several supplemental RAIs, the staff determined that the DCD needed to include the Minimum Inventory and the process to develop it. RAI 18.5-27 was being tracked as an open item in the SER with open items. In the applicant's response to RAI 18.5-27 and related RAIs, the applicant revised DCD Tier 2, Revision 6, Section 18.5.1, to describe the process used to determine Minimum Inventory and included the Minimum Inventory in DCD Tier 2, Revision 6, Tables 18.1-1a and 18.1-1b. The staff evaluates Minimum Inventory and its development as set forth in Section 18.14 of this report and finds it acceptable. Based on the applicant's response and DCD revisions, RAI 18.5-27 is resolved.

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

Evaluation of Criterion (6)

NEDO-33221, Revision 4, Sections 4.1.4 and 4.2.4, identify system-level task analysis and plant-level task analysis outputs, respectively, for HSIs, procedures, and training program design. NEDO-33221, Revision 4, Figure 3, depicts the relationship between these two sections. The staff evaluated the suitability of the task analyses to support these later design activities during the July 2007 regulatory audit. The sample results illustrated the analysis and break down of high-level functions into the detailed tasks needed to accomplish these functions. These tasks were decomposed into discrete steps that provide a suitable input to procedure development. In fact, the methodology is structured in a way that procedures can be developed directly from the task analysis itself. The availability of results using this format provides detailed input to training development as well. Furthermore, as noted in the discussion of Criterion (3), the HSI requirements for task step completion are defined. Thus, the task analysis

methodology provides comprehensive and detailed input to the development of HSIs, procedures, and training program development. Accordingly, the staff finds the Task Analysis Plan's treatment of the criterion for task analysis input to other HFE elements acceptable.

18.5.3.2 Relationship to Other Documents

18.5.3.2.1 DCD Tier 1, Section 3.3, "Human Factors Engineering"

DCD Tier 1, Revision 6, Table 3.3-2, contains the Tier 1 ITAAC developed by the applicant for HFE. Table 3.3-2 contains 10 items, one for each element of NUREG-0711 (except HFE program management, procedures and training) plus one item that addresses integrated system validation scenarios. Each item in Table 3.3-2 is linked to the corresponding ESBWR element IP. As described in Section 14.3.9 of this report, DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the task analysis is completed in accordance with the IP (NEDE-33221P, Revision 4), which the staff has reviewed and approved.

18.5.3.2.2 DCD Tier 2, Section 18.5, "Task Analysis"

In RAI 18.5-30, the staff identified that the task analysis methodology presented in NEDO-33221, Revision 1, was not consistent with the methodology summarized in DCD Tier 2, Revision 3, Section 18.5. For example, the IP discusses two major levels of analysis - plant and system - while the DCD did not. RAI 18.5-30 was being tracked as an open item in the SER with open items. In its response, the applicant explained that while different terminology is used, the DCD Tier 2, Chapter 18, identifies both plant-level and system-level analyses. In addition, the applicant rewrote DCD Tier 2, Revision 5, Section 18.5 to address the staff's concerns. As described below, the staff finds the revised Section 18.5 acceptable. Based on the applicant's response and revisions to the DCD, RAI 18.5-30 is resolved.

DCD Tier 2, Revision 6, Section 18.5, provides a high-level description of the ESBWR task analysis that ensures that the applicant's task analysis identifies the specific tasks that are needed for function accomplishment and the information and design elements needed for task accomplishment. This section of the DCD also references the detailed IP (NEDE-33221P, Revision 4), and is designated as Tier 2*. As discussed above, NEDE-33221P, Revision 4, describes a task analysis methodology which addresses the NUREG-0711 criteria for task analysis. Thus, Tier 2, together with the referenced IP provides an acceptable description of the ESBWR task analysis.

18.5.4 Conclusions

The staff reviewed the task analysis at an IP level (see Section 18.1.4 of this report for a discussion of review levels) using the review criteria in Section 5.4 of NUREG-0711. The staff concludes that the ESBWR task analysis, as described in NEDE-33221P, Revision 4, provides an acceptable methodology for analyzing the number and qualifications of personnel in a systematic manner that demonstrates a thorough understanding of operational functions and tasks. DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the task analysis is completed in accordance with the IP (NEDE-33221P, Revision 4), which the staff has reviewed and approved. Accordingly, the staff concludes that the applicant's task analysis is acceptable at the IP level.

18.6 Staffing and Qualifications

18.6.1 Regulatory Criteria

The objective of reviewing staffing and qualifications is to verify that the applicant has systematically analyzed the need for the number and qualifications of personnel and has demonstrated a thorough understanding of task requirements and regulatory requirements.

The NUREG-0711 criteria addressing staffing and qualification have a small overlap with the SRP Section 13.1 which addresses plant staff organization. The overlap is limited to verifying 10 CFR 50.54(m) is met. In accordance with SRP Chapter 13, the staff evaluates plant staff organization as an operational program. In SRP Chapter 18, the staff evaluates staffing and qualifications as input to the HFE design. Initial staffing levels and qualifications may be assumed but the analysis completed as part of the HFE design verifies that these assumptions are correct for the full range of plant conditions and operating tasks. This HFE analysis is not addressed in the operational program element of SRP Chapter 13.1. Consequently, use of an ITAAC to assess the completed design product is appropriate.

To review the applicant's staffing and qualifications plan, the staff used the review criteria in NUREG-0711, Section 6.4.

18.6.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.6, "Staffing and Qualifications," describes the ESBWR staffing and qualifications. DCD Tier 2, Revision 6, Section 18.6, incorporates by reference NEDE-33217P, Revision 6, and NEDO-33266, Revision 3, "ESBWR Human Factors Engineering Staffing and Qualifications Implementation Plan, May 2008."

The staff also reviewed the following ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 6
- ESBWR DCD Tier 2, Chapter 19, "PRA & Severe Accident," Revision 6
- NEDO-33201, "ESBWR Probabilistic Risk Assessment," Revision 5
- GEH response to RAIs 18.6-1 through 18.6-10 (MFN 06-402 and MFN 08-088)
- General Electric ESBWR Baseline Record Review (BRR), Draft 1A, January 2007, (audited material)
- GEH ABWR FOAKE Plant Staffing Evaluation, Revision 0, May 24, 1996, (audited material)

18.6.3 Staff Evaluation

The staff performed an IP level of review as described in NUREG-0711 and Section 18.1 of this report. This section presents the applicable review criteria from NUREG-0711 (reproduced below) followed by an evaluation of each criterion. In addition, this section also addresses related documents (i.e., DCD Tier 1 and Tier 2 information).

18.6.3.1 NUREG-0711 Review Criteria

NUREG-0711 includes four criteria for this topic, as described below.

(1) Staffing and qualifications should address applicable guidance in SRP Section 13.1 and 10 CFR 50.54.

Evaluation of Criterion (1)

NEDO-33266, Revision 3, Section 3.2, Table 1, specifies the initial baseline shift staffing and qualifications for the ESBWR. This includes two senior reactor operators (SROs) (the shift manager and the CR supervisor), two reactor operators, and two auxiliary operators. This satisfies the minimum requirements specified in 10 CFR 50.54(m)(2)(i) for a single-unit nuclear power plant. DCD Tier 2, Revision 6, Section 18.6.2, Section 18.6.3, and Table 18.6-1, also specify the ESBWR initial baseline staffing assumptions, which are the same as those in the plan. The staff finds this acceptable.

DCD Tier 2, Chapter 13, "Conduct of Operations," addresses the other aspects of 10 CFR 50.54(i) through 10 CFR 50.54(m) (e.g., requirements for an operator at the controls). DCD Tier 2, Section 13.1.1, Revision 6, identifies COL Item 13.1.1-A, which states that the COL applicant referencing the ESBWR will submit documentation that demonstrates that its organizational structure is consistent with the ESBWR HFE design and complies with the requirements of 10 CFR 50.54(i) through 10 CFR 50.54(m). The staff finds this COL information item acceptable since it identifies that the COL needs to address the remaining aspects of this criterion. Section 13.1 of this report further evaluates the COL item. Accordingly, the staff finds the Staffing and Qualifications Plan's treatment of the criterion for SRP Section 13.1 and the requirements of 10 CFR 50.54, "Conditions of Licenses," acceptable.

(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 Section 2.4.1, Criterion 5).

Evaluation of Criterion (2)

NEDO-33266, Revision 3, Section 1.2, specifies that the staffing analyses address activities during normal power operation, as well as during transient and accident events included in the plant design basis. Section 1.3.1 of the plan defines transient events as initiating events that can result in emergency conditions requiring prompt operator actions to avoid damage or accidents that damage structures, systems, or components (SSCs).

The plant staff must carry out tasks related to qualification, repair, maintenance, recordkeeping, configuration control, monitoring, surveillance, and testing of plant equipment during startup, normal operations, abnormal operations, transient conditions, low power, and shutdown conditions. NEDO-33266, Revision 3, Section 1.2, also identifies the applicable plant personnel addressed by the HFE program, including licensed CR operators, nonlicensed operators, shift supervisor, shift technical advisor, instrument and control technicians, electrical and mechanical maintenance personnel, radiological protection technicians, chemistry technicians, and engineering support personnel. In addition, any other plant personnel who perform tasks that

are directly related to plant safety are addressed. This includes all of the personnel identified in the HFE program management element of NUREG-0711, Section 2.4.1, Criterion (5).

The Staffing and Qualifications Plan identifies the number and background of personnel for the full range of plant conditions and tasks as described in detail above. Accordingly, the staff finds the Staffing and Qualifications Plan's treatment of the criterion for number and background of personnel acceptable.

(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.

Evaluation of Criterion (3)

NEDO-33266, Revision 3, Figures 1 and 2, illustrate the staffing analysis process, including how it depends on, and interfaces with, the other HFE program elements. Table 1 of the plan shows the preliminary operational staffing assumptions for reactor control and monitoring. Figures 1 and 2 illustrate the feedback loops and possible modification of staffing and qualifications as the various elements are completed. This includes blocks for OER, FRA, FA, task analysis, HRA/PRA, and procedures and training. Sections 3 and 4 describe these processes both graphically and narratively. Section 3.1 states the following:

> The number of qualified staff for the ESBWR must be adequate to provide safe operation under design basis and risk important accident conditions. To meet this goal, consideration is given to the numbers and functions of the staff needed to safely perform all required plant operations, maintenance, and technical support for each operational mode...

Sections 3 and 4 provide details on how this is accomplished.

The Staffing and Qualifications Plan is iterative in that it includes reviewing and modifying the initial staffing goal as other analyses are completed as described in detail above. Accordingly, the staff finds the Staffing and Qualifications Plan's treatment of the criterion for an iterative analysis acceptable.

(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 IN 95-48, "Results of Shift Staffing Study"
  - staffing considerations described in NRC IN 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 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, 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

Evaluation of Criterion (4)

As noted under Criterion (3) above, NEDO-33266, Revision 3, ensures that the basis for staffing and qualification includes consideration of OER, FRA, FA, task analysis, HRA/PRA, and procedures and training. A clear link exists between HSI design and the staffing and qualifications defined in the program. The plan includes an initial baseline staffing and qualifications level based on OER from the BWR and ABWR reference plants. A second phase comprises a deterministic analysis that considers the deterministic rules established in the regulations and lessons learned from worldwide operating experience of all reactors, with a focus on BWRs. This phase also considers the SFRA, FA, and task analysis. Phase 3 uses the insight from the HRA/PRA and incorporates feedback in both the staffing analysis and the HRA/PRA. Phase 4 includes screening the various tasks to determine if they are to be performed by the normal crew or whether additional station personnel should be assigned.

Phase 5 determines whether the recommended staffing and qualifications are adequate to safely operate the ESBWR. This is accomplished by evaluating the interface between CR staff, the CR HFE design elements and plant procedures. Part of this evaluation occurs during the HFE V&V program. Further reviews take place as part of the training program development. Section 4.6 of NEDO-33266 describes the phase 5 aspects related to verifying plant staffing and qualifications. Accordingly, the staff finds the Staffing and Qualifications Plan's treatment of the criterion for consideration of HFE program elements acceptable.

18.6.3.2 Relationship to Other Documents

18.6.3.2.1 DCD Tier 1, Section 3.3, “Human Factors Engineering”

DCD Tier 1, Revision 6, Table 3.3-2, Item 1, contains the Tier 1 ITAAC developed by the applicant for HFE. Table 3.3-2 contains 10 items, one for each element of NUREG-0711 (except HFE program management, procedures and training) plus one item that addresses integrated system validation scenarios. Each item in Table 3.3-2 is linked to the corresponding ESBWR element IP. As described in Section 14.3.9 of this report, DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that plant staffing and qualifications are completed in accordance with the IP (NEDO-33266, Revision 3), which the staff has reviewed and approved.

18.6.3.2.2 DCD Tier 2, Section 18.6, “Staffing and Qualifications”

In RAI 18.6-13, the staff requested that the applicant correct the date for NEDO-33266, Revision 1, from March 2007 to January 2007 in DCD Tier 2, Section 18.6.8. In its response, the applicant stated that it would correct the date in DCD Tier 2, Revision 5, which the staff has confirmed. Based on the applicant’s response RAI 18.6-13 is resolved.

DCD Tier 2, Revision 6, provides a high-level description of the staffing and qualifications for the ESBWR, which includes the background, the objectives and scope of staffing and qualification analyses, the ESBWR baseline staffing assumptions, a discussion of the staffing and qualifications IP, and a summary of the methodology of the staffing and qualification analyses. This section of the DCD also references the detailed IP (NEDO-33266, Revision 3), which is designated as Tier 2*. As discussed above, NEDO-33266, Revision 3 describes a staffing and qualification program that addresses the NUREG-0711 criteria for staffing and qualification. Thus, Tier 2 together with the referenced IP provides an acceptable description of the ESBWR staffing and qualification program. Accordingly, the staff finds the DCD Tier 2, Chapter 18 treatment of staffing and qualifications acceptable.

18.6.4 Conclusions

The staff reviewed the ESBWR staffing and qualifications at an IP level (see Section 18.1.4 of this report for a discussion of review levels) using the review criteria in Section 6.4 of NUREG-0711. For reasons set forth above, the staff concludes that the ESBWR staffing and qualifications plan, as described in NEDO-33266, Revision 3, provides an acceptable methodology for analyzing the number and qualifications of personnel in a systematic manner which demonstrates a thorough understanding of operational tasks and applicable regulatory requirements. DCD Tier 1, Section 3.3, provides sufficient ITAAC to confirm that the staffing and qualifications are completed in accordance with the IP (NEDO-33266, Revision 3), which the staff has reviewed and approved. Accordingly, the staff concludes that the applicant’s staffing and qualifications are acceptable at the IP level.

18.7 Human Reliability Analysis

18.7.1 Regulatory Criteria

The objective of reviewing HRA integration is to verify that (1) the applicant has addressed human-error mechanisms in the design of the HFE aspects of the plant to minimize the likelihood of personnel error and to verify errors are detected and recovered from and (2) the HRA activity effectively integrates the HFE program and PRA and risk analysis.

To review the applicant's human reliability analysis plan, the staff used the review criteria in NUREG-0711, Section 7.4.

18.7.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.7, "Human Reliability Analysis," describes the ESBWR HRA. DCD Tier 2, Revision 6, Section 18.7, incorporates by reference NEDE-33217P, Revision 6, and NEDO-33267, Revision 4, "ESBWR Human Factors Engineering Human Reliability Analysis Implementation Plan."

The staff also reviewed the following ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 6
- ESBWR DCD Tier 2, Chapter 19, "PRA & Severe Accident," Revision 6
- NEDO-33201, "ESBWR Probabilistic Risk Assessment," Revision 5
- GEH responses to RAIs 18.7-1 through 18.7-16 (MFN 06-403, MFN 07-499, MFN 8-154, MFN 08-262, MFN 08-298, MFN 08-481, MFN 08-907, MFN 09-297, and MFN 09-753)
- GEH letter, "Submittal of ESBWR DCD Chapter 18, Human Factors Engineering—RAI to DCD Roadmap Document," June 27, 2007 (MFN 07-334)
- NEDO-33411, "Risk Significance of Structures, Systems and Components for the Design Phase of the ESBWR," Revision 0, March 2008

18.7.3 Staff Evaluation

The staff performed an IP level of review as described in NUREG-0711 and Section 18.1 of this report. This section presents the applicable review criteria from NUREG-0711 (reproduced below) followed by an evaluation of each criterion. In addition, this section also addresses related documents (i.e., DCD Tier 1 and Tier 2 information).

18.7.3.1 NUREG-0711 Review Criteria

NUREG-0711 includes four criteria for this topic.

(1) Risk-important HAs 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.

Evaluation of Criterion (1)

In three related RAIs (RAIs 18.7-7, 18.7-8, and 18.7-9) the staff requested that the applicant clarify the list of risk-important HAs, the criteria for determining the risk-important HAs, and the PRA inputs used to determine the risk-important HAs. RAIs 18.7-7, 18.7-8, and 18.7-9 were being tracked as open items in the SER with open items. Through responses to multiple supplemental RAIs, the applicant provided information sufficient for the staff to complete its review of the risk-important HA criteria. The applicant incorporated this information on risk-important HAs into DCD Tier 2, Section 18.7, and NEDO-33267. The staff evaluation of DCD Tier 2, Section 18.7; NEDO-33267; and NEDO-33201, as updated through the RAI responses, is described below. Based on the applicant's responses and document revisions, RAIs 18.7-7, 18.7-8, and 18.7-9 are resolved. Some additional modification to the treatment of risk-important HAs in NEDO-33267 resulted from RAI 18.7-16, as discussed below. These modifications were necessary to address inconsistencies between NEDO-33267, Revision 3, and the ESBWR PRA (NEDO-33201).

DCD Tier 2, Revision 6, Section 18.7.1, provides the scope for using HRA in HFE activities. NEDO-33267, Revision 4, provides a well-detailed overview of the HRA and its integration with the design of the ESBWR and the HFE program. The report 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. NEDO-33267, Revision 4, also provides an overview of the HRA methodology itself and its relationship to the PRA.

NEDO-33267, Revision 4, Section 1.2, states that the scope of the plan includes developing a process for using HRA/PRA (e.g., Level 1, Level 2, internal and external events) to support the design of the ESBWR HSI. DCD Tier 2, Revision 6, Section 18.7.2, states that the process for determining the risk-important HAs includes the use of Level 1, Level 2, internal and external events, and the low power and shutdown PRA. NEDO-33267, Revision 4, defines a HA as a manual response to achieve one task or objective and a human interaction as a set of HAs or a single HA. Section 3.2.1.1 further states that each individual PRA model for core damage frequency (CDF) and large release fraction (LRF) are used to evaluate human interaction importance. Each PRA importance measure is applied to the top event of all PRA submodels (i. e., CDF for Level 1 internal events, LRF for Level 2); all external events, such as fire and flooding; and the shutdown PRA. The importance of each modeled human interaction is measured using risk achievement worth (RAW) and Fussell-Vesely (FV) at each stage of PRA development.

Either HAs or human interactions can be represented as a basic event in a PRA fault tree or as a branch point in the PRA event tree. NEDO-33267, Section 3.2.1 states that the ranking of human interaction tasks will use the risk importance measures of RAW and FV. Section 3.2.1.1 states that the ESBWR PRA first identifies potentially risk-important human interactions and that a goal of the HRA and HFE analyses is to keep the quantitative risk importance of these potentially risk-important actions as low as practical.

For the purpose of HRA and HFE, the applicant initially classified human interactions with an FV value greater than 0.1 and a RAW greater than 2.0 as important to risk. These are typical and acceptable criteria, but the staff noted that these criteria were inconsistent with those in Chapter 17 of the ESBWR PRA (NEDO-33201, Revision 5), which classifies risk-significant actions using values of FV greater than 0.01 and RAW greater than 5.0. In addition, the Design Reliability Assurance Program, described in DCD Tier 2, Section 17.4, uses thresholds similar

to those in the PRA to determine risk-significant SSCs. In RAI 18.7-16, the staff requested that the applicant address this discrepancy.

In its response, the applicant proposed to revise the risk thresholds for the HFE program to agree with those of the PRA. They provided markups of the HRA IP and DCD Tier 2, Chapter 19 that illustrated the changes. The risk-important thresholds are an FV value greater than or equal to 0.01 or a RAW value greater than or equal to 5.0. The staff determined that the RAI response and DCD changes were acceptable because these changes result in the use of consistent criteria for risk-important HA across the applicant's HRA-related documents. The staff notes that both sets of threshold criteria result in the same number of risk important HAs. The staff confirmed the implementation of these changes in NEDO-33267, Revision 4 (the HRA IP). Based on the applicant's response, RAI 18.7-16 is resolved.

Chapter 17 of the ESBWR PRA (NEDO-33201, Revision 5) documents the RAW and FV values of all the HAs in the various portions of the PRA and orders them by each of the importance values. Tables 17.7-1 through 17.7-24 contain this information. Table 17.1-3 summarizes the 39 risk-important HAs that exceed the thresholds; these HAs have not changed with the revised thresholds. Additionally, all of the operator actions listed within the tables of Section 17.7 will be included as inputs to the HFE program.

The DCD and NEDO-33267, Revision 4 is sufficient to define the set of criteria to be used for determining the risk-important HAs for the ESBWR. Accordingly, the staff finds the HRA Plan's treatment of the criterion for risk-important HAs acceptable.

(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).

Evaluation of Criterion (2)

NEDO-33267, Revision 4, Section 3.3, "Application to the ESBWR," states that these relative risk-important human interactions from the HRA/PRA will be used as input to the HFE program (i.e., to support function allocation analyses, task analyses, HSI design, procedure development, and training). This section further notes that the design effort demonstrates how these HA tasks are well supported by the HSI design and that suitable crew members and sufficient time are available to accomplish the action given that the need is detected. Section 4.2 notes that the HRA/PRA information is used to help prioritize maintenance tasks. Accordingly, the staff finds the HRA Plan's treatment of the criterion for use of HRA results in other HFE elements acceptable.

(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.

Evaluation of Criterion (3)

NEDO-33267, Revision 4, Section 3.3, states that HA tasks are analyzed with an emphasis on human error mechanisms. This will minimize the likelihood of operator error for risk-important

HAs by first identifying key human-error mechanisms and then providing means for error detection and recovery capability within the HSI design, procedures, and training elements under the HFE program. Section 3.3 provides examples of how the PRA, HRA, and HFE design processes evaluate human interactions and provide the means necessary to ensure that (1) the human tasks are well supported by the HSI design, (2) sufficient crew members are available, and (3) sufficient time is available to accomplish the actions. Section 4.3.1 notes that, by using importance rankings from the ESBWR PRA, insights are developed for HAs that need attention during design and operation. Where necessary, the HRA/PRA recovery actions are modeled (see discussion in Section 4.4.3) and any that are risk important are identified. These risk-important recovery actions are then processed through the HFE program to provide the HFE support needed to reliably perform the actions. Accordingly, the staff finds the HRA Plan's treatment of the criterion for use of HRA results for error detection and recovery acceptable.

(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.

Evaluation of Criterion (4)

Several sections of NEDO-33267, Revision 4, address this criterion.

Section 3.1, states that the HRA task interacts with the HFE verification and validation program to provide test scenarios and update quantitative evaluations based on data from the validation process.

Section 3.3 notes that a variety of HRA assumptions are validated by using experienced crews with simulation and talk-through analyses.

Section 4.3.3 states that HRA assumptions, risk-important HAs involving diagnosis, decision-making, planning, and implementation strategies during accident responses are validated by techniques such as event simulations or talk through analyses. Personnel with operating experience participate in these exercises.

Section 4.4 states that items listed as assumptions for HRA quantification are confirmed during initial part-task simulations and during the V&V.

Thus, the HRA IP provides commitments and details sufficient to ensure that HRA assumptions will be validated as part of the HSI design and validation process.

Accordingly, the staff finds the HRA Plan's treatment of the criterion for validation of HRA assumptions acceptable.

18.7.3.2 Relationship to Other Documents

18.7.3.2.1 DCD Tier 1, Section 3.3, "Human Factors Engineering"

DCD Tier 1, Revision 6, Table 3.3-2, contains 10 items, one for each element of NUREG-0711 (except HFE program management, procedures and training) plus one item that addresses integrated system validation scenarios. Each item in Table 3.3-2 is linked to the corresponding ESBWR element IP. As described in Section 14.3.9 of this report, DCD Tier 1, Section 3.3,

provides sufficient ITAAC to confirm that the HRA integration is completed in accordance with the IP (NEDO-33267, Revision 4), which the staff has reviewed and approved.

18.7.3.2.2 DCD Tier 2, Section 18.7, "Human Reliability Analysis"

DCD Tier 2, Revision 6, provides a high-level description of the HRA integration activities for the ESBWR that includes the objectives, scope, and methodology for using the HRA/PRA in HFE activities. This section of the DCD also references the detailed IP, NEDO-33267, Revision 4, which is designated as Tier 2*. As discussed above, NEDO-33267, Revision 4 describes an HRA integration program that conforms to the NUREG-0711 criteria for HRA. Thus, DCD Tier 2, Chapter 18, together with the referenced IP provides an acceptable description of the ESBWR HRA integration program. Accordingly, the staff finds the DCD Tier 2, Chapter 18 treatment of HRA acceptable.

18.7.4 Conclusions

The staff reviewed the ESBWR HRA integration at an IP level (see Section 18.1.4 of this report for a discussion of review levels) using the review criteria in Section 7.4 of NUREG-0711. For the reasons set forth above, the staff concludes that the HRA integration program, as described in NEDO-33267, Revision 4, provides an acceptable methodology to (1) address human-error mechanisms in the design of the HFE aspects of the plant to minimize the likelihood of personnel error and (2) verify that errors are detected and recovered from. This methodology also provides the means to ensure that the HRA activity effectively integrates the HFE program and HRA/PRA. DCD Tier 1, Section 3.3 provides ITAAC sufficient to confirm that the HRA integration is completed in accordance with the IP (NEDO-33267, Revision 4), which the staff has reviewed and approved. Accordingly, the staff concludes that the applicant's HRA integration is acceptable at the IP level.

18.8 Human-System Interface Design

18.8.1 Regulatory Criteria

The objective of reviewing HSI design is to verify the process by which HSI design requirements are developed and HSI designs are identified and refined. The review should verify that the applicant has appropriately translated functional and task requirements to the detailed design of alarms, displays, controls, and other aspects of the HSI through the systematic application of HFE principles and criteria.

To review the applicant's HSI design plan, the staff used the review criteria in NUREG-0711, Section 8.4.

18.8.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.8, "Human-System Interface Design," describes the ESBWR HSI design. DCD Tier 2, Revision 6, Section 18.8, incorporates by reference NEDE-33217P, Revision 6; NEDO-33268, Revision 5, "ESBWR Human-System Interface Design Implementation Plan"; and NEDE-33268P, Revision 5.

The staff also reviewed the following ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 6

- GEH responses to RAIs 18.8-1 through 18.8-59 (MFN 06-443, MFN 07-408, MFN 08-050, MFN 08-481, MFN 08-655, MFN 08-661, MFN 09-024, MFN 09-263, MFN 09-264, MFN 09-305, and MFN 09-328)

18.8.3 Staff Evaluation

The staff performed an IP level review as described in NUREG-0711 and Section 18.1 of this report. This section presents the applicable review criteria from NUREG-0711 (reproduced below) followed by an evaluation of each criterion. In addition, this section also addresses related documents (i.e., DCD Tier 1 and Tier 2 information).

HSI design review topics include the following:

- HSI design inputs (four review criteria)
- concept of operations (one review criterion)
- functional requirement specification (three review criteria)
- HSI concept design (five review criteria)
- HSI detailed design and integration (10 review criteria)
- HSI tests and evaluations (two subtopics)
  - tradeoff evaluations (two review criteria)
  - performance-based tests (nine review criteria)
- HSI design documentation (two review criteria)

The staff reviewed the proposed SPDS using the requirements of 10 CFR 50.34(f)(2)(iv) and the criteria set forth in NUREG-0711 and Section 5 of NUREG-0700, "Human-System Interface Design Review Guidelines," issued May 2002. Although the HSI design can be considered a part of the HSI detailed design and integration, the staff reviewed this topic in a separate section because of its importance and the existence of separate review criteria.

Moreover, in addition to reviewing the GEH design documents, the staff conducted regulatory audits in January and July, 2007, to examine the initial application of the processes described in these documents to the ESBWR design and to evaluate the documentation of the results. Following design certification, the staff will need to verify the final results of the design analyses, either in the COL application or through the ITAAC process, to ensure that the design was completed in accordance with the process specified in the design certification.

18.8.3.1 NUREG-0711 Review Criteria

There were nine RAI open items associated with multiple criteria in this section. The applicant has satisfactorily addressed them all, as described below. With the resolution of the RAIs, which in some cases resulted in significant changes to the IP, the applicant now has an IP that

can be evaluated systematically using the NUREG-0711 criteria. Accordingly, only a brief summary of the previously open RAIs is presented to preserve the flow of the remainder of the evaluation against the individual NUREG-0711 criteria.

In RAI 18.8-2, the staff requested that the applicant provide step-by-step guidance on how to perform the HSI design in the HSI Design Plan. As documented through several supplemental RAIs, the staff determined that the necessary level of detail was in the applicant's internal work instructions and needed to be incorporated into the IP, NEDE-33268P. RAI 18.8-2 was being tracked as an open item in the SER with open items. In response to this RAI, the applicant provided the information at a level of detail sufficient for the staff to complete its review of the HSI design criteria and incorporated this information into NEDE-33268P, Appendix A, Revision 5. The staff's evaluation of the IP, as updated through the RAI response, is described below. Based on the applicant's responses and the NEDE-33268P revisions, RAIs 18.8-2 is resolved.

In RAI 18.8-8, the staff requested that the applicant clarify the references to old documents that have been superseded by documents more applicable to modern technology. RAI 18.8-8 was being tracked as an open item in the SER with open items. In its response, the applicant stated that it would reference the latest industry standards and delete references to obsolete standards. The staff then reviewed the references in NEDO-33268, Revision 3 and determined that the applicant referenced appropriate standards. Based on the applicant's response and the NEDO-33268 revision, RAI 18.8 is resolved.

In RAI 18.8-12, the staff requested that the applicant explain the item, "Expanding available information to cover implicit data," in a list of information processing functions in NEDO-33268 Section 4.3.4.16, Revision 0. In its RAI response, the applicant indicated that it would remove the item. The staff determined that the applicant's response was acceptable since the subject item is not a necessary information processing function. Based on the applicant's response RAI 18.8-12 was resolved in the SER with open items. RAI 18.8-12 was being tracked as a confirmatory item in the SER with open items. The staff verified that the item was removed in NEDO-33268, Revision 3 and the confirmatory item is closed.

In RAI 18.8-16, the staff requested clarification of (1) whether the ESBWR alarm response procedures will be computerized, and (2) a statement in NEDO-33268 that "an alarm is annunciated where the operator has the necessary means for initiating corrective actions." RAI 18-8.16 was being tracked as an open item in the SER with open items. Through multiple supplemental responses, the applicant clarified these statements and modified (1) NEDO-33268, Section 4.1.4 Revision 2 to identify that online computer-based procedures are an output of the design process and (2) NEDO-33268, Section 4.3.4.11, Revision 3, item 3.c, to state that, "an alarm is presented as a visual and audible cue in close proximity to where the operator can take corrective action." The staff determined that the applicant's responses are acceptable because they clearly describe the strategy being used to communicate and respond to alarm conditions. This addresses NUREG-0711 guidance stating that the HSI design should be documented to include the detailed HSI description including its form, function and performance characteristics. Based on the applicant's responses, RAI 18.8-16 is resolved

In RAI 18.8-17, the staff requested that the applicant clarify the source of anthropometric data used in HSI design. RAI 18.8-17 was being tracked as an open item in the SER with open items. Through multiple supplemental responses, the applicant clarified that it will use the anthropometric guidance from NUREG-0700 and will justify any deviations from NUREG-0700. The staff determined that the response is acceptable since NUREG-0700 is an appropriate source of anthropometric data. The staff verified that the applicant implemented the proposed

changes in NEDO-33268, Revision 3. Based on the applicant's responses and changes to NEDO-33268, RAI 18.8-17 is resolved.

In RAI 18.8-18, the staff requested that the applicant clarify ambiguous statements on the placement and the form of controls discussed in NEDO-33268, Section 4.3.4.9, Revision 0. RAI 18.8-18 was being tracked as an open item in the SER with open items. Through multiple supplemental responses, the applicant clarified that it would delete the statement on the placement of controls and modify the statement on the form of controls to state that the selection of the type of control is consistent with what the operator needs to navigate or take process control action and with the associated guidance provided in NUREG-0700. The staff determined that the response was acceptable since the meaning of these statements is now clear.NUREG-0700 is an appropriate source for guidance on selecting controller attributes. The staff verified that the applicant implemented the proposed changes in NEDO-33268, Revision 3. Based on the applicant's responses and changes to NEDO-33268, RAI 18.8-18 is resolved.

In RAI 18.8-31, the staff requested that the applicant clarify overlapping and inconsistent descriptions of HSI design and evaluation tools, techniques, methods, and procedures throughout NEDO-33268, Revision 0. RAI 18.8-31 was being tracked as an open item in the SER with open items. Through multiple supplemental responses, the applicant clarified that it would include the same list of items in Sections 3.3.5.6 and 4.3.4.6 of NEDO-33268, Revision 3. The staff determined that the applicant's responses are acceptable since the description of these design and evaluation are now internally consistent. The staff verified that applicant implemented the proposed changes in NEDO-33268, Revision 3. Based on the applicant's responses and changes to NEDO-33268, RAI 18.8-31 is resolved.

In RAI 18.8-32, the staff requested that the applicant clarify an ambiguous statement in NEDO-33268, Revision 0, regarding the criteria to be used in the selection of HSI design and evaluation tools. RAI 18.8-32 was being tracked as an open item in the SER with open items. Through multiple supplemental responses, the applicant clarified that checklists, drawings, mockups, and questionnaires and interviews would be used to gather HSI tests and evaluation data and information. The staff determined that the applicant's responses are acceptable since the description of design selection and evaluation tools is now clear and is consistent. This appropriately addresses the NUREG-0711 guidance stating that the HSI design should be documented to include the detailed HSI description including its form, function and performance characteristics. . The staff verified that applicant implemented the proposed changes in NEDO-33268, Revision 3. Based on the applicant's responses and changes to NEDO-33268, RAI 18.8-32 is resolved.

In RAI 18.8-43 and its supplement, the staff requested that the applicant describe aspects of the HSI plan as it relates to RG 1.22, "Periodic Testing of Protection System Actuation Functions (Safety Guide 22)"; RG 1.47, "Bypassed and Inoperable Status Indication for Nuclear Power Plant Safety Systems"; RG 1.62, "Manual Initiation of Protective Actions"; RG 1.97, "Criteria for Accident Monitoring Instrumentation for Nuclear Power Plants"; RG 1.105, "Setpoints for Safety-Related Instrumentation"; and NUREG-0696, "Functional Criteria for Emergency Response Facilities." RAI 18.8-43 was being tracked as an open item in the SER with open items. In response to the supplement, the applicant added a discussion of these guidelines to NEDO-33268, Section 3.1.3, Revision 3. The staff determined that the applicant's response is acceptable. The HSI design IP now specifically addresses the criterion stating that applicable regulatory requirements should be identified as inputs to the HSI design process. The staff verified that the applicant implemented the proposed changes in NEDO-33268, Revision 3. Based on the applicant's responses and changes to NEDO-33268, RAI 18.8-43 is resolved.

18.8.3.1.1 Human-System Interface Design Inputs

NUREG-0711 identifies several sources of information that provide input to the HSI design process. The review criteria in this section identify these sources of information.

(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.

Evaluation of Criterion (1)

In RAI 18.8-41, the staff requested that the applicant clarify ambiguous design inputs in the HSI design process block diagram in NEDO-33268, Figure 2, Revision 0. RAI 18.8-41 was being tracked as an open item in the SER with open items. Through multiple supplemental responses, the applicant clarified that it added information to address this criterion through other RAIs, including an alternative Figure 2, and that the block diagram was no longer necessary and therefore was deleted. The staff determined that the response is acceptable since sufficient information to address the criterion is available, as described below, without the block diagram.

The staff verified that the applicant implemented the proposed changes in NEDO-33268, Revision 3. Based on the applicant's responses and changes to NEDO-33268, RAI 18.8-41 is resolved.

NEDO-33268, Revision 5, Sections 3.1.4 and 4.1.2, discuss the input of task analysis results to the HSI design. NEDO-33268, Revision 5, Figures 1 and 2, provide a graphic overview of the HSI design process that details the inputs to the process. Key inputs to the process are the results of the OER, operations analysis (including FRA, FA, and task analysis), and staffing analyses.

Regarding OER, Section 3.2.1, "Background," item 1a, specifically states that the ABWRs are included in the OER input for the ESBWR CR design. In addition, the plan commits to reviewing other plant designs with similar HSIs not limited to nuclear plants. Aspects of HSI addressed include use of flat screen displays, soft controls, and alarm prioritization. Lessons learned are incorporated into the OER/BRR for use by system designers.

FRA and FA define the level of automation and the human role, which is further analyzed in task analysis to identify specific displays, data processing, controls, and job support aids needed to accomplish tasks. The HSI design supports these requirements. Section 4.1.2 lists these elements, along with associated attributes identifying decision making, response, and task support needs. Staffing analyses provide input, as well, by identifying tasks performed by individual crew members.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for personnel task requirements development acceptable.

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

Evaluation of Criterion (2)

In accordance with NEDE-33217P, Revision 6, the design process integrates the design of I&C and HFE. This integration provides adequate assurance that the HSI design reflects the constraints imposed by the I&C system. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for I&C system constraints acceptable.

(3) Regulatory Requirements—Applicable regulatory requirements should be identified as inputs to the HSI design process.

Evaluation of Criterion (3)

The applicant has identified applicable NRC requirements and guidance as input to its process, including 10 CFR Part 50, NUREG-0711, and NUREG-0700. NUREG-0696 provides guidance for HSIs for the emergency response facilities. These documents are identified in Section 2.3 and as inputs in various sections of the plan. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for regulatory requirement input acceptable.

(4) Other Requirements—The applicant should identify other requirements that are inputs to the HSI design.

Evaluation of Criterion (4)

In NEDO-33268, Revision 5, the applicant identified additional inputs to the HSI design, including the HRA/PRA and diversity and defense-in-depth (D3) analyses. These are appropriate sources of requirements for HSI design. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for other requirements acceptable.

18.8.3.1.2 Concept of Operations

(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 [with], 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 [are] 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 crew member activities, such as the interaction with auxiliary operators and coordination of maintenance and operations should be addressed.

Evaluation of Criterion (1)

The "Concept of Operation" describes the operator's interface with the HSI design. NEDO-33268, Revision 5 in Sections 3.1.3 and 3.3.5.4 describes the methodology used to develop the concept of operations. In Section 3.1.3, the applicant addresses personnel functions and tasks, staffing and qualifications, and the working environment, including various types of HSIs. Section 3.3.5.4 provides additional detail on the treatment of staffing and qualifications. Staffing composition and roles and responsibilities of individual staff members will be identified. In addition, the concept of operations will address the relationship of plant staff with automation, including its role of monitoring, interacting with, and backing up automated systems. The analysis will include not only process automation, but also automation that will be used in support systems such as computerized procedures.

In RAI 18.8-50, the staff requested that the applicant provide details on how the concept of operations will be developed and documented. As documented through several supplemental RAIs, the staff determined that the necessary level of detail was in the applicant's internal work instructions and needed to be incorporated into the IP, NEDE-33268P. RAI 18.8-50 was being tracked as an open item in the SER with open items. In response to this RAI, the applicant provided the information at a level of detail sufficient for the staff to complete their review of the criterion for concept of operations development and incorporated this information into NEDE-33268P, Appendix A, Revision 4. The staff evaluation of the IP, as updated through the RAI response, is described below. Based on the applicant's responses and the NEDE-33268P revisions, RAI 18.8-50 is resolved.

NEDE-33268P, Revision 5, Appendix A, provides additional proprietary detail on the steps used by the design team to implement the plan. Eight steps are described to develop the concept of operations**.** The proprietary SER outlines these steps to demonstrate how the method conforms to the NUREG criterion. A concept of operations document will be prepared to document the results of the effort. This methodology will provide a suitable concept of operations in support of detailed HSI design.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for concept of operations development acceptable.

18.8.3.1.3 Functional Requirement Specification

(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

Evaluation of Criterion (1)

NEDO-33268, Revision 5, Section 3.1.3, and NEDE-33268P, Revision 5, Appendix A, discuss functional requirements for the HSIs. The concept of operations is developed as described above. The results define HFE design attributes. The design attributes are collected into functional requirements that become design input for the HFE design process.

NEDO-33268, Revision 5, Figure 2, graphically illustrates the relationship between functional requirements and other HSI design activities. Inputs to functional requirements development are shown as OER/BRR, FRA, FA, task analysis and staffing and qualifications analyses. Section 4.1.2 provides additional information in terms of the contributions of these analyses to functional requirement development. Personnel functions and tasks are addressed in each of these 4 elements of the HFE design process. In each element HFE design attributes are identified and collected into functional requirements that become design input to the HFE design process. .

NEDE-33268P, Revision 5, Appendix A provides additional information on functional requirements development. The requirements identified are entered into the requirements tracking software where they are assessed for conformity with NUREG-0700 and incorporated into the style guide. Implementation of HSI guidelines contained in NUREG-0700 provides for an effective interface between the equipment and operators, as well as a safe and comfortable work environment.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for the establishment of functional requirements acceptable.

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

Evaluation of Criterion (2)

In RAI 18.8-51, the staff requested that the applicant provide details on how the HFE team would develop and document the functional requirements for the HSI. As documented through several supplemental RAIs, the staff determined that the necessary level of detail was in the applicant's internal work instructions and needed to be incorporated into the IP, NEDE-33268P. RAI 18.8-51 was being tracked as an open item in the SER with open items. In response to this RAI, the applicant provided the information at a level of detail sufficient for the staff to complete its review of the criterion for concept of operations development and incorporated this information into NEDE-33268P, Revision 4. The staff evaluation of the IP, as updated through the RAI response, is described below. Based on the applicant's responses and the NEDE-33268P revisions, RAI 18.8-51 is resolved.

NEDO-33268, Revision 5, Section 3.1.3, indicates that HSI functional requirements address CDAs. As noted in the evaluation of Criterion (1) above, HSI requirements are tracked using a requirements tracking software and ultimately incorporated into the ESBWR style guide which provides a description of all HSI resources, including CDAs. NEDO-33268, Revision 5, Section 4.3.4.10, "Display Systems," provides examples of functional requirements for the display system.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for identifying CDA specifications acceptable.

18.8.3.1.4 Human-System Interface Concept Design

The development of an HSI concept design, which is mainly discussed in NEDO-33268, Revision 5, Sections 3.1 and 4.1, is one of three key elements of the HSI Design Plan (along with style guide development and detailed HSI design).

(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.

Evaluation of Criterion (1)

The ESBWR concept design is an evolution from a predecessor design, the ABWR (as discussed above). The applicant identified the functional requirements specification as an input to the design process, along with the other inputs discussed in SER Section 18.8.3.1.3 above. Human performance of the predecessor is captured in the OER, documented in the OER/BRR, and made available to the design team. NEDO-33268, Revision 5, Section 4.1.2, discusses how the OER is assessed to provide input to the HSI design process. In NEDE-33268P, Revision 5, the applicant provided specific procedures describing how OER information is used. The HSI implications identified through the analysis of HSI-related OER items is entered into the requirements tracking software, where it is assessed for conformance with NUREG-0700 and incorporated into the style guide. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for concept design acceptable.

(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

Evaluation of Criterion (2)

NEDO-33268, Revision 4, Section 3.1, states that performing an assessment of state-of-the-art HSI technologies is part of the design process. In the July 2007 regulatory audit, the applicant summarized its comprehensive technology assessment, which included evaluations of complex systems beyond current nuclear plant applications. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for a survey of the state of the art acceptable.

(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.

Evaluation of Criterion (3)

The applicant is using a variety of approaches, including the use of operating experience and simulation assessments to enhance the design. In the July 2007 regulatory audit, the applicant provided a review of its assessment of alternative approaches and explained how its analyses are being used to select methods for incorporation into the ESBWR design. These regulatory audit results indicated that the applicant was seriously evaluating alternative approaches in a systematic manner. In NEDO-33268, Revision 5, Section 3.1, the applicant states that they will evaluate alternative concept designs using tradeoff evaluations (evaluations that compare the positive and negative attributes of one design solution against another and identify the better solution). Section 3.3.5.6 provides additional information as to how these evaluations will be accomplished. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for alternative approaches acceptable.

(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.

Evaluation of Criterion (4)

In accordance with NEDE-33268P, Revision 5, Section 3.1, "Concept Design," the ESBWR HSI design reflects the evolution of the ABWR HSIs by taking advantage of ABWR operating experience, as well as that of other complex systems. As an evolutionary design, a list of standard features has been identified to serve as an overall framework for developing the design. The standard features are those ABWR resources, such as the large overview display and workstation arrangement, that are the starting place for the design. Any issues identified in

operating experience, for example, are resolved in the design process. Thus, the applicant is evaluating alternative designs at the level of HSI design details. These evaluations are performed using information from operating experience, literature evaluations, tradeoff studies, and engineering evaluations. Figures in NEDE-33268P, Appendix B, Revision 5, provide forms and measures for performing these analyses. The staff considers this an appropriate approach for an evolutionary design that is based on a proven HSI design with successful operating experience. Such an approach provides selected improvements to the design rather than a complete redesign. Accordingly, the staff finds the HSI Design Plan's treatment of Criterion (4) for evaluating alternative approaches acceptable.

(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.

Evaluation of Criterion (5)

NEDE-33268P, Revision 5, Section 3.1, indicates that HSI performance requirements are based on functional requirements that are refined to reflect HSI considerations identified in a survey that the applicant conducted of state-of-the-art HSI technology. HSI performance requirements are also considered as one of the factors in the HSI tradeoff evaluations. NEDE-33268P, Revision 5, Figure B-2, lists proprietary examples of the factors used. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for design performance requirements acceptable.

18.8.3.1.5 Human System Interface Detailed Design and Integration

During its review of NEDO-33268, Revision 0, the staff determined that it needed additional detail to evaluate Criterion (1) and Criteria (3) through (9). The staff initiated RAIs for each criterion. While the applicant committed to meet each of the objectives in Criterion (1) and Criteria (3) through (9), the applicant provided no guidance on how the objectives would be met. In RAIs 18.8-2 and 18.8-52 through 18.8.58, the staff requested that the applicant provide (1) step-by-step direction on how to perform the HSI design in the HSI Design Plan (Criterion (1), RAI 18.8-2), (2) details on the design and methodology used for minimizing error associated with risk-important actions (Criterion (3), RAI 18.8-52), (3) details on the design and methodology for developing monitoring and control measurements (Criterion (4), RAI 18.8-53), (4) details on the design of the HSI layout (Criterion (5), RAI 18.8-54), (5) guidance on accommodating varying staffing levels in the CR (Criterion (6), RAI 18.8-55), (6) details on the impact on HSIs of fatigue over a shift (Criterion (7), RAI 18.8-56), (7) details on the use of HSIs under a full range of environmental conditions (Criterion (8), RAI 18.8-57), and (8) details on HSI support for test, inspection, and maintenance (Criterion (9), RAI 18.8-58).

For each of these RAIs, as documented through several supplemental RAIs, the staff determined that the necessary level of detail was in the applicant's internal work instructions and needed to be incorporated into the IP, NEDE-33268P. RAIs 18.8-2 and 18.8-52 through 18.8.58 were being tracked as open items in the SER with open items. In response to these RAIs, the applicant provided the information at a level of detail sufficient for the staff to complete its review of the criteria for HSI detailed design and integration and incorporated this information into NEDE-33268P, Appendix A, Revision 5. The applicant also clarified where the methodology to address HSI design is made available, clarified issues regarding the

implementation and use of the HSI style guide, and corrected references to tables, figures, and the appendix in its response to RAI 18.8-2. The staff evaluation of the IP, as updated through the RAI responses, is described below. Based on the applicant's responses and the NEDE-33268P revisions, RAIs 18.8-2 and 18.8-52 through 18.8.58 are resolved.

(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

Evaluation of Criterion (1)

NEDO-33268, Revision 5, Sections 3.2 and 4.2, discuss the development and application of the ESBWR style guide. The style guide addresses the topics outlined throughout the HSI plan which include HSI resources such as CDAs, and SPDS. The materials to be used as an input to the style guide include the operating experience of the ABWR, HFE guidance documents

(such as NUREG-0700), appropriate RGs, and the results of the applicant's evaluation of design tradeoffs. Provisions for modification of the contents of the style guide are identified. In addition, NEDO-33268, Revision 5, Appendix A, provides sample pages from the draft style guide to illustrate the results of the process used and the level of detail provided in the guidance. The guidance is expressed in concrete unambiguous terms. This will permit the guide to be used consistently by design engineers.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for style guide development acceptable.

(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 describes high-level HSI design review principles that the detailed design should reflect.

Evaluation of Criterion (2)

NEDO-33268, Revision 5, Section 3.3.5.2, discusses the general approach the applicant took to addressing the primary role of plant personnel in terms of monitoring/detection, situation awareness, interpretation and planning, control, and feedback. NEDO-33268, Revision 5, Section 3.2, specifies that the ESBWR style guide contain detailed guidance for supporting these roles in terms of the HFE design of individual HSI systems. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for personnel support acceptable.

(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.

Evaluation of Criterion (3)

NEDO-33268, Revision 5, Section 3.3.4 indicates that the design seeks to minimize the probability of errors involving risk-important actions and maximize the probability of error detection. NEDE-33268P, Revision 5, Appendix A, provides proprietary work process steps to accomplish this objective. In general, many different factors that affect the operator's ability to perform each HA are evaluated. The proprietary SER provides a summary of these work steps to illustrate how the process conforms to the NUREG criterion.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for addressing risk-important actions acceptable.

(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

Evaluation of Criterion (4)

NEDO-33268, Revision 5, Section 3.3.4, indicates that, in developing HSI monitoring and control measures, the following considerations are addressed: (1) communication, coordination, and workload; (2) feedback; (3) local environment; (4) inspection, test, and maintenance; and (5) risk-importance. In NEDE-33268P, Revision 5, Appendix A, the applicant provides additional proprietary information adressing each of the considerations. The proprietary SER summarizes the process used for each consideration so that there is a clear demonstation of how each consideration is managed. By describing what considerations are addressed as well as how they are managed, the applicant provides a complete explanation of how its HSI design process conforms to this criterion.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for monitoring and control capabilities acceptable.

(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.

Evaluation of Criterion (5)

NEDO-33268, Revision 5, Section 3.3.4 indicates that the layout of HSIs is based on a job analysis; strategies for organization, such as by importance; and accommodation of D3 (defense in depth, diversity) design considerations. NEDE-33268P, Revision 5, Appendix A, provides proprietary work process steps to accomplish these objectives. The proprietary SER identifies the specific steps that demonstrate conformance to this criterion.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for HSI layout acceptable.

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

Evaluation of Criterion (6)

NEDO-33268, Revision 5, Section 3.3.4 indicates that the HSI design will support personnel and task performance during different staffing levels. NEDE-33268P, Revision 5, Appendix A, provides proprietary work process steps to accomplish this objective. The proprietary SER identifies the specific steps that demonstrate conformance to this criterion. The approach addresses the HSI design's accommodation of varying staffing levels.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for accommodation of varying staffing levels acceptable.

(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.

Evaluation of Criterion (7)

NEDO-33268, Revision 5, Section 3.3.4, indicates that the HSI design process will address the use of HSIs across a shift. NEDE-33268P, Revision 5, Appendix A, provides proprietary work

process steps to accomplish this objective. The proprietary SER identifies the specific steps that demonstrate conformance to this criterion. The approach addresses the HSI design's accommodation of shift duration.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for accommodation of shift duration acceptable.

(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).

Evaluation of Criterion (8)

NEDO-33268, Revision 5, Section 3.3.4, indicates that the HSI will support human performance under a range of environmental conditions. NEDE-33268P, Revision 5, Appendix A, provides proprietary work process steps to accomplish this objective. The proprietary SER identifies the specific steps that demonstrate conformance to this criterion. The approach addresses the HSI design's support for human performance under a range of environmental conditions.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for accommodation of environmental conditions acceptable.

(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).

Evaluation of Criterion (9)

NEDO-33268, Revision 5, Section 3.3.4, indicates that the HSI will be designed to support test, inspection, and maintenance activities. NEDE-33268P, Revision 5, Appendix A, provides proprietary work process steps to accomplish this objective. The proprietary SER identifies the specific steps that demonstrate conformance to this criterion. The approach addresses the HSI design's support for test, inspection, and maintenance activities.

Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for accommodation of test, inspection and maintenance activities acceptable.

18.8.3.1.6 Human System Interface Tests and Evaluations

There were three RAI open items associated with multiple criteria in this section. All eleven criteria for the HSI tests and evaluations review topic (including the two criteria for trade-off evaluations and the nine criteria for performance based tests) had open items identified in the SER with open items. The applicant has satisfactorily addressed all of these open items as described below. With the resolution of the RAIs, which in some cases resulted in significant changes to the IP, the applicant now has an IP that can be evaluated systematically against the

NUREG-0711 criteria. Accordingly, only a brief summary of the previously open RAIs is presented to preserve the flow of the remainder of the evaluation against the individual NUREG-0711 criteria.

In RAI 18.8-33, the staff requested the that applicant clarify the HFE activities and ratings listed in NEDO-33268, Revision 2, Figure 5, "Appropriate Data Collection Methods for HFE Activities." RAI 18.8-33 was being tracked as an open item in the SER with open items. In its RAI response, the applicant indicated that it would remove the figure from NEDO-33268. The staff determined that the applicant's response was acceptable since the matrix is not necessary to address the HSI test and evaluation criteria. The staff confirmed that the applicant removed the figure from NEDO-33268, Revision 3. Based on the applicant's response and NEDO-33268 revision, RAI 18.8-33 is resolved.

In RAIs 18.8-35 and 18.8-59, the staff requested that the applicant provide details on (1) the methods used for HSI tests and evaluations (RAI 18.8-35) and (2) tradeoff evaluations. As documented in each of these RAIs and several supplemental RAIs, the staff determined that the necessary level of detail was in the applicant's internal work instructions and needed to be incorporated into the IP, NEDE-33268P. RAIs 18.8-35 and 18.8-59 were being tracked as open items in the SER with open items. In response to these RAIs, the applicant provided the information at a level of detail sufficient for the staff to complete its review of the criteria for HSI tests and evaluations and incorporated this information into NEDE-33268P, Appendix B, Revision 5. The staff evaluation of the IP, as updated through the RAI responses, is described below. Based on the applicant's responses and the NEDE-33268P revisions, RAIs 18.8-35 and 18.8-59 are resolved.

18.8.3.1.6.1 Trade-Off Evaluations

(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.

Evaluation of Criterion (1)

NEDO-33268, Revision 5, Section 3.3.5.6, and NEDE-33268P, Revision 5, Appendix B, describe the use of tradeoff evaluations. These sections provide a proprietary list of key criteria to compare in trade-off evaluations. The proprietary SER describes how this list is used and provides examples of key selection criteria that include those in this criterion as well as others the applicant has added. This approach acceptably addresses the identification of selection criteria for tradeoff evaluations. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for tradeoff evaluation criteria acceptable.

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

Evaluation of Criterion (2)

NEDO-33268, Revision 5, Section 3.3.5.6, and NEDE-33268P, Revision 5, Appendix B, describe the use of tradeoff evaluations. These sections indicate that the HFE team uses tradeoff evaluations to determine the relative benefits of selected design alternatives. NEDE-33268P, Revision 5, Appendix B, provides a proprietary explanation of the selection process. In general the methods being used are quantitative. The proprietary SER summarizes the explanation to demonstrate conformance to the NUREG criterion. The approach acceptably identified the explicit benefits of each design alternative and the basis for the alternative selected. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for benefits of design alternatives and basis for selection acceptable.

18.8.3.1.6.2 Performance-Based Tests

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

Evaluation of Criterion (1)

NEDO-33268, Revision 5, Section 3.3.5.6, describes performance-based tests. This section recognizes that performance tests must be specifically defined so the test satisfies the objective. Appendix B section B.3(3) of the same document directs that an "appropriate hypothesis for testing" be identified. A proprietary testing process is specifically defined in Appendix B, section B.1, "Evaluation of Goal Establishment." In general the process requires specific information on the proposed test and its purpose. The proprietary SER summarizes how this testing process is initiated which illustrates how conformance to this criterion is obtained. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for hypothesis structuring acceptable.

(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.

Evaluation of Criterion (2)

NEDO-33268, Revision 5, Section 3.3.5.6, describes performance-based tests. This section indicates that the tests performed will depend on the specific purpose of the evaluation, the questions being addressed, and the maturity of the design. Appendix B, Section B.1 describes how test objectives are developed as part of "evaluation Goal Establishment." The evaluation of Criterion (1) above describes how this is done. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for test objective development acceptable.

(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.

Evaluation of Criterion (3)

NEDO-33268, Revision 5, Section 3.3.5.6, and NEDE-33268P, Revision 5, Appendix B, describe performance-based tests. Design feature definition is identified in the test and evaluation direction found in NEDE-33268P, Revision 5, Appendix B, Section B.1, paragraph 1 and Figure B-1. Appendix B further identifies that specific design features or characteristics to be evaluated in a test. This includes a description of how features are systematically varied as part of the test. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for feature definition acceptable.

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

Evaluation of Criterion (4)

NEDO-33268, Appendix B, Section 3.3.5.6, and NEDE-33268P, Revision 5, Appendix B, describe performance-based tests. These sections indicate that testbed selection is based on testing objectives and design maturity. A variety of testbeds are discussed, including mockups and part-task simulators. Full-scope simulators will be used for integrated system validation. The plan states that dynamic simulators are used when the detailed design analysis relies upon critical human performance. NEDE-33268P, Revision 5, Appendix B, Section B3, paragraph 4, identifies proprietary procedures for testbed selection. Generally the criteria are specific and address those areas identified in the criterion. The proprietary SER provides examples of specific criteria use for test bed selection in order to demonstrate conformance with the NUREG criterion. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for testbed selection acceptable.

(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.

Evaluation of Criterion (5)

NEDO-33268, Revision 5, Section 3.3.5.6, describes performance-based tests. This section indicates that performance measures are selected based on measurement characteristics, identification and selection of variables, and performance criteria. A variety of performance measurement categories are identified, including system measures, personnel primary task measures, secondary tasks, errors, situation awareness, workload, and communications. NEDE-33268P, Revision 5, Appendix B, provides additional detail on how tests and evaluations are performed. Figure B-4 provides additional proprietary information on some of the specific measures to be used and their acceptance criteria. The proprietary SER provides an example of a measure and its acceptance criteria to demonstrate conformance with the NUREG criterion.

The applicant has provided a reasonable basis for the performance measures they are using. The specificity of the performance measures provides reasonable assurance that specific,

meaningful conclusions can be reached on the testing objectives. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for performance measurement acceptable.

(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.

Evaluation of Criterion (6)

NEDO-33268, Revision 5, Section 3.3.5.6, and NEDE-33268P, Revision 5, Appendix B, describe performance-based tests. These sections indicate that the selection of participants depends on the purpose of the evaluation and design maturity. NEDE-33268P, Revision 5, Appendix B, Section B3, paragraphs 8 and 9, provide proprietary details on how participant selection is accomplished. The proprietary SER identifies the specific detail that demonstrates the selection process conforms to this NUREG criterion. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for participant selection acceptable.

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

Evaluation of Criterion (7)

NEDO-33268, Revision 5, Section 3.3.5.6, and NEDE-33268P, Revision 5, Appendix B, describe performance-based tests. These sections indicate that the test design will minimize bias, confounds, and error variance. NEDE-33268P, Revision 5, Appendix B, Section B3, paragraph 10, addresses minimizing bias, confounds, and error variance. Specific proprietary techniques are described to exlain how this is accomplished. The proprietary SER summarizes this material to illustrate how conformance to the NUREG criterion is accomplished. . Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for minimizing bias, confounds, and error variance acceptable.

(8) Test data should be analyzed using established analysis techniques.

Evaluation of Criterion (8)

NEDE-33268P, Revision 5, Appendix B, Section B3, paragraph 5, describes proprietary approaches to data analysis. The proprietary SER summarizes this material to illustrate how conformance to the NUREG criterion is accomplished. The tests identified are acceptable in the applications in which they are being used. Accordingly, the staff finds the HSI Design Plan' treatment of the criterion for data analysis acceptable.

(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.

Evaluation of Criterion (9)

NEDO-33268, Revision 5, Section 3.3.5.6, and NEDE-33268P, Revision 5, Appendix B, describe performance-based tests. These sections indicate that design solutions are developed to address problems that are identified during the testing and evaluation of the HSI design. NEDE-33268P, Revision 5, Appendix B, Section B3, paragraph 13, indicates that test reports should identify recommendations for potential design resolutions, for example, (e.g.,

modifications to HSIs) or training. The design procedures described in NEDE-33268P, Revision 5, Appendix A, are used to address the analysis of potential solutions. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for development of design solutions acceptable.

18.8.3.1.7 Human System Interface Design Documentation

(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.

Evaluation of Criterion (1)

NEDO-33268, Revision 5, Section 5.1, identifies the contents of the results summary report. The plan specifies that the summary report is written in sufficient detail to document how the HSI design methodology presented in the plan was implemented to provide the results. Included in its contents are the approach to HSI design, the style guide and design bases, the methods used for test and evaluation, and the process for refining and updating the HSI design.

The HSI Design Plan provides for documenting the HSI design, including the detailed HSI design description, the basis for the HSI requirements and design characteristics, and records of the basis for design changes as described in detail above. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for HSI design documentation acceptable.

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

Evaluation of Criterion (2)

As noted in the evaluation under Criterion (1) above, the applicant's HSI design plan specifies that a results summary report is prepared to document the methodology presented in the plan. This includes activities described in NEDO-33268, Revision 5, Section 3.3.5.6, "Tests and Evaluations." The HSI Design Plan also includes documenting the outcomes of tests and evaluations performed in support of HSI design. Accordingly, the staff finds the HSI Design Plan's treatment of the criterion for documentation of outcomes acceptable.

18.8.3.2 Safety Parameter Display System Design

The staff focused its review on an evaluation of 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), and the criteria contained in NUREG-0711 and NUREG-0700, Section 5. The NRC previously used NUREG-0737, "Clarification of TMI Action Plan Requirements," Supplement 1, and NUREG-1342, "A Status Report Regarding Industry Implementation of Safety Parameter Display System," issued April

1989, for review guidance, but this guidance has been subsumed into Section 5 of NUREG-0700. NUREG-0711, Section 8.4.5, "HSI Detailed Design and Integration," which is evaluated above, also refers to NUREG-0700. This review considered the extent to which the applicant's design processes support the functions required for the SPDS because the applicant has not completed the detailed design of the CR displays. Accordingly, an evaluation of conformance to the requirements of 10 CFR 50.34(f)(2)(iv) and the guidelines of NUREG-0700, Section 5, follow.

(1) 10 CFR 50.34(f)(2)(iv): General SPDS Requirements

Title 10, Subsection 50.34(f)(2)(iv) of the *Code of Federal Regulations* 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.

Evaluation of Criterion (1)

The applicant has requested an exemption from the requirements of 10 CFR 50.34(f)(2)(iv). The applicant addresses the criteria in 10 CFR 50.12, "Specific Exemptions," by proposing an alternative means of meeting the underlying purpose of 10 CFR 50.34(f)(2)(iv). As described in NEDO-33268, Revision 5, Section 4.3.4.18, "SPDS," the applicant addressed the SPDS concerns and criteria with an integrated design, rather than a stand-alone, add-on system as is used at most currently operating plants. The ESBWR design will address the regulatory requirements by integrating features to comply with the SPDS requirements into the design of the alarm and display systems. In the SRP, the staff indicated that' for applicants who are in the early stages of the CR design, the "function of a separate SPDS may be integrated into the overall control room design."

The staff has determined that the special circumstances described in10 CFR 50.12(a)(2)(ii) exist in that application of 10 CFR 50.34(f)(2)(iv) would serve the underlying purpose of that rule in the context of ESBWR design. The applicant has provided an acceptable alternative that accomplishes the purpose of the regulation. The requirement for an SPDS console need not be applied in this particular circumstance to achieve 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 SPDS should provide a concise display of critical plant variables to CR operators to aid them in rapidly and reliably determining the safety status of the plant. For the ESBWR, this purpose is accomplished by the plant alarm and display systems.

On this basis, the staff concludes that special circumstances are present for the proposed exemption from the requirements of 10 CFR 50.34(f)(2)(iv) for an SPDS console. In addition, the proposed exemption is authorized by law, will not present an undue risk to public health and safety, and is consistent with the common defense and security. NUREG-0700 addresses other design guidelines which are evaluated below.

(2) NUREG-0700 Section 5: Specific SPDS guidelines state:

The primary function of these monitoring systems, which operate during all plant conditions, is to present information to aid control room personnel during abnormal and emergency conditions in determining the safety status of the plant and in assessing whether conditions warrant

corrective actions by operators to avoid a degraded core. This function is particularly important during anticipated transients and in the initial phase of an accident.

Evaluation of Criterion (2)

In RAI 18-8.44, the staff requested that the applicant address the guidelines of NUREG-0700, Revision 2, Section 5, since NEDO-33268, Revision 0, only committed to follow the guidelines in the older document, NUREG-0737, Supplement 1. In its response, the applicant stated that it would revise NEDO-33268 to state that the SPDS design is implemented in accordance with NUREG-1342 and NUREG-0700, Revision 2, Section 5, in addition to NUREG-0737, Supplement 1. The staff determined that the applicant's response is acceptable since the applicant committed to a comprehensive set of guidance for the SPDS design. Based on the applicant's response, RAI 18.8-44 is resolved. RAI 18-8.44 was being tracked as a confirmatory item in the SER with open items. The staff verified that the applicant implemented the proposed changes in NEDO-33268, Revision 3. Based on the NEDO-33268 revision, the confirmatory item is closed.

In RAI 18.8-45, the staff requested that the applicant clarify the optional display of SPDS variables in the TSC and EOF as described in NEDO-33268, Section 4.3.4.18, Revision 0. The staff had determined that this approach was inconsistent with NUREG-0696 because the SPDS variables should be available in the TSC and EOF. In its response, the applicant clarified that the SPDS variables that are displayed in the CR will be available in the TSC and EOF. Based on the applicant's response, RAI 18.8-45 is resolved. RAI 18.44 was being tracked as a confirmatory item in the SER with open items. The staff verified that the applicant implemented the proposed changes in NEDO-33268, Revision 3. Based on the NEDO-33268 revision, the confirmatory item is closed.

NEDO-33268, Revision 5, Sections 3.3.5.18 and 4.3.4.18, discuss the SPDS for the ESBWR. The SPDS will display critical plant variables on the wide display panel for the following critical safety functions:

- reactivity control
- reactor core cooling and heat removal from the primary system
- reactor coolant system integrity
- radioactivity control
- containment conditions

These variables are continuously displayed on the large screen display as an integral part of the fixed-position displays. The plan indicates that the SPDS design will be implemented using the guidance from NUREG-0737, Supplement 1; NUREG-1342; and NUREG-0700, Revision 2, Section 5. The SPDS variables that are displayed in the CR will be available in the TSC and EOF as well.

Based on the above, the staff finds the HSI Design Plan's treatment of the NUREG-0700, Section 5 guidelines acceptable. Accordingly, the staff finds the HSI Design Plan's treatment of the SPDS design acceptable.

18.8.3.3 Relationship to Other Documents

18.8.3.3.1 DCD Tier 1, Section 3.3, “Human Factors Engineering”

DCD Tier 1, Revision 6, Table 3.3-2, contains the Tier 1 ITAAC developed by the applicant for HFE. Table 3.3-2 contains 10 items, one for each element of NUREG-0711 (except HFE program management, procedures and training) plus one item that addresses integrated system validation scenarios. Each item in Table 3.3-2 is linked to the corresponding ESBWR IP. As described in Section 14.3.9 of this report, DCD Tier 1, Section 3.3 provides ITAAC sufficient to confirm that the HSI Design is completed in accordance with the IP (NEDO-33268, Revision 5), which the staff has reviewed and approved.

18.8.3.3.2 DCD Tier 2, Section 18.8, “Human-System Interface Design”:

In RAI 18.8-49, the staff identified that the HSI design methodology presented in NEDO-33268, Revision 2, was not consistent with the methodology summarized in DCD Tier 2, Revision 3, Section 18.8. For example, the IP described three major activities: concept design, style guide development, and detailed design and integration; while the DCD did not address concept design. RAI 18.8-49 was being tracked as an open item in the SER with open items. In its response, the applicant explained that, while different terminology is used, the DCD does address concept design. In addition, the applicant rewrote DCD Tier 2, Revision 5, Section 18.8, to address the staff’s concerns. The staff finds the revised Section 18.8 acceptable because the IP and the DCD are now consistent. Based on the applicant’s response and revisions to the DCD, RAI 18.8-49 is resolved.

DCD Tier 2, Revision 6, Section 18.8, provides a high-level description of the ESBWR HSI design process. This section of the DCD also references the detailed IP (NEDE-33268P, Revision 5), which is designated as Tier 2*. As discussed above in Section 18.8.3, NEDO-33268, Revision 5 describes an HSI design process which addresses the NUREG-0711 criteria for HSI design. Thus, Tier 2 together with the referenced IP provides an acceptable description of the ESBWR HSI design process.

18.8.4 Conclusions

The staff reviewed the HSI design at an IP level (see Section18.1.4 of this report for a discussion of review levels) using the review criteria in Section 8.4 of NUREG-0711. For the reasons set forth above the staff concludes that the ESBWR HSI design process, as described in NEDE-33268P, Revision 5, provides an acceptable methodology to (1) develop HSI design inputs and identify and refine HSI designs; and (2) translate functional and task requirements to the detailed design of CDAs and other aspects of the HSI through the systematic application of HFE principles and criteria. DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the HSI design is completed in accordance with the IP (NEDE-33268P, Revision 5), which the staff has reviewed and approved. Accordingly, the staff concludes that the applicant’s HSI design is acceptable at the IP level.

18.9 Procedure Development

18.9.1 Regulatory Criteria

With the exception of NUREG-0711, criterion 7 related to computer based procedures (CBPs), the staff’s evaluation of the applicant’s procedure program is addressed in Section 13.5 of this

report. It has not been included here to avoid redundancy and confusion. With the exception of criterion 7, NUREG-0711 criteria addressing procedure development are a subset of the review criteria contained in the regulatory guidance associated with SRP Section 13.5 which provides guidance on the development and implementation of plant procedures.

In addition to NUREG-0711, Revision 2, the staff also used the following guidance documents for the review of CBPs:

- NUREG-0700, "Human-System Interface Design Review Guidelines," Revision 2, May, 2002

- DI&C-ISG-05, "Highly-Integrated Control Rooms—Human Factors Issues," Revision 1, November 3, 2008

18.9.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.9, "Procedure Development," describes the ESBWR procedure development. DCD Tier 2, Revision 6, Section 18.9, incorporates by reference NEDE-33217P, Revision 6, and NEDO-33274, Revision 5, "ESBWR Human Factors Engineering Procedures Development Implementation Plan."

18.9.3 Staff Evaluation

NUREG-0711, review criteria 1-6 and 8-9 are associated with the applicant's procedure program, which is addressed in Section 13.5 of this report. Therefore, NUREG-0711, review criteria 1-6 and 8-9 are not addressed below. The staff reviewed the use of CBPs using criterion 7 of NUREG-0711, and applicable guidance in NUREG-0700 and DI&C- ISG-05. This review is limited to the HFE design of the CBP interface. It does not address the procedures that are incorporated into the CBP interface.

18.9.3.1 NUREG-0711 Review Criteria

(7): An analysis should be conducted to determine the impact of providing 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.

Evaluation of Criterion (7)

DCD Tier 2, Revision 6, provides a brief discussion of CBPs and references the procedures IP. NEDO-33274, Revision 5, describes the approach to using CBPs and paper backup procedures to operate the ESBWR. NEDO-33274, Revision 5, Section 4.1.3.4, states that, unless the iterative HFE processes shown in Figure 2 dictate otherwise, CBPs are the normal presentation medium for all plant procedures. Duplicate paper-based procedures will provide backup in the event CBPs are not available. CBPs and paper-based procedures are created, revised, and validated using the processes in NEDO-33274, Revision 5.

Section 4.1.3.4 also states that the ESBWR style guide specifies HSI requirements for CBPs and that the appropriate procedure writer's guide specifies the formatting and content for the

CBPs. Section 3.1.4 states that procedures are inputs to the V&V process where they are evaluated to ensure that they meet all necessary attributes.

Based on ongoing technology development, the use of CBPs with paper backups is a generally accepted approach. The NRC has also developed guidance for the evaluation of CBPs in NUREG-0700, Section 8, and DI&C-ISG-05, Criteria 25 through 30. Hence, the staff did not expect the applicant to provide the specific types of analyses identified in the criterion, but rather the information described above.

NEDO-33274, Revision 5, Section 1, "Overview," states that hard copy procedures are developed and maintained for use in the event that the CBP system is lost. CBP and hard copy procedures are developed and written in a coordinated manner to facilitate the smooth transition between the two presentation mediums. Section 4.1.3.1 states that writer's guide requirements and guidelines will insure that CBP and hard copy procedures are developed and written in a coordinated manner to facilitate the smooth transition between the two presentation mediums. Section 4.1.3.3 states that V&V testing and evaluations ensure that both CBPs and hard copy procedures can be effectively performed as written. CBPs and hardcopy procedures for the same tasks are verified to be similarly written, presented, and performed. The philosophy and methods of transitioning between CBPs and hardcopy procedures that are built into the HSI are verified to support smooth transitions. This verification includes both planned transitions to and from CBPs and unplanned transitions from CBPs to hardcopy procedures due to CBP system degradation or failure. The proposed activities for back-up procedures conform to Criteria 25 through 30 of DI&C-ISG-05. Based on the above, the staff finds the Procedures Development Plan treatment of the CBPs acceptable.

18.9.3.2 Relationship to Other Documents

There is no ITAAC for the operational programs, and, therefore, there is no interface with the DCD Tier 1 ITAAC.

DCD Tier 2, Section 18.9, describes procedure development implementation activities. Section 18.9 references NEDO-33274, Revision 5.

18.9.4 Conclusions

The staff reviewed the ESBWR plan for using CBPs and concludes that it conforms to all applicable regulatory guidance as described above.

18.10 Training Program Development

18.10.1 Regulatory Criteria

The staff's evaluation of the applicant's training program is addressed in Section 13.2 of this report. It has not been included here to avoid redundancy and confusion. NUREG-0711 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.

18.10.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.10, "Training Program Development," describes the ESBWR training program development. DCD Tier 2, Revision 6, Section 18.10 incorporates by reference NEDE-33217P, Revision 6, and NEDO-33275, Revision 4, "ESBWR Human Factors Engineering Training Development Implementation Plan."

18.10.3 Staff Evaluation

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

There is no ITAAC for the operational programs, and, therefore, there is no interface with the DCD Tier 1 ITAAC.

18.10.4 Conclusions

The staff's concusions on the applicant's training program are documented in Section 13.2 of this report.

18.11 Human Factors Verification and Validation

18.11.1 Regulatory Criteria

The objective of reviewing human factors V&V is to verify the following:

- The applicant has identified a sample of operational conditions that (1) includes conditions that are representative of the range of events that could be encountered during operation of the plant, (2) reflects the characteristics that are expected to contribute to system performance variation, and (3) considers the safety significance of HSI components. These sample characteristics are best identified through the use of a multidimensional sampling strategy to 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 acceptably 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 operational 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 integrated system validation is not to test the procedures, the opportunity is used to assess whether procedures can be improved and provide a better solution to validation deficiencies than what an HFE design modification would provide. Similarly operator training is relied on to provide the operators participating in the validation test with knowledge of general plant operations and a good knowledge of controls and control board layout. While the primary purpose of the integrated system validation is not to test the operators' ability, the opportunity is used to assess whether training can be improved and provide a better solution to validation deficiencies than what an HFE design modification would provide.

To review the applicant's V&V plan, the staff used the criteria in NUREG-0711, Section 11.4.

18.11.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.11, "Human Factors Verification and Validation" describes the ESBWR HFE V&V. DCD Tier 2, Revision 6, Section 18.11, incorporates by reference NEDE-33276P, Revision 4, "ESBWR HFE Verification and Validation Implementation Plan." The staff also reviewed the following ESBWR documents:

- NEDO-33276, Revision 4, "ESBWR HFE Verification and Validation Implementation Plan"

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 6

- GEH responses to RAIs 18.11-1 through 18.11-37 (MFN 06-386, MFN 08-153, MFN 08-088, MFN 08-281, MFN 08-156, MFN 08-172, MFN 08-481, MFN 08-615, MFN 08-672, MFN 09-017, MFN 09-418, MFN 09-310, MFN 09-264, and MFN 09-714)

18.11.3 Staff Evaluation

The staff identified that significant portions of NEDO-33276 Revision 1, were written as a programmatic description rather than an IP and therefore could not be reviewed at an IP level. In RAI 18.11-36, the staff requested that the applicant provide a detailed IP for V&V rather than a programmatic description of V&V. RAI 18.11-36 was being tracked as an open item in the SER with open items. In its response, the applicant indicated that it would provide information to support an IP level of review through the resolution of the remaining RAIs related to DCD Tier 2, Section 18.11. The applicant provided the level of detail necessary to address these RAIs primarily by incorporating information from its procedures (work instructions) into the IP. As described below, the applicant provided sufficient information to address the NUREG-0711 review criteria and to support an IP level of review. The staff confirmed NEDE-33276P, Revision 2, included the proposed changes.

At an IP level of review, an applicant needs to provide a detailed methodology for developing integrated system validation scenarios and the actual scenarios. Actual scenarios are needed to ensure that integrated system validation produces repeatable results. However, with the information discussed above, the applicant still did not provide actual integrated system validation scenarios to complete the IPs. As an alternative, the applicant proposed an ITAAC to develop actual scenarios by adding Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2. Design Commitment 12 states the following:

> Integrated system validation scenarios are developed that incorporate detailed information related to sampling dimensions, scenario identification, scenario definition, simulation of remote actions, performance measurement characteristics, performance measurement selection, performance measurement criteria, test design, and data analysis.

The ITAAC acceptance criteria state the following:

> The integrated system validation scenarios were developed in accordance with the HF V&V implementation plan and meet the review criteria in the following sections of NUREG-0711, Rev. 2:
>
> - 11.4.1.2.1, Sampling Dimensions
> - 11.4.3.2.2, Validation Test Beds
> - 11.4.3.2.4, Scenario Definition
> - 11.4.3.2.5, Performance Measurement
> - 11.4.3.2.6, Test Design
> - 11.4.3.2.7, Data Analysis and Interpretation"

The staff finds the above use of ITAAC acceptable. As described in the following sections, the applicant has provided an acceptable methodology for developing integrated system validation scenarios. Regarding actual scenarios, the applicant identified that selection and definition of scenarios are predicated on the output of the HFE design process (i.e., producing results from other HFE IPs). The detailed methodologies for developing integrated system validation scenarios as accepted below provide reasonable assurance that the resulting scenarios will result in repeatable integrated system validation. In addition, the use of ITAAC ensures that actual scenarios are produced and made available as a well-defined product. Therefore, providing the actual scenarios through the ITAAC is acceptable. The staff confirmed that DCD Tier 1, Revision 6, included the above ITAAC.

Accordingly, based on the staff evaluation of the applicant's response, the revision to NEDO-33276 and the ITAAC for integrated system validation scenarios, RAI 18.3-36 is resolved.

In addition, this section also addresses related documents (i.e., DCD Tier 1 and Tier 2 information).

As previously noted, the staff performed an IP level of review, as described in NUREG-0711 and Section 18.1 of this report. This section presents an evaluation of the applicant's V&V activities with respect to the applicable review criteria from NUREG-0711 (reproduced below). 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 of which none are applicable)
- design verification (three review topics)
  - inventory and characterization (three review criteria)
  - HSI task support verification (six review criteria of which five are applicable)
  - HFE design verification (four review criteria of which three are applicable)
- integrated system validation (ISV) (nine 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 of which six are applicable)

The criteria not applicable to the ESBWR safety review are those addressing V&V of plant modifications.

Note that criteria that are identified as not applicable to the ESBWR safety review are those addressing V&V of plant modifications.

18.11.3.1 NUREG-0711 Review Criteria

18.11.3.1.1 Operational Conditions Sampling

NUREG-0711, Section 11.4.1, states the following:

> 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

NEDE-33276P, Revision 4, Section 4, discusses operational condition sampling.

18.11.3.1.1.1 Sampling Dimensions

In RAI 18.11-3 and its supplements, the staff requested that the applicant provide detailed implementation information for sampling dimensions rather than a programmatic description, including providing the method to be used to select the set of operational conditions supporting

the sampling dimensions described in NEDO-33276. RAI 18.11-3 was being tracked as an open item in the SER with open items. In its responses, the applicant provided the level of detail to address sampling dimensions primarily by incorporating information from its procedures (work instructions) into the IP. As described below, the staff determined that the applicant provided sufficient information to address the NUREG-0711 review criteria for sampling dimensions and to support an IP level of review. The staff confirmed that NEDE-33276P, Revision 2, included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-3 is resolved.

The sampling dimensions addressed in NUREG-0711, Section 11.4.1.2, include plant conditions, personnel tasks, and situational factors known to challenge personnel performance.

NEDE-33276P, Revision 4 summarizes several areas that will provide input to OCS that include HRA/PRA, task analysis, procedures, the ANSI/ANS standard on simulators for nuclear power plant training, and HED resolutions. Section 4.3 addresses OCS for the ISV.
Section 18.11.3.1.2 of this report addresses the selection of areas for other aspects of design verification.

This section will address each of the three criteria for the sampling dimensions review topic.

(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 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 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] 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.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 4.4.1, Inputs, establishes the overall process for OCS that employs a representative set of conditions and tasks and weighting factors to use in the selection. Section 4.4.1.2, "Minimum Conditions and Tasks," and other portions of Section 4.4, identify the following plant conditions that ISV scenarios will include:

- normal operational events
- failure events, including support system failures (electrical, cooling water, and air), Non-Safety-Related Distributed Control and Information System failure, automation failure, and software display system failure
- transients and accidents, including the use of EOPs, abnormal operating procedures (AOPs), and alarm response procedures (ARPs) that will exercise each leg of the EOP/SAMG flow charts
- risk-important PRA scenarios
- use of various operator panels in the CR, back panels, LCSs, and the remote shutdown station

The above conditions cumulatively address the five sets of plant conditions identified in Criterion (1). Accordingly, the staff finds the V&V Plan's treatment of the criterion for selection of plant conditions acceptable.

(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 SER. Situations where human monitoring of an automatic system is risk-important should be considered. Additional factors should be sampled that contribute highly to risk, as defined by the PRA, including:
  - dominant HA (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. RG 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 [call for] 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 [an] SGTR may [warrant] 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:
  - MCR operators (e.g., operations, shift turnover walkdowns)
  - MCR operators and auxiliary operators
  - MCR operators and support centers (e.g., the technical support center and the emergency offsite facility)
  - MCR operators with plant management, NRC, and other outside organizations
- Tasks that are performed with high frequency.

Evaluation of Criterion (2)

NEDE-33276P, Revision 4, Sections 4.4.1.2 and Section 4.4.1.3, both address the selection of personnel tasks to be included in the ISV. These sections specify that the following types of tasks will be included:

- all risk significant HAs
- all safety systems
- risk-important scenarios within the scope of the EOPs and SAMGs
- risk-important abnormal operational occurrences
- risk-important transients within the scope of the AOPs and ARPs
- operationally difficult tasks from the ESBWR OER

- tasks addressed by procedures in the following categories: administrative, normal plant operations, EOP, AOPs, ARPs, surveillances, testing, maintenance, chemistry, and radiation control

- knowledge-based tasks—each leg of the EOP/SAMG flow charts, support system failures, automation failures, tasks identified in the task analyses as knowledge-based

- operation of first-of-a-kind systems in the ESBWR design

- range of cognitive demands: detection and monitoring, diagnostic, situation assessment, decision making, planning, plant manipulations, monitoring plant response

- range of communication demands as follows: among CR personnel, between the CR and the field, between the CR and emergency support centers, between the CR and plant management, between the CR and other agencies such as local government and the NRC

These sections cumulatively address the six types of personnel tasks identified in Criterion (2). Accordingly, the staff finds the V&V Plan's treatment of the criterion for types of personnel tasks acceptable.

(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.

Evaluation of Criterion (3)

NEDE-33276P, Revision 4, Section 4.4.1.3, addresses further the multidimensional sampling of conditions for selection of ISV scenarios. This section presents measures for addressing a range of situational factors, including the following:

- operationally difficult tasks identified via the ESBWR OER
- scenarios designed to generate human errors
- scenarios with different crew sizes and containing both high and low workload situations
- tasks to examine fatigue and circadian factors
- tasks identified in the ESBWR task analysis as having environmental factors, such as poor lighting, high noise, or radiation

These measures cumulatively address the range of situational factors identified in Criterion (3). Accordingly, the staff finds the V&V Plan's treatment of the criterion for range of situational factors acceptable.

18.11.3.1.1.2 Identification of Scenarios

In RAI 18.11-4 and its supplements, the staff requested that the applicant provide detailed implementation information for identification of scenarios rather than a programmatic description, including the method that it will be us to develop the scenarios so that they reflect the scenario characteristics described in NEDO-33276. RAI 18.11-4 was being tracked as an open item in the SER with open items. In its responses, the applicant provided the necessary level of detail to address the identification of scenarios primarily by incorporating information from its procedures (work instructions) into the IP. As described below, the staff determined that the applicant provided information sufficient to address the NUREG-0711 review criteria for identification of scenarios and to support an IP level of review. The staff confirmed NEDE-33276P, Revision 2, included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-4 is resolved.

This section of the SER addresses each of the two criteria for the identification of scenarios review topic.

(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.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 4.4.1.4, "Weighted Selection of Integrated System Validation Scenarios," describes how the results of the OCS process are combined using a

weighted selection process to identify the actual scenarios for ISV. This ensures that operational diversity is met.

Accordingly, the staff finds the V&V Plan's treatment of the criterion for combining the results of sampling acceptable.

(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)

Evaluation of Criterion (2)

NEDE-33276P, Revision 4, Section 4.4.2, "Scenario Identification and Development," describes in some detail the structured process used to develop the actual scenarios. This section not only describes the overall objective of the scenario development, but also the detailed aspects of constructing scenarios, such as the specification of initial conditions, selecting failure events, and determining other scenario attributes, both qualitative and quantitative. Section 4.4.3, "Measures Taken to Eliminate or Control Bias," lists techniques used to control bias, including procedurally controlled scenario development and validation, pilot studies designed to identify bias, and "backcasting"(An approach that uses both desirable and undesirable outcomes, and develops scenarios with conditions and events that vary the likelihood of reaching the outcome,) After scenario development is completed, the resulting set of scenarios is evaluated to identify any of the challenges identified in this criterion.

Accordingly, the staff finds the V&V Plan's treatment of the criterion for avoiding bias in scenario selection acceptable.

18.11.3.1.2 Design Verification

18.11.3.1.2.1 Inventory and Characterization

NEDE-33276P, Revision 3, Section 3.1, discusses HSI inventory and characterization.

(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.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 3.1.1, describes the scope of the HSI inventory characterization. The plan indicates that the scope includes the personnel tasks associated

with the operational conditions defined as part of the sampling process. This includes HSIs used for interface management tasks. Accordingly, the staff finds the V&V Plan's treatment of the criterion for inventory and characterization scope acceptable.

(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 video display unit screens, and similar samples of HSI components should be included in the HSI inventory and characterization.

Evaluation of Criterion (2)

NEDE-33276P, Revision 4, Section 3.1.4, describes the approach to HSI inventory characterization. The plan specifies that the inventory characterization includes the unique identifier, plant system, personnel functions, HSI characteristics, user interaction types, location in the data management system, and the physical location. Thus the applicant's plan addresses

a methodology to characterize the items in the HSI inventory identified in NUREG-0711. Accordingly, the staff finds the V&V Plan's treatment of the criterion for HSI characterization acceptable.

(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.

Evaluation of Criterion (3)

NEDE-33276P, Revision 4, Section 3.1.3 identifies the inputs and includes software design requirements established during task analysis as well as task analysis, HSI design and other design engineering documents. The applicant's methodology for inventory development specifies the inclusion of photographs, VDU screens, and similar samples of HSI components as part of the inventory. This provides assurance that the subsequent V&V activities are based on an inventory reflecting the current state of the HSI. Accordingly, the staff finds the V&V Plan's treatment of the criterion for inventory information sources acceptable.

18.11.3.1.2.2 Human-System Interface Task Support Verification

NEDE-33276P, Revision 4, Section 3.2, discusses HSI task support verification.

(1) Criteria Identification—The criteria for Task Support Verification come from task analyses of HSI requirements for performance of personnel tasks that are selected operational conditions should be defined. [That is, the criteria for Task Support Verification are the HSI requirements identified by task analysis.]

Evaluation of Criterion (1)

In RAI 18.11-7 and its supplements, the staff requested that the applicant clarify the criteria used in task support verification, including criteria used to evaluate the HSIs that support tasks. RAI 18.11-7 was being tracked as an open item in the SER with open items. In its responses, the applicant provided a detailed description of the task support verification methodology. As described below, the staff determined that the applicant provided information sufficient to address the NUREG-0711 review criterion for the criteria used to identify scenarios. The staff confirmed that NEDE-33276P, Revision 2 included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-7 is resolved.

NEDE-33276P, Revision 4, Section 3.2.4, discusses the methods and procedures for conducting task support verification. It indicates that HSIs are evaluated with respect to the need for HSIs identified in task analysis and provides a detailed breakdown into the aspects of the tasks that are considered. These include task-level objectives and task accomplishments as well as individual task steps.

Accordingly, the staff finds the V&V Plan's treatment of the criterion for task support verification criteria identification acceptable.

(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.

Evaluation of Criterion (2)

In RAI 18.11-8 and its supplements, the staff requested that the applicant clarify the organizational responsibilities for HSI task support verification and explain why the evaluation appeared limited to drawings and computer generated displays. RAI 18.11-8 was being tracked as an open item in the SER with open items. The applicant indicated the HFE design team is responsible for task support verification. The applicant also indicated that the NEDO contains an expanded scope for this analysis, which includes CDAs. As described below, the staff determined that the applicant provided information sufficient to address the NUREG-0711 review criterion for the general methodology for task support verification. The staff verified that NEDE-33276P, Revision 2, contained the proposed changes, Revision 2. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-8 is resolved.

NEDE-33276P, Revision 4, Section 3.2.4, presents the applicant's methodology. The methodology involves comparing the ESBWR HSIs to the personnel task specifications identified in task analysis. This will be accomplished using several available tools, such as full-scope and part-task simulators and computer-generated displays.

Accordingly, the staff finds the V&V Plan's treatment of the methodology for task support verification acceptable.

(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.

Evaluation of Criterion (3)

NEDE-33276P, Revision 4, Section 3.2.5, identifies the conditions for identifying HEDs. These include tasks that are unsupported by HSIs (e.g., a needed alarm is not available), partially supported tasks (e.g., when an HSI does not meet all the task demands), and HSI characteristics that do not match personnel task specifications (e.g., a display that provides a necessary plant parameter, but is not of the precision needed for the task). Accordingly, the staff finds the V&V Plan's treatment of the criterion for task requirement HED identification acceptable.

(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.

Evaluation of Criterion (4)

NEDE-33276P, Revision 4, Section 3.2.5, identifies unnecessary HSI components as a condition warranting an HED. Such an HED is identified if an HSI is not supporting personnel tasks. Accordingly, the staff finds the V&V Plan's treatment of the criterion for identifying unnecessary HSI components acceptable.

(5) 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).

Evaluation of Criterion (5)

NEDE-33276P, Revision 4, Section 3.2.5, discusses the documentation of task support verification results. The documentation includes the HSIs involved, the task criteria, and the basis for any identified deficiencies. The results are maintained in the HFEITS until resolved. Accordingly, the staff finds the V&V Plan's treatment of the criterion for HED documentation acceptable.

18.11.3.1.2.3 Human Factors Engineering Design Verification

(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.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 3.3, discusses HFE design verification. Section 3.3 indicates that this evaluation verifies that each HSI component meets the HFE guidelines contained in the ESBWR HFE style guide. Section 3.3.2, “Objectives,” reinforces this and indicates that the objective of the verification is to ensure that the implemented HSI component design and environment conform to the ESBWR HFE style guide.

NEDE-33276P, Revision 4, Section 3.3.4.1, discusses the application of the criteria within the overall methodology. HFE design verification will address the individual HSI components, consistency across HSIs, panel configurations, room layouts, and environmental factors in the MCR, RSS, and risk-significant LCSs.

Accordingly, the staff finds the V&V Plan’s treatment of the criterion for criteria identification acceptable.

(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.

Evaluation of Criterion (2)

In RAI 18.11-13 and its supplements, the staff requested that the applicant clarify the methodology and acceptance criteria to be used for HFE design verification because the scope and the description of the methodology and acceptance criteria in NEDO-33276, Revision 0, were inconsistent. RAI 18.11-13 was being tracked as an open item in the SER with open items. In its responses, the applicant reorganized and augmented its description of the methodology and acceptance criteria to be used for HFE design verification. As described below, the staff determined that the applicant provided information sufficient to address the NUREG-0711 review criterion for general methodology for HFE design verification. The staff confirmed NEDE-33276P, Revision 2 included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-13 is resolved.

NEDE-33276P, Revision 4, Sections 3.3, discusses HFE design verification methodology. The general methodology is to compare HSI design features to the applicable criteria from the ESBWR HFE style guide. The verification also encompasses panel and workstation layouts, relationships between individual HSI components, HSI reach and accessibility, HSI visibility, seating, and local environment. This is an acceptable approach to HFE design verification because it ensures design specifications have been implemented in the final design.

Section 3.3.5 addresses the identification of HEDs. Any instance of noncompliance with the design specifications is identified as an HED. This includes partial noncompliance as well as full noncompliance. HEDs reflecting standardized features will address changes across HSIs employing that feature.

The design verification methodology described in the plan provides for a detailed comparison of the final HFE design against design specifications. Deviations are recorded, tracked and resolved. Accordingly, the staff finds the V&V Plan's treatment of the criterion for HFE design verification methodology acceptable.

(3) 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.

Evaluation of Criterion (3)

NEDE-33276P, Revision 4, Section 3.3.5, discusses the documentation of HEDs. Any instance of noncompliance, either full or partial, is logged into the HFEITS along with the nature of the discrepancy. Accordingly, the staff finds the V&V Plan's treatment of the criterion for HED documentation acceptable.

18.11.3.1.3 Integrated System Validation

18.11.3.1.3.1 Test Objectives

(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. The staff should verify that the applicant validates that the functions and tasks allocated to plant personnel can be accomplished effectively when the integrated design is implemented.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 5.2, describes the objectives of the validation program. The 13 objectives include validation of the operator role, shift staffing, HSI support for personnel

functions and tasks, time and performance criteria for personnel tasks, error tolerant features, HRA/PRA assumptions, and the other considerations identified in the staff's review criterion. Accordingly, the staff finds the V&V Plan's treatment of the criterion for test objectives acceptable.

18.11.3.1.3.2 Validation Testbeds

In RAI 18.11-19, the staff requested that the applicant clarify (1) the use of simulators in integrated system validation (review Criteria (1) through (7)) and (2) which actions outside the CR should be included in validation scenarios and how these actions will be modeled (Criterion (8)). RAI 18.11-19 was being tracked as an open item in the SER with open items. In its response to item 1 concerning the use of simulators, the applicant clarified the purpose, properties, and scope of simulators to be used as testbeds to be consistent with their description in NEDO-33275. The applicant also clarified that it will use a full-scope simulator that conforms to the guidance of ANSI 3.5 and RG 1.149 for integrated system validation. In its response to item 2 regarding validation scenarios, the applicant modified NEDE-33276P, Revision 4, Section 5.4.1.5, to explain how risk-important LCSs and their HSIs are addressed. Integrated system validations that call for actions to be performed at LCSs are performed utilizing action durations, simulated feedback indications in the HSI, and communication mechanisms used in the plant. Scenarios will model local tasks important to scenario timing and fidelity as well as the local tasks important to risk or safety. The staff determined that these changes adequately address the treatment of actions outside the CR because they ensure that local control actions are properly integrated into the validation scenarios. The staff confirmed that NEDE-33276P, Revision 4, contained the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-19 is resolved.

Review Criteria (1) through (7) in Section 11.4.3.2.2 of NUREG-0711 provide for the review of simulation testbed fidelity. The NUREG states that one approach to identifying a testbed that meets the staff's fidelity criteria is to ensure its compatibility with ANSI/ANS 3.5-1988. NEDE-33276P, Revision 4, Section 5.4.1, indicates that the simulator testbed to be used for validation will conform to the guidance in ANS 3.5 as well as RG 1.149. Accordingly, the staff finds the V&V Plan's treatment of Criterion (1) through (7) pertaining to simulator fidelity acceptable. For completeness, the individual criteria are listed below.

(1) Interface Completeness—The testbed should completely represent the integrated system. This should include HSIs and procedures not specifically [provided for] 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.

Evaluation of Criterion (1)

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

(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.

Evaluation of Criterion (2)

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

(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.

Evaluation of Criterion (3)

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

(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.

Evaluation of Criterion (4)

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

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

Evaluation of Criterion (5)

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

(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.

Evaluation of Criterion (6)

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

(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.

Evaluation of Criterion (7)

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

(8) For important actions at complex HSIs remote from the MCR, where timely and precise HA 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.)

Evaluation of Criterion (8)

NEDE-33276P, Revision 4, Section 5.4.1.5, discusses the validation of risk-important local control operations. Section 5.4.3.7 discusses the use of "critical task" summaries and "safety significant tasks." The validation of risk-important local control operations is performed using simulations and mockups and verifies that the cues, indications, communications, and feedback built into the scenario guide are accurate and timely. The simulations will include all of the risk-important local control operations. The scenarios will model other local tasks that might not be risk-important, if they are important to scenario timing and fidelity. Accordingly, the staff finds the V&V Plan's treatment of the criterion for evaluating important local actions acceptable.

(9) The testbeds should be verified for conformance to the testbed characteristics identified above before validations are conducted.

Evaluation of Criterion (9)

NEDE-33276P, Revision 4, Section 5.4.1, addresses testbed verification. Testbeds are compared to the plant design as it develops and modified for consistency. Accordingly, the staff finds the V&V Plan's treatment of the criterion for testbed fidelity acceptable.

18.11.3.1.3.3 Plant Personnel

(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.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 5.4.2, identifies the participants in the validation exercises. The crews used are individuals trained to be ESBWR reactor operators and SROs. Accordingly, the staff finds the V&V Plan's treatment of the criterion for participant representation acceptable.

(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.

Evaluation of Criterion (2)

The staff identified that NEDO-33276, Revision 1, did not address several aspects of participant selection. In RAI 18.11-21 and its supplements, the staff requested that the applicant clarify (1) how the sample of participants will account for human variability (Criterion (2)), (2) how minimum and normal crew configurations will be assembled and what they will consist of (Criterion (3)), and (3) how sampling bias will be prevented (Criterion (4)). RAI 18.11-21 was being tracked as an open item in the SER with open items. In their responses, the applicant revised NEDO-33276 to address each of these topics. As described below, the staff determined that the applicant provided sufficient information to address the NUREG-0711 review criteria for

plant personnel. The staff confirmed that NEDE-33276P, Revision 2, included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-21 is resolved.

NEDE-33276P, Revision 4, Section 5.4.2.1, indicates that a sample of participants will be developed based on considerations of factors anticipated to create variability, such as license and qualifications, degree of skill and experience, age, and general demographics. NEDE-33276P, Revision 4, defines each of these factors. In addition, NEDE-33276P, Revision 4, Section 5.4.2.2, indicates that a minimum of three crews will participate in the validation exercises. Derivation of a sample using these factors and conducting tests with a minimum of three crews reasonably accounts for human variability. Accordingly, the staff finds the V&V Plan's treatment of the criterion for accounting for human variability acceptable.

(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.

Evaluation of Criterion (3)

NEDE-33276P, Revision 4, Section 5.4.2.2, discusses crew configurations. Normal crews will consist of two licensed operators and an SRO. Minimal crew size will consist of two operators (one SRO and one reactor operator). Additionally, some scenarios will include a maximum crew size consisting of two licensed operators, an SRO, a shift manager, and a shift technical advisor. This provides a reasonable and acceptable variation in crew configurations. Accordingly, the staff finds the V&V Plan's treatment of crew configuration size acceptable.

(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.

Evaluation of Criterion (4)

NEDE-33276P, Revision 4, Section 5.4.2.3, addresses the prevention of sample bias. The applicant identified three groups as ineligible to participate in evaluations. These three groups are participants from the design organization, those involved in prior evaluations, and participants selected on the basis of some specific biasing characteristic. Identification of these three groups conforms to the NUREG-711 guidance. Accordingly, the staff finds the V&V Plan's treatment of the participant sampling bias acceptable.

18.11.3.1.3.4 Scenario Definition

The staff identified that NEDO-33276, Revision 1, did not provide sufficient detail for scenario definition to support an IP level of review. In RAI 18.11-22 and its supplements, the staff requested that the applicant provide (1) an approach for developing validation scenarios consistent with the NUREG-0711 criteria, and (2) the specific scenarios to be run on testbeds.

RAI 18.11-22 was being tracked as an open item in the SER with open items. In its responses, the applicant provided a detailed approach for developing validation scenarios. As discussed with RAI 18.11-36 in Section 18.11.3 of this report, the applicant provided an acceptable alternative approach of providing DAC for integrated system validation scenarios versus providing specific scenarios in NEDE-33276P. As described below, the staff determined that the applicant provided information sufficient to address the NUREG-0711 review criteria for scenario definition and to support an IP level of review. The staff confirmed that NEDE-33276P, Revision 2, included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-22 is resolved.

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

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

Evaluation of Criterion (1)

In NEDE-33276P, Revision 4, Section 4.4.2, the applicant discussed its approach to scenario development. Section 5.4.3 discusses the scenario definition process. The applicant also describes detailed procedures for developing detailed scenarios from the operating condition identified. For example, with respect to initial conditions, Section 4.4.2.2 indicates that scenarios are assigned a set of initial conditions to allow the simulated scenario to commence realistically. The conditions are the types of situations that would exist in the ESWBR at the time in the plant operating cycle in which the scenario is to take place. Additional initial

conditions will be included for realism, such as tagged-out components or systems, in-progress maintenance, or testing. Some initial conditions are included that have no bearing on subsequent scenario events.

As another example, Section 4.4.2.3 describes the development of scenario events. The plan indicates that a sequence of events designed to achieve the scenario's objectives is developed. Each event either directly supports or contributes to the support of one or more objectives. Scenarios are developed so that various systems are affected by each type of event, such as degradation or failure of instruments, controls and components, major plant transients and accidents, and normal plant maneuvering. Realistic conditions limit the predictability, recognizability, and potential bias from operator expectations of scenario event timelines. Some scenarios incorporate equipment failures that cause or exacerbate problems in other systems. This practice allows validation of the operators' understanding of system and component interactions, integrated system operations, and the integrated HSI performance across a broad range of conditions.

Section 5.4.3 presents the means for documenting scenario details and includes proprietary examples of forms, instruction, and guidance associated with scenario documentation. The proprietary SER lists specific information collected to demonstrate that the information collected conforms to the NUREG criterion. The plan describes how each method for collecting data or defining scenario detail is accomplished.

The applicant's plan does not provide the results of these activities for individual scenarios. As described in Section 18.11.3 of this report, additional detail related to this criterion is developed as part of Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2. Accordingly, the staff finds the V&V Plan's treatment of scenario details acceptable.

(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.

Evaluation of Criterion (2)

NEDE-33276P, Revision 4, Section 5.4.3, presents the means for documenting scenario details which were described in the evaluation of Criterion (1) above. The level of detail to be developed for each scenario results in a high-degree of task fidelity (reflects actual operating conditions). The proprietary SER provides an example of the level of detail specified by the implementation plan to illustrate conformance to the NUREG criterion.

As described in Section 18.11.3 of this report, additional detail related to this criterion is developed as part of Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2. Accordingly, the staff finds the V&V Plan's treatment of scenario task fidelity acceptable.

(3) When evaluating performance associated with operations remote from the MCR, 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).

Evaluation of Criterion (3)

NEDE-33276P, Revision 4, Section 5.4.1.5, “Risk Significant Local Control Panels,” indicates that integrated system validations that call for actions at LCSs are performed utilizing action durations, simulated feedback indications in the HSI, and communication mechanisms used in the plant. Scenarios will model local tasks important to scenario timing and fidelity as well as the local tasks important to risk or safety. The scenario guide, which was written to govern performance of the simulation, specifies in detail all of the factors associated with local operations. The scenario validation process verifies that remote manual action cues, indications, communications, and feedback built into the scenario guide are accurate and timely. Thus, scenarios that contain remote actions are accurately rendered and support validation of the integrated system HSI. The proprietary SER describes the method the applicant will use to account for time delays introduced by remote actions and the staff’s basis for finding this method to be acceptable.

As described in Section 18.11.3 of the report, additional detail related to this criterion is developed as part of Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2. Accordingly, the staff finds the V&V Plan’s treatment of evaluating remote operations acceptable.

18.11.3.1.3.5 Performance Measurement

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

18.11.3.1.3.5.1 Measurement Characteristics

(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.

Evaluation of Criterion (1)

In RAI 18.11-23 and its supplements, the staff requested that the applicant provide additional detail on measurement characteristics supporting integrated system validation. RAI 18.11-23 was being tracked as an open item in the SER with open items. In its responses to this RAI and to RAIs 18.11-24 and 18.11-26, the applicant provided a detailed discussion of measurement characteristics. As described below, the staff determined that the applicant provided sufficient information to address the NUREG-0711 review criteria for measurement characteristics and to support an IP level of review. The staff confirmed NEDE-33276P, Revision 3, included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-23 is resolved.

In NEDE-33276P, Revision 4, Section 5.4.4, the applicant described the performance measures that will be used in validation testing. The measures themselves are evaluated in the next section of this report, which concerns performance measurement selection. The description of each performance measure includes the measurement characteristics and a discussion of why it is applicable. The list of performance measures and their characterisitics are proprietary. The proprietary SER uses an example of one of the measures and its associated characteristics to illustrate how the implementation plan conforms to the NUREG criteria. In general the staff found that the applicant used the applicable characteristics from the NUREG criterion and that these measurement characteristics provide reasonable assurance that the performance measure itself will be of good quality. 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 Plan's treatment of the criterion for measurement characteristics acceptable.

18.11.3.1.3.5.2 Performance Measure Selection

In RAI 18.11-24 and its supplements, the staff requested that the applicant provide a hierarchal set of performance measures and their associated acceptance criteria consistent with the review criteria in NUREG-0711. RAI 18.11-24 was being tracked as an open item in the SER with open items. In its responses, the applicant provided a detailed discussion of performance measures and identified associated changes to NEDE-33276P. As described below, the staff determined that the applicant provided sufficient information to address the NUREG-0711 review criteria for performance measurement selection and to support an IP level of review. The staff confirmed that NEDE-33276P, Revision 3, included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-24 is resolved.

In RAI 18.11-25 and its supplements, the staff requested that the applicant clarify the use of performance measures for automation, procedures, and displays because these measures do not directly correspond to the NUREG-0711 review criteria. RAI 18.11-25 was being tracked as an open item in the SER with open items. In its responses to this RAI and RAI 18-11-24, the applicant provided a hierarchal set of performance measures that no longer involves separate measures for automation, procedures, and displays. As described below, the staff determined that the revised set of performance measures is conforms to the NUREG-0711 criteria. The staff confirmed NEDE-33276P, Revision 3, included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-25 is resolved.

(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.

Evaluation of Criterion (1)

In NEDE-33276P, Revision 4, Section 5.4.4, the applicant described the performance measures for plant-level and system-level performance, operator task performance, crew communication and coordination, situation awareness, workload, and anthropometric and physiological factors that will be used in validation testing.

The measures are divided into pass/fail and supplemental measures. The proprietary SER describes the pass/fail measures that will be used. These measures are acceptable to demonstrate that the control room staff can safely control the plant to achieve the objectives of the validation scenario. The use of supplemental measures to identify HEDs to be resolved through the HFE resolution process is appropriate since the measures selected identify opportunities to optimize the design.

Accordingly, the staff finds the V&V Plan's treatment of the criterion for hierarchal measurement acceptable.

(2) Plant Performance Measurement—Plant performance measures representing functions, systems, components, and HSI use should be obtained.

Evaluation of Criterion (2)

NEDE-33276P, Revision 4, Section 5.4.4.1, identifies plant-level measures the applicant proposes. These measures are described in the proprietary SER. The staff determined that the measures, when met, demonstrate that the control room staff can safely control the plant within acceptable time limits to accomplish the objectives of the validation scenario. Additional plant measures accurately reflecting operating requirements are used in this application to assess HSI effectiveness. These measures will be defined for each scenario.

Another form of plant measure addresses the performance of risk significant actions from the PRA and HRA. In NEDE-33276P, Revision 4, Section 5.4.4.2, the applicant described how this measure is applied. The proprietary SER includes details on this measure. The staff finds that this measure is acceptable to validate that the control room staff can safely perform risk

significant actions in scenarios within acceptable time limits to accomplish the objectives of the validation scenario.

The approach described by the applicant is comprehensive and addresses key aspects of plant performance, including risk-important actions. These measures will be developed uniquely for each scenario. NEDE-33276P provides direction for developing scenario specific measures. Examples are also included to illustrate application of the direction. The scenario-specific measures will be developed in accordance with Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2, which is discussed in Section 18.11.3 of this report. Accordingly, the staff finds the V&V Plan's treatment of the criterion for measurement of personnel tasks acceptable.

(3) Personnel Task Measurement—For each specific scenario, the tasks that personnel are [needed] to 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 [need to] 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

Evaluation of Criterion (3)

NEDE-33276P, Revision 4, Section 5.4.4.3, states that, for each integrated system validation scenario, the tasks that personnel perform during the scenario are identified. Tasks identified during scenario development are assessed during scenario performance to validate that the integrated HSI adequately supports task performance. NEDE-33276P, Revision 4, describes other proprietary task performance measures to support the validation of the integrated plant and HSI design.

NEDE-33276P, Revision 4, also provides a proprietary three-part approach to personnel task measurement. The proprietary SER summarizes this plan including the measured attributes and assessment techniques to demonstrate conformance to the NUREG criterion.

This three-part approach to personnel task measurement provides a comprehensive approach to the assessment of both scenario-specific and general task performance. The first two types of task measures are developed uniquely for each scenario. NEDE-33276P provides direction for developing scenario-specific measures. Examples are also included to illustrate application of the direction. The scenario specific measures will be developed in accordance with Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2, which is discussed in Section 18.11.3 of this report. Accordingly, the staff finds the V&V Plan's treatment of the criterion for measurement of personnel tasks acceptable.

(4) Situation Awareness—Personnel situation awareness should be assessed. The approach to situation awareness measurement should reflect the current state-of-the-art.

Evaluation of Criterion (4)

NEDE-33276P, Revision 4, Section 5.4.4.5, addresses situation awareness measurement. NEDE-33276P, Revision 4, includes proprietary information identifying the technique to be used and how it is applied. The proprietary SER summarizes this information to illustrate how conformance to the NUREG criterion is accomplished. The method described in NEDE-33276P, Revision 4 to assess situation awareness of the control room staff is appropriate for use in validation tests.

This measure is developed uniquely for each scenario. NEDE-33276P provides direction for developing scenario specific-measures. Examples are also included to illustrate application of the direction. The scenario specific measures will be developed in accordance with Design Commitment 12 in (DCD Tier 1, Section 3.3, Table 3.3-2, which is discussed in Section 18.11.3 of this report. Accordingly, the staff finds the V&V Plan's treatment of the criterion for measurement of personnel tasks acceptable.

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

Evaluation of Criterion (5)

NEDE-33276P, Revision 4, Section 5.4.4.6, addresses cognitive workload. NEDE-33276P, Revision 4, includes proprietary information identifying the technique to be used andf how it is applied. The proprietary SER summarizes this information to illustrate how conformance to the NUREG criterion is accomplished. The method described in NEDE-33276P, Revision 4 to

assess the workload of the control room staff is appropriate for use in validation tests. Accordingly, the staff finds the V&V Plan's treatment of the criterion for measurement of workload acceptable.

(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.

Evaluation of Criterion (6)

NEDE-33276P, Revision 4, Section 5.4.4.7, 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, visibility of indications, and seating comfort. Operator debriefing comments will also be obtained concerning these aspects of the design. These measures will provide for a comprehensive assessment of these factors.

Accordingly, the staff finds the V&V Plan's treatment of the criterion for measurement of anthropometric and physiological factors acceptable.

18.11.3.1.3.5.3 Performance Criteria

This section includes two NUREG-0711 review criteria: one addressing specific criteria for each performance measurement and the other addressing the basis for the criteria. For continuity of discussion, the evaluation section of Criterion (1) addresses both.

(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.

Evaluation of Criterion (1)

In RAI 18.11-26 and its supplements, the staff requested that the applicant provide specific acceptance criteria for performance measures used in deciding whether the design is validated or not. RAI 18.11-26 was being tracked as an open item in the SER with open items. In its responses to this RAI and RAI 18.11-24, the applicant discussed in detail the acceptance criteria associated with performance measures and identified associated changes to NEDE-33276P. As described below, the staff determined that the applicant provided information sufficient to address the NUREG-0711 review criteria for performance criteria and to support an IP level of review. The staff confirmed that NEDE-33276P, Revision 3, included the proposed changes. Based on the applicant's responses and the revision to NEDE-33276P, RAI 18.11-25 is resolved.

Plant measures are both pass/fail and supplemental measures. Tested attributes (HSIs, procedures, training elements, etc.) that do not meet pass/fail criteria constitute a failure of the scenario being validated. The bases for the criteria identified are "requirements referenced" (i.e., Operating specifications for system, subsystem, and operator performance defined through engineering analysis). NEDE-33276P, Revision 4, Section 5.4.4.1 and 5.4.4.2 state specific proprietary pass/fail measures that are summarized in the proprietary SER. These measures are acceptable to validate that the control room staff can safely control the plant and perform risk significant actions in scenarios within acceptable time limits to accomplish the objectives of the validation scenario. Scenarios that exceed established acceptance limits result in integrated system validation failure.

This is an appropriate approach to criteria determination and the use of key measures as pass/fail criteria.

Task measures consist of both pass/fail and supplemental measures used to better understand personnel performance. NEDE-33276P, Section 5.4.4.3, contains a proprietary description of how success and failure criteria for task measures are developed and evaluated. In general the criteria are specific and quantifiable. The proprietary SER summarizes this material so there is specific information as to how the V&V Plan conforms to the NUREG criterion. The approach described provides reasonable criteria to define acceptable and unacceptable performance and the need for corrective actions.

The situation awareness measure is supplemental. NEDE 33276P, Section 5.4.4.5, contains a proprietary description of how success and failure criteria for the situation awareness measure is developed and evaluated. In general the criteria are specific and quantifiable. The proprietary SER summarizes this material so there is specific information as to how the V&V Plan conforms to the NUREG criterion. This approach to identifying situation assessment criteria is reasonable and appropriate.

Workload is a supplemental measure. NEDE 33276P, Section 5.4.4.6, contains a proprietary description of how success and failure criteria for the workload measure is developed and evaluated. In general the criteria are specific and quantifiable. The proprietary SER summarizes this material so there is specific information as to how the V&V Plan conforms to the NUREG criterion. This approach to identifying workload criteria is a reasonable and appropriate approach.

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. This is an appropriate approach to criteria determination for this category of measure.

For the reasons discussed above, the criteria identified for each category of performance measurement provide reasonable standards against which to evaluate performance. Accordingly, the staff finds the V&V Plan's treatment of the criterion for criteria specification and their bases acceptable.

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

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 Plan's treatment of the criterion for criteria bases acceptable.

18.11.3.1.3.6 Test Design

The staff identified that NEDO-33276, Revision 1, did not address several aspects of test design sufficiently to support an implementation level of review. In RAI 18.11-27 and its supplements, the staff requested that the applicant describe the methodology used for certain aspects of test design. These aspects include presentation of scenarios to crews, test procedures, training of test conductors and participants, and pilot studies. RAI 18.11-27 was being tracked as an open item in the SER with open items. In its responses, the applicant revised NEDO-33276 to address each of these topics. As described below, the staff determined that the applicant provided information sufficient to address the NUREG-0711 review criteria for test design and to support an IP level of review. The staff confirmed that NEDE-33276P, Revision 3, included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-27 is resolved.

The staff considered five review criteria for test design—coupling crews and scenarios, test procedures, training of test conductors, training of test participants, and conduct of pilot studies.

18.11.3.1.3.6.1 Coupling Crews and Scenarios

(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.

Evaluation of Criterion (1)

In RAI 18.11-28, the staff requested that the applicant clarify the reuse of scenarios with the same crew. Specifically, the concern was that if a crew is subject to the same scenario twice, the crew may recognize the scenario and any data collected may be invalid. RAI 18.11-28 was being tracked as an open item in the SER with open items. In its response, the applicant added a discussion of scenario assignment and sequencing in NEDE-33276P. The applicant also clarified that an individual scenario would be presented to the same crew only under exceptional circumstances. As described below, the staff determined that the applicant provided sufficient information to address the NUREG-0711 review criteria for scenario assignment. The staff confirmed that NEDE-33276P, Revision 2, included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-28 is resolved.

NEDE-33276P, Revision 4, Section 5.4.5.1 addresses the presentation of scenarios to crews. With respect to scenario assignment, the applicant indicated that scenarios will be balanced across crews to ensure that each crew receives a representative range of scenarios. NEDE-33276P, Revision 4, Section 4.4.4, provides detailed proprietary procedures for accomplishing the balance. The proprietary SER summarized the procedures to demonstrate conformance to this NUREG criterion. This process results in a reasonable distribution of scenarios for each

crew and is, therefore, acceptable. In addition, the methodology supports the identification of the impact of crew variability.

NEDE-33276P, Revision 4 provides an acceptable methodology for scenario assignments. Specific scenario assignments will be developed in accordance with Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2, which is discussed in Section 18.11.3 of this report.

Accordingly, the staff finds the V&V Plan's treatment of the criterion for scenario assignments acceptable.

(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.

Evaluation of Criterion (2)

NEDE-33276P, Revision 4, Section 5.4.5.1, indicates that the order in which scenarios are presented to crews will be balanced. Balancing of scenarios is discussed in the previous criterion.

In view of the foregoing, NEDE-33276P, Revision 4, provides an acceptable methodology for the development of scenario sequencing. The specific scenario sequencing will be developed in accordance with Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2, which is discussed in Section 18.11.3 of this report. Accordingly, the staff finds the V&V Plan's treatment of the criterion for scenario sequencing acceptable.

18.11.3.1.3.6.2 Test Procedures

(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.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 5.4.5.2, addresses test procedures. It provides a high-level methodology for developing detailed procedures for individual scenarios. As part of Criterion (2) above in Section 18.11.3.1.3.6.1, scenario order is discussed and evaluated. Standardized instructions will be developed for each scenario. The proprietary SER contains a description of these instructions. The staff determined that the instructions identified important conditions of the scenario and established protocol for data collection, observer interactions, and unanticipated events.

In view of the above, NEDE-33276P, Revision 4 provides an acceptable methodology for test procedure development. The specific test procedures will be developed in accordance with Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2, which is discussed in Section 18.11.3 of this report. Accordingly, the staff finds the V&V Plan's treatment of the criterion for test procedures acceptable.

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

Evaluation of Criterion (2)

In regard to minimizing bias, NEDE-33276P, Revision 4 describes plans to use well-developed procedures for the test program. NEDE-33276P, Revision 4 identifies several proprietary actions, including protocol for observer interaction, that will be taken to minimize bias. The proprietary SER lists these actions.

NEDE-33276P, Revision 4, provides an acceptable methodology for minimizing bias in test procedures. The specific procedures will be developed in accordance with Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2, which is discussed in Section 18.11.3 of this report. Accordingly, the staff finds the V&V Plan's treatment of the criterion for minimizing test bias acceptable.

18.11.3.1.3.6.3 Test Personnel Training

(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.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 5.4.5.3 indicates that test personnel receive training on coordination of simulator sessions, observation and evaluation of operator performance, use of test procedures, experimenter bias, problem documentation, crew interaction, use of data collection tools, and note taking. NEDE-33276P, Revision 4, further states that the training will be accomplished in accordance with the National Academy for Nuclear Training, "Guidelines for Instructor Training and Qualifications" (ACAD 97-014). Based on the scope of the training program and the use of an accepted industry standard for accomplishing the training the plan provides an acceptable approach to the training of test personnel. Accordingly, the staff finds the V&V Plan's treatment of the criterion for test personnel training acceptable.

18.11.3.1.3.6.4 Participant Training

(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.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 5.4.5.3, addresses training of test participants. The plan indicates that operators will receive formal classroom training as well as simulator training prior to participation. The training will be similar to existing BWR operator license training. All

participants undergo comprehensive examination in a full-scope simulator covering job performance measures. Accordingly, the staff finds the V&V Plan's treatment of the criterion for high-fidelity training of participants acceptable.

(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.

Evaluation of Criterion (2)

NEDE-33276P, Revision 4, Section 5.4.5.3 addresses training of test participant*s*. All participants will undergo a comprehensive examination in a full-scope simulator covering job performance measures. NEDE-33276P, Revision 4, further indicates that after ESBWR training, test participants will exhibit an acceptably stable level of performance across trials. Accordingly, the staff finds the V&V Plan's treatment of the criterion for stable participant performance acceptable.

18.11.3.1.3.6.5 Pilot Testing

(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.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 5.4.6, addresses pilot studies. A pilot test will be conducted before the actual validation trials. The pilot test will use essentially the same methods as the tests themselves. Accordingly, the staff finds the V&V Plan's treatment of the criterion for conducting pilot tests before validation acceptable.

(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 given to provide reasonable assurance that the participants do not become so familiar with the data collection process that it may result in response bias.

Evaluation of Criterion (2)

NEDE-33276P, Revision 4, Section 5.4.6, addresses pilot studies. Section 5.4.6 states that participants in the pilot test will differ from participants in the validation tests. If a participant must be used in both tests, scenarios will be different. Accordingly, the staff finds the V&V Plan's treatment of the criterion for participant selection acceptable.

18.11.3.1.3.7 Data Analysis and Interpretation

The staff identified that NEDO-33276, Revision 1, did not address the five criteria below for the data analysis and interpretation review topic and Criterion (2) for the validation conclusions review topic to support an implementation level of review. In RAI 18.11-29 and its supplements, the staff requested that the applicant describe the methodology used for data analysis and interpretation, including (1) what methods will be used to analyze data and to assess performance criteria, (2) how HEDs will be identified, (3) how consistency across different measures will be evaluated, and (4) how data analysis will be verified for correctness. RAI 18.11-29 was being tracked as an open item in the SER with open items. In its responses, the applicant revised NEDO-33276 to address each of these topics. As described below, the staff determined that the applicant provided information sufficient to address the NUREG-0711 review criteria for data analysis and interpretation and validation conclusions and to support an IP level of review. The staff confirmed that NEDE-33276P, Revision 3, included the proposed changes. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-29 is resolved.

(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.

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 5.4.7 addresses data analysis and interpretation. Analyses will be conducted for four levels of performance measures. These measures are described in the proprietary SER. The specific analyses will depend on the type and quality of the data. For each level, NEDE-33276P identifies the comparisons to be made between actual data collected and the performance criteria established. These comparisons will generally be made using quantitative comparisons. Qualitative assessment will also be made using observer and participant evaluations. These evaluations will address, for example, the influence of factors such as lighting and noise level.

NEDE-33276P, Revision 4, provides an acceptable methodology for data analysis. The specific analyses will be developed in accordance with Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2, which is discussed in Section 18.11.3 of this report. Accordingly, the staff finds the V&V Plan's treatment of the criterion for data analysis acceptable.

(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.

Evaluation of Criterion (2)

NEDE-33276P, Revision 4, Section 5.4.7 indicates that plant core thermal-hydraulic, plant HRA/PRA, and personnel task measures are used for pass/fail criteria. For these measures, if a failure occurs, it must be resolved before the design can be validated. For the other "supplemental" measures, HEDs are defined if a measure's criterion is not met.

In view of the above, NEDE-33276P, Revision 4 provides an acceptable methodology for the treatment of pass/fail criteria and other measures. The specific test procedures will be developed in accordance with Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2, which is discussed in Section 18.11.3 of this report. Accordingly, the staff finds the V&V Plan's treatment of the criterion for treatment of pass/fail criteria and other measures acceptable.

(3) The degree of convergent validity should be evaluated, i.e., the convergence or consistency of the measures of performance.

Evaluation of Criterion (3)

NEDE-33276P, Revision 4, Section 5.4.7, indicates that convergent validity will be assessed by comparing the results of performance measures that measure the same or closely related aspects of performance. An HED will be created where measures that are expected to converge do not do so. The staff finds this approach acceptable because it ensures data consistency across similar performance measures.

NEDE-33276P, Revision 4, provides an acceptable methodology for development of measures for the treatment of convergent validity. The specific measures used in convergent validation will be developed in accordance with Design Commitment 12 in DCD Tier 1, Section 3.3, Table 3.3-2, which is discussed in Section 18.11.3 of this report. Accordingly, the staff finds the V&V Plan's treatment of the criterion for convergent validity acceptable.

(4) The data analyses should be independently verified for correctness of analysis.

Evaluation of Criterion (4)

NEDE-33276P, Revision 4, Section 5.4.7 indicates that data analyses and conclusions will be independently verified. Accordingly, the staff finds the V&V Plan's treatment of the criterion for analysis verification acceptable.

(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.

Evaluation of Criterion (5)

NEDE-33276P, Revision 4, Section 5.4.7, indicates that when making inferences from observed performance to estimated real-world performance, an allowance for margin for error will be made. The staff concludes that the V&V IP conforms to the NUREG criterion. The direction is general but sufficient because the applicant's use of a full scope simulator for integrated system validation will minimize differences between testing and real world performance. Where inferences are needed, specific error margins will be developed in accordance with DCD Tier 1, Section 3.3, Table 3.3-2, Design Commitment 12, which is discussed in Section 18.11.3 of this report. Accordingly, the staff finds the V&V Plan's treatment of the criterion for error margins acceptable.

18.11.3.1.3.8 Validation Conclusions

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

Evaluation of Criterion (1)

NEDE-33276P, Revision 4, Section 5.5, addresses the documentation of results and indicates that the results report documents the validation conclusions and their bases. Accordingly, the staff finds the V&V Plan's treatment of the criterion for validation conclusions acceptable.

(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).

Evaluation of Criterion (2)

NEDE-33276P, Revision 4, Section 5.5, 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 NEDO-33278, "ESBWR Human Factors Engineering Design Implementation Plan." Accordingly, the staff finds the V&V Plan's treatment of the criterion for validation limitations acceptable.

18.11.3.1.4 Human Engineering Discrepancy Resolution

In RAI 18.11-32 and its supplements, the staff requested that the applicant describe the methodology for the evaluation and resolution of HEDs. RAI 18.11-32 was being tracked as an open item in the SER with open items. In its responses, the applicant revised NEDO-33276 to provide a detailed methodology for HED evaluation and resolution. As described below, the staff determined that the applicant provided sufficient information to address the NUREG-0711 review criteria for HED resolution and to support an IP level of review. The staff confirmed that the proposed changes were included in NEDE-33276P, Revision 2. Based on the applicant's responses and revision to NEDE-33276P, RAI 18.11-32 is resolved.

(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.

Evaluation of Criterion (1)

NEDE 33276P, Revision 4, Section 6, describes the HED identification and resolution process. Section 6.4.2 provides the methodology for HED justification. Technical bases for HED justification are identified and include the analysis of new information, current practices, tradeoff studies, and engineering evaluations. The methodology does not permit HEDs that constitute safety concerns or performance problems to be justified. Accordingly, the staff finds the V&V Plan's treatment of the criterion for HED justification acceptable.

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

- Plant system—the potential effects of all HEDs relevant to a single plant system should be evaluated. The potential effects of these HEDs on plant safety and personnel performance should be determined, in part, by the safety significance of the plant system(s), their effect on SAR accident analyses, and their relationship to risk significant sequences in the plant PRA.

- HED scope

  – Global features HEDs—these are HEDs that relate to configurational and environmental aspects of the design such as lighting, ventilation, and traffic flow. They relate to general human performance issues.

  – Standardized features HEDs—these are HEDs that relate to design features that are governed by the applicant's design guidelines used across various controls and displays of the HSI (e.g., display screen organization and conventions for format, coding, and labeling). Because a single guideline may be used across many aspects of the design, a single HED could be applicable to many personnel tasks and plant systems.

  – Detailed features HEDs—these are HEDs that relate to design features that are not standardized, thus [their] generality has to be assessed.

  – Other—this subcategory specifically pertains to HEDs identified from integrated system validation that cannot be easily assigned to any of the three preceding categories.

- Individual HSI or procedure—HEDs should be analyzed with respect to individual HSIs and procedures. The potential effects of these HEDs on plant safety and personnel performance are determined, in part, by the safety significance of the plant system(s) that are related to the particular component.

- Personnel function—HEDs should be analyzed with respect to individual personnel functions. The potential effects of these HEDs is determined, in part, by the importance of the personnel function to plant safety (e.g., consequences of failure) and their cumulative effect on personnel performance (e.g., degree of impairment and types of potential errors).

- HEDs should also be analyzed with respect to the cumulative effects of multiple HEDs on plant safety and personnel performance. While an individual HED might not be considered sufficiently severe to require correction, the combined effect of several HEDs upon the single aspect of the design could have significant consequences to plant safety and, therefore, necessitate corrective action. Likewise, when a single plant system is associated with multiple HEDs that affect a number of HSI components, then their possible combined effect on the operation of that plant system should be considered.

- In addition to addressing the specific HEDs, the analysis should treat the HEDs as indications of potentially broader problems. For example, identifying multiple HEDs associated with one particular aspect of the HSI design, such as the remote shutdown panel, could also indicate that there are other problems with that aspect of the design, such as inconsistent use of procedures and standards. In some cases, the evaluation of HEDs could warrant further review in the identified areas of concern.

Evaluation of Criterion (2)

NEDE 33276P, Revision 4, Section 6.4, describes the HED analysis and resolution 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 entered into HFEITS 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.

Accordingly, the staff finds the V&V Plan's treatment of the criterion for HED analysis acceptable.

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

- are required by personnel tasks but are not provided by the HSI

- do not satisfy all personnel information needs (e.g., information not presented with the proper range or precision)

- contain deviations from HFE guidelines that are likely to lead to errors that would prevent personnel from performing the task.

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

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

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

Evaluation of Criterion (3)

NEDE 33276P, Revision 4, Section 6.4.3, describes the HED prioritization. The HED analysis provides extensive criteria for sorting HEDs into four categories. The first category contains safety issues, the second contains plant or personnel performance issues, the third contains HFE issues without major safety or performance implications, and finally, the fourth contains the remaining items. The degree of analysis is commensurate with the degree of importance of the issue. Accordingly, the staff finds the V&V Plan's treatment of the criterion for HED prioritization acceptable.

(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.

Evaluation of Criterion (4)

NEDE 33276P, Revision 4, Section 6.5, describes the HED documentation. All HEDs are entered into the HFEITS database. This provides an auditable system that fully describes the HED and its resolution. It includes identifying information; any justification (if applicable); the results of the HED analysis (including systems, HSIs, personnel functions, procedures, and training that is impacted by the HED); the HED's priority and its basis; the solutions developed; the solution implementation; and the resolution effectiveness evaluation. Accordingly, the staff finds the V&V Plan's treatment of the criterion for HED documentation acceptable.

(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.

Evaluation of Criterion (5)

NEDE 33276P, Revision 4, Section 6.4.5, addresses the development of design solutions. HEDs are analyzed to determine their cause, and solutions are developed to address them. This analysis considers the cumulative impact of other open HEDs that may be related to the affected system, HSIs, procedures, or processes. Solutions considered include design change to a system or component, software, task or reallocation, HSIs, procedure, training, and staffing/qualification. Accordingly, the staff finds the V&V Plan's treatment of the criterion for design solution development acceptable.

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

Evaluation of Criterion (6)

NEDE-33276P, Revision 4, Section 6.4.7, addresses the evaluation of HED resolutions. All HEDs are evaluated to verify their effectiveness. Depending on the type of solution implemented, the approaches include additional verifications and validations. The portions of the V&V process that are impacted by the HED resolution are repeated. These evaluations also ensure that no new HEDs are inadvertently created by the solution. If the V&V activities do not support the finding that the resolution is effective, the HED remains open in the HFEITS and is reevaluated. HEDs are closed only after they are verified as effectively resolved. Accordingly, the staff finds the V&V Plan's treatment of the criterion for design solution evaluation acceptable.

18.11.3.2 Relationship to Other Documents

18.11.3.2.1 DCD Tier 1, Section 3.3, "Human Factors Engineering"

DCD Tier 1, Revision 6, Table 3.3-2, Item 1, contains the Tier 1 ITAAC developed by the applicant for HFE. Table 3.3-2 contains 10 items, one for each element of NUREG-0711 (except HFE program management, procedures and training), plus one Item which addresses integrated system validation scenarios. Each item in Table 3.3-2 is linked to the corresponding ESBWR element IP. As described in Section 14.3.9 of this report, DCD Tier 1, Section 3.3

provides sufficient ITAAC to confirm that the V&V plan is completed in accordance with the IP (NEDO-33276, Revision 4), which the staff has reviewed and approved.

18.11.3.2.2 DCD Tier 2, Section 18.11, "Human Factors Verification and Validation"

In RAIs 18.11-35 and 18.11-37, the staff requested that the applicant address inconsistencies between DCD Tier 2, Section 18.11, and NEDE-33276P and clarify references to NEDE-33276P and NEDE-33217P. RAIs 18.11-35 and 18.11-37 were being tracked as open items in the SER with open items. In its responses, the applicant corrected the inconsistencies between DCD Tier 2, Section 18.11, and NEDE-33276P and corrected the references. The staff confirmed that DCD Tier 2, Section 18.11, Revision 6, included the proposed changes. Based on the applicant's responses, RAIs 18.11-35 and 18.11-37 are resolved.

DCD Tier 2, Revision 6, Section 18.11, "Human Factors Verification and Validation," provides a high-level description of the ESBWR V&V process. This section of the DCD also references the detailed IP (NEDO-33276, Revision 4), which is designated as Tier 2*. As discussed above, NEDE-33276P, Revision 4 describes a V&V program that addresses the NUREG-0711 criteria for V&V. Thus, Tier 2, together with the referenced IP provides an acceptable description of the ESBWR V&V program.

18.11.4 Conclusions

The staff reviewed the ESBWR HFE V&V at an IP level (see Section 18.4.1 of this report for a discussion of review levels), using the review criteria in Section 11.4 of NUREG-0711. For the reasons set forth above, the staff concludes that the ESBWR V&V Program, as described in NEDE-33276P, Revision 4, 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

DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the V&V is completed in accordance with the IP (NEDO-33276, Revision 4), which the staff has reviewed and approved. Accordingly, the staff concludes that the applicant's V&V is acceptable at the IP level.

18.12 Design Implementation

18.12.1 Regulatory Criteria

The objective of reviewing design implementation is to verify that the applicant's as-built design conforms to the verified and validated design that resulted from the HFE design process.

To review the applicant's design implementation plan, the staff used the review criteria in NUREG-0711, Section 12.4.

18.12.2 Summary of Technical Information

DCD Tier 2, Revision 6, Section 18.12, describes the ESBWR design implementation. DCD Tier 2, Revision 6, Section 18.12, incorporates by reference NEDE-33217P, Revision 6, and NEDO-33278, Revision 4, "ESBWR Human Factors Engineering Design Implementation Plan."

The staff also reviewed the following ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 6
- GEH responses to RAIs 18.12-1 though 18.12-7 (MFN Letters 06-443, 07-499, 08-088, 08-154, and 08-481)

18.12.3 Staff Evaluation

The staff performed an IP level of review as described in NUREG-0711 and Section 18.1 of this report. This section presents the applicable review criteria from NUREG-0711 (reproduced below), followed by an evaluation of each criterion. In addition, this section also addresses related documents (i.e., DCD Tier 1 and Tier 2 information).

18.12.3.1 NUREG-0711 Review Criteria

NUREG-0711 includes three criteria for this topic.

(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.

Evaluation of Criterion (1)

According to NEDO-33278, Revision 4, Section 1.1, one purpose of design implementation is to verify aspects of the design that may not have been evaluated previously in the V&V process, including any hardware, software, or new or modified displays that were absent from the simulator-based integrated V&V process, and any physical or environmental (e.g., noise, lighting) differences between those present at the V&V process and the as-built CR.

NEDO-33278, Revision 4, Section 3.3 describes the methodology, and NEDO-33278, Revision 4, Section 4.3 describes its implementation. Section 3.3 outlines a scope in accordance with the criterion that specifies the aspects of the design that are included in this verification. Accordingly, the staff finds the Design IP's treatment of aspects of the design not addressed in V&V acceptable.

(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.

Evaluation of Criterion (2)

In RAI 18.12-2, the staff requested that the applicant clarify the criteria that will be used to determine whether the plant as-built design is consistent with the HFE design that was verified and validated. RAI 18.12-2 was being tracked as an open item in the SER with open items. In its response, the applicant explained that an HSI report provides the basis for acceptance criteria for as built design verification. The staff determined that the response is acceptable since the revised NEDO-33278 conforms to the NUREG-0711 guidance to verify the actual HFE design is consistent with the design that was verified and validated. The staff confirmed that NEDO-33278, Revision 3, includes the proposed changes. Based on the applicant's response, RAIs 18.12-2 is resolved.

In RAI 18.12-3 and its supplements, the staff requested that the applicant clarify the as-built design itself is verified and not just design documentation such as procurement, construction, and engineering change documentation. RAI 18.12-3 was being tracked as an open item in the SER with open items. In its responses, the applicant identified that the verification will be performed on the as-built design. The staff determined that the response is acceptable since it conforms to the NUREG-0711 guidance to verify the actual physical HFE design. The staff confirmed that NEDO-33278, Revision 3, included the proposed changes. Based on the applicant's response, RAI 18.12-3 is resolved.

In RAI 18.12-4 and its supplements, the staff requested that the applicant clarify the responsibilities for as-built design verification between the vendor, the COL holder, and the owners' group. The staff also requested clarification of whether as-built design verification would be performed only for the initial plant or all plants. RAI 18.12-4 was being tracked as an open item in the SER with open items. In its responses, the applicant clarified that as-built design verification is the responsibility of the COL holder and that it will be performed on each plant. The staff determined that the revised NEDO-33278 describes a design verification process that conforms to NUREG-0711. The staff confirmed that NEDO-33278, Revision 3, includes the proposed changes. Based on the applicant's response, RAI 18.12-4 is resolved.

According to NEDO-33278, Revision 4, Section 1.1, another purpose of design implementation is to "confirm that the final HSIs, procedures and training (as-built) HFE design conforms to the ESBWR standard plant design resulting from the HFE design process and V&V activities." It also states, "Any identified discrepancies are assessed and properly addressed." Two sections provide the methodology for doing so—Section 3.1 addresses verification of the as-built HSIs, and Section 3.2 addresses the verification of the as-built procedures and training. Sections 4.1 and 4.2 describe the implementation of these methodologies.

With respect to verification of the as-built HSIs, DCD Tier 2, Revision 6, Section 18.12.2.1, states that the HSIs and their design characteristics are established in the HSI design activity, and they are subsequently evaluated and confirmed in the HFE V&V. Following the HFE V&V, the HSIs and their design characteristics are revised and become part of the plant's design basis and also become the acceptance criteria for the verification of the equipment in the as-built installation.

NEDO-33278, Revision 4, Section 3.1.3, states that the final as-built HSIs and their design characteristics are compared with the HSIs in the detailed standard plant design to verify that they conform to the design that resulted from the HFE design process and V&V activities. Section 3.1.4 states that this verification of the as-built HSIs will be accomplished by performing a physical as-built verification of the MCR, panels and HSIs, and ascertaining that the HSI screens are the same file and revision as used for the HFE V&V. Section 4.1.2.3 states that this as-built verification will ensure that any critical dimensions or physical attributes that may affect the operators' interaction with the HSI are the same as those tested in the HFE V&V, and that a review of the HSI screen files will verify that the file name and revision are the same as was used for the HFE V&V. Section 3.1.4(2) states that an HED is written to resolve the following types of issues: if an as-built verification indicates a variance from the HSI design specifications; or if there is insufficient documentation to confirm that the as-built HSI software is the same as that verified in the HFE V&V.

With respect to verification of as-built procedures and training, Tier 2, Revision 6, Section 18.12.2.2, states that the approach is to conduct an audit of the as-built plant procedures and training.

NEDO-33278, Revision 4, Section 3.2.2, states that the goal of the audit of the standard as-built plant procedures and training is to compare the as-built" documents to the corresponding documents used in the HFE V&V and assess any differences. Section 3.2.3 states that the final as-built procedures and training are compared with the standard plant procedures and documentation to verify that they conform to the design that resulted from the HFE design process and V&V activities. Section 3.2.4 states that an HED is written to resolve any deviations or changes.

Accordingly, the staff finds the Design IP's treatment of the final as-built comparison acceptable.

(3) All HFE-related issues documented in the issue tracking system should be verified as adequately addressed.

Evaluation of Criterion (3)

NEDO-33278, Revision 4, Section 1.1, indicates that one purpose of design implementation is to "verify resolution of remaining Human Engineering Discrepancies (HEDs) and open items from the Human Factors Engineering Issue Tracking System (HFEITS)." Section 3.4 describes the methodology for doing so. Section 3.4.1 states that the HFE V&V of the standard plant design addresses the bulk of the HEDs from the HFE design and development. Following acceptance of the standard plant design, the responsibility for HFEITS is transferred to the fleetwide owners' group. During and after design implementation, for each plant built based on the standard plant design, issues and HEDs continue to be identified and resolved in the HFEITS under the responsibility of the COL holder with support from the fleetwide owners' group. Section 3.4.2 states that a goal of the design implementation is to evaluate the

remaining HEDs and open issues in HFEITS, for the ESBWR standard plant design, for their impact on the safe operation of the plant.

Accordingly, the staff finds the Design IP's treatment of verification of the issue tracking system acceptable.

18.12.3.2 Relationship to Other Documents

18.12.3.2.1 DCD Tier 1, Section 3.3, "Human Factors Engineering"

DCD Tier 1, Revision 6, Table 3.3-2, contains the Tier 1 ITAAC developed by the applicant for HFE. Table 3.3-2 contains 10 items, one for each element of NUREG-0711 (except HFE program management, procedures and training), plus one Item which addresses integrated system validation scenarios. Each item in Table 3.3-2 is linked to the corresponding ESBWR element IP. As described in Section 14.3.9 of this report, DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the design implementation is completed in accordance with the IP (NEDO-33278, Revision 4), which the staff has reviewed and approved.

18.12.3.2.2 DCD Tier 2, Section 18.12, "Design Implementation"

In RAI 18.12-7, the staff requested that the applicant address inconsistencies between DCD Tier 2, Section 18.12, Revision 3, and NEDO-33278, Revision 2. RAI 18.12-7 was being tracked as an open item in the SER with open items. In its response, the applicant proposed changes to DCD Tier 2 to be consistent with NEDO-33278. The staff confirmed that DCD Tier 2, Section 18.12, Revision 5, which included additional modifications beyond the RAI response, was consistent with NEDO-33278, Revision 3. Based on the applicant's response and the DCD revision, RAI 18.12-7 is resolved.

DCD Tier 2, Section 18.12, provides a high-level description of the ESBWR design implementation activities, including the objectives and scope, and the key elements of the design implementation methodology. This section of the DCD also references the detailed IP (NEDO-33278, Revision 4), which is designated as Tier 2*. As discussed above, NEDO-33278, Revision 4 describes a design implementation program that addresses the NUREG-0711 criteria for design implementation. Thus, Tier 2, together with the referenced IP provides an acceptable description of the ESBWR design implementation program.

18.12.4 Conclusions

The staff reviewed the ESBWR design implementation at an IP level (see Section 18.1.4 of this report for a discussion of review levels), using the review criteria in Section 12.4 of NUREG-0711. For the reasons set forth above, the staff concludes that the ESBWR design implementation program, as described in NEDO-33278, Revision 4, provides an acceptable methodology to ensure that the as-built design conforms to the verified and validated design that resulted from the HFE design process. DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the design implementation is completed in accordance with the IP (NEDO-33278, Revision 4), which the staff has reviewed and approved. Accordingly, the staff concludes that the applicant's design implementation is acceptable at the IP level.

18.13 Human Performance Monitoring

18.13.1 Regulatory Criteria

The objective of reviewing human performance monitoring is to verify that the 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 and to provide adequate assurance that the conclusions that have been drawn from the evaluation remain valid over time. The applicant may incorporate this monitoring strategy into its problem identification and corrective action program.

To review the applicant's human performance monitoring (HPM) plan, the staff used the review criteria in NUREG-0711, Section 13.4.

18.13.2 Summary of Technical Information

The ESBWR HPM is described in DCD Tier 2, Revision 6, Section 18.13, "Human Performance Monitoring." DCD Tier 2, Revision 6, Section 18.13, incorporates by reference NEDE-33217P, Revision 6, and NEDO-33277, Revision 4, "ESBWR Human Factors Engineering Human Performance Monitoring Implementation Plan."

The staff also reviewed the following ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 6
- NEDE-33276P, "ESBWR HFE Verification and Validation Implementation Plan," Revision 4
- GEH response to RAIs 18.13-1 through 18.13-5 (MFN 06-470)

18.13.3 Staff Evaluation

The staff performed an IP level of review as described in NUREG-0711 and Section 18.1 of this report. This section presents the applicable review criteria from NUREG-0711 (reproduced below) followed by an evaluation of each criterion. In addition, this section also addresses related documents (i.e., DCD Tier 1 and Tier 2 information).

18.13.3.1 NUREG-0711 Review Criteria

NUREG-0711 includes five criteria for this topic.

(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.

- HA can be accomplished within time and performance criteria.

- The acceptable level of performance established during the integrated system validation is maintained.

Evaluation of Criterion (1)

The first bullet of Criterion (1) for the HPM element in NUREG-0711 states that the performance monitoring strategy should provide reasonable assurance that personnel can effectively use the design, including within the control room and between the CR and LCSs and emergency planning support centers. DCD Tier 2, Revision 6, Section 18.13, addresses this item at a high level. NEDO-33277, Revision 4, Section 1.2, "Scope," addresses it more specifically, noting the various locations for personnel actions.

DCD Tier 2, Revision 6, Section 18.13, states that the HPM program provides reasonable assurance of the following:

- The HSI design is effective during a variety of conditions ranging from normal operations through design basis accidents and key PRA scenarios.

- Changes made to the initial HSIs, 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 the Institute of Nuclear Power Operations as part of the Human Performance Enhancement System.

NEDO-33277, Revision 4, Section 3, references the V&V portion of the design phase and describes how that provides the baseline showing the effective use of the various HSIs by personnel. Section 3.2 states that the operational phase of the HPM program provides reasonable assurance of the following:

- The acceptable level of performance established during the integrated V&V is maintained.

- Changes made to the standard ESBWR HSIs, procedures, staffing, and training are evaluated for design impact and consistently applied at all ESBWRs in a timely manner.

- Changes made to the HSI are tested in the full-scope simulator before implementation in the plant.

NEDO-33277, Revision 4, Section 3.2.4, states that periodic evaluation and trending of operators' performance of tasks with respect to time and accuracy goals are undertaken to demonstrate performance consistent with that developed during the various analyses that support the design.

In view of the foregoing, the staff finds the HPM Plan's treatment of the criterion for scope acceptable.

(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 [warrants] 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.

Evaluation of Criterion (2)

NEDO-33277, Revision 4, and DCD Tier 2, Revision 6, Section 18.13, provide the overview of a detailed plan for HPM during the design, V&V, and operational phases of the ESBWR. The plan includes activities for the nuclear steam supply system designer (GEH), the fleetwide ESBWR owners' group, and the COL holder (ESBWR licensee). The strategy includes well-coordinated activities. The HPM Plan outlines the use of various existing programs in the overall scheme, including the HFE V&V, the startup testing program, the CAP, the Maintenance Rule program, PRA and HRA activities, inservice inspection and inservice testing programs, the operator training program, the HFEITS, and the operating experience program. The HPM strategy is also structured to ensure standardization across the fleet of ESBWRs. Accordingly, the staff finds the HPM Plan treatment of the criterion for strategy development acceptable.

(3) The program should be structured such that

- HAs 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).

Evaluation of Criterion (3)

NEDO-33277, Revision 4, states that the objective of the ESBWR HPM Plan is to ensure that no safety degradation occurs because of changes in design, procedures, training, or staffing. Section 3.1.1 states that HAs are monitored commensurate with risk importance. The report also discusses risk screening of operational events for importance in Sections 1.2.2, 1.2.3, and 3.2.4. Section 3.2.4 mentions precursor and PRA analyses that are used for prioritization. Section 3.2.4 and Chapter 4 discuss the use of the full-scope simulator. The HPM Plan also discusses the use of trending and root cause analysis to understand the impact of an issue on plant operation and safety. NEDO-33277, Revision 4, Figure 2, outlines the overall structure of the program. The HPM program includes data collection, screening for importance, analyzing events to determine the cause and to trend the events, and developing corrective actions. Together, these actions should provide for a robust program that detects and corrects issues before plant safety is compromised. In this regard, Section 1.2 of the plan outlines the responsibilities of GEH, the fleetwide ESBWR owners' group, and ESBWR licensees.

Accordingly, the staff finds the HPM Plan's treatment of the criterion for the structure of the HPM strategy acceptable.

(4) Plan of 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.

Evaluation of Criterion (4)

The HPM program provides for the use of a combination of operating experience data, an ESBWR full-scope simulator, data analysis, and the involvement of the ESBWR vendor, the licensee, and the fleetwide ESBWR owners' group. This combination should provide for data and experience that are as close to actual demand conditions as is reasonably achievable. NEDO-33277, Revision 4, Chapter 3 lists the portions of the program that show its breadth. Accordingly, the staff finds the HPM Plan's treatment of the criterion for approximating performance data acceptable.

(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 [recurrence of] 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.

Evaluation of Criterion (5)

Using an ESBWR licensee's CAP, the HPM program has a built-in method for identifying causes of human performance issues or degradations and correcting identified issues. Industry CAPs also include trending features, and NEDO-33277, Revision 4, Section 3.2.3, notes that the licensee's CAP provides for the evaluation of conditions and trends for their potential to impact the standard ESBWR design. NEDO-33277, Revision 4, Section 3.2, states that the program addresses the significance of the failure through application of precursor analysis and HRA /PRA importance measures. The fleetwide ESBWR owners' group will be able to address the generic aspects of failures. CAPs also have features to address significant failures and to prevent the recurrence of such failures. Accordingly, the staff finds the HPM Plan's treatment of the criterion for cause determination acceptable.

18.13.3.2 Relationship to Other Documents

18.13.3.2.1 DCD Tier 1, Section 3.3, "Human Factors Engineering"

DCD Tier 1, Revision 6, Table 3.3-2, contains the Tier 1 ITAAC developed by the applicant for HFE. Table 3.3-2 contains 10 items, one for each element of NUREG-0711 (except HFE program management, procedures and training), plus one Item that addresses integrated system validation scenarios. Each item in Table 3.3-2 is linked to the corresponding ESBWR

element IP. As described in Section 14.3.9 of this report, DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the HPM is completed in accordance with the IP (NEDO-33277, Revision 4), which the staff has reviewed and approved.

18.13.3.2.2 DCD Tier 2, Section 18.13, "Human Performance Monitoring"

DCD Tier 2, Section 18.13 provides a high-level description of the ESBWR HPM implementation activities, including the purpose, the strategy, and the key elements of the HPM process. This section of the DCD also references the detailed IP (NEDO-33277, Revision 4), which is designated as Tier 2*. As discussed above, NEDO-33277, Revision 4, describes an HPM program, which addresses the NUREG-0711 criteria for HPM. Thus, Tier 2, together with the referenced IP, provides an acceptable description of the ESBWR HPM program.

18.13.4 Conclusions

The staff reviewed the ESBWR HPM at an IP level (see Section 18.1.4 of this report for a discussion of review levels) using the review criteria in Section 13.4 of NUREG-0711. For the reasons set forth above, the staff concludes that the ESBWR HPM program, as described in NEDO-33277, Revision 4, provides an acceptable methodology for developing a monitoring strategy that ensures no significant safety degradation occurs because of plant changes. DCD Tier 1, Section 3.3, provides ITAAC sufficient to confirm that the HPM is completed in accordance with the IP (NEDO-33277, Revision 4), which the staff has reviewed and approved. Accordingly, the staff concludes that the applicant's HPM is acceptable at the IP level.

18.14 Minimum Inventory

18.14.1 Regulatory Criteria

The staff reviewed the Minimum Inventory in accordance with SRP Section 14.3.9, "Human Factors Engineering—Inspections, Tests, Analyses, and Acceptance Criteria," issued March 2007. The Minimum Inventory is acceptable if it meets the guidelines of the agency's policy prescribed in the SRM on SECY-92-0053. The staff evaluates the Minimum Inventory using the direction provided in SRP Section 14.3.9, with recognition that the NUREG-0711 process, as implemented by DCD Tier 2, Chapter 18, will validate and continue to develop the design characteristics associated with the parameters that constitute the Minimum Inventory. For clarity, in this section "Minimum Inventory" is capitalized when referring to the inventory of CDAs specifically covered by the SRM on SECY-92-0053 and SRP Section 14.3.9.

18.14.2 Summary of Technical Information

DCD Tier 1, Section 3.3, and Tier 2, Section 18.1 list the ESBWR Minimum Inventory. Tier 2, Section 18.5A, incorporates a process description.

The staff also reviewed the following ESBWR documents:

- MFN 8-859 (RAI 18.8-47 S02), MFN 09-024 (RAI 18.8-47 SO3), MFN 09-264 (RAIs 18.5-35 to 18.5-40), MFN 09-305 (RAI 18.5-33), MFN 09-328 (RAI 18.5-34), MFN 09-297 (RAI 18.7-7 SO5), MFN 09-636 (RAI 18.4-41), MFN 09-753 (RAI 18.7-16), MFN 09-780 (RAI 18.5-41 S01)

- "ESBWR Design Comparison to BWROG EPG/SAG," Revision 2 (ESBWR delta document)

- NEDE-33221P, Revision 4, "ESBWR Human Factors Engineering Task Analysis Implementation Plan"

- NEDO-33267, Revision 4, "ESBWR Human Factors Engineering Human Reliability Analysis Implementation Plan"

- NEDO-33201, Revision 5, "ESBWR Probabilistic Risk Assessment," Chapter 17, "Results Summary"

18.14.3 Staff Evaluation

In RAI 18.8-47, the staff requested that the applicant explain how Minimum Inventory is identified and state the criteria used in the selection process. As documented through several supplemental RAIs, the staff determined that the Minimum Inventory and the process to develop it should to be included in the DCD. RAI 18.8-47 was being tracked as an open item in the SER with open items. In the applicant's response to RAI 18.8-27 and related RAIs, the applicant revised DCD Tier 2, Revision 6, Section 18.5.1, to describe the process used to determine Minimum Inventory and included the Minimum Inventory in DCD Tier 2, Revision 6, Tables 18.1-1a and 18.1-1b. The staff evaluation of Minimum Inventory and its development described below and the staff finds them acceptable. Based on the applicant's response and the DCD Revisions, RAI 18.8-47 is resolved.

SRP Section 14.3.9, Criterion (6), states:

> Minimum Inventory of Displays, Alarms and Controls:
>
> Tier 1 includes a Minimum Inventory of displays, controls, and alarms that are necessary to carry out the vendor's emergency procedure guidelines (i.e., Owners' Groups Generic Technical Guidelines) and critical actions identified from the applicant's PRA and task analysis of operator actions. The reviewer's evaluation of the Minimum Inventory will encompass a multi-disciplinary effort consisting of human factors, I&C, PRA, and plant, reactor, and electrical system engineering. The Minimum Inventory list has been implemented through the rule-making process for four certified designs (10 CFR Part 52 Appendixes A, B, C, and D). The criteria used to determine acceptability of the inventory includes assuring that:
>
> (1) the scope of these items in the Generic Technical Guidelines and PRA effort are adequately considered,
>
> (2) the task analysis is detailed and comprehensive,
>
> (3) RG 1.97, Revision 3, Category 1 variables or RG 1.97, Revision 4, Type A, B, and C variables for accident monitoring are included, and
>
> (4) important system displays and controls described in Tier 1 system design descriptions necessary for transient mitigation are included.

The staff has evaluated the four criteria as described below:

Criterion (1)—The scope of these items in the Generic Technical Guidelines and PRA effort is adequately considered.

Evaluation of Criterion (1)

In DCD Tier 2, Section 18.5.1.2, the applicant states that the BWROG EPGs are used to develop the Minimum Inventory. The applicant explains that these more generic guidelines are used because the detailed plant design needed to draft an ESBWR-specific EPG is not complete. A functional analysis of the ESBWR design was completed to link the strategy and task guidance contained in the BWROG document with the design specifics and system capabilities of the ESBWR.

The function and task elements identified in the functional analysis (for both design similarities and differences) were documented in a "delta document" and subsequently used as input to a task analysis that identified CDAs needed to meet plant design goals and safety analysis assumptions. This subset of CDAs makes up the Minimum Inventory. Within the context of the Minimum Inventory process, the ESBWR delta document was characterized as an analytical tool used for the derivation of the ESBWR Minimum Inventory. It was not used to document the task analysis results on a step-by-step basis. This limits the staff's ability to audit the process but is consistent with the level of detail accepted for documenting Minimum Inventory in other design centers.

The staff considers the applicant's use of the BWROG EPGs as a starting point to be an alternate method to the guidance provided in the SRP. While the BWROG EPGs are a complete set of guidelines for the design-basis accidents applicable to the ESBWR, they are generic rather than ESBWR-specific EPGs. However, the BWROG EPGs are the basis for operating BWR EOPs, and as such they incorporate substantial design and operating experience. Because the BWROG EPGs reflect this operating experience, the staff determined them to be an acceptable starting point for the Minimum Inventory analysis when paired with an ESBWR delta document that identifies the ESBWR design similarities and differences. The staff also noted that the tasks associated with Minimum Inventory would be subject to additional detailed reviews during the task analysis described in DCD Tier 2, Section 18.5.2. This task analysis is part of the detailed HFE design process that implements NUREG-0711 guidance.

In DCD Tier 2, Section 18.5.1.2, the applicant describes how HAs identified in DCD Tier 2, Chapter 19, "Probabilistic Risk Analysis (PRA)," were selected for the evaluation supporting identification of the Minimum Inventory. In summary, operator actions that would contribute greater than or equal to 10 percent of the NRC safety goals (i.e., CDF 1×10^{-4}/year, LRF 1×10^{-6}/year), if not completed successfully, were identified from the larger set of risk important HAs. Four operator actions met these criteria. A task analysis of each action was subsequently completed to identify the Minimum Inventory. While only the highest risk HAs are analyzed for their potential impact on the Minimum Inventory list, NEDO-33201 identifies approximately 40 risk-important HAs identified in Chapter 17, Table 17.1-3. These actions are all evaluated within the scope of the detailed task analysis described in DCD Tier 2, Section 18.5.2.

In view of the above, the staff determined that appropriate risk-important HAs from the ESBWR PRA were identified for inclusion in the Minimum Inventory analysis.

Criterion (2)—The task analysis is detailed and comprehensive.

Evaluation of Criterion (2)

The applicant's process uses a functional analysis of the ESBWR design to link the ESBWR operating and accident mitigation strategies identified in the BWROG EPG and ESBWR PRA with the specific design and system capabilities of the ESBWR. A task analysis of each of the resulting elements was then completed to determine the CDAs needed to meet ESBWR plant design goals and safety analysis assumptions. Different combinations of CDAs were identified depending upon whether the analyzed element's emphasis was on alerting, monitoring, diagnosing, and/or operating equipment.

The staff reviewed the completed ESBWR delta document. The staff determined that the document contained sufficient depth to ensure that design similarities and differences were properly identified and that it was an acceptable analytical tool for supporting the determination of the Minimum Inventory. The staff also reviewed the Minimum Inventory list that resulted from the task analysis. Because the staff could not draw a direct correlation between each step in the delta document and the Minimum Inventory list, the following concerns warranted additional clarification from the applicant:

- The delta document identifies several design differences that appeared to warrant additional CDAs for systems such as fuel and auxiliary pool cooling system (FAPCS), condensate, and control rod drive. Several RAI open items were associated with these differences. They have all been satisfactorily addressed by the applicant as described below.

  In RAI 18.5-37, the staff requested that the applicant clarify why additional controls and displays for the FAPCS were not included on the Minimum Inventory list. In response to this RAI, the applicant stated that the suppression pool cooling function of the FAPCS initiates automatically and does not credit additional operator alarms or tools for manual initiation (controls and indications). The operator verifies successful initiation using the suppression pool temperature response, and additional indications, controls, and alarms are not credited. The staff determined that this position conformed to regulatory guidance contained in the Standard Review Plan Section 14.3.9. Additional details are provided below. Based on the applicant's response, RAI 18.5-37 is resolved.

  In RAI 18.5-38, the staff requested that the applicant clarify why additional alarms for some analog signals of 4–20 milliamperes, such as containment water level, wetwell pressure, containment radiation, gravity-driven cooling pool level, and standby liquid control (SLC) accumulator level are not included on the Minimum Inventory list. In response to this RAI, the applicant provided the following information:

  Containment Water Level—The BWROG EPG does not describe any operator action that applies to the ESBWR design and relies on a specific setpoint for containment water level. A display is provided as a tool for determining correct system performance.

  Wetwell Pressure—Wetwell pressure is tied directly to drywell pressure The BWROG EPG does not describe any operator action that applies to the ESBWR design and relies on a specific setpoint for wetwell pressure. A display is provided as a tool for determining correct system performance.

Containment Radiation—The BWROG EPG does not describe any operator action that applies to the ESBWR design and relies on a specific setpoint for containment radiation level. This action is employed in the performance of the severe accident management guidelines: however, severe accident management is not included in the minimum inventory scope.

Gravity-Driven Cooling Pool Level—The BWROG EPG does not describe any operator action that applies to the ESBWR design and relies on a specific setpoint for gravity driven cooling pool level. The operator verifies successful initiation of the gravity-driven cooling system using reactor vessel level indication. A display is provided as a tool for determining correct system performance.

SLC Accumulator Level—The BWROG EPG does not describe any operator action that applies to the ESBWR design and relies on a specific setpoint for SLC accumulator level. The operator verifies successful accumulator isolation on low level using reactor power, pressure, and level indications

The staff finds this response acceptable because there were no operator actions based on the specific parameter setpoints. This position conforms to regulatory guidance contained in the Standard Review Plan, Section 14.3.9. Based on the applicant's response, RAI 18.5-37 is resolved.

In the RAI responses, the applicant provided additional information on how they performed the minimum inventory analysis. In summary, during the task analysis phase, plant analysts selected "primary mitigating function(s)" for steps that contained multiple options. Typically, the primary function is the automatic protective action for the ESBWR design. Manual actions are included as alternate actions. The staff determined that using primary versus alternate actions from the EOPs is consistent with the objective of Minimum Inventory in that it identifies the minimum CDAs needed to safely shut down the reactor. While not evaluated as part of the Minimum Inventory, the applicant will evaluate alternate actions as part of the detailed design task analysis described in DCD Tier 2, Section 18.5.2. Other steps in the BWROG EPGs identify operator actions to monitor the effectiveness of automatic system performance. Also, in the task analysis, plant analysts evaluated each HA within the context of the task sequence involving that action. The applicant compiled the Minimum Inventory for the following functions:

– HSIs needed to support decision making
– HSIs needed to support plant manipulations
– HSIs needed to prompt action
– HSIs needed to support the monitoring of task success criteria

The staff concluded that this strategy was acceptable for development of the Minimum Inventory because the proposed process provides reasonable assurance that all Minimum Inventory controls, alarms and displays are identified.

- The isolation condenser system with alarm, display, and control functions is included in the Minimum Inventory Tier 1 table for RSS, but it is not included in the Minimum Inventory Tier 1 table for the CR which instead lists isolation condenser valves with display and control functions. The applicant explained that manual control from the remote shutdown panel is assumed for the isolation condenser system, and therefore,

alarms, controls and displays are included in the RSS Minimum Inventory. Automatic operation occurs from the control room. Valve position indication and control functions are provided to ensure that system automatic functions are completed. The staff determined that this is an acceptable position as it reflects design differences between the CR and the RSS.

Similarly, there was no documentation of the task analysis results specific to each of the risk-important HAs evaluated. The following are the four pertinent HAs from NEDO 33210, Table 17.1-3 are:

- The operator fails to recognize the need for low pressure makeup after depressurization
- The operator closes the lower drywell hatch.
- The operator fails to recognize the need to makeup ICS/PCCS pool level.
- The operator fails to actuate U43 in low-pressure coolant injection (LPCI) mode.

The staff was able to correlate actions 1 and 3 to appropriate controls, alarms and displays contained in the Minimum Inventory list. In RAI 18.5-41, the staff requested the applicant to explain how actions 2 and 4 were dispositioned. In their response, the applicant provided the following information.

- Action 2: No CDAs (for example, hatch closure indication) are included in the Minimum Inventory list for this risk-important HA. The circumstance in which the action could be necessary is a plant refuel/maintenance period during which the lower drywell hatches are open. In this condition, personnel would likely be working in the drywell or its immediate vicinity and drywell access and status would be monitored and controlled in accordance with the facility administrative procedures. Under 10 CFR 50.65(a)(4), the licensee is required to assess and manage the increased risk that may result from maintenance activities. Based on current industry practice, the administrative procedures to satisfy the requirements of 10 CFR 50.65(a)(4) would address the risk aspects of the hatch being open and would provide direction for contingency planning. In the case of a LOCA with the lower drywell hatches open, the contingency action would be to close the lower drywell hatches.

- The task of closing the lower drywell hatches in the case of a LOCA requires no additional CR CDAs. The CR CDAs needed to prompt action are a reactor water level alarm and display, which are already included in the ESBWR Minimum Inventory. The CR display needed to support decision making is a Containment Water Level display, which is also already included in the ESBWR Minimum Inventory. No CR CDAs are needed to support plant manipulations or monitoring success criteria as the task (closing the hatches) is performed locally in the reactor building.

- The staff has determined that the applicant's response is acceptable since the applicant's proposed control method provides reasonable assurance that the hatch position will be effectively controlled without additional CR indication.

The applicant provided the following information on Action 4:

- Action 4: The applicant has performed additional analysis to determine whether CR indication and/or control to support actuation of the U43 LPCI mode (use of the fire

protection system to provide core cooling) would substantially improve the operator's ability to ensure that this task is completed. The next paragraph provides the analysis.

The task of aligning the fire protection system to provide core cooling involves starting a backup LPCI pump located in the fire pump enclosure and establishing a flowpath using valves F346 and F332A or F332B (see DCD Tier 2, Figure 9.1-1). This diverse injection mode does not require offsite power or the standby diesel generators, uses the fire protection tank for a source of water, and can be operated locally. The task of aligning fire protection for these sequences is performed in the plant locally. CR indication and/or control for system alignment would not substantially improve in the operator's ability to complete the task. The CR display and alarm that prompt the need for the task (low or lowering reactor water level) are a reactor water level alarm and display, which are included in the ESBWR Minimum Inventory. The CR display needed to determine if a task prerequisite is met (pressure below injection system limits) is a reactor pressure display, which is also included in the ESBWR Minimum Inventory. Monitoring of task success (restore reactor water level above top of active fuel) would warrant a CR display for reactor water level. As noted above, this display currently exists in the ESBWR Minimum Inventory.

Based on the assessment above, the applicant concluded that the task of aligning the Fire protection system to provide core cooling would not call for additional CR controls, displays or alarms.

The staff has determined that the applicant's response is acceptable since the applicant's proposed control method provides reasonable assurance that alignment of the fire protection system to provide core cooling will be effectively controlled without additional CR CDAs. The applicant has appropriately supplemented PRA information with design-basis information supporting the configuration. The staff also notes that the valves that are repositioned for this alternate action are manual valves and this alternate action would not be needed until at least 72 hours after an event occurs. Use of a manually initiated alternate core cooling path provides additional diversity to the core cooling function, and the action occurs after the high workload associated with event initiation. Accordingly, RAI 18.5-41 is resolved.

With this additional information, the staff concludes that the task analysis is sufficiently rigorous to provide reasonable assurance that the applicant identified a complete Minimum Inventory. The applicant provided an adequate basis for the CDAs that were on the list, as well as those that were not. An interdisciplinary review of the inventory did not identify any inconsistencies.

Criterion (3)—Ensuring that RG 1.97, Revision 3, Category 1 variables, or RG 1.97, Revision 4, Type A, B, and C variables for accident monitoring are included.

Evaluation of Criterion (3)

The Minimum Inventory list in DCD Tier2, Chapter 18.1 does not explicitly include RG 1.97 variables. While RG 1.97 variables and the CDAs relied upon to implement EPGs overlap significantly, the process proposed by the applicant does not include RG 1.97 variables as input to the Minimum Inventory. The RAI response in MFN 09-024 summarizes how the applicant proposed to address these variables. The applicant stated:

Regulatory Guide 1.97 focus is fundamentally different from that of SECY-92-053 in that it focuses on the execution of the detailed control room design process.

> The Regulatory Guide specifies accident monitoring instrument selection criteria and assigns design requirements that the detailed design process must accommodate. By contrast, the SECY-92-053 Minimum Inventory precedes the detailed design process. The two concepts significantly overlap in the area of variable selection but SECY-92-053 Minimum Inventory culminates in design certification while Regulatory Guide 1.97 & IEEE 497 guide the detailed design process and culminate in the final design.

Both the HFE and I&C chapters of the SRP address the implementation of RG 1.97 guidance. Both areas have been approved as "DAC ITAAC" where the actual physical design is deferred because it is subject to rapidly changing technology. Consequently, if RG 1.97 variables were to be included in the Minimum Inventory process, the detailed design process would either have to be expedited (which is inconsistent with DAC ITAAC guidance) or a different, potentially less robust process, would have to be used. The staff has determined that following the detailed design process, which is evaluated and approved as part of the DCD, provides a more systematic and thorough approach to the overall CR design. Accordingly, the staff finds the applicants plan for addressing the interface between RG 1.97 and Minimum Inventory to be acceptable

Another supporting factor in this decision is that the applicant is committed to implementing Revision 4 of RG 1.97, which is summarized below.

> Revision 4 to Regulatory Guide 1.97 represents a significantly different approach to the topic from the previous revisions. Revision 4 is based on IEEE Std. 497-2002, which establishes flexible, performance-based criteria for the selection, performance, design, qualification, display, and quality assurance of accident monitoring variables. There is no prescriptive list of accident monitoring parameters or associated functional requirements on a parameter-by-parameter basis.

Unlike previous RG 1.97 revisions, Revision 4 does not provide a specific list of parameters. Revision 4 calls for the detailed I&C design process to be completed before specific parameters are available.

The staff finds the applicant's plan to incorporate guidance from RG 1.97 and IEEE standard 497-2002 "IEEE Standard Criteria for Accident Monitoring Instrumentation for Nuclear Power Generating Stations—Description," in detailed design review to be an acceptable alternative to addressing the variables within Minimum Inventory. Fundamentally, the staff believes this provides a more thorough assessment of the CR HFE design, as it keeps important decisions within the framework of the detailed design processes for HFE and I&C, rather than addressing the guidance within the potentially less rigorous process used to develop Minimum Inventory. DCD Tier 1, Section 3.3 ITAAC 3, 6, and 9 are sufficient to confirm the RG 1.97 parameters are addressed in the HFE design

Criterion (4)—Ensuring the inclusion of important system displays and controls described in Tier 1 system design descriptions necessary for transient mitigation are included.

Evaluation of Criterion (4)

A multidisciplinary group consisting of human factors, I&C, PRA, and plant, reactor, and electrical system engineering reviewed the Minimum Inventory list. The staff determined that the list provides a complete list of CDAs needed to address EPGs and applicable risk-important HAs. While this design information provides definition to the CR design, the detailed design process as described in the IPs submitted as part of the DCD Chapter 18 will integrate the Minimum Inventory with the complete CR design. The Minimum Inventory list provides an acceptable starting point for the CR design. The detailed HSI and CR design process implemented in satisfying the ITAAC will provide the final complete design.

18.14.4 Conclusions

The staff concludes that the ESBWR methodology used to develop the Minimum Inventory list and the resulting list conforms to the guidelines of SRP Section14.3.9 that apply to minimum inventory. Accordingly, the staff concludes that the ESBWR Minimum Inventory conforms to the applicable guidelines in the SRM on SECY-92-053.

18.15 Generic Issues Related to Human Factors Engineering

Generic issues determined to be applicable to the ESBWR design and related to HFE are evaluated below.

18.15.1 Human Factors Issues

Issue HF1.1: Shift Staffing

This issue addresses (1) ensuring that the numbers and capabilities of the staff at nuclear power plants are adequate to operate the plant so as to provide adequate protection to the public health and safety and (2) determining the minimum appropriate shift crew staffing composition. To address this issue, an applicant should consider the number and functions of the staff needed to safely perform all necessary plant operations, maintenance, and technical support for each operational mode; the minimum qualifications of plant personnel in terms of education, skill, knowledge, training, experience, and fitness for duty; and appropriate limits and conditions for shift work, including overtime, shift duration, and shift rotation.

The requirements governing this issue are set forth in 10 CFR 50.54(m), and the review criteria for this issue appear in SRP Sections 13.1.2–13.1.3, which address operating organization, SRP Section 18, NUREG-0711 element on “Staffing and Qualifications,” and RG 1.114, “Guidance to Operators at the Controls and to Senior Operators in the Control Room of a Nuclear Power Unit.” The applicant has addressed staffing at an appropriate level of detail for a design certification review in Tier 1, Section 3.3, Design Commitment 4; Tier 2 Section 18.6; and NEDO-33266, Revision 3. This review is addressed in Section 18.6 of this report. Therefore, Issue HF1.1 is resolved for the ESBWR design.

Section 13.1 of this report evaluates the organizational structure of the applicant as described in DCD Tier 2, Revision 5, Chapter 13.

Issue HF4.1: Inspection Procedure for Upgraded Emergency Operating Procedures

As discussed in NUREG-0933, Issue HF4.1 addresses the development of criteria by the NRC to provide assurance during inspections that operating plant EOPs are adequate and can be used effectively. The staff published lessons learned from its inspections of EOPs at plants in NUREG-1358, "Lessons Learned from the Special Inspection Program for Emergency Operating Procedures," issued April 1989. The NRC later issued Temporary Instruction (TI) 2515/92, "Emergency Operating Procedures Team Inspections," containing guidance for conducting these inspections. The issue was resolved with no new requirements.

DCD Tier 2, Sections 13 and 18.9, address procedures. DCD Tier 2, Section 18.9 incorporates by reference NEDO-33274. Section 13.5 of this report provides the staff's evaluation of plant procedures, as described in DCD Tier 2, Revision 6, Sections 13.5 and 18.9. Therefore, Issue HF4.1 is resolved for the ESBWR design.
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Issue HF4.4: Guidelines for Upgrading Other Procedures

As discussed in NUREG-0933, this issue addresses efforts by the staff to evaluate the quality of, and the problems associated with, existing plant procedures to ensure that plant procedures (other than EOPs, which are discussed in Issue HF4.1 above) are adequate and effective, and to guide operators in maintaining plants in a safe state under all operating conditions. The NRC was to evaluate the need to develop technical guidance for use by industry in upgrading normal and abnormal operating procedures. To satisfy the objective of this issue, an applicant should (1) develop guidelines for preparing and criteria for evaluating normal operating procedures and other procedures that affect plant safety and (2) upgrade the procedures, train the operators in their use, and implement the upgraded procedures. Note that item (2) applies only to operating plants.

The review criteria for this issue appear in SRP Sections 13.5.1, "Administration Procedures," and 13.5.2, "Operating and Maintenance Procedures," and IN 86-64, "Deficiencies in Upgrade Programs for Plant Emergency Operating Procedures," dated August 14, 1986.

In Section 13.5.3 of this report, the staff evaluated a COL action item that calls for the COL applicant to generate a plant operating procedure development plan. The plan will describe the methods and criteria for the development, V&V, implementation, maintenance, and revision of procedures that address off-normal or alarm condition operations, integrated operations, emergency operation, maintenance, modifications, radiation control, calibration, inspection, and testing. The staff concluded that the plan had appropriate scope. Issue HF4.4, guidelines for upgrading other procedures is resolved for the ESBWR design.

HF5.1: Local Control Stations

As discussed in NUREG-0933, Issue HF5.1 addresses the assurance that operator interfaces at local control stations and auxiliary operator interfaces are adequate for the safe operation and maintenance of a nuclear power plant. The concerns associated with this issue include the assurance that indications and controls available to operators at local control stations outside of the CR and remote shutdown room are sufficient and appropriate for their intended use. CR crew activities should be analyzed to establish and describe communication and control links between the CR and the auxiliary control stations. Additionally, the potential impact of the actions of auxiliary personnel on plant safety should be analyzed.

The NRC resolved this generic issue and established no new requirements. In DCD Tier 2, Table 1.11-1 for HF 5.1, the applicant stated that its ongoing program for the design of I&C systems and MMISs incorporates all applicable HFE requirements.

DCD Tier 1, Revision 6, Section 3.3, Design Commitment 6, and DCD Tier 2, Revision 6, Section18.8, "Human-System Interface Design," address HSI design. DCD Tier 2, Revision 6, Section 18.8, incorporates by reference NEDO-33268, Revision 4, "ESBWR Human-System Interface Design Implementation Plan." Section 18.8 of this report provides the staff's review of this material. The scope of the HFE program addresses the MCR, remote shutdown panel, and the local LCSs. Therefore, Issue HF5.1 is resolved for the ESBWR design.

Issue HF5.2: Review Criteria for Human Factors Aspects of Advanced Controls and Instrumentation

As discussed in NUREG-0933, Issue HF5.2 addresses the use of advanced I&C, in particular with respect to plant annunciators. The then-existing human engineering guidelines for CRs addressed the control, display, and information concepts and technologies used in process control systems. The NRC recognized that these guidelines would not be adequate for advanced and developing technologies that could be introduced into future designs. The agency expected that improved alarm systems using advanced technologies would become available, and that the staff would develop guidelines for the use and evaluation of these longer term alarm improvements.

This issue focused on the potential risk that could result from human error in the use of CR alarms. The staff stopped work on this issue when the RES integrated the development of review guidance for advanced alarms into its program to develop an advanced human-interface design review guideline. This issue was resolved with no new requirements. The NRC has subsequently issued Revision 2 of NUREG-0700, which includes HFE guidance for a variety of advanced HSIs, including advanced alarm systems.

In DCD Tier 2, Revision 6, Table 1.11-1 for HF 5.2, the applicant stated that its ongoing program for the design of I&C systems and MMISs incorporates all applicable HFE requirements. DCD Tier 1, Revision 6, Section 3.3, Design Commitment 6, and DCD Tier 2, Revision 6, Section 18.8, "Human-System Interface Design," address HSI design. DCD Tier 2, Revision 6, Section 18.8, incorporates by reference NEDO-33268, Revision 4. Section 18.8 of this report provides the staff's review of this material. The design and the documents include an advanced alarm system and computer-based procedures. These can be acceptably reviewed using NUREG-0711 and NUREG-0700. While the design and the reviews are not complete, the process is in place, and the regulatory guidance for the review is available. Thus, Issue HF5.2 is resolved for the ESBWR design.

18.15.2 Task Action Plan Items

Item B-17: Criteria for Safety-Related Operator Actions

As discussed in NUREG-0933, Item B-17 involves the development of a time criterion for safety-related operator actions, including a determination of whether automatic actuation is necessary. Current plant designs call for the operator to act in response to certain transients. Consequently, it became necessary to develop appropriate criteria for SROAs. The criteria would include a method to determine those actions that should be automated in lieu of operator

actions and development of a time criterion for safety-related operator actions. Such automation is much less necessary in the new passive plants, such as the ESBWR.

The ANSI and ANS issued ANSI/ANS 58.8-1994 to provide criteria that address this issue. NUREG-0711, Section 4, "Functional Requirements Analysis and Function Allocation," provides guidance for determining areas to be automated.

In DCD Tier 2, Revision 6, Table 1.11-1, for Item B-17, the applicant stated that the ESBWR satisfies NRC requirements concerning automation of safety-related operator actions and operator response times. The ESBWR design calls for no operator action earlier than 72 hours for any design-basis accident and has eliminated the need for operator actions for several accidents and transients.

The ESBWR plant systems are designed to provide the operator with the alarms and information needed so that plant conditions can be monitored and the performance of both passive systems and active systems can be evaluated. The non-safety-related systems are designed to provide defense in depth for plant events, and preclude unnecessary actuation of the safety-related passive systems. Backup manual initiation exists for both the passive and active systems.

DCD Tier 1, Revision 6, Section 3.3, Design Commitment 2, and DCD Tier 2, Revision 6, Section 18.4, address functional requirements analysis and function allocation. DCD Tier 2, Revision 6, Section 18.4, incorporates by reference NEDO-33219, Revision 4, and NEDO-33220, Revision 3. Therefore, Item B-17 is resolved for the ESBWR design.

18.15.3 Three Mile Island Action Plan Issues

Issue I.D.1: Control Room Design Reviews

As discussed in NUREG-0933, TMI Issue I.D.1 addresses licensee performance of a detailed review of the CR using HFE techniques and guidelines to identify and correct design deficiencies. NUREG-0737 clarifies this issue, and NUREG-0700 provides review guidance. The staff considered this issue resolved for operating plants with completion of the DCRDRs.

For new plants, the NRC addressed this issue via 10 CFR 50.34(f)(2)(iii), which requires applicants to provide, for Commission review, a CR design that reflects state-of-the-art human factors principles before committing to fabrication of CR panels and layouts. This regulation has been implemented via SRP Chapter 18 and then, by reference, NUREG-0711

ESBWR DCD Tier 1, Revision 6, Section 3.3 and DCD Tier 2, Revision 6, Section 18, address the HFE design of the control room. DCD Tier 2, Revision 6, Section 18.2 incorporates by reference NEDE-33217P, Revision 6, "ESBWR Man-Machine Interface and Human Factors Engineering Implementation Plan (or the MMIS-HFE Plan)." The non-proprietary version of NEDE-33217P is designated as NEDO-33217. These were reviewed in Section 18.2 of this report. In so far as the staff has reached a determination on the information considered in Section 18.2 of this report, the applicant is employing state of the art human factors principles to design the control room. As described in Section 14.3.9 of this report, DCD Tier 1, Section 3.3 provides ITAAC sufficient to confirm the completion of all HFE elements addressed in NUREG-0711 and NEDE-33217P, Revision 6, in accordance with the applicable IPs, which have been reviewed and approved by the staff. Therefore, Issue I.D.1 is resolved for the ESBWR design.

Issue I.D.2: Plant Safety Parameter Display Console

As discussed in NUREG-0933, Issue I.D.2 addresses the improvement of the presentation of information for monitoring the safety status of the plant provided to CR operators. Supplement 1 to NUREG-0737 provides guidance for improving safety function monitoring. This issue raised the need for an SPDS that clearly displays a minimum set of parameters determining the safety status of the plant. The regulation in 10 CFR 50.34(f)(2)(iv) requires a plant SPDS console to provide such a display to operators, to be capable of displaying a full range of important plant parameters and data trends on demand, and to be capable of indicating when process limits are being approached or exceeded. SRP Section 18.II.A.7 and other documents referenced therein provide regulatory guidance for implementing this requirement (including NUREG-1342).

ESBWR DCD Tier 2, Revision 6, Table 1A-1, "TMI Action Plan Items," discusses Item I.D.2 and explains how the principal functions of the SPDS are integrated into the CR design as part of the overall HFE design process. Table 1A-1 states that the ESBWR CR operator interface design incorporates the SPDS function as part of the plant status summary information that is continuously displayed on the large display panel. It will also be available on screen-based video display units. Section 18.8.3 of this report provides the staff's review of the SPDS design, which found the design acceptable. Thus, Issue I.D.2 is resolved for the ESBWR design.

18.15.4 Generic Letters

GL 81-04: Emergency Procedures and Training for Station Blackout Events

GL 81-04, dated February 25, 2010, states that the staff was assessing SBO events on a generic basis (Task Action Plan Item A-44). The GL notes that the results of the SBO study would identify the extent to which design provisions should be included to reduce the potential for or consequences of an SBO event. The unresolved safety issue has subsequently been completed and an SBO rule (10 CFR 50.63, "Loss of All Alternating Current Power") issued. Thus, this GL is encompassed by the SBO rule and related guidance documents.

As stated in ESBWR DCD Appendix 1C, Table 1C-1, the ESBWR does not need emergency alternating current (ac) power to achieve safe shutdown in an SBO event. Therefore, the applicant concluded that this issue (GL 81-04) is not applicable to the ESBWR standard plant design. DCD Tier 2, Table 1.11-1, with regard to Task Action Plan Item A-44, "Station Blackout," makes a similar statement. Section 8.4.2.1 of this report provides the staff's review of the need for emergency ac power. The staff concluded that the safety-related passive systems are capable of withstanding a loss of all ac power for 72 hours and that the ESBWR design will be in compliance with the provisions of 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants," General Design Criteria 17, "Electric Power Systems," and 10 CFR 50.63, as they relate to the capability to achieve and maintain hot or stable shutdown in the event of an SBO. In addition, DCD Tier 2, Table 8.1-1, includes a note to state that procedures and training for SBO response guidelines, ac power restoration, and severe weather guidelines are developed according to Sections 13.2 and 13.5. Therefore, GL 81-04 is resolved for the ESBWR design.

GL 82-33: "Supplement 1 to NUREG-0737—Emergency Response Capabilities"

GL 82-33, dated December 17, 1982, clarifies the various post-TMI items for emergency response capabilities. Section 13 of this report addresses GL 82-33 as it relates to the TSC and EOF. Section 7.1.1.3.5 of this report addresses GL 82-33 as it relates to accident monitoring instrumentation. With respect to human factors, GL 82-33 clarifies the post-TMI items for the SPDS, detailed CR design review, upgrade of EOPs, and the functionality of emergency response facilities. Section 18.15.3, Issue I.D.2, of this report addresses human factors criteria for SPDS. Section 18.15.3, Issue I.D.1, of this report addresses the detailed CR design review. Section 18.2 of this report addresses the application of human factors principles to the EOF and TSC. Accordingly, GL 82-33, as it relates to HFE, is resolved for the ESBWR design.

GL 83-05: "Safety Evaluation of 'Emergency Procedure Guidelines,' Revision 2, NEDO-24934, June 1982"

GL 83-05, dated February 8, 1983, addresses the NRC review and approval of EPGs for the operating fleet of BWRs and the subsequent development of EOPs based on the EPGs. The discussion of Issue HF4.1 in Section 18.15.1 of this report addresses this area.

GL 89-06: "Task Action Plan Item I.D.2—Safety Parameter Display System—10 CFR 50.54(f)"

GL 89-06, dated April 12, 1989, addresses NRC findings related to the adequacy of SPDS installations at operating reactor facilities and forwards additional guidance in the form of NUREG-1342 for their use. Section 18.15.3, TMI Issue I.D.2, of this report fully addresses this item.