18. Human Factors Engineering

18.1 Introduction

This chapter of the safety evaluation report (SER) provides the staff's review of the human factors engineering (HFE) of the General Electric Hitachi Nuclear America, LLC (GEH) Economic Simplified Boiling-Water Reactor (ESBWR) as part of the design certification review being conducted by the U.S. Nuclear Regulatory Commission (NRC) under Title 10, Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," of the *Code of Federal Regulations* (10 CFR Part 52). This review is being conducted 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.

18.1.1 Purpose of Review

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

- 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.

18.1.2 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.

- HFE Program Management
- Operating Experience Review
- Functional Requirements Analysis and Function Allocation
- Task Analysis
- Staffing and Qualifications
- Human Reliability Analysis
- Procedure Development
- Training Program Development
- Human-System Interface Design
- Human Factors Verification and Validation (V&V)
- Human Performance Monitoring

The ESBWR review was accomplished and documented using the review criteria from NUREG-0711 for the above areas of review. In addition, for a limited number of specific topics, the NRC staff used criteria from other review guidance documents. These are identified in the appropriate sections. Sections 18.2 through 18.13 of this report detail the results of the review.

18.1.3 Regulatory Criteria Applicable to All Areas of Review

Many of the regulatory criteria are applicable to all 12 areas of review and so are described here once to reduce redundancy.

10 CFR 52.47 requires that applications for design certification of new reactor designs meet the technically relevant portions of the Three Mile island (TMI) requirements contained in 10 CFR 50.34(f) (except for 10 CFR 50.34(f)(1)(xii), (f)(2)(ix), and (f)(3)(v)). The NRC bases its HFE review on current regulatory requirements established post-TMI in 10 CFR 50.34(f), "Additional TMI-Related Requirements." The NRC reviews HFE aspects of new control rooms to verify that they reflect "state-of-the-art human factors principles" as required by 10 CFR 50.34(f)(2)(iii) and that personnel performance is appropriately supported. 10 CFR 50.34 also requires a safety parameter display system (SPDS), automatic indication of bypassed and operable status of safety systems, and monitoring capability in the control room for a variety of system parameters.

For plants licensed under 10 CFR Part 52, the requirements of 10 CFR 50.34(f) are incorporated via 10 CFR 52.47 and 10 CFR 52.79. 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 human interfaces, considering both hardware and software.

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

18.1.4 Levels of Review

The staff performed three different levels of review, depending on the type of information provided: complete element level, implementation plan level, and programmatic level.

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 “Implementation Plan” level of review is performed when the applicant has not completed an HFE activity. Page 2 of NUREG-0711 states the following: “An implementation plan gives the applicant’s proposed methodology for meeting the acceptance criteria of the element. An implementation plan review gives the applicant the opportunity to obtain staff review of and concurrence in the applicant’s approach before conducting the activities associated with the element. Such a review is desirable from the staff's perspective because it provides the opportunity to resolve methodological issues and provide input early in the analysis or design process when staff concerns can more easily be addressed than when the effort is completed.” The staff will need to verify the final results of the design analyses to ensure that the design was completed in accordance with the process specified in the implementation plans in accordance with the design acceptance criteria (DAC) approach. This may occur via a design certification (DC) amendment, the combined operating license (COL) application review, or through the inspection, test, analysis, and acceptance criteria (ITAAC) closure process.

For a “Programmatic” level review, the staff uses the NUREG-0711 criteria to determine whether the applicant’s documentation provides a top-level identification of the substance of

each criterion. This level of review is used when an applicant has not developed the methodology for performance of an HFE activity in sufficient detail to conduct an implementation plan review. When an HFE activity is reviewed at the programmatic level, the staff will review the detailed implementation plan and the results of the HFE activities conducted in accordance with the implementation plan when they are submitted. For the ESBWR design certification, all areas have been reviewed to at least the implementation plan level.

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

18.1.5 Generic Issues Related to Human Factors Engineering

Section 18.14 provides an evaluation of the generic issues related to HFE. A brief summary of each generic issue is provided followed by 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 HFE 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. Also, the team should 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 verifying that all aspects of the HSI, procedures, and training are developed, designed, and evaluated on the basis of accepted HFE principles.

To review GEH's HFE Program Management, the staff used the review criteria in NUREG-0711, Section 2.4.

18.2.2 Summary of Technical Information

The ESBWR HFE Program Management is described in design control document (DCD) Tier 2, Revision 3, Section 18.2, "MMIS [Man-Machine Interface System] and HFE Program Management." DCD Tier 2, Revision 3, Section 18.2 incorporates by reference NEDE-33217P (proprietary), Revision 3, "ESBWR Man-Machine Interface System and Human Factors Engineering Implementation Plan (or the MMIS-HFE Plan)." The non-proprietary version of NEDE-33217P is designated as NEDO-33217.

The staff also reviewed the following GEH ESBWR documents:

- Proposed changes to NEDE-33217P, Revision 3 as described in October 30, 2007, letter (MFN 07-428)
- ESBWR DCD Tier 2, Chapter 19, "PRA & Severe Accidents," Revision 3
- GEH responses to RAIs 18.2-1 through 18.2-17 (MFN-06-163)
- GEH Baseline Record Review (BRR), Draft 1A, January 2007 (Audited material – will be documented in an audit report)
- GEH quality assurance plan (NP-2010, "COL Demonstration Project Quality Assurance Plan," NEDO-33181)
- GE Nuclear Energy Quality Assurance Program Description, NEDO-11209-04A, Rev. 8, March 31, 1989

In addition to reviewing the GEH design documents, the staff conducted design audits in January and July 2007 to examine how GEH initially applied the processes described in these documents to the ESBWR design and to evaluate the documentation of the results. Post design certification, the staff will need to verify the final results of the design analyses for the other HFE elements, 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.

18.2.3 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 (6 review criteria)
- HFE team and organization (4 review criteria)
- HFE process and procedures (6 review criteria)
- HFE issues tracking (4 review criteria)
- technical program (3 review criteria)

In RAI 18.2-19, the staff requested that GEH identify as Tier 2* in the DCD NEDE-33217P, Revision 3, and the detailed implementation plans for the HFE activities reviewed in Sections 18.3 through 18.13 of this chapter. **RAI 18.2-19 is being tracked as an open item.**

18.2.3.1 NUREG-0711 Review Of Criteria

18.2.3.1.1 General HFE Program Goals and Scope

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

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

- personnel tasks can be accomplished within time and performance criteria
- the HSIs, procedures, staffing/qualifications, training and management and organizational support will support a high degree of operating crew situation awareness
- the plant design and allocation of functions will maintain operation vigilance and provide acceptable workload levels i.e., to minimize periods of operator underload and overload
- the operator interfaces will minimize operator error and will provide for error detection and recovery capability

Evaluation of Criterion (1)

NEDE-33217P, Revision 3, Section 3.2.2, states the program goals in human-centered terms. These include personnel task accomplishment, support for situation awareness, acceptable workload, and minimizing error and support for recovery when they occur, which are the four general directives in NUREG-0711. Accordingly, the staff finds the MMIS-HFE Plan 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 3, 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 implementation plan references appropriate DCD sections that further address these aspects of the design. Accordingly, the staff finds the MMIS-HFE Plan 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 3, Section 1.2, Item 2, specifies the facilities to which the MMIS-HFE Plan applies. These include the facilities in NUREG-0711: the main control room, remote shutdown control station, technical support center (TSC), emergency operations facility (EOF), and local control stations that have a safety function or have been identified by the task analysis as being important to safe plant operation. 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 3, Section 1.2, Item 3, notes the applicable human-system interfaces (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 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 3, 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 treatment of the criterion for applicable personnel acceptable.

18.2.3.1.2 HFE 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 3, Section 3.1.4, 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 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 its areas of responsibility are accomplished and to identify problems in the implementation of the overall plant design. The team should have the authority to control further processing, delivery, installation, or use of HFE products until the disposition of a nonconformance, deficiency, or unsatisfactory condition has been achieved.

Evaluation of Criterion (2)

NEDE-33217P, Revision 3, Section 3.1.4.1, describes the project organization and the responsibilities of key functions in the organization. Figure 3.1.4-1 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 implementation plans and for the use of these plans in designing the HFE aspects of the ESBWR. The overall guidance for HFE activities are described in NEDE-33217P. The HFE team designs, controls, and manages the HFE activities and oversees the verification and validation (V&V) of the design and implementation of the HFE aspects of the plan. As per the responsibilities of the HFE team defined in NEDE-33217P, the team has the authority to ensure that all responsibilities are accomplished and to determine where its inputs are necessary and control over all use of its work products. This authority includes control over any non-conformance 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 GEH 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 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 3, Section 3.1.4.1, describes the team's expertise and skills, which include the areas of expertise identified in NUREG-0711. In response to Requests for Additional Information (RAIs) 18.2-5 and 18.2-6 (MFN 06-163), GEH provided Attachment A, a

skills matrix for HFE activities, and Attachment B, 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 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)

In response to RAIs 18.2-5 and 18.2-6 (MFN 06-163), GEH provided Attachment A, a skills matrix for HFE activities, and Attachment B, 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 Design Process Audits. GEH provided detailed job descriptions and assignment information for the individual team members and their qualifications. Accordingly, the staff finds the MMIS-HFE Plan treatment of the criterion for the HFE team staffing acceptable.

18.2.3.1.3 HFE Process and Procedures

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

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

Evaluation of Criterion (1)

NEDE-33217P, Revision 3, Section 3.1.4.2, addresses general process procedures. The plan references the GEH Quality Assurance (QA) plan (NEDO-33181, Revision 1, 2005). 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, Revision 1 provides the overall scope of the QA program and how it relates to and incorporates aspects of other QA requirements and guidance, including 10 CFR Part 50 Appendix B and ISO standard 9001, 2000. NEDO-33181, Revision 1 endorses NEDO-11209-04A and related detailed implementing procedures for use with the ESBWR design project. The NEDO-11209-04A QA program was previously reviewed by NRC as part of the ABWR design certification and found acceptable. As discussed under the previous two acceptance criteria, GEH provided satisfactory information related to the assignment of HFE activities to team members and the overall structure and management of the team. Design control and design review are addressed by Section 3 of NEDO-11209-04A.

The staff further evaluated general process procedures during the January and July 2007 Design Process Audits at which GEH explained the use of its procedures. GEH provided lists of

personnel on the human factors team and organization charts showing personnel. GEH introduced personnel on team to the NRC audit team and various responsible personnel on the team gave presentations on the progress in their respective areas. 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 were being satisfactorily implemented at the time of the audit.

In view of the forgoing, the staff finds the MMIS-HFE Plan 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 GEH clarify if the documents addressing general process management tools will be submitted as part of the design certification. NEDE-33217P, Revision 3, Section 3.1.4.2, Item 6, identifies process management tools and indicates that Section 4 of the report, which describes the technical program, provides further discussion. However, in MFN 07-428, GEH indicated to the staff that it plans to significantly revise the section of the plan addressing the technical program. GEH provided a markup of the plan's table of contents, which offered a high-level overview of the changes planned. The staff requested GEH to submit Revision 4 of the plan incorporating these changes. **RAI 18.2-10 is being tracked as an open item**.

(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 3, Section 3.2.2, Item 3, addresses the integration of HFE and other plant design activities. Figure 1.2 of the plan depicts 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 implementation plans 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 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 3, Section 3.4.1.2, Item 10, and Figure 3.1.4-2 identify HFE milestones, thus enabling the effectiveness of the HFE effort to be evaluated at critical checkpoints. The milestones are shown 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 GEH to include a COL Item concerning the schedule for DAC closure. In accordance with RG 1.206 guidance, the staff requests GEH to add a COL information item to the DCD for the applicant to identify those design areas for which detailed information cannot be provided and should supply the NRC with a schedule for completion of detailed engineering supporting implementation of the DAC in the areas that DAC were approved for the ESBWR design certification. **RAI 14.3-210 is being tracked as an open item.**

(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 3, Section 3.1.4.2, Item 13, addresses HFE documentation. This section states that the GEH QA plan, which includes retention and limited access provisions, controls the HFE documentation and document management. The GEH QA plan, NEDO-33181, Revision 1, provides general overall QA for the HFE program aspects of the project.

In addition, NEDE-33217P, Revision 3 identifies the documentation associated with individual HFE activities discussed in subsequent sections of this report. Accordingly, the staff finds the MMIS-HFE Plan 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 3, Section 3.1.4.2, Item 14, addresses subcontractor efforts. It specifies that each subcontract include requirements for HFE and that these requirements are verified in accordance with the GEH QA plan. The GEH QA Plan, NEDO-33181, Rev. 1, provides general overall QA for the HFE program aspects of the project. Accordingly, the staff finds the MMIS-HFE Plan treatment of the criterion for subcontractor HFE requirements acceptable.

18.2.3.1.4 HFE 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 3, Section 3.1.4.3 describes the GEH HFE Issue Tracking System (HFEITS) that ensures that HFE issues and concerns 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 Operating Experience Review and were determined to be appropriate for inclusion into the ESBWR design (see Section 18.3 of this report for the staff's review of operating experience). The plan specifies that the control room design team develops the administrative procedure that addresses 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 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 3, Section 3.4.1.3 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 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 3, Section 3.4.1.3 and Appendix A, demonstrate that the proposed HFEITS appropriately documents and tracks issues. As discussed in Appendix A, the proposed HFEITS has 24 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 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 3, Section 3.4.1.3 and Appendix A, demonstrate that responsibilities are appropriately specified. The proposed HFEITS has 24 fields for inputting information, including fields to clearly identify the name of the issue originator (field 3), the person responsible for addressing the issue (field 11), and resolution verification (field 19). Accordingly, the staff finds the MMIS-HFE Plan 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 implementation plans, analyses, and evaluation of the following should be identified and described:

- operating experience review (OER)
- functional requirements analysis and function allocation
- task analysis
- staffing and qualifications
- human reliability analysis (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 requested that NEDE-33217P reference the individual HFE activity implementation plans. In MFN 07-428, GEH indicated to the staff that it plans to significantly revise the section of the plan addressing the technical program. GEH provided a markup of the plan's table of contents, which provided a high-level overview of the changes planned. Revision 4 of the plan, which has not yet been submitted for staff review, will implement these changes. Thus, this criterion will be reviewed upon receipt of the revised plan. The revised plan should reference the individual HFE activity implementation plans for detailed methodology descriptions. **RAI 18.2-18 is being tracked as an open item.**

(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 3, 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 Electric Power Research Institute. The list includes all appropriate documents. Accordingly, the staff finds the MMIS-HFE Plan 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 3, Section 3.2.1, describes HFE facilities, tools, equipment, and techniques used in the HFE Program. The report presents the general approach and discusses the use of dynamic models, control room mockups, part-test simulators, and full-scope simulators (FSSs). In the January and July 2007 Design Process Audits, the staff obtained additional information on the GEH 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 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"

Section 3.3, Design Description, 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.

In RAI 18.2-20, the staff requested that GEH update the reference to the ESBWR MMIS and HFE Implementation Plan. DCD Tier 1, Revision 4, Section 3.3, Design Description, summarizes the ESBWR MMIS and HFE Implementation Plan. It is the staff's understanding that the plan will undergo a significant revision, mainly to remove redundant discussions of HFE program elements already documented in the individual implementation plans. Once the revision is completed, GEH is requested to ensure that the Tier 1 Design Description and the revised plan are consistent. In addition, the Tier 2 description of HFE Program Management in DCD Section 18.2 should be reviewed and modified for consistency as well and should reference the revised plan. **RAI 18.2-20 is being tracked as an open item.**

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

DCD Tier 2, Revision 3, Section 18.2, describes HFE program management. As per RAI 18.2-20, Section 18.2 should be reviewed for consistency with the revised NEDE-33217P and modified accordingly.

18.2.4 Conclusions

Because of the open items still to be resolved for HFE program management, the staff was unable to finalize its conclusions regarding acceptability.

18.3 Operating Experience Review

18.3.1 Regulatory Criteria

The objective of reviewing operating experience review is to verify that the applicant 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 GEH's operating experience review, the staff used the review criteria in NUREG-0711, Section 3.4.

18.3.2 Summary of Technical Information

The ESBWR Operating Experience Review is described in DCD Tier 2, Revision 3, Section 18.3, "Operating Experience Review." DCD Tier 2, Revision3, Section 18.3 incorporates by reference NEDE-33217P, Revision 3, and NEDO-33262, Revision 1, "ESBWR Operational Experience Review (Human Factors) Implementation Plan."

The staff also reviewed the following GEH ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 3
- ESBWR DCD Tier 2, Chapter 19, "PRA & Severe Accident," Revision 3
- NEDO-33021, "ESBWR Probabilistic Risk Assessment," Revision 2
- GEH Response 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," Rev. 0, February 2, 1996 (Audited material – will be documented in an audit report)
- GEH, "Standby Liquid Control Functional Requirements Analysis Report (Lungmen)," October 16, 1997 (Audited material – will be documented in an audit report)
- GEH, "Reactor Water Clean-up Functional Requirements Analysis Report (Lungmen)," October 16, 1997 (Audited material – will be documented in an audit report)
- General Electric ESBWR Baseline Record Review (BRR), Draft 1A, January 2007 (Audited material – will be documented in an audit report)

In addition to reviewing the GEH design documents, the staff conducted a design 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. Post 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 design certification, as reflected in the DAC.

18.3.3 Staff Evaluation

The staff performed an implementation plan 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 (5 review criteria)
- Issue analysis, tracking, and review (3 review criteria)

In addition, this section also 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.

(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 1, discusses the review of human factors issues associated with predecessor plants in several ways. First, GEH 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 response to RAI 18.3-1, GEH stated that the ESBWR OER includes operational experience gained from previous BWRs with isolation condensers. NEDO-33262, Revision 1, 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.

NEDO-33262, Revision 1, 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 1, Section 3.1.3, states that the HFE design team interviews 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, GEH discussed a trip to Japan made specifically to gather OER-type information from the operating Japanese ABWRs. NEDO-33262, Revision 1 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 as described in detail above. Accordingly, the staff finds the OER Plan treatment of the criterion for predecessor/related plants and systems acceptable.

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

- unresolved safety issues/generic 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 1, 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 1, 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 1, Section 3, "Methods," lists further areas and sources to be reviewed.

NEDO-33262, Revision 1, 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. GEH provided this as an example for conducting an OER for the ESBWR, specifically, how the ESBWR OER team reviews this experience as possible input to the ESBWR design.

Also, in Section 3.2.3.5, GEH notes that the ESBWR design is an extension of the ABWR design that 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 1 specifies that the ESBWR HFE design team reviews 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 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 1, Section 1.2, states that review of experience and identification of problems in prior MMIS implementations, including human factors problems, is 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/qualifications, and job design. NEDO-33262, Revision 1, Section 5.1 specifies that the results summary report includes the review of HSI equipment/technologies.

The OER Plan considers related HFE technology as described in detail above. Accordingly, the staff finds the OER Plan 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 steam line break, positive reactivity addition, control rod insertion at power, control rod ejection, anticipated transients without scram (ATWS), and various-sized loss-of-coolant accidents (LOCA))
  - 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 1, 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. GEH 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 facility, GEH 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 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 human actions. These human actions should be identified as requiring special attention during the design process to lessen their probability of failure.

Evaluation of Criterion (5)

NEDO-33262, Revision 1, 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. NEDO-33262, Revision 1, Section 3.2.3.2 specifies that the HFE design team prepares risk-based criteria to be used to decide which OER issues will go into HFEITS. 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.

Sections 4.1, “Quantitative Reliability Evaluations,” and 4.2, “Special Qualitative Evaluations,” provide good information relative to the process for ensuring adequate reliability and availability of the MMIS for the ESBWR.

The OER Plan considers risk-important HAs that have been identified as different from predecessor plants or where errors have occurred in the execution of risk important human actions as described in detail above. Accordingly, the staff finds the OER Plan 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.

(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 1, 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. The purpose of the classification is to place issues into categories to facilitate their disposition.

NEDO-33262, Revision 1, 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 control room 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 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 1, 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. GEH 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 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 3, describes the overall methodology for the functioning of the HFEITS. In particular, Sections 3.1.4.2 and 3.2.4.3, 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 1, 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 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 3, Table 3.3-1, Item 1, contains the Tier 1 ITAAC developed by GEH for OER. Table 3.3-1 contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall “MMIS and HFE Implementation Plan” rather than the implementation plan for the specific element. In RAI 14.3-211, the staff requested that GEH update the 11 design descriptions to refer to the applicable implementation plans. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

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

Section 18.3 of the DCD provides the primary description of OER activities, which summarizes the OER program, including the purpose, objectives and scope, OER methodology, and OER results. The implementation plan provides more details on the OER program.

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.3.4 Conclusions

Because of the open items still to be resolved for Operating Experience Review, the staff was unable to finalize its conclusions regarding acceptability.

18.4 Functional Requirements Analysis and Function Allocation

18.4.1 Regulatory Criteria

The objective of reviewing functional requirements analysis and function allocation is to verify that the applicant has (1) defined the plant's functions that must be performed to satisfy plant safety objectives, and (2) that the allocation of those functions to human and system resources has resulted in a role for personnel that takes advantage of human strengths and avoids human limitations.

To review GEH's function requirements analysis and function allocation, the staff used the review criteria in NUREG-0711, Section 4.4.

18.4.2 Summary of Technical Information

The ESBWR Functional Requirements Analysis and Function Allocation is described in DCD Tier 2, Revision 3, Section 18.4, "Functional Requirements Analysis and Allocation of Functions." DCD Tier 2, Revision 3, Section 18.4 incorporates by reference NEDE-33217P, Revision 3; NEDO-33219, Revision 1, "ESBWR System Functional Requirements Analysis Implementation Plan"; and GEH, NEDO-33220, Revision 1, "ESBWR Allocation of Functions Implementation Plan."

The staff also reviewed the following GEH ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 3
- ESBWR DCD Tier 2," Chapter 19, "PRA & Severe Accident," Revision 3
- NEDO-33021, "ESBWR Probabilistic Risk Assessment," Revision 2
- GEH responses to RAIs 18.4-1 through 18.4-25 (MFN 06-400 and MFN 07-499)
- GEH, "Standby Liquid Control Functional Requirements Analysis Report (Lungmen)," October 16, 1997 (Audited material – will be documented in an audit report)
- GEH, "Reactor Water Clean-up Functional Requirements Analysis Report (Lungmen)," October 16, 1997 (Audited material – will be documented in an audit report)

GEH 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 provided RAIs on these documents. GEH provided responses to the Section 18.4 RAIs on November 1, 2006, and updated NEDO-33219, Revision 1, in January 2007 and NEDO-33220, Revision 1, in March 2007. Revision 1 to these implementation plans constituted a significant revision leading to several followup RAIs.

In addition to reviewing the GEH design documents, the staff conducted a design 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. Post 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.

18.4.3 Staff Evaluation

The staff performed an implementation plan 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).

18.4.3.1 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)

NEDO-33219, Revision 1, describes the GEH approach to functional requirements analysis (FRA), and NEDO-33220, Revision 1, describes the GEH approach to function allocation (FA).

NEDO-33219, Revision 1, 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 1, Figures 1 through 4. In accordance with NEDO-33219, Revision 1, Section 1, the FRA determines the functions necessary to achieve plant 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, and reconcile any differences between plant-level analyses and the SDS. NEDO-33219, Revision 1, Section 1.2 specifies that plant-level and system-level goals and functions are systematically analyzed concurrently. In 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. Examples of this process were reviewed during the onsite audit at GEH during July, 2007. 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, as shown in NEDO-33219, Revision 1, Section 3.1, Figures 2 and 4. 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 1, describes the GEH approach to allocating the functions analyzed by the NEDO-33219, Revision 1, FRA methodology. It also describes a structured methodology for allocating functions to personnel and automation and for the evaluation of that allocation. 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 1.1.2 of the FA plan, the scope of the analysis is broad and includes all functions identified in the FA. Section 3 of the FRA Plan describes the general methodology, and Section 4 describes the means of implementing the methodology.

NEDO-33220, Revision 1, Section 3.1.1.1, defines a set of goals for the allocation of function process that emphasizes human performance objectives. They include considerations such as minimizing errors and performance of normal, abnormal, and emergency functions.

NEDO-33220, Revision 1, 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 for whether the function should be automated or not. Such considerations are at the core of function allocation 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 significance
- OER/BRR significance
- human cognitive limitations
- human response time limitations
- human physical limitations
- hostile environment including atmosphere, temperature, and radiation

While this constitutes an appropriate set of considerations for evaluating a function for automation, no additional guidance is provided to the analyst as to how to apply the criteria. For example, NEDO-33220, Revision 1 does not direct the analyst on how to use HRA significance to conclude that automation is desirable. NEDO-33220, Revision 1, Appendix A, includes some guidance for several human performance considerations (from NUREG/CR-2623, "The Allocation of Functions in Man-Machine Systems: A Perspective and Literature Review", 1982), but the plan does not reference the appendix and the list of considerations in the appendix is not the same as those presented in the implementation description. In RAI 18.4-21, the staff questioned the role of the appendix and this issue remains open. In the absence of additional guidance, the interpretation of these criteria could vary significantly among analysts, and the methodology may not be consistently applied. The staff requested information on this aspect of the methodology in RAI 18.4-16. In RAI 18.4-16(b), the staff asked this question again as a follows: "This section contains many criteria for allocating functions. Most are stated at a very general level. Are more specific criteria available for analysts to use as part of the decision making process?" **RAIs 18.4-16(b) and 18.4-21 are being tracked as open items.**

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.

For non-safety functions for which configuration change is required during normal or emergency operations, the FRA methodology assumes the function is handled by the plant automation system (see Figure 3). NEDO-33220, Revision 1, does not clearly present the rationale for this. It would seem that the same set of human performance considerations should be made for both safety and non-safety functions. In RAI 18.4-16f, the staff asked a new item as follows: "For non-safety functions for which configuration change is required during normal or emergency operations, the methodology assumes the function is handled by the Plant Automation System (see Figure 3). It would seem that the same set of human performance considerations should be made here as for safety functions. The staff requested that GEH clarify the rationale for using the Plant Automation System as this is not clearly presented in NEDO-33220, Revision 1." **RAI 18.4-16(f) is being tracked as an open item.**

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 1, Figure 4.

The FRA Plan provides a structured, documented methodology reflecting HFE principles for performing a FRA as described in detail above. Accordingly, the staff finds the FRA part of this criterion as described in NEDO-33219, Revision 1, acceptable. Additional information is needed, as identified in RAIs 18.4-16(b) and (f) and 18.4-21, on the FA portion, which is described in NEDO-33220, Revision 1.

(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 1, describes the iterative nature of the operational analyses that include both FRA and FA. This is shown in Figure 2 and described in Sections 3.1, 3.2, and 4. This methodology inherently ensures that the FRA is kept current over the life cycle of design development.

Additionally, NEDE-33217P, Revision 3, Section 3.1.4.2, "Management Process and Procedures," states, "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. The COL Owners Group (COLOG) provides a means of coordination among 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 re-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 1, Sections 3 and 4.1, describe the top-level or plant FRA to be performed. These analyses provide the general picture of the major functions needed to achieve the plant goals, both safety and economic. The analyses then proceed to a lower level to identify processes, critical safety functions, subfunctions, indications, controls, and accident monitoring parameters. NEDO-33219, Revision 1, Figure 4, summarizes this process.

NEDO-33219, Revision 1, 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 1, Figure 5, depicts the system-level FRA.

NEDO-33219, Revision 1, Section 3.3, also describes a gap analysis that is performed to address any discrepancies between the plant- and system-level FRAs. Any discrepancies are addressed in the design or added to the HFEITS for later correction. Figure 6 summarizes the gap analysis.

In addition, the staff reviewed two examples of typical system FRAs, one for the ABWR standby liquid control (SLC) system and one for the reactor water cleanup (RWCU) system, during an onsite audit. The staff notes the FRAs were generally performed as per the implementation plan and provided appropriate analyses of the system functions. They also included information from the OER performed for the system being evaluated.

The FRA Plan provides descriptions of functions and systems and also identifies differences between proposed and reference plants. The FRA Plan also 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 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 requested that GEH describe the plant-level functional requirements analysis (PFRA) work instruction in NEDO-33219. NEDO-33219, Revision 0, Sections 7.1 and 7.2, described a method and the documentation that was to be developed for plant performance and for system-level functions. Sample tables were provided that included functions, parameters, ranges, limits on parameters, and related comments. This detail no longer exists in Revision 1. In response to RAI 18.4-26, GEH responded as follows:

> Detailed guidance for the conduct of the PFRA is contained in the PFRA Work Instruction that has been drafted to implement NEDO-33219, Revision 1. The work instruction requires that the information specified in NUREG-0711, Section 4, Criterion 4 be determined and documented for each high level function. This data for each high level function will be an integral part of the PFRA structure, and as such will be validated and summarized along with the PFRA data structure. A draft copy of the PFRA Work Instruction will be available for review during the on-site audit scheduled for July 25, 2007.

The staff determined that this response is acceptable and requested that GEH include this description of the PFRA work instruction in the implementation plan. **RAI 18.4-26 is being tracked as an open item.**

(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 PFRA is used to determine the technical basis for each high-level function in the ESBWR. NEDO-33219, Revision 1, Section 3.1 states, “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 predecessor designs are embedded in the system designs that were inherited from these earlier BWR plants. NEDO-33219, Revision 1, Section 3, discusses the system functional requirements analysis (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 1, Section 3.3 describes this process, which is summarized above and which could result in engineering design changes if needed. The staff finds 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 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 1, Section 4.1.3, indicates that the function allocation process is documented in formal records that capture the criteria, rationale, and analysis method used. NEDO-33220, Revision 1, Section 5, describes the reports that are generated.

As part of the design process audit discussed earlier, the staff examined examples of the GEH 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. Accordingly, the staff finds the FA Plan 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 1, Section 4.1.3, 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 BRR, provide input to the ESBWR analysis. OER is defined as one criterion for making allocation decisions (see discussion of NUREG-0711, criterion 1 above). NEDO-33219, Revision 1, 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 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 function allocations as described in detail above. Accordingly, the staff finds the FA Plan 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 automation's role in backing up personnel performance. Accordingly, the staff finds the FRA Plan 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 GEH FRA and FA methodology incorporates both plant- and system-level analyses (see NEDO-33220, Rev. 1, Figure 2). 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 are 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 FRA and FA Plans treatment of the criterion for the integrated role of personnel 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 1 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 1, Section 3.1.1.3, page 16, states, "The

V&V provide 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 should ensure a coherent role for plant personnel. Accordingly, the staff finds the FRA and FA Plans treatment of the criterion for verification of analyses to be acceptable.

18.4.3.2 Relationship to Other Documents

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

Table 3.3-1, Design Commitment 2, contains the Tier 1, Revision 3, ITAAC for FRA and FA. Table 3.3-1 contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall "MMIS and HFE Implementation Plan" rather than the implementation plan for the specific element. In RAI 14.3-211, the staff requested that GEH change the 11 design descriptions to refer to the applicable implementation plans. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

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

Section 18.4.1 discusses the FRA implementation plan. This provides a reasonable, high-level discussion of the FRA that is described in more detail in NEDO-33219, Revision 1.

In RAI 18.4-25, the staff requested that GEH clarify and update the DCD, DCD Tier 2, Revision 3, Section 18.4.2 addresses FA. The content of DCD Tier 2, Revision 3, Section 18.4.2 is not consistent with NEDO-33220, Revision 1. The staff requested that GEH clarify and update DCD Tier 2, Section 18.4.2. **RAI 18.4-25 is being tracked as an open item.**

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.4.4 Conclusions

Because of the open items still to be resolved for Functional Requirements Analysis and Allocation of Functions, the staff was unable to finalize its conclusions regarding acceptability.

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

18.5.2 Summary of Technical Information

The ESBWR Task Analysis is described in DCD Tier 2, Revision 3, Section 18.5, "Task Analysis." DCD Tier 2, Revision 3, Section 18.5 incorporates by reference NEDE-33217P, Revision 3, and NEDO-33221, Revision 1, "ESBWR Task Analysis."

The staff also reviewed the following GEH ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 3
- ESBWR DCD Tier 2," Chapter 19, "PRA & Severe Accident," Revision 3
- NEDO-33021, "ESBWR Probabilistic Risk Assessment," Revision 2

In addition to reviewing the GEH design documents, the staff conducted a design 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. Post 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 implementation plan 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 7 criteria for this topic. However, the 7th 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)

GEH's operational analyses include FRA, FA, and task analysis. These analyses are performed in an iterative, top-down fashion. NEDO-33221, Revision 1, 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
- 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

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 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 RAI 18.5-5, the staff requested that GEH clarify the HFE task analysis methodology. An implementation plan should provide step-by-step, specific guidance on how to perform task analysis. NEDO-33221, Revision 1, is an extensive revision of Revision 0. However, the methodology is presented in outline form with little explanation of how the task analysis is actually performed. Most of the implementation sections are limited to bullet lists (see Section 4). This does not provide sufficient information to evaluate the methodology to be used.

NEDO-33221, Revision 1, also does not appear to describe the actual methodology being used that GEH discussed during the July 2007 Design Process Audit. The methodology shown by GEH in July 2007 (depicted in the task analysis slides on pages 145 to 158 of Enclosure 1 to MFN 07-502) included many considerations that cannot be found in the implementation plan, such as the evaluation of critical steps. Many of the terms used to describe the methodology and the examples shown cannot be found in the Task Analysis Plan. While this apparent difference may in part be the result of differences in the level of detail, it does illustrate the staff's concern that an engineer using the plan would not clearly produce the type of results

shown during the audit. Clarification is needed of (1) the relationship between the plan and the actual task analysis, and (2) how an engineer makes the transition from the plan to the actual conduct of the analysis. **RAI 18.5-5 is being tracked as an open item.**

In RAI 18.5-19, the staff requested that GEH clarify the evaluation of risk-important tasks. NEDO-33221, Revision 1, on page 3, makes the commitment to perform task analysis for "tasks identified as risk-important as determined by the HRA/PRA." NEDO-33267, the PRA/HRA Integration Plan, should be referenced since that is where the criteria for risk-important actions are identified. **RAI 18.5-19 is being tracked as an open item.**

(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 1, Page 1, states that the GEH 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." The staff evaluated the level of detail of the analysis during the July 2007 Design Process 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. Accordingly, the staff finds the Task Analysis Plan 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 requested that GEH clarify the treatment of task integration. NEDO-33221, Revision 1, Sections 4.1.3.6 and 4.2.3.6, provide some information regarding workload assessments that list considerations such as workload, crew member skills, and work allocation; however, the Task Analysis Plan does not provide information about how such considerations are made. **RAI 18.5-26 is being tracked as an open item.**

(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 GEH explain how minimum inventory is identified and what criteria will be used in the selection process. The response to RAI 18.5-27 is very broad and seems to include all the task requirements identified through task analyses in the minimum inventory. This response needs further explanation. The GEH responses to RAIs 18.8-13 and 18.8-23 also address minimum inventory. While they are not all the same, the GEH RAI responses clearly indicate that the minimum inventory is still being developed.

GEH's tasks analysis methodology in NEDO-33221, Revision 1 also does not fully address minimum inventory. In a supplemental RAI, the staff requested that GEH provide a discussion and clarification on how minimum inventory is identified consistent with DI&C-ISG-05, "Digital Instrumentation and Controls Interim Staff Guidance on Highly-Integrated Control Rooms – Human Factors Issues (HICR-HF)," dated September 28, 2007. **RAI 18.5-27 is being tracked as an open item.**

(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 1, 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 1, Figure 2 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 Design Process 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 GEH 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 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"

Table 3.3-1, Design Commitment 3, contains the Tier 1, Revision 3, ITAAC for task analysis. Table 3.3-1 contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall "MMIS and HFE Implementation Plan" rather than the implementation plan for the specific element. In RAI 14.3-211, the staff requested that GEH change the 11 design descriptions to refer to the applicable implementation plans. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

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

In RAI 18.5-30, the staff requested that GEH clarify how changes to the implementation plan will be reflected in the DCD. The task analysis methodology presented in NEDO-33221, Revision 1 is not consistent with the methodology summarized in DCD Tier 2, Revision 3, Section 18.5. For example, the implementation plan discusses two major levels of analysis, plant and system. This is not addressed in the DCD. The staff requested that GEH revise DCD, Section 18.5 to ensure consistency with the NEDO-33221, Revision 1 and any modifications made to address other 18.5 RAIs. **RAI 18.5-30 is being tracked as an open item.**

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.5.4 Conclusions

Because of the open items still to be resolved for Task Analysis, the staff was unable to finalize its conclusions regarding acceptability.

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.

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

18.6.2 Summary of Technical Information

The ESBWR Staffing and Qualifications is described in DCD Tier 2, Revision 3, Section 18.6, "Staffing and Qualifications." DCD Tier 2, Revision 3, Section 18.6 incorporates by reference NEDE-33217P, Revision 3, and NEDO-33266, Revision 1, "ESBWR Human Factors Engineering Staffing and Qualifications Plan."

The staff also reviewed the following GEH ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 3
- ESBWR DCD Tier 2, Chapter 19, "PRA & Severe Accident," Revision 3
- NEDO-33021, "ESBWR Probabilistic Risk Assessment," Revision 2
- GEH response to RAIs 18.6-1 through 18.6-10 (MFN 06-402)
- GEH Baseline Record Review (BRR), Draft 1A, January 2007 (Audited material – will be documented in an audit report)
- GEH ABWR FOAKE Plant Staffing Evaluation, Revision 0, May 24, 1996 (Audited material – will be documented in an audit report)

18.6.3 Staff Evaluation

The staff performed an implementation plan 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 4 criteria for this topic.

(1) Staffing and qualifications should address applicable guidance in SRP Section 13.1 and [the requirements of] 10 CFR 50.54.

Evaluation of Criterion (1)

NEDO-33266, Revision 1, 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 control room 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 3, Section 18.6.2 also specifies the ESBWR initial baseline staffing assumptions, which are the same as those in the plan. The staff finds this acceptable.

Chapter 13, "Conduct of Operations," of a safety analysis report/DCD typically addresses the other aspects of 10 CFR 50.54(i) through (m) (e.g., requirements for an operator at the controls). Neither Chapter 18 nor Chapter 13 of the ESBWR DCD Tier 2, Revision 3 or NEDO-33266, Revision 1, discusses these other aspects. Section 13.1, "Organizational Structure of the Applicant," of the ESBWR DCD is noted to be the responsibility of the COL applicant. To track completion of this matter against 10 CFR 50.54, "Conditions of Licenses," and SRP Section 13.1, the applicant developed a COL item which is included in Chapter 13.

(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 1, Section 1.2, specifies that the staffing analyses address activities during normal power operation as well as during transient 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.

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 1, Section 1.2 also identifies the applicable plant personnel addressed by the HFE program, including licensed control room operators, non-licensed

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 includes determining 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 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 1, 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 show 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, PRA/HRA, and procedures and training. These processes are depicted in the figures and described in Sections 3 and 4. Section 3.1 states, “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 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 1, ensures that the basis for staffing and qualification includes consideration of OER, FRA, FA, task analysis, PRA/HRA, and procedures and training. There is also a clear link between HSI design and the staffing and qualifications defined in the program. The plan includes an initial baseline staffing and qualifications level based on an 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, specifically BWRs. This phase also considers the SFRA, FA, and task analysis. Phase 3 uses the insight from the PRA/HRA and incorporates feedback in both the staffing analysis and the PRA/HRA. Phase 4 includes screening the various tasks, and Phase 5 determines whether the recommended staffing and qualifications are adequate to safely operate the ESBWR. This produces a generic ESBWR staffing plan which is then applied to and verified for each ESBWR implementation. Accordingly, the staff finds the Staffing and Qualifications Plan 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 3, Table 3.3-1, Item 4 contains the Tier 1 ITAAC for staffing and qualification. Table 3.3-1 contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall “MMIS and

HFE Implementation Plan" rather than the implementation plan for the specific element. In RAI 14.3-211, the staff requested that GEH change the 11 design descriptions to refer to the applicable implementation plans. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

18.6.3.2.2 DCD Tier 2, Section 18.6, "Staffing and Qualifications"

DCD Tier 2, Revision 3, provides a high-level description of the staffing and qualifications for the ESBWR that includes the background, the objectives and scope of staffing and qualification analyses, the ESBWR baseline staffing assumptions, a discussion of the staffing and qualifications plan, and a summary of the methodology of the staffing and qualification analyses. NEDO-33266, Revision 1, which is reviewed in this SER chapter, provides more detail. The staff finds the DCD Chapter 18 treatment of staffing and qualifications acceptable.

In RAI 18.6-13, the staff requested that GEH correct the reference to the staffing implementation plan. DCD Tier 2, Revision 4, Section 18.6.8, "References", has the incorrect date for the staffing implementation plan, NEDO-33266, Revision 1. It is listed as March, 2007, rather than January, 2007. **RAI 18.6-13 is being tracked as an open item.**

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.6.4 Conclusions

Because of the open items still to be resolved for Staffing and Qualifications, the staff was unable to finalize its conclusions regarding acceptability.

18.7 Human Reliability Analysis

18.7.1 Regulatory Criteria

The objective of reviewing human reliability analysis 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 verify errors are detected and recovered from; and (2) the HRA activity effectively integrates the HFE program and PRA and risk analysis.

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

18.7.2 Summary of Technical Information

The ESBWR Human Reliability Analysis is described in DCD Tier 2, Revision 3, Section 18.7, "Human Reliability Analysis." DCD Tier 2, Revision 3, Section 18.7 incorporates by reference NEDE-33217P, Revision 3, and NEDO-33267, Revision 2, "ESBWR Human Factors Engineering Human Reliability Analysis Plan."

The staff also reviewed the following GEH ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, “Human Factors Engineering,” Revision 3
- ESBWR DCD Tier 2, Chapter 19 “PRA & Severe Accident,” Revision 3
- NEDO-33021, “ESBWR Probabilistic Risk Assessment,” Revision 2
- GEH responses to RAIs 18.7-1 through 18.7-15 (MFN 06-403 and MFN 07-499)
- GEH letter “Submittal of ESBWR DCD Chapter 18, Human Factors Engineering—RAI to DCD Roadmap Document,” June 27, 2007 (MFN 07-334)

18.7.3 Staff Evaluation

The staff performed an implementation plan 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 4 criteria for this topic.

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

Evaluation of Criterion (1)

NEDO-33267, Revision 2, 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 2, also provides an overview of the HRA methodology itself and its relationship to the PRA.

NEDO-33267, Revision 2, Section 1.2, states that the scope of the plan includes developing a process for using PRA/HRA (e.g., level 1, level 2, internal and external events) to support the design of the ESBWR HSI. DCD Tier 2, Revision 3, 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. In RAI 18.7-9, the staff in part asked GEH to clarify why NEDO-33267 does not specifically commit to using all of these analyses to determine the risk-important HAs. The response to RAI 18.7-9 on October 1, 2007 (discussed further below), adds the following bullet to NEDO-33267, Revision 2, Section 1.2, the scope of the HRA Plan:

- Using both the ESBWR PRA level 1 and level 2 analyses and both internal and external events analysis to determine the risk important HAs. The approach for determining risk importance of human actions is described in section 3.2.1.

The staff finds that this portion of the response addresses the staff concern with the scope of NEDO-33267 and will confirm the addition in the next revision of NEDO-33267.

NEDO-33267, Revision 2, Sections 1 and 3 state, "the HFE design effort will give special attention to those plant scenarios, risk-important human actions, and HSIs that have been identified by PRA/HRA as being important to plant safety and reliability." Section 3.3 notes, "These analyses will use a variety of importance measures and HRA sensitivity analyses assumptions to ensure that risk important actions are not overlooked." Section 3.2.1 mentions the use of risk achievement worth (RAW), risk reduction worth, and the Fussell-Vesely (FV) importance measures.

Section 1.2 notes that the HRA iterates with the PRA, task analysis, and OER to reevaluate the impact of operator actions on risk as the HSI design develops and changes.

NEDO-33267, Revision 2 and DCD Tier 2, Revision 3, Section 18.7, state in several places that the PRA/HRA provides a listing of potentially risk-important human interactions for use in several portions of the HFE program. GEH has completed the initial PRA/HRA for the ESBWR and submitted it to the NRC along with Chapter 19 of the DCD. Therefore, sufficient information is available to develop the initial list of risk-important actions using the methods discussed in this report. In MFN 07-334, GEH states that this information will be documented in a Phase 0 HRA summary report. (MFN 07-334, the RAI to DCD roadmap document, generally explains how GEH has incorporated the RAI responses into later revisions of the plan.)

While the overall description is acceptable, there are some points of clarification that are needed to complete the review as noted in the three RAIs discussed below.

In RAI 18.7-7, the staff requested that GEH address the parts of the original RAI that are still open. The staff asked for additional information in RAI 18.7-7 regarding the PRA/HRA which was addressed; however, the following parts of the original RAI are still open:

2. Table 19.1-3, Importance Analysis Results, is not discussed or explained in the text of Ch. 19. Col. 2 of the Table gives the basis for inclusion of items in the Table as RAW, FV, and CDF [core damage frequency], but does not list values or selection criteria. Revision 2 of Plan gives acceptance criteria as FV greater than 0.1 and RAW of 2.0 for both CDF [core damage frequency] and LERF [large early release frequency]. However, these criteria are not specifically linked to the RI HAs. This should be clarified.

8. The row for Human Actions in Table 19.2-1 states that "No operator actions are required for safety function success in the ESBWR for the first 72 hours of an event." This is a deterministic statement. What does the PRA analysis show? Are the important HAs, as identified in the PRA, from the pre-72 hour regime? This RAI was not satisfactorily answered. GEH is requested to provide a response.

9. For Item 2b in Table 19.2-3 (spurious actuation of GDCS deluge to containment) was an error of commission modeled in the PRA? The Roadmap answer provided a discussion of the EOC method used for the HRA but didn't answer the specific question related to Item 2b.

RAI 18.7-7 is being tracked as an open item.

In RAI 18.7-8, the staff requested that GEH provide the importance measures (IMs) and the criteria to be used for determining the risk important HAs. NEDO-33267, Revision 2, Section 4 states, "These analyses will use a variety of importance measures and HRA sensitivity analyses assumptions to ensure that risk important actions are not overlooked." However, the report does not provide the particular importance measures to be used and the acceptance criteria (or cutoff values) for determining which HAs are risk important. It is noted that DCD Tier 2, Section 19.5.2, specifies cutoff values, using the RAW and FV importance measures (IMs) for important structures, systems, and components. The staff asked GEH to provide the IMs and the criteria to be used for determining the risk-important HAs. NEDO-33267 Revision 2, Section 3.2.1, cites a RAW value of greater than 2.0 and an FV value of greater than 0.1. The staff asked GEH to clarify that these are the criteria for selection of the risk-important HAs that the HFE program will address. **RAI 18.7-8 is being tracked as an open item.**

In RAI 18.7-9, the staff requested that GEH clarify how PRA will be used to compute the actual list of risk-important HAs. The ESBWR PRA, as submitted, includes both level 1 and level 2 analyses and both internal and external events analyses. The staff asked GEH to clarify why NEDO-33267 does not specifically commit to using all of these analyses to determine the risk-important HAs. The response to RAI 18.7-9 on October 1, 2007, adds the following bullet to NEDO-33267, Revision 2, Section 1.2, the scope of the HRA Plan:

- Using both the ESBWR PRA level 1 and level 2 analyses and both internal and external events analysis to determine the risk important HAs. The approach for determining risk importance of human actions is described in section 3.2.1.

DCD Tier 2, Revision 3, 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. This is acceptable, but the plan should be revised in accordance with the RAI and should be clear on how all of these portions of the PRA will be used to compute the actual list of risk-important HAs. **RAI 18.7-9 is being tracked as an open item.**

(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 2, Section 4.1, "HRA Interactions with HFE Tasks," states that "risk-important human interactions from the PRA/HRA are used as input to the HFE design effort (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 there is suitable crew availability and time to accomplish the action given that the need is detected." This section also

notes that the PRA/HRA information is used to help prioritize maintenance tasks. Accordingly, the staff finds the HRA Plan 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-33276, Revision .2, Section 3.3, states that HA tasks are analyzed with an emphasis on human error mechanisms so that "the likelihood of operator error is minimized for risk-important HAs by 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 4.3.1 notes that, for the ESBWR, "The HSI design supports manual interventions better than predecessor designs do. This minimizes the potential for human factor problems that negatively affect plant safety and performance...." Accordingly, the staff finds the HRA Plan 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)

NEDO-33267, Revision 2, Section 3.1, states, "The HRA task interacts with the HFE verification and validation program to provide test scenarios and updating quantitative evaluations based on data from the validation process." Section 3.3 notes that validations are performed for the ESBWR to support as-designed quantification of the PRA.

Section 4.1 states the following:

> The HRA interacts with the HFE V&V program by supporting the design of test scenarios and updating quantitative evaluations based on validation results. The HRA models establish a basis for future human performance monitoring and help prioritize corrective actions. The HRA task permits examination of assumptions used in designing the HSI with regard to the ability of licensed operators to perform needed tasks.

Section 4.2.3 states the following:

> HRA assumptions in risk-important HAs involving diagnosis, decision-making, planning and implementation strategies during accident responses are validated by techniques such as event simulations using experienced crews, or walkthrough analyses using personnel with operating experience to apply procedures for specific scenario conditions.

These statements provide for validation of HRA assumptions through walkthroughs or simulations with personnel with operational experience in accordance with the criterion. Accordingly, the staff finds the HRA Plan 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 3, Table 3.3-1, contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall "MMIS and HFE Implementation Plan" rather than the implementation plan for the specific elements. In RAI 14.3-211, the staff requested that GEH change the 11 design descriptions to refer to the applicable implementation plans. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

18.7.3.2.2 DCD Tier 2, Section 18.7, Human Reliability Analysis

DCD Chapter 18, Revision 3, acceptably addresses at a high level the NUREG-0711 HRA criteria and thus addresses the interaction between the PRA/HRA and the HFE of the ESBWR facility.

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.7.4 Conclusions

Because of the open items still to be resolved for Human Reliability Analysis, the staff was unable to finalize its conclusions regarding acceptability.

18.8 Human-System Interface Design

18.8.1 Regulatory Criteria

The objective of reviewing human-system interface design is to verify that 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 GEH's HFE Program Management, the staff used the review criteria in NUREG-0711, Section 8.4.

18.8.2 Summary of Technical Information

The ESBWR Human-System Interface Design is described in DCD Tier 2, Revision 3, Section 18.8, "Human-System Interface Design." DCD Tier 2, Revision 3, Section 18.7

incorporates by reference NEDE-33217P, Revision 3, and NEDO-33268, Revision 2, "ESBWR Human-System Interface Design: Implementation Plan."

The staff also reviewed the following GEH ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 3

- GEH responses to RAIs 18.8-1 through 18.8-49 (MFN 06-443 and MFN 07-408)

18.8.3 Staff Evaluation

The staff performed an implementation plan 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 (4 review criteria)
- Concept of operations (1 review criterion)
- Functional requirement specification (3 review criteria)
- HSI concept design (5 review criteria)
- HSI detailed design and integration (10 review criteria)
- HSI tests and evaluations (2 sub-topics)
  - Trade-Off Evaluations (2 review criteria)
  - Performance-Based Tests (9 review criteria)
- HSI design documentation (2 review criteria)

The staff reviewed the proposed safety parameter display system (SPDS) using the requirements of 10 CFR 50.34(f)(2)(iv) and the criteria set forth in NUREG-0711 and NUREG-0700, Section 5. Although this can be considered a part of the HSI detailed design and integration, it is reviewed in a separate section because of its importance, and the existence of separate review criteria.

The staff reviewed the GEH minimum inventory using the criteria contained in SRP Section 14.3.9 and DI&C-ISG-05, Section 2, "Minimum Inventory." Minimum inventory refers to the minimum inventory of HSIs (alarms, controls, and displays) needed to implement the ESBWR emergency operating procedures, bring the plant to a safe condition, and carry out those operator actions shown to be risk important by the applicant's PRA.

In addition to reviewing the GEH design documents, the staff conducted a design 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. Post 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 General Review of the HSI Design Plan

NEDO-33268, Revision 2 provides an implementation plan for the design of the ESBWR HSIs. In the course of reviewing this document, the staff identified numerous areas needing

clarification before the NUREG-0711 review could be completed. These areas of clarification have been grouped into the RAIs discussed below. Additional RAIs are included in the NUREG-0711 criteria reviews that follow the discussion of these general RAIs.

In RAI 18.8-2, the staff requested that GEH provide step-by-step, specific guidance on how to perform the HSI design in the HSI Design Plan. NEDO-33268, Revision 2, stops short of providing step-by-step procedures. Much of the plan identifies considerations for design without providing designers with the basis or procedures to make decisions based on the considerations. For example, page 24 of NEDO-33268, Revision 2, states that the "auditory environment of the HSI is designed considering a relevant database of human capabilities and characteristics." However, the document does not define the databases to be used. Absence of specific procedural steps makes this document difficult for users, and the intended methodology may be incorrectly and inconsistently applied. As another example, NEDO-33268, Section 3.3.3, describes general conformance to HFE review criteria and guidance. However, the discussion is at a high level and the document does not provide the methodological details as to how to achieve these criteria. While a later section of NEDO-33268, Revision 2, addresses some of these considerations, others are not addressed at all. For example, Section 3.3.2 discusses the GEH commitment to develop a concept of operations. However, none of the subsequent plan materials or documentation descriptions addresses a concept of operations. Thus, the staff requested that GEH provide detailed methodological steps.

The GEH response to this RAI indicated that NEDO-33268, Revision 2, is a high-level document and that it will be revised to provide step-by-step guidance to develop the ESBWR Human Factor (HF) Guidance Manual that will include a style guide. This manual will provide the design engineers with step-by-step guidance. GEH indicated that such a manual has not yet been developed.

At the July 2007 HFE Audit, GEH said the detailed steps are in detailed work plans. The staff reviewed one sample work plan (for allocation of function), but that plan provided little additional guidance to that found in the implementation plan.

NEDO-33268, Revision 2, does not mention a Guidance Manual nor does it make reference to an HSI Design Work Plan. It does discuss the development of a style guide, but such a document would not typically include the detailed step-by-step design guidance to be used by engineers. Thus the initial concern still exists. To illustrate: The steps for developing a concept design are listed on NEDO-33268, Revision 2 Page 19. Step 3 addressed the alarm system design. The step says "The alarm system is defined including conceptual display hierarchy, presentation, and layout." This is a high-level step description that could not be used by an engineer to develop an alarm concept design. The staff requested that GEH clarify where the methodology to address HSI design is made available to the design team. The staff will need to review the document(s) before a review of the HSI design element can be completed. Note that many of the HSI Design RAIs reflect concern over the lack of detail in the methodology description provided in NEDO-33268, Revision 2.

Similar issues arise when considering the development and use of the style guide. It is discussed in Sections 3.2 and 4.2 of NEDO-33268, Revision 2. However, little information is provided regarding its structure, content, level of detail and usage by the design team. NEDO-33268, Revision 2, contains many high-level guidelines pertaining to the HSI rather than the process. The staff requested that GEH clarify the relationship between these guidelines and those that will be developed for the style guide. Note that many of the responses to the RAIs for this section indicated that the details will be provided in the HF Manual (style guide). The

treatment of guidance in Revision 0 Sections 5 and 6 seem to follow this approach (they were removed from the NEDO, see RAI 18.8-36). Yet much of this guidance is still in the NEDO. For example, the response to RAI 18.8-22 concerning operator access to suppressed alarms indicated that the topic would be addressed in the manual. The GEH roadmap stated that the style guide has the details. But it is, in fact, addressed in NEDO-33268, Revision 2 (on Page 70, last bullet above Workstations). The staff requested that GEH clarify the relationship between the HSI guidelines in NEDO-33268, Revision 2 and those to be included in the style guide.

In addition, many of the individual guidelines are expressed in high-level form rather than in specific design descriptions. The staff requested that GEH clarify the level of detail that it expects to present in the style guide.

Additionally, in NEDO-33268, Revision 2, the Tables, Figures, and Appendix may have been overlooked. There are three tables, but none are referenced in the document. The appendix is not referenced. All six figures are referenced, but not always correctly. For example, on page 14, reference is made to Figure 3. That reference was correct for NEDO-33268, Revision 0, but should be changed to Figure 4 in Revision 2. The next revision of the NEDO should address inconsistencies of this type.

To summarize, the staff requested the following information:

- Clarify where the detailed HSI design methodology is located.
- Clarify the relationship between the HSI guidelines in the NEDO and those to be included in the style guide or other design documentation.
- Clarify how detailed the guidance presented in the style guide will be.
- Clarify the use of tables, figures, and the appendix in the NEDO.

RAI 18.8-2 is being tracked as an open item.

In RAI 18.8-8, the staff requested that GEH clarify references to old documents. Following the review of NEDO-33268, Revision 0, the staff noted that Section 2 makes reference to older documents (many of which were published in the 1980s). The staff asked what role these documents play in the plan. Many of the versions of the documents referenced have been replaced by newer, updated material. For example, MIL-STD-1472D is referenced, although that document has been revised and is now in Revision F. Some of these older documents may contain outdated and potentially incorrect guidance. For example, EPRI-NP3701, which provides computer-generated display system guidelines, was published in 1984. Technology and display development approaches have advanced so much since 1984 that the guidance is not fully applicable to today's systems. These documents have been replaced by a new generation of guidance documents. The GEH response to the RAI indicated that the references would be revised and updated. NEDO-33268, Revision 2, Section 2, provides a revised document list; however, many of the concerns raised in the RAI still apply—specifically the large number of older, outdated documents. As noted in the RAI, the applicability of these older documents to today's HSIs is questionable. **RAI 18.8-8 is being tracked as an open item.**

In RAI 18.8-12, the staff requested that GEH clarify a statement in NEDO-33268. Following the review of NEDO-33268, Revision 0, page 29, the staff requested clarification of the statement

that the information processing functions should support “expanding availability information to cover implicit data.” In accordance with the GEH additional responses to RAIs (MFN 07-408), this has not been modified in Revision 2, but will be in the next plan revision. The staff will confirm the modification in the next revision of NEDO-33268. **RAI 18.8-12 is being tracked as a confirmatory item.**

In RAI 18.8-16, the staff requested that GEH clarify the use of computer-based alarm response procedures (ARPs). Following the review of NEDO-33268, Revision 0, the staff requested clarification of (1) whether the ESBWR ARPs 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." GEH’s response to this RAI stated that on-line computer based procedures are planned and NEDO-33268, Revision 2, Section 4.1.4, identifies them as an output of the design process. Thus this aspect of the RAI is acceptably addressed. However, GEH has not clarified the statement regarding corrective actions and the statement is still presented in Revision 2 (see [NEDO-33268, Revision 2] Page 69). The staff requested that GEH clarify the statement. **RAI 18.8-16 is being tracked as an open item.**

In RAI 18.8-17, the staff requested that GEH clarify the source of anthropometric data. NEDO-33268, Revision 0, Page 39, indicates that mechanical characteristics of control elements, such as size, force needed to operate a control, and tactile feedback, meet the capabilities and characteristics specified in the anthropometric database. The staff asked GEH to clarify to which database it referred. The GEH response to this RAI clearly indicated that the anthropometric data will come from NUREG-0700, “Human-System Interface Design Review Guidelines,” and deviations from it will be justified. GEH indicated that this information would be included in NEDO-33268, Revision 2. Section 3.2 of NEDO-33268, Revision 2, suggests the use of available anthropometric data from HFE guidelines (page 20); however, the source of the data is not clearly identified. The staff requested that GEH clarify the source of anthropometric data. **RAI 18.8-17 is being tracked as an open item.**

In RAI 18.8-18, the staff requested that GEH clarify two statements concerning the guidance on controls. GEH’s response to this RAI clearly indicated that NEDO-33268 would be revised to refer to the HF Guidance Manual for this guidance. While the first statement, "Placement of controls in keeping with their conformance to safety functions,” has been removed, the second statement, “The form of control adopted is consistent with HSI requirements,” still appears in NEDO-33268, Revision2, Section 4.3.4.9, as Item 3 (on Page 62). The staff requested that GEH clarify this statement. **RAI 18.8-18 is being tracked as an open item.**

In RAI 18.8-31, the staff requested that GEH clarify the terms used and provide a consistent discussion regarding tools, techniques, methods and procedures for the HSI Design. Revision 0 of NEDO-33268, Section 4.7.1, discusses “Criteria Used in Selecting HFE/HSI Design and Evaluation *Tools* (emphasis added).” Item 1 identifies “tools and techniques” and presented a list of seven “procedures” appropriate to HSI evaluation. Item 2 provides criteria for selecting “techniques.” Section 4.7.2 is entitled, “Definition of the Design/Evaluation Tools for the HSI Design Analysis.” The introductory paragraph in this section addresses “techniques.” The section defined four “techniques,” including checklists, drawings, mockups, and questionnaires/interviews. Two of these “techniques” were the same as those identified in the listing of “procedures” in the previous section. Section 4.7.1 referenced Figures 4 and 5. Figure 4 identifies “methods” of data collection that were the same as the seven “procedures” listed on page 64. Figure 5 identified five “methods” of design evaluation that included things such as the FSS. Since the use of these terms was unclear, the staff requested clarification.

The GEH response to the RAI indicated that a consistent discussion of the design and evaluation tools would be provided in Revision 2. However, the material has been included in Revision 2 (in Section 3.3.5.5, Tests and Evaluations, specifically Pages 34-36) with little modification and without the requested clarification. The staff notes that Revision 0, Figure 4, is Figure 5 in NEDO-33268, Revision 2 and Revision 0, Figure 5, does not appear in Revision 2. Section 4.3.4.6 contains the same list of techniques and criteria as is listed on Pages 34-35 except an additional criterion related to "safety and/or risk significance" has been added. It is unclear why this information is relisted in Section 4 and why an additional criterion has been added. The staff requested GEH to provide the clarifications requested. **RAI 18.8-31 is being tracked as an open item.**

In RAI 18.8-32, the staff requested that GEH clarify the criteria used in selecting HFE/HSI design and evaluation tools. NEDO-33268, Revision 0, page 65, states, "Considering the criteria listed in Section 3, Criteria to be used in selecting HFE/HSI Design and Evaluation Tools, the following techniques are used in the conduct of the HSI design analyses." The staff requested clarification as to how the Section 3 material was to be used for this purpose and why the criteria were not provided in Section 4.7.1 (including Figures 4 and 5). Following the review of NEDO-33268, Revision 2, the staff noted that the statement is now in Section 3.3.5.6 (on page 35) and still references Section 3. This section states, "Considering the criteria listed in Section 3 and criteria to be used in selecting HFE/HSI Design and Evaluation Tools, the following techniques are used in the conduct of the HSI design analyses." GEH needs to clarify which Section 3 criteria are being referred to and which criteria are being referred to by the phrase, "criteria to be used in selecting HFE/HSI Design and Evaluation Tools." **RAI 18.8-32 is being tracked as an open item.**

In RAI 18.8-43, the staff requested that GEH describe the ESBWR-specific implementation of HSI. NUREG-0711, Section 8.5, references several other regulatory documents that specify HSI-related systems in the control room or other control facilities for the power plant. The staff requested that GEH describe the ESBWR-specific implementation of HSI for the following six key aspects of the plant HSI:

(1) Provision for periodic testing of protection systems actuation functions, as described in Regulatory Guide (RG) 1.22, "Periodic Testing of Protection System Actuation Functions (Safety Guide 22)," issued February 1972

(2) Bypassed and inoperable status indication for nuclear power plant safety systems, as described in RG 1.47, "Bypassed and Inoperable Status Indication for Nuclear Power Plant Safety Systems," issued May 1973

(3) Manual initiation of protective actions, as described in RG 1.62, "Manual Initiation of Protective Actions," issued October 1973

(4) Instrumentation for light-water-cooled nuclear power plants to assess plant and environmental conditions during and following an accident, as described in RG 1.97, "Criteria for Accident Monitoring Instrumentation for Nuclear Power Plants"

(5) Instrumentation setpoints, as described in RG 1.105, "Setpoints for Safety-Related Instrumentation"

(6) HSIs for the emergency response facilities (TSC and EOF), as described in NUREG-0696, "Functional Criteria for Emergency Response Facilities"

In accordance with the GEH additional responses to RAIs (MFN 07-408), GEH recognized that this aspect of implementation had not been modified in NEDO-33268, Revision 2, but committed to modifying it in the next plan revision. In addition, GEH provided additional wording to address the staff's concern that the next NEDO revision will include. This wording addresses the six areas of HSI design listed in the staff's RAI. The staff will confirm the wording changes in the next revision. **RAI 18.8-43 is being tracked as a confirmatory item.**

18.8.3.2 NUREG-0711 Review Criteria

18.8.3.2.1 HSI Design Inputs

NUREG-0711 identifies several sources of information as providing 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)

NEDO-33268, Revision 2, Sections 3.1 and 4.1.2, discuss the input of task requirements to the HSI design. NEDO-33268, Revision 2, Figures 1, 2, 3, and 4 provide 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 control room design. In addition, the plan commits to reviewing other plant designs with similar HSIs. Lessons learned are incorporated into the BRR for use by system designers.

In RAI 18.8-41, the staff requested that GEH clarify the design inputs listed in NEDO-33268, Figure 3 (which was Figure 2 in NEDO-33268, Revision 0). The staff also requested answers to the following questions:

- Where are the general human factors requirements listed?
- To what does HSI technology refer?
- How is a list of minimum displays, controls, and alarms an input?
- To what does operating crew refer?

GEH provided clarification in its response to the staff's questions concerning the figure. GEH indicated that the NEDO revision would include the clarifying material, but it was not included. These clarifications included revising NEDO-33268 to establish the preparation of the ESBWR Human Factors Guidance Manual to include the guidance for HSI design from the RAI response. The staff requested that GEH include these clarifications in the next revision. **RAI 18.8-41 is being tracked as an open item.**

(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 3, the GEH design process integrates the design of instrumentation and control (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 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)

GEH has identified applicable NRC requirements and guidance as input to its process, including 10 CFR 50, NUREG-0711, and NUREG-0700. 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 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 2, GEH identified additional inputs to the HSI design including the PRA/HRA 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 treatment of the criterion for other requirements acceptable.

18.8.3.2.2 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)

In RAI 18.8-50, the staff requested that GEH clarify the development of the concept of operations. In NEDO-33268, Revision 2, Section 3.3.5.4, “Staffing and Qualifications,” GEH committed to the development of a concept of operations that partially encompasses the considerations reflected in the review criterion (focusing on the first bullet above). Section 3.1.2 identifies the concept of operations as an input to the HSI design process.

The staff requested that GEH provide additional clarification as to how the HFE team will develop the concept of operations, what factors will be included in the concept of operations description, and how it will be documented. Note that NEDO-33268, Revision 2, Section 5, “Results,” does not identify the concept of operations. **RAI 18.8-50 is being tracked as an open item.**

18.8.3.2.3 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)

See discussion under Criterion 2, below.

(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 GEH clarify the development of functional requirements. NEDO-33268, Revision 2, Section 3.1.3, states that the HFE team will develop functional requirements for the HSI that encompass the considerations identified in the two criteria for the Functional Requirements Specification. However, no additional information is provided. Additional clarification is needed as to how the requirements will be developed by the HFE team and how it will be documented. Note that the functional requirements are not identified in Section 5, Results. **RAI 18.8-51 is being tracked as an open item.**

18.8.3.2.4 HSI Concept Design

The development of an HSI concept design is one of three key elements of the HSI Design Plan (along with style guide development and detailed HSI design). It is mainly discussed in NEDO-33268, Revision 2, Sections 3.1 and 4.1.

(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). GEH identified the functional requirements specification as an input to the design process along with the other inputs discussed in Section 18.8.3.2.1 above. Human performance of the predecessor is captured in the BRR and made available to the design team. Accordingly, the staff finds the HSI Design Plan 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)

In NEDO-33268, Revision 2, Section 3.1 identifies that performing an assessment of state-of-the-art HSI technologies is part of the design process. In the July 2007 Design Process Audit, GEH summarized its technology assessment. NEDO-33268, Revision 2, Section 4.2.2 specifies that the ESBWR style guide documents the results of these evaluations. Accordingly, the staff finds the HSI Design Plan treatment of the criterion for a survey of 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)

GEH is using a variety of approaches, including the use of operating experience and simulation assessments to enhance the design. In the July 2007 Design Process Audit, GEH provided a review of its assessment of alternative approaches and how its analyses are being used to select methods for incorporation into the ESBWR design. NEDO-33268, Revision 2, Section 4.2.2 specifies that the ESBWR style guide documents the results of these evaluations. Accordingly, the staff finds the HSI Design Plan 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)

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. Thus, alternative designs are being considered at the level of HSI design details. 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 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)

NEDO-33268, Revision 2, Section 1 indicates that HSI performance requirements are developed and reflect a survey of HSI technology. Section 4.1.2 identifies the functional requirements analyses as a determinant of performance requirements. Section 3.3.5.6, Tests and Evaluations, also identifies the consideration of HSI performance requirements as one of the factors considered in the HSI tradeoff evaluations. Accordingly, the staff finds the HSI Design Plan treatment of the criterion for design performance requirements acceptable.

18.8.3.2.5 HSI Detailed Design and Integration

(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 2, Sections 3.2 and 4.2 discuss the development and application of the ESBWR style guide. The topics and content of the style guide are outlined throughout the HSI plan and include topics such as alarms, displays, control, workstations, 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) and the results of the GEH evaluation of design tradeoffs. Provisions for modification of the contents of the style guide are identified.

While the plan for style guide development is generally consistent with the consideration in the review criteria, there is a question regarding the level of detail at which the guidance is presented to the HFE design team. RAI 18.8-2 raised this issue. Once that RAI is resolved, the staff can complete its evaluation of this review criterion. **RAI 18.8-2 is being tracked as an open item.**

Evaluation of Criterion (2)

(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 2, Section 3.3.5.2, discusses the GEH general approach to addressing the primary role of plant personnel in terms of monitoring/detection, situation awareness, interpretation and planning, control, and feedback. NEDO-33268, Revision 2, Section 3.2 specifies that the ESBWR style guide contains detailed guidance for supporting these roles in terms of the HFE design of individual HSI systems, such as alarms, displays, and controls. Accordingly, the staff finds the HSI Design Plan 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)

In RAI 18.8-52, the staff requested that GEH address the design objective for risk-important HAs. In NEDO-33268, Revision 2, Section 3.3.4, “General Approach,” GEH states that, with respect to risk-important actions, the design seeks to minimize the probability that errors occur and maximize the probability that an error is detected if one should be made. However, the methodology provides no guidance for how this design objective will be achieved. **RAI 18.8-52 is being tracked as an open item.**

(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)

In RAI 18.8-53, the staff requested that GEH address the design objective for developing requirements for monitoring and control. In NEDO-33268, Revision 2, Section 3.3.4, GEH states that the factors identified in the criterion are to be considered in the development of requirements for monitoring and control capabilities. However, the methodology provides no guidance for how this design objective will be achieved. **RAI 18.8-53 is being tracked as an open item.**

(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)

In RAI 18.8-54, the staff requested that GEH address the design objective for layout of HSIs. In NEDO-33268, Revision 2, Section 3.3.4, GEH states that the layout of HSIs is based on the considerations presented in the review criterion. However, the methodology provides no guidance for how this design objective will be achieved. **RAI 18.8-54 is being tracked as an open item.**

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

Evaluation of Criterion (6)

In RAI 18.8-55, the staff requested that GEH address the design objective for performance during varying staffing levels In NEDO-33268, Revision 2, Section 3.3.4, GEH states that personnel performance during minimal, nominal, and high staffing levels should be considered. However, the methodology provides no guidance for how this design objective will be achieved. **RAI 18.8-55 is being tracked as an open item.**

(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)

In RAI 18.8-56, the staff requested that GEH address the design objective for the use of HSIs over a shift. In NEDO-33268, Revision 2, Section 3.3.4, GEH states that the designer should consider use of the HSIs over a shift. However, the methodology provides no guidance for how this design objective will be achieved. RAI 18.8-56 is being tracked as an open item.

(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)

In RAI 18.8-57, the staff requested that GEH address the design objective for the use of HSIs under a full range of environmental conditions. In NEDO-33268, Revision 2, Section 3.3.4, GEH states that the designer should consider the use of HSIs under a full range of environmental conditions. However, the methodology provides no guidance for how this design objective will be achieved. **RAI 18.8-57 is being tracked as an open item.**

(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)

In RAI 18.8-58, the staff requested that GEH address the design objective for HSI support for test, inspection, and maintenance activities. In NEDO-33268, Revision 2, Section 3.3.4, GEH states that the designer should consider HSI support for test, inspection, and maintenance activities. However, the methodology provides no guidance for how this design objective will be achieved. **RAI 18.8-58 is being tracked as an open item.**

18.8.3.2.6 HSI Tests and Evaluations

Sections 3.3.5.6 and 4.3.4.6 of the plan describe HSI design tests and evaluation. The review of this material has led to the following general RAI.

In RAI 18.8-59, the staff requested that GEH address the review criteria for HSI tests and evaluations. NEDO-33268, Revision 2, Sections 3.3.5.6 and 4.3.4.6, identify both tradeoff evaluations and performance-based tests. However, the descriptions provide little information beyond the staff's review criteria identified for the two activities below. Additional information on how the design team is to conduct these evaluations is needed in order to review the material using the review criteria contained in NUREG-0711, Section 8.4.6. In addition, with respect to trade-off evaluations, GEH needs to clarify how the factors identified on NEDO-33268, Revision 2, page 33 are to be used to develop selection criteria and how they are to be applied by the HFE engineer. In addition, the staff requested that GEH explain how HFE engineers will determine the relative benefits of design alternatives and document the basis for their selection. The staff requested that GEH also identify the guidance that will be provided to design engineers for the conduct of performance-based tests, including the selection of participants, testbeds, performance measures, and analyses. **RAI 18.8-59 is being tracked as an open item.**

The 11 criteria below for the HSI Tests and Evaluations review topic (including the two criteria for Trade-off Evaluations and the nine criteria for Performance Based Tests), will be addressed as part of this open item.

In addition to this general request for further information concerning the test and evaluation methodology, the staff developed two additional RAIs to clarify specific details of the NEDO-33268, Revision 2 methodology.

In RAI 18.8-33, the staff requested that GEH clarify the list of HFE activities provided in NEDO-33268, Revision 2, Figure 5, "Appropriate Data Collection Methods for HFE Activities." NEDO-33268, Revision 0, Figure 4, page 95, lists HFE activities across the top of the matrix. The staff asked why these activities were chosen and what the performance models meant (i.e., they did not seem to be an activity). In addition, the staff asked how "MMI Evaluation" and "Evaluation of Alternative Designs" differed and how the ratings in the cells of the table were determined. The GEH response to this RAI indicated that the plan would be revised for clarification and the "table" (figure 4?) would be eliminated. However, the clarification has not been provided and the figure remains in the plan. (It is now Figure 5 in NEDO-33268, Revision 2.) Clarification of this material is needed. **RAI 18.8-33 is being tracked as an open item.**

In RAI 18.8-35, the staff requested that GEH provide a description of the methods of evaluation listed in NEDO-33268, Section 3.3.5.6. NEDO-33268, Revision 0, Section 4.7.2.5.2, "Methods of Evaluation," lists three evaluation methods. However, the actual methods are not described. For example, the first item listed is "Electronic Evaluation"; however, the section did not describe how a user of the document conducts this evaluation. The staff asked GEH why several of the methods (listed in Figure 5 and shown in Figure 7) were omitted (e.g., the FSS). The descriptions of the methods of evaluation from the original RAI are now on pages 37–38 of NEDO-33268, Revision 2, and have been slightly abbreviated. The same need for clarification still exists. Also, the lead-in paragraph references Figure 6, but Figure 6 does not address methods of evaluation. In Revision 0, the same paragraph referenced Figure 7, which did illustrate how multiple methods of evaluation can be sequenced, but this figure has been removed in Revision 2. Clarification of this material is needed. **RAI 18.8-35 is being tracked as an open item.**

18.8.3.2.6.1 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)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

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

Evaluation of Criterion (2)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

Since the review of both trade-off evaluations criteria are pending the GEH response to RAI 18.8-59, this section is being tracked as an open item under RAI 18.8-59.

18.8.3.2.6.2 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)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

(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)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

(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)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

(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)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

(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)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

(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)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

(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)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

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

Evaluation of Criterion (8)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

(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)

The review of this criterion is pending the GEH response to RAI 18.8-59 above.

Since the review of all performance-based tests criteria are pending the GEH response to RAI 18.8-59, this section is being tracked as an open item under RAI 18.8-59.

18.8.3.2.7 HSI 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 2, 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 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, GEH'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 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 treatment of the criterion for documentation of outcomes acceptable.

18.8.3.3 SPDS and Minimum Inventory

18.8.3.3.1 SPDS 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), 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 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," 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 control room displays.

Evaluation of SPDS Design

NEDO-33268, Revision 2, Section 3.3.5.18, discusses the SPDS for the ESBWR.

In RAI 18.8-44, the staff requested that GEH provide information on how the proposed implementation of SPDS for ESBWR compares to the criteria of NUREG-0700, Revision 2, Section 5. NEDO-33268, Revision 0, discusses the SPDS for the ESBWR and compares it to NUREG-0737 and not the more recent set of criteria in NUREG-1342, ("A Status Report Regarding Industry Implementation Of Safety Parameter Display Systems," 1989) and NUREG-0700, Revision 2, Section 5 ("Human-System Interface Design Review Guidelines," 2002). The staff asked GEH to provide information on how the proposed implementation of the SPDS for the ESBWR compares to the criteria of NUREG-0700, Revision 2, Section 5. In the supplemental GEH response to the RAI (MFN 07-408), GEH clarified that the SPDS design is implemented using the guidance from NUREG-0737, Supplement 1, NUREG-1342 and NUREG-0700 Revision 2, Section 5. GEH will incorporate this clarification in NEDO-33268, Revision 3. The staff will confirm the changes in the next revision. **RAI 18.8-44 is being tracked as a confirmatory item.**

In RAI 18.8-45, the staff requested that GEH update NEDO-33268 to address NUREG-0696, Section 8. NEDO-33268, Revision 0, states that the SPDS "may" be provided in the TSC and "optionally" in the EOF. However, NUREG-0696, Section 8, "Emergency Response Facility Integration," specifies that the variables displayed by the SPDS and the RG 1.97, "Criteria for Accident Monitoring Instrumentation for Nuclear Power Plants," Type A, B, C, D, and E variables should be available for use in the TSC and EOF.

In the supplemental GEH response to the RAI (MFN 07-408), GEH clarified that the SPDS variables that are displayed in the main control room will be available in the TSC and EOF. GEH will incorporate this clarification in NEDO-33268, Revision 3. The staff will confirm the changes in the next revision. **RAI 18.8-45 is being tracked as a confirmatory item.**

18.8.3.3.2 Minimum Inventory of HSIs

As part of the general resolution of the issue pertaining to a lack of control room detail, the staff has requested that applicants for design certification identify a minimum group of fixed-position alarms, controls, displays, (HSIs) that are necessary for transient and accident mitigation. SRP Section 14.3.9 and DI&C-ISG-05, Section 2, "Minimum Inventory," provide the review criteria for the minimum inventory.

Evaluation of Minimum Inventory of HSIs

NEDO-33268 Revision 2 does not specifically address the minimum inventory of HSIs. Thus, additional information is necessary.

In RAI 18.8-47, the staff requested that GEH provide information relative to the selection criteria and selection process for the minimum inventory of HSIs for ESBWR as it is described in SRP 14.3.9. GEH has taken the position that the minimum inventory of HSIs will be defined as a product of the operations analysis. The staff maintains a position that the design certification application should detail the specific parameters to be included in the minimum inventory (recently articulated in DI&C-ISG-05, Section 2, Staff Position 3). In related RAI 18.5-27, the staff requested that GEH discuss and clarify how minimum inventory of HSIs is identified consistent with DI&C-ISG-05. This RAI will remain open pending the resolution of RAI 18.5-27. **RAI 18.8-47 is being tracked as an open item.**

18.8.3.4 Relationship to Other Documents

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

DCD Tier 1, Revision 3, Table 3.3-1, Item 9, contains the Tier 1 ITAAC for HSI design. Table 3.3-1 contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall "MMIS and HFE Implementation Plan" rather than the implementation plan for the specific element. In RAI 14.3-211, the staff requested that GEH change the 11 design descriptions to refer to the applicable implementation plans. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

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

In RAI 18.8-49, the staff requested that GEH ensure that the DCD and NEDO-33268 are consistent. DCD Tier 2, Revision 3, Section 18.8, describes the HSI design process. The described process is not consistent with the process discussed in NEDO-33268, Revision 2. For example, the plan describes three major activities—concept design, style guide development, and detailed design and integration. DCD Tier 2, Revision 3, Section 18.8 does not address concept design. Similarly, DCD Tier 2, Revision 3, Section 18.8 discusses “procedures governing permissible operator initiated changes to HSIs” that are not addressed in NEDO-33268, Revision 2. The staff requested that GEH revise the DCD to be consistent with NEDO-33268, Revision 2, and any changes that result from modifications made as a result of these RAIs. **RAI 18.8-49 is being tracked as an open item.**

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.8.4 Conclusions

Because of the open items still to be resolved for HSI design, the staff was unable to finalize its conclusions regarding acceptability.

18.9 Procedure Development

18.9.1 Regulatory Criteria

The objective of reviewing procedure development is to verify that the applicant has applied HFE principles and guidance, along with all other design requirements, to develop procedures that are technically accurate, comprehensive, explicit, easy to use, and validated.

To review GEH’s procedure development, the staff used the review criteria in NUREG-0711, Section 9.4.

18.9.2 Summary of Technical Information

The ESBWR Procedure Development is described in DCD Tier 2, Revision 3, Section 18.9, “Procedure Development.” DCD Tier 2, Revision 3, Section 18.9 incorporates by reference NEDE-33217P, Revision 3, and NEDO-33274, Revision 2, “ESBWR Human Factors Engineering Procedures Development Implementation Plan.”

The staff also reviewed the following GEH ESBWR documents:

- NEDO-33276, “ESBWR HFE Verification and Validation Implementation Plan,” Revision 1
- ESBWR DCD Tier 1, Section 3.3, “Human Factors Engineering,” Revision 3
- ESBWR DCD Tier 2,” Chapter 19, “PRA & Severe Accident,” Revision 3
- GEH responses to RAIs 18.9-1 through 18.9-10 (MFN 06-444)

- American National Standards Institute/American Nuclear Society (ANSI/ANS)-3.2-1994 (reaffirmed 1999), "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants"

- GEH letter "ESBWR DCD Chapter 18, Human Factors Engineering—RAI to DCD Roadmap Document," June 27, 2007 (MFN 07-334)

18.9.3 Staff Evaluation

The staff performed an implementation plan 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).

18.9.3.1 NUREG-0711 Review Criteria

NUREG-0711 includes 9 criteria for this topic.

(1) Procedures should address applicable [guidance] of NUREG-0800, Section 13.5.

Evaluation of Criterion (1)

DCD Tier 2, Revision 3, Section 13.5, describes the ESBWR plant procedures. Section 13.5 of this report provides an evaluation of the ESBWR plant procedures using SRP Section 13.5 consistent with this criterion.

(2) The basis for procedure development should include:

- plant design bases
- system-based technical requirements and specifications
- task analyses results
- risk-important human actions identified in the HRA/PRA
- initiating events to be considered in the emergency operation procedures (EOPs), including those events in the design bases
- Generic Technical Guidance (GTG) for EOPs

Evaluation of Criterion (2)

In several sections, NEDO-33274, Revision 2, discusses the basis and the process for procedure development. Section 3.1.1 states that the process includes consideration of "experience from previous BWR and ABWR designs through the OER/BRR, technical guidance derived from plant design bases, system-based technical requirements and specifications, and critical HAs identified in the HRA/PRA." Section 3.1.3 states that GEH uses task analysis to develop information and control needs for each action in procedures. Other sections of NEDO-33274, Revision 2, describe the use of task analysis, and NEDO-33221, Revision 1, provides a more detailed discussion on this topic.

According to NEDO-33274, Revision 2, Section 3.1.3, in the case of backup and response actions, GEH uses HRA/PRA evaluations to identify risk-important HAs that need to be performed via EOPs; if HRA/PRA results show that reprioritization of actions minimizes human error and reduces plant risk, then GEH can adjust the emergency procedure guidelines (EPGs) and EOPs accordingly.

NEDO-33274, Revision 2, Section 3.1.5, explains how GEH uses generic technical guidance (GTG) in the development of procedures and states that the EOP writer's guide incorporates guidance from the current fleet of BWRs (U.S. Boiling Water Reactor Owners Group (BWROG) Emergency Procedure and Severe Accident Guideline (EPG/SAG), Rev. 2), which is used to generate ESBWR generic emergency procedures. Further, NEDO-33274 Revision 2, Section 4.1.2, Item 4, states the following:

> EPGs that have been applied in previous BWR designs, such as the ABWR, are adapted to the ESBWR to develop the EOPs and SAMGs. The EPGs are based on analysis of transients and accidents that are specific to the ESBWR plant design and operating philosophy. Thus, the EPGs provide guidance for the ESBWR EOPs in both content (e.g., strategies and intent) and form of presentation.

In RAI 18.9-1, the staff requested that GEH clarify the process for developing EPGs for the ESBWR. NEDO-33274, Revision 2, is still not clear on the development and use of ESBWR-specific EPGs and their submittal to NRC. The staff requested that GEH provide more detail on the development process for the ESBWR-specific EPGs, and a schedule for their completion. If not planned for design certification, GEH is requested to provide a justification as to why the EPGs are not required for design certification. **RAI 18.9-1 is being tracked as an open item.**

(3) A writers guide should be developed to establish the process for developing technical procedures that are complete, accurate, consistent, and easy to understand and follow. The guide should contain objective criteria so that procedures developed in accordance with it are consistent in organization, style, and content. The guide should be used for all procedures within the scope of this element. It should provide instructions for procedure content and format including the writing of action steps and the specification of acceptable acronym lists and acceptable terms to be used.

Evaluation of Criterion (3)

NEDO-33274, Revision 2, Section 4.1.3.1, "Writer's Guide," notes that the procedure development process includes the development of writer's guides for the ESBWR. These guides apply to all the procedures governed by the implementation plan and include general plant procedures, system operating procedures, surveillance test procedures, alarm response procedures, abnormal operating procedures, emergency operating procedures, calibration and inspection procedures, maintenance procedures, and radiation control procedures.

NEDO-33274, Revision 2, Section 4.1.3.1 specifies that the writer's guides contain objective criteria and ensure consistent, properly human-factored, and accurate procedures. The writer's guides also address organization, style, content, format, action steps, and acronym lists. Accordingly, the staff finds the Procedures Development Plan treatment of the criterion for a writer's guide acceptable.

(4) The content of the procedures should incorporate the following elements:

- title and identifying information, such as number, revision, and date
- statement of applicability and purpose
- prerequisites
- precautions (including warnings, cautions, and notes)
- important human actions
- limitations and actions
- acceptance criteria
- checkoff lists
- reference material

Evaluation of Criterion (4)

NEDO-33274, Revision 2, Section 4.1.3.1, identifies the specific procedure elements of the above criterion. Additionally, Chapter 13 of the DCD commits to ANSI/ANS-3.2-1994 (reaffirmed 1999). ANS 3.2, Section 5.3, "Preparation of Procedures," contains among other items the necessary components of procedures, which include the above elements.

In RAI 18.9-2, the staff requested that GEH clarify conformance to RG 1.33, Revision 2. DCD Tier 2, Revision 3, Chapter 13.5 shows the commitment to ANSI/ANS-3.2 1994: R1999 (R=Reaffirmed), Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants. RG 1.33 Revision 2, February 1978 endorses an earlier version of ANS 3.2, namely 1976. The reference by ESBWR to the later version of ANS 3.2 is acceptable since it provides more up to date guidance that is acceptable to the staff. However, RG 1.33 provides added guidance beyond the ANS standard that should also be addressed by the applicant. The staff requested that GEH clarify whether all aspects of procedure development addressed in RG 1.33 will be met, for example procedures in Appendix A of RG 1.33. **RAI 18.9-2 is being tracked as an open item.**

NEDO-33274, Revision 2, Section 3.1.3, states that computer-based procedures (CBPs) displayed in the HSI conform to NUREG-0700, Revision 2 (plus errata), Section 8, regarding HFE principles for computer-displayed controls and procedures. This section of the NUREG-0700 includes guidance on the format and content of CBPs.

(5) GTGs and EOPs should be symptom-based with clearly specified entry conditions.

Evaluation of Criterion (5)

NEDO-33274, Revision 2, Section 3.1.5, Item 2, states that the writer's guides specify the use of a symptom-based format for emergency procedures. It further states that the symptom-based format of the EOPs allows operators to take mitigation actions without first diagnosing the specific event cause or component failure. Further, the monitored variables support detecting cues for use as entry conditions for the EOPs. NEDO-33274, Revision 2, Section 4.1.3.2, states that the EOPs and severe accident management guidelines (SAMGs) should be symptom-based with clearly specified entry conditions. NEDO-33275, Revision 1, Appendix A, "Summary of Emergency Operating Procedure (EOP) and Severe Accident Management Guidelines (SAMGs)," describes the EPGs and SAMGs, shows that they are, in fact, symptom-based, and provides example entry conditions. Accordingly, the staff finds the Procedures Development Plan treatment of the criterion for symptom-based procedures acceptable.

(6) All procedures should be verified and validated, including:

- A review should be conducted to verify they are correct and can be carried out.
- Their final validation should be performed in a simulation of the integrated system as part of the V&V activities described in the Human Factors V&V element.

Evaluation of Criterion (6)

NEDO-33274, Revision 2, Section 4.1.3.3, "Procedure V&V," describes the V&V of procedures, and it includes the high-level purpose "to verify that the procedures are correct, meet HFE requirements, and can be carried out as stand alone procedures." The purpose of verification is to determine that procedures are consistent and do not conflict with each other. GEH validates all normal and abnormal procedures and EOPs either through simulator testing or via a walk-through/talk-through process. Section 4.1.3.3 includes discussion of the use of various types of simulators up to and including the FSS. NEDO-33274, Revision 2, Figures 1 and 2, also present the procedure V&V, and NEDO-33276, Revision 1, addresses the overall HFE V&V program. NEDO-33274, Revision 2, Section 4.1.3.3, also discusses the treatment of issues identified during V&V. Section 18.11 of this SER presents in full the NRC's review of HFE V&V.

In RAI 18.9-6, the staff requested that GEH address the verification of procedures. The GEH response to RAI 18.9-6, Part C, provides a similar restriction in scope to the original NEDO-33274, Revision 0. In accordance with NUREG-0711, Element 11, both HSI task support verification and HFE design verification should apply to HSIs that are contained in both normal and emergency procedures. The actual tests and verification would be selected using operational condition sampling of the V&V program. In the Purpose section, NEDO-33274, Revision 2, does include Task Support Verification, but it does not appear in the methodology portion. Revision 2 also specifies that procedures are developed using an appropriate writer's guide, however, there doesn't seem to be a selective design verification that would check or verify the application of HFE principles into procedures when they are completed. The staff requested that GEH provide for verification of procedures in accordance with the V&V guidance of NUREG-0711. **RAI 18.9-6 is being tracked as an open item.**

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

Evaluation of Criterion (7)

DCD Tier 2, Revision 3, and NEDO-33274, Revision 2, describe the approach to use CBPs and paper backup procedures to operate the ESBWR. NEDO-33274, Revision 2, 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 2.

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 they meet all necessary attributes.

Based on ongoing technology development, the use of CBPs with paper backups is a generally accepted approach. NRC has also developed guidance for the evaluation of CBPs in NUREG/CR-6634, "Computer-Based Procedure Systems: Technical Basis and Human Factors Review Guidance," dated March 2000. Hence it is not expected that the applicant would provide the specific types of analyses identified in the criterion, but rather the information described above. Based on the forgoing, the staff finds the Procedures Development Plan treatment of the CBPs acceptable.

(8) A plan for procedure maintenance and control of updates should be developed. Procedure modifications should be integrated across the full set of procedures; alterations in particular parts of the procedures should not conflict nor be inconsistent with other parts.

Evaluation of Criterion (8)

NEDO-33274, Revision 2, Section 4.1.3.5, "Procedure Maintenance," discusses the updating of procedures to improve them, address plant modifications, and reduce the potential for human errors. This section indicates that persons undergoing training to be licensed operators of an ESBWR can identify procedure improvement issues during preoperational training on the FSS. It also notes that improvements to the HSI and procedures continue into the operational phase. When GEH turns over the plant design to the COL applicant GEH will continue to seek, evaluate, track, and resolve improvements to the HSI and procedures. The training program provides similar feedback.

Additionally, DCD Tier 2, Revision 3, Section 13.5, commits to ANSI/ANS-3.2-1994 (reaffirmed 1999), which contains in Section 5.2.2 requirements for administrative procedures that control procedure maintenance and updating. Accordingly, the staff finds the Procedures Development Plan treatment of the criterion for procedure maintenance acceptable.

(9) The physical means by which operators access and use procedures, especially during operational events, should be evaluated as part of the HFE design process. This criterion generally applies to both hard-copy and computer-based procedures, although the nature of the issues differs somewhat depending on the implementation. For example, the process should address the storage of procedures, ease of operator access to the correct procedures, and laydown of hard-copy procedures for use in the control room, remote shutdown facility, and local control stations.

Evaluation of Criterion (9)

NEDO-33274, Revision 2, Section 4.1.3.6, "Procedure Access and Use," discusses various aspects of operator access to and use of procedures. This section notes that GEH assesses the HSI design, the main control room, the remote shutdown systems (RSSs), and risk-significant local control stations to ensure that procedure plans for the ESBWR adequately address the storage of procedures, ease of operator access to the correct procedures, and the laydown of paper-based procedures. Also, Section 4.1.3.4 discusses various aspects of operator usage of CBPs.

In RAI 18.9-8, the staff requested that GEH clarify whether laydown space for the paper backup procedures would be provided at the RSS and local control stations. Also, while the loss of CBPs is noted in Operational Conditional Sampling in the V&V Plan, the staff requested that the loss of CBPs be addressed in the Procedure Development Plan, i.e., NEDO-33274.. The GEH response to this RAI stated in part that, "The remote shutdown panel area and local control stations do not have dedicated lay down areas for plant procedures, but empty area room space is available for temporary procedure carts, work tables, or other devices for procedure use." The aspects related to laydown space are acceptable. Further clarification is needed on how loss of CBPs will be addressed procedurally and in NEDO-33274. **RAI 18.9-8 is being tracked as an open item.**

18.9.3.2 Relationship to Other Documents

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

DCD Tier 1, Revision 3, Table 3.3-1, Item 11, contains the Tier 1 ITAAC developed by GEH for procedure development. Table 3.3-1 contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall "MMIS and HFE Implementation Plan" rather than the implementation plan for the specific element. In RAI 14.3-211, the staff requested that GEH change the 11 design descriptions to refer to the applicable implementation plans. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

18.9.3.2.2 DCD Tier 2, Section 18.9, "Procedure Development"

DCD Tier 2, Section 18.9, contains the main description of procedure development implementation activities. This section provides a reasonable summary of the procedure development program, including its purpose, objectives, scope, and methodology. The implementation plan provides more details on the procedure development program.

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.9.4 Conclusions

Because of the open items still to be resolved for Procedure Development, the staff was unable to finalize its conclusions regarding acceptability.

18.10 Training Program Development

18.10.1 Regulatory Criteria

The objective of reviewing training program development is to verify that the applicant has a systematic approach for the development of personnel training. The training development should include the following five activities:

- a systematic analysis of tasks and jobs to be performed

- development of learning objectives derived from an analysis of desired performance following training

- design and implementation of training based on the learning objectives

- evaluation of trainee mastery of the objectives during training

- evaluation and revision of the training based on the performance of trained personnel in the job setting

To review GEH's training program development, the staff used the review criteria in NUREG-0711, Section 10.4.

18.10.2 Summary of Technical Information

The ESBWR Training Program Development is described in DCD Tier 2, Revision 3, Section 18.10, "Training Program Development." DCD Tier 2, Revision 3, Section 18.10 incorporates by reference NEDE-33217P, Revision 3, and NEDO-33275, Revision 1, "ESBWR Human Factors Engineering Training Development Implementation Plan."

The staff also reviewed the following GEH ESBWR documents:

- NEDO-33276, "ESBWR HFE Verification and Validation Implementation Plan," Revision 1

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 3

- ESBWR DCD Tier 2," Chapter 19, "PRA & Severe Accidents," Revision 3

- GEH response to RAIs 18.13-1 through 18.13-5 (MFN 06-470)

- GEH response to RAIs 18.10-1, 18.10-2 (MFN 06-445)

- GEH letter "ESBWR DCD Chapter 18, Human Factors Engineering—RAI to DCD Roadmap Document," June 27, 2007 (MFN 07-334)

18.10.3 Staff Evaluation

The staff performed an implementation plan 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).

Training Program Development review topics include the following:

- General Approach (3 review criteria)
- Organization of Training (3 review criteria)
- Learning Objectives (2 review criteria)
- Content of Training Program (4 review criteria)

- Evaluation of Training (3 review criteria)
- Periodic Re-training (2 review criteria)

18.10.3.1 NUREG-0711 Review Criteria

18.10.3.1.1 General Approach

(1) A systems approach to the training of plant personnel should be developed that address[es] applicable guidance in NUREG-0800 Section 13.2 (“Training”), as defined in 10 CFR 55.4, and as required by 10 CFR 52.78 and 50.120.

Evaluation of Criterion (1) (partial evaluation)

NEDO-33275, Revision 1, Section 1.1, and DCD Tier 2, Revision 3, Section 18.10.1, describe the systems approach to the training of plant personnel used by the ESBWR training program,. This includes the five key training activities defined in 10 CFR 55.4, “Definitions,” and specified in 10 CFR 50.120,“Training and Qualification of Nuclear Power Plant Personnel”—analysis of jobs, learning objectives, design and implementation of training, evaluation of trainee mastery of objectives, and evaluation and revision of training.

The staff will perform the full review of NEDO-33275 using SRP Sections 13.2 and 13.4 as part of the operational program review. That review cannot take place until a COL applicant develops the procedures and the training program. Procedure development is addressed in Tier 1, Table 3.3-1, ITAAC # 7. The actual development of the Training Program is classified as an operational program.

(2) The overall scope of training should be defined including the following:

- categories of personnel (e.g., senior reactor operator) to be trained
- specific plant conditions (normal, upset, and emergency)
- specific operational activities (e.g., operations, maintenance, testing and surveillance)
- HSIs (e.g., in the main control room, emergency operations facility, remote shutdown panel, local control stations)

Evaluation of Criterion (2)

NEDO-33275, Revision 1, Section 1.2, “Scope,” and Section 3.1.3, “Requirements,” address all of the categories of nuclear plant personnel, both licensed and nonlicensed, who require training in accordance with 10 CFR 52.78, “Contents of applications; training and qualification of nuclear power plant personnel,” and 10 CFR 50.120. NEDO-33275, Revision 1, Section 1.2 and DCD Tier 2, Revision 3, Section 18.10.2 outline the various plant conditions within the scope of the training program, including normal, upset, and emergency conditions. NEDO-33275, Revision 1, Sections 1.2 and 4.1.3 also note the various types of activities the training should cover, including operations, surveillance and testing, and maintenance. Section 4.1.3 provides additional detail on various types of procedures in which personnel are trained. Section 1.2 also addresses the variety of HSI locations as specified in the NUREG-0711 criteria. Accordingly,

the staff finds the Training Development Plan treatment of the criterion for scope of training acceptable.

(3) The training program should provide reasonable assurance that personnel have the qualifications commensurate with the performance requirements of their jobs. Training should address:

- the full range of positions of operational personnel including licensed and non-licensed personnel whose actions may affect plant safety
- the full range of plant functions and systems including those that may be different from those in predecessor plants (e.g., passive systems and functions)
- the full range of relevant HSIs (e.g., main control room, remote shutdown panel, local control stations) including characteristics that may be different from those in predecessor plants (e.g., display space navigation, operation of "soft" controls)
- the full range of plant conditions

Evaluation of Criterion (3)

NEDO-33275, Revision 1, Section 1.2, states that the training program covers all plant personnel whose actions may affect plant safety. Such personnel receive training on all plant functions and systems and the full range of plant conditions, with emphasis on risk-important functions and systems. The training also addresses relevant HSIs, including those with new and different characteristics, such as soft controls. Additionally, Section 3.1.2, "Goals," states the training program provides assurance that personnel have qualifications commensurate with the performance requirements of their job assignments. Accordingly, the staff finds the Training Development Plan treatment of the criterion for personnel qualifications acceptable.

18.10.3.1.2 Organization of Training

(1) The roles of all organizations, especially the applicant and vendors, should be specifically defined for the development of training requirements, development of training information sources, development of training materials, and implementation of the training program. For example, the role of the vendor may range from merely providing input materials (e.g., EPG) to conducting portions of specific training programs.

Evaluation of Criterion (1)

In RAI 18.10-3, the staff requested that GEH specify organizational training responsibilities and associated qualifications. GEH's response states that NEDO-33275 will be updated to show that the training development process will be performed by GEH and supported by COL Applicant participation through the completion of training material development specific to the ESBWR. This would include development of training requirements (or specifications), training information sources, and training materials. NEDO-33275, Revision1, Figure 2, provides added information related to the specific items to be developed and the relationship of the parts of the training development process to one another.

The response to RAI 18.10-3 also notes that training implementation and evaluation is the responsibility of COL Applicants. GEH has the ability to provide ESBWR training to the COL

Applicant's instructors and to support the COL Applicant's training program. This is a typical approach in current nuclear power plants and is acceptable.

Additionally, the RAI response states that NEDO-33275, Section 4.1.4.1, will be updated so that the training program guidelines will provide a definition of the roles of the various organizations involved in the training program. **RAI 18.10-3 is being tracked as a confirmatory item.**

In RAI 18.10-2, the staff requested that GEH update the reference to ANS 3.2. Part B of RAI 18.10-2 stated that "NEDO-33275, Section 2.2, Codes and Standards, lists the 1976 version of ANS 3.2 but should refer to the current 1994 version (reaffirmed 1999)." NEDO-33275, Revision 1, still refers to the 1976 version. GEH's response to this RAI states that they will change NEDO-33275 to reference ANS 3.2, 1994 version (reaffirmed 1999). This is acceptable. **RAI 18.10-2 is being tracked as a confirmatory item.**

The staff finds that, with the committed changes, the Training Development Plan treatment of the criterion for roles of organizations acceptable.

(2) The qualifications of organizations and personnel involved in the development and conduct of training should be defined.

Evaluation of Criterion (2)

The response to RAI 18.10-3 states that NEDO-33275, Section 4.1.4.1, will be updated to show that the ESBWR training program guidelines will delineate the overall structure of the training program and will (among other items) provide the ".qualification requirements for organizations and personnel developing or conducting training and the process for documenting compliance with these requirements." This provides an acceptable way at this of ensuring that qualifications are appropriately defined. **RAI 18.10-3 is being tracked as a confirmatory item.**

The staff finds that, with the committed changes, the Training Development Plan treatment of the criterion for qualifications of organizations is acceptable.

(3) Facilities and resources such as plant-referenced simulator and part-task training simulators needed to satisfy training design requirements and the guidance contained in ANSI 3.5 and RG 1.149 should be defined.

Evaluation of Criterion (3)

NEDO-33275, Revision 1, Section 3.1.4.1, states that, "resources such as the part task, full scope, and representative training simulators are utilized in the ESBWR HFE implementation process for both design verification and training." NEDO-33275, Revision1, Section 3.1.3, states that the COL training program meets the guidance contained in both ANSI 3.5, "Nuclear Power Plant Simulators for Use in Operator Training (2005)" and RG 1.149, "Nuclear Power Plant Simulation Facilities for Use in Operator Training and License Examinations (2001)".

In RAI 18.10-1, the staff requested that GEH clarify the simulators and scope of the training program to be certified. The response to RAI 18.10-1 provides definitions of the three types of simulators to be used as part of the HFE program and the training program and identifies related changes to the NEDO-33275. These simulators are: the part task simulator at GEH in Wilmington, NC; the full scope simulator (FSS) also located at GEH in Wilmington, NC; and the site specific training simulator to be located at each ESBWR plant site.

The part task simulator is used for: development and testing related to the HSI design; development of the plant normal, abnormal and emergency procedures; and initial development of plant training material. This is the typical use of this sort of simulator and helps to ensure a robust and well-tested design. NEDO-33275, Revision 1, Section 1.3.1 specifies that the FSS meets the guidelines of ANSI 3.5 and RG 1.149. The response to RAI 18.10-1 identifies that the FSS is used for validation of the main control room, procedures, and training material. The site specific training simulators are used for reactor operator and SRO training and for operator licensing exams. Verification of changes to the plan is a confirmatory item (18.10-1). Accordingly, the staff finds that, with the identified changes, the Training Development Plan treatment of the criterion for simulators acceptable. **RAI 18.10-1 is being tracked as a confirmatory Item.**

18.10.3.1.3 Learning Objectives

(1) Learning objectives should be derived from the analysis that describes desired performance after training. This analysis should include but not be limited to training needs identified in the following:

- Licensing Basis—Final Safety Analysis Report, system description manuals and operating procedures, facility license and license amendments, licensee event reports, and other documents identified by the staff as being important to training
- Operating Experience Review—previous training deficiencies and operational problems that may be corrected through additional and enhanced training, and positive characteristics of previous training programs
- Function Analysis and Allocation—functions identified as new or modified
- Task Analysis—tasks identified during task analysis as posing unusual demands including new or different tasks, and tasks requiring a high degree [of] coordination, high workload, or special skills
- Human Reliability Analysis—coordinating individual roles to reduce the likelihood and/or consequences of human error associated with risk-important HAs and the use of advanced technology
- HSI Design—design features whose purpose or operation may be different from the past experience or expectations of personnel
- Plant Procedures—tasks that have been identified during procedure development as being problematic (e.g., procedure steps that have undergone extensive revision as a result of plant safety concerns)
- V&V—training concerns identified during V&V, including HSI usability concerns identified during validation or suitability verification and operator performance concerns (e.g., misdiagnoses of plant event) identified during validation trials

Evaluation of Criterion (1)

NEDO-33275, Revision 1, Section 3.1.4.2, states that the training program establishes learning objectives derived from the analyses of jobs, tasks, and responses. The learning objectives establish desired performance capabilities for personnel after completion of initial training. Section 3.1.4.2 also lists 16 areas that provide input on necessary training needs, including the areas specified in the Criterion 1 above. Accordingly, the staff finds the Training Development Plan treatment of the criterion for derivation of learning objectives acceptable.

(2) Learning objectives for personnel training should address the knowledge and skill attributes associated with all relevant dimensions of the trainee's job, such as interactions with the plant, the HSIs, and other personnel.

Evaluation of Criterion (2)

NEDO-33275, Revision 1, Section 3.1.4.2, states that learning objectives for personnel training also address the knowledge and skill attributes associated with all relevant dimensions of the trainee's job, such as interactions with the plant, the HSIs, and other personnel. NEDO-33275, Revision 1, Table 7, also provides example skill and knowledge dimensions. This table provides additional information related to each of the three noted dimensions. Accordingly, the staff finds the Training Development Plan treatment of the criterion for knowledge and skill attributes acceptable.

18.10.3.1.4 Content of Training Program

(1) The design of the training program should be defined to specify how learning objectives will be conveyed to the trainee. The definition should include:

- The use of lecture, simulator, and on-the-job training to convey particular categories of learning objectives should be defined.
- Specific plant conditions and scenarios to be used in training programs should be defined.
- Training implementation considerations such as the temporal order and schedule of training segments should be defined.

Evaluation of Criterion (1)

NEDO-33275, Revision 1, Section 3.1.4.3.1, "Training Design," addresses this criterion and specifies how trainees achieve learning objectives in the training program. In NEDO-33275, Revision 1, GEH provides a commitment to the above criterion without details. This criterion is a COL applicant responsibility that the staff will evaluate as part of the operational programs review. This criterion is associated with COL items 13.2-1-A, "Reactor Operating Training," and 13.2-2-A, "Training for Non-Licensed Plant Staff."

(2) Factual knowledge should be taught within the context of actual tasks so that personnel learn to apply it in the work environment. The context of the job should be defined, and it should be represented meaningfully to help trainees to link the knowledge to the job's requirements. Training that addresses theory should be integrated with training in using procedures.

Evaluation of Criterion (2)

NEDO-33275, Revision 1, Section 3.1.4.3.2, “Factual Knowledge,” addresses this criterion and specifies how the training program presents factual knowledge within the context of real tasks. In NEDO-33275, Revision 1, GEH provides a commitment to the above criterion without details. This criterion is a COL applicant responsibility that the staff will evaluate as part of the operational programs review. This criterion is associated with COL items 13.2-1-A and 13.2-2-A.

(3) Training programs for developing skills should be structured so that the training environment is consistent with the level of skill being taught. It should support skill acquisition by allowing trainees to manage cognitive demands. For example, trainees should not be placed in environments teaching high-level skills, such as coordinating control actions among crew members, before they have mastered requisite, low-level skills, such as how to manipulate control devices.

Evaluation of Criterion (3)

NEDO-33275, Revision 1, Section 3.1.4.3.3, “Skill Development,” addresses this criterion and specifies how the structure of the training program ensures appropriate skill development. In NEDO-33275, Revision 1, This criterion is a COL applicant responsibility that the staff will evaluate as part of the operational programs review. This criterion is associated with COL items 13.2-1-A and 13.2-2-A.

(4) Training should address rules for decision-making related to plant systems, HSIs, and procedures. It should include rules for accessing and interpreting information and rules for interpreting symptoms of failures of systems, HSIs, and procedures. This training should cover acquiring new decision-making rules and eliminating existing ones that are not appropriate to the design.

Evaluation of Criterion (4)

NEDO-33275, Revision 1, Section 3.1.4.3.4, “Decision-Making Rules,” addresses this criterion and describes how the training program addresses decisionmaking. In NEDO-33275, Revision 1, GEH provides a commitment to the above criterion without details. This criterion is a COL applicant responsibility that the staff will evaluate as part of the operational programs review. This criterion is associated with COL items 13.2-1-A and 13.2-2-A.

18.10.3.1.5 Evaluation and Modification of Training

(1) Methods for evaluating the overall effectiveness of the training programs and trainee mastery of training objectives should be defined, including written and oral tests and review of personnel performance during walkthrough, simulator exercises, and on-the-job. Evaluation criteria for training objectives should be defined for individual training modules. Methods for assessing overall proficiency should be defined and coordinated with regulations, where applicable.

Evaluation of Criterion (1)

NEDO-33275, Revision 1, Sections 3.1.5.3 and 4.1.3.5 discuss the evaluation process for the training program. Section 3.1.5.3 states that the evaluation process determines whether trainees are mastering the training elements. There are defined assessment methods, which

are coordinated with regulations for licensed personnel. Section 4.1.3.5 specifies written and oral tests, walkthroughs, use of simulators, and on-the-job training observations. Accordingly, the staff finds the Training Development Plan treatment of the criterion for training evaluation methods acceptable.

(2) Methods for verifying the accuracy and completeness of training course materials should be defined.

Evaluation of Criterion (2)

NEDO-33275, Revision 1, Section 3.1.5.3 states that the evaluation process determines whether the training program is accurate, complete and effective. Evaluation criteria that would illustrate the trainees' satisfaction of training objectives will be defined in the COL training program plan. These criteria assist in verifying the completeness of the training material. Also, simulator training incorporates lessons learned from operational events at ESBWRs and other plants. More details on the evaluation process will be available when the full operational training program is developed. Methods for verifying the training course materials will receive detailed review as part of the COL application operational program review. Accordingly, the staff finds the Training Development Plan treatment of the criterion for verifying training accuracy acceptable.

(3) Procedures for refining and updating the content and conduct of training should be established, including procedures for tracking training course modifications.

Evaluation of Criterion (3)

NEDO-33275, Revision 1, Section 4.1.3.7 states that when the COL applicant takes over the plant, the human performance monitoring (HPM) process is used to seek, evaluate, track, and resolve improvements to the HSI, training, and procedures. The HPM process ensures the ongoing refinement of training practices, materials, and presentations based on industry/ESBWR OER and plant modifications. Accordingly, the staff finds the Training Development Plan treatment of the criterion for updating training acceptable.

18.10.3.1.6 Periodic Retraining

The area of periodic retraining, as addressed in criteria 1 and 2 below, is well in the future and is a COL applicant responsibility that the staff will evaluate as part of the operational programs review.

(1) Personnel should undergo periodic retraining.

Evaluation of Criterion (1)

This criterion is a COL applicant responsibility. Since training is an operational program, as specified in NUEG-0800, Section 13.4, it is the responsibility of the COL holder; no COL item is necessary.

(2) The applicant should evaluate whether any changes or increases in retraining are warranted following plant modernization programs.

Evaluation of Criterion (2)

This criterion is a COL applicant responsibility that the staff will evaluate as part of the operational programs review.

18.10.3.2 Relationship to Other Documents

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

DCD Tier 1, Revision 3, ITAAC Table 3.3-1, Item 8, addresses training. Table 3.3-1 contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall "MMIS and HFE Implementation Plan" rather than the implementation plan for the specific element. In RAI 14.3-211, the staff requested that GEH change the 11 design descriptions to refer to the applicable implementation plans. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

18.10.3.2.2 DCD Tier 2, Section 18.10, "Training Program Development"

DCD Tier 2, Revision 3, Section 18.10, provides a high-level overview of the training program development that basically summarizes the program as described in NEDO-33275, Revision 1. It provides the purpose of the implementation plan for training program development and states that the program meets the five aspects of a systems approach to training. It also discusses the general approach to training, organization of training, learning objectives, content of the training program, evaluation of training, and periodic retraining.

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.10.4 Conclusions

Because of the open items still to be resolved for Training Development, the staff was unable to finalize its conclusions regarding acceptability.

18.11 Human Factors Verification and Validation

18.11.1 Regulatory Criteria

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

- the applicant has identified a sample of operational conditions that (1) includes conditions that are representative of the range of events that could be encountered during operation of the plant, (2) reflects the characteristics that are expected to contribute to system performance variation, and (3) considers the safety significance of HSI components. These sample characteristics are best identified through the use of a multidimensional sampling strategy to provide reasonable assurance that variation along important dimensions is included in the V&V evaluations.

- the applicant's HSI inventory and characterization accurately describes 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 Human Engineering Discrepancy (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.

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

18.11.2 Summary of Technical Information

The ESBWR Procedure Development is described in DCD Tier 2, Revision 3, Section 18.11, "Human Factors Verification and Validation," DCD Tier 2, Revision 3, Section 18.11 incorporates by reference NEDE-33217P, Revision 3, and NEDO-33276, Revision 1, "ESBWR HFE Verification and Validation Implementation Plan"

The staff also reviewed the following GEH ESBWR document:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 3

18.11.3 Staff Evaluation

Following the staff's initial review of NEDO-33276, Revision 1, and receipt of GEH responses to RAIs that requested methodological details, the staff determined that GEH had not provided sufficiently detailed information to support an implementation level review for a significant portion of the review topics. The staff determined that a programmatic level review would be more appropriate. During a January 24, 2008, teleconference on RAI 18.11-36, GEH requested that the staff perform an implementation plan level of NEDO-33276, Revision 1. The staff agreed to this request as reflected in the RAIs in this section.

However, if GEH is not able to provide the requested information at this time, the staff expects the following RAI to be addressed.

In RAI 18.11-36, the staff requested that GEH develop a detailed HFE V&V implementation plan. The staff requested that GEH add a COL action item as follows, or alternatively, GEH is requested to provide the requested information as part of the design certification scope: The COL applicant shall develop a detailed HFE V&V implementation plan that provides the methodology and procedures for operation condition sampling, design verification, integrated system validation, and human engineering discrepancy resolution. The plan [should] be submitted to the NRC staff for review using the review criteria contained in NUREG-0711, Section 11. **RAI 18.11-36 is being tracked as an open item.**

Thus, the staff performed an implementation plan 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).

V&V review sections and topics include the following:

- Operation condition sampling (3 review topics)
  - Sampling Dimensions (3 review criteria)
  - Identification of Scenarios (2 review criteria)
  - Special Considerations for Plant Modernization Programs (4 review criteria – 0 applicable)
- Design verification (3 review topics)
  - Inventory and Characterization (3 review criteria)
  - HSI Task Support Verification (6 review criteria – 5 applicable)
  - HFE Design Verification (4 review criteria – 3 applicable)
- Integrated system validation(3 review topics)
  - Test Objectives (1 review criteria)
  - Validation Testbeds (9 review criteria)
  - Plant Personnel (4 review criteria)
  - Scenario Definition (3 review criteria)
  - Performance Measurement (5 review criteria)
  - Test Design (9 review criteria)
  - Data Analysis and Interpretation (5 review criteria)
  - Validation Conclusions (2 review criteria)
- HED resolution (7 review criteria – 6 applicable)

18.11.3.1 NUREG-0711 Review Criteria

18.11.3.1.1 Operational Conditions Sampling

NUREG-0711, Section 11.4.1, states, “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.” NEDO-33276, Revision1, Sections 4.2.1 and 4.3.1, discuss operational condition sampling.

18.11.3.1.1.1 Sampling Dimensions

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.”

In RAI 18.11-3, the staff requested that GEH address the Sampling Dimensions review criteria. NEDO-33276, Revision 1 provides a high-level summary of the sampling dimensions in Section 4.1.4.1. Items 1 through 3 in the section largely restate the review criteria for sampling dimensions in NUREG-0711 (Section 11.4.1.2). The staff cannot perform an implementation plan review when the plan simply restates the staff's review criteria. The plan should identify the operational conditions to be used for V&V and the process by which the sampling dimensions were used to identify them. The staff can then use the NUREG-0711 criteria in NUREG-0711 to review the acceptability of the operational conditions that have been identified. **RAI 18.11-3 is being tracked as an open item.**

Each of the three criteria for the Sampling Dimensions review topic will be addressed as part of this open item.

(1) The following plant conditions should be included:

- normal operational events including plant startup, plant shutdown or refueling, and significant changes in operating power
- failure events, e.g.,
  - instrument failures [e.g., safety-related system logic and control unit, fault tolerant controller, local "field unit" for multiplexer (MUX) system, MUX controller, and break in MUX line] including I&C failures that exceed the design basis, such as a common mode I&C failure during an accident
  - HSI failures (e.g., loss of processing and/or display capabilities for alarms, displays, controls, and computer-based procedures)
- transients and accidents, e.g.,
  - transients (e.g., turbine trip, loss of off-site power, station blackout, loss of all feedwater, loss of service water, loss of power to selected buses or main control room (MCR) power supplies, and safety and relief valve transients)
  - accidents (e.g., main steam line break, positive reactivity addition, control rod insertion at power, anticipated transient without scram, and various-sized loss-of-coolant accidents)
  - reactor shutdown and cooldown using the remote shutdown system
- reasonable, risk-significant, beyond-design-basis events, which should be determined from the plant specific PRA
- consideration of the role of the equipment in achieving plant safety functions [as described in the plant safety analysis report (SAR)] and the degree of interconnection with other plant systems. A system that is interconnected with other systems could cause the failure of other systems because the initial failure could propagate over the connections. This consideration is especially important when assessing non-class 1E electrical systems.

Evaluation of Criterion (1)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-3.

(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 human actions (selected via sensitivity analyses)
  - dominant accident sequences
  - dominant systems (selected via PRA importance measures such as Risk Achievement Worth or Risk Reduction Worth)
- OER-identified difficult tasks—The sample should include all personnel tasks identified as problematic during the applicant's review of operating experience.
- Range of procedure guided tasks—These are tasks that are well defined by normal, abnormal, emergency, alarm response, and test procedures. The operator should be able to, as part of rule-based decision-making, understand and execute the specified steps. 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:

  - main control room operators (e.g., operations, shift turnover walkdowns)

  - main control room operators and auxiliary operators

  - main control room operators and support centers (e.g., the technical support center and the emergency offsite facility)

- main control room operators with plant management, NRC, and other outside organizations

• Tasks that are performed with high frequency.

Evaluation of Criterion (2)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-3.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-3.

18.11.3.1.1.2 Identification of Scenarios

In RAI 18.11-4, the staff requested that GEH address the Identification of Scenarios review criteria. NEDO-33276, Revision 1 provides a high-level summary of the scenario identification in Section 4.1.4.2. The section largely restates the review criteria for scenario identification in

NUREG-0711 (Section 11.4.1.3). The staff cannot perform an implementation plan review when the plan simply restates the staff's review criteria. The plan should identify scenarios to be used and how the selected operational conditions were developed into scenarios. The plan should also identify how bias was avoided in the development of scenarios. The staff can then use the NUREG-0711 criteria in NUREG-0711 to review the acceptability of the scenarios that have been identified. **RAI 18.11-4 is being tracked as an open item.**

Each of the two criteria for the Identification of Scenarios review topic will be addressed as part of this open item.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-4.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-4.

18.11.3.1.2 Design Verification

18.11.3.1.2.1 Inventory and Characterization

NEDO-33276, Revision 1, Section 4.3.2.4 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)

NEDO-33276, Revision 1, Section 4.2.4, describes the general approach to HSI inventory characterization. The plan indicates that it is based on tasks associated with the operational conditions defined as part of the sampling process. This provides assurance that the COL

applicant's detailed V&V plan addresses a methodology to identify the HSI inventory. Accordingly, the staff finds the V&V Plan 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 VDU screens, and similar samples of HSI components should be included in the HSI inventory and characterization.

Evaluation of Criterion (2)

NEDO-33276, Revision 1, Section 4.2.4, describes the general approach to HSI inventory characterization. The plan specifies that the inventory characterization includes the unique identification code, plant system, personnel functions, HSI characteristics, user interaction types, and location. This provides assurance that the COL applicant's detailed V&V plan addresses a methodology to characterize the items in the HSI inventory identified in NUREG-

0711. Accordingly, the staff finds the V&V Plan 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)

NEDO-33276, Revision 1, Section 4.2.4, describes the general approach to HSI inventory characterization. The inventory is initially based on system, hardware, and software specifications, piping and instrumentation drawings, and logic diagrams. GEH'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 treatment of the criterion for inventory information sources acceptable.

18.11.3.1.2.2 Human-System Interface Task Support Verification

NEDO-33276, Revision 1, Sections 3.2 and 4.2, discuss 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)

NEDO-33276, Revision 1, Section 4.2.4, discusses the methods and procedures for conducting task support verification. This section states, "Task performance requirements (e.g., HSI Design Implementation Plan, Style Guide for Graphical User Interfaces, and Display Primitives Design Specification) are imposed on the various HSI hardware and software components. These requirements are included (directly or by reference) in hardware and software specifications (e.g., DCIS Hardware/Software Specification)" (pp. 35–36). The documents listed as performance requirements seem to be HSI requirements rather than task-driven requirements. However, the plan indicates that HSIs and their characteristics are compared to the personnel task requirements identified in the task analyses.

In RAI 18.11-7, the staff requested that GEH clarify the criteria to be used in task support verification. GEH's response referred to their response to RAI 18.11-5. However, GEH's response to RAI 18.11-5 addresses the criteria for selecting tasks rather than the requested clarification of the criteria to be used to evaluate the Human-Systems Interfaces (HSIs) that support tasks. The applicant should clarify the criteria to be used in task support verification. **RAI 18.11-7 is being tracked as an open item**.

(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, the staff requested that GEH clarify its task support verification methodology. NEDO-33276, Revision 1, Section 4.2.4.1 describes the review of panel drawings as part of task support verification. The section states, "HSI Task Support Verification of panel drawings is achieved through an iterative process of reviews by several groups and organizations." GE's response referred to their response to RAI 18.11-2 and 18.11-5. The staff followed up indicating that those RAI responses do not pertain to this question. The applicant should clarify the organization(s) that are responsible for task support verification and why the evaluation appears limited to drawings and computer-generated displays. It should also note how the other HSIs are evaluated. **RAI 18.11-8 is being tracked as an open item.**

(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)

NEDO-33276, Revision 1, Section 4.2.4 identifies the conditions for defining HEDs. These include HSIs needed for task performance and HSIs that do not match task requirements. Accordingly, the staff finds the V&V Plan 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)

NEDO-33276, Revision 1, Section 4.2.4 identifies the conditions for defining HEDs. These include HSIs needed for identifying potentially unnecessary HSIs. Accordingly, the staff finds the V&V Plan 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)

NEDO-33276, Revision 1, Section 4.2.9, 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 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)

NEDO-33276, Revision 1, Sections 3.3 and 4.3, discuss HFE design verification. Section 3.3 indicates that this evaluation verifies that each HSI component meets the HFE guidelines contained in the ESBWR style guide. Section 4.3.2, “Objectives,” reinforces this and indicates that the objective of the verification is to ensure that the HSI characteristics conform to the ESBWR style guide.

NEDO-33268, Revision 2, Sections 3.2 and 4.2 discuss the development and application of the ESBWR style guide. The topics and content of the style guide are outlined throughout the HSI Design plan and include topics such as alarms, displays, control, workstations, 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) and the results of the GEH evaluation of design tradeoffs. Provisions for modification of the contents of the style guide are identified. The staff evaluation of GEH’s style guide development process is in Section 18.8.3.2.5, HSI Detailed Design and Integration, Criterion 1, of this report.

The V&V Plan identifies the ESBWR style guide as the criteria for HFE design verification. The HSI Design Plan identifies the process for developing the ESBWR style guide. Accordingly, the staff finds the V&V Plan 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)

NEDO-33276, Revision 1, Sections 3.3 and 4.3, discuss HFE design verification. The general methodology to compare HSI design features to the ESBWR style guide is an acceptable approach to HFE design verification. Section 3.3 states that designs are compared to HFE guidelines to determine whether they account for human characteristics and capabilities. Deviations from accepted HFE guidelines, standards, and principles are documented as HEDs for resolution or correction and acceptably justified on the basis of documented rationale such as trade study results, literature-based evaluations, demonstrated operational experience, tests, and experiments. Furthermore, Section 4.3.6 states that HFE guidelines are the criteria for verifying the design. Section 4.3.9 identifies the criteria for specifying HEDs. These criteria are consistent with the staff's review guidance.

However, the method described in Section 4.3.4 discusses evaluations outside the scope of this verification or that are otherwise unclear.

In RAI 18.11-13, the staff requested that GEH clarify its HFE design verification methodology. The staff identified the following specific concerns:

- Section 4.3.4.1 discusses HFE design verification for panel anthropometrics. Rather than discussing the comparison of panel characteristics to HFE guidelines, the section discusses the validation of operator actions. Thus, it is unclear how the verification will be performed.

- Section 4.3.4.3 discusses HFE design verification for HSI components. Rather than discussing the comparison of HSI characteristics to HFE guidelines, the section discusses verification criteria such as ease of monitoring and usability. Thus, it is unclear how the verification will be performed.

The applicant should clarify precisely the methodology and criteria that will be used for HFE design verification of panel anthropometrics and HSI components. **RAI 18.11-13 is being tracked as an open item.**

(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)

NEDO-33276, Revision 1, Section 4.3.9, discusses the documentation of HEDs. It states that any noncompliance, either full or partial, is logged into the HFEITS along with the nature of the discrepancy. Noncompliance is identified as a discrepancy between an HSI characteristic and the HFE guidelines. Accordingly, the staff finds the V&V Plan 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)

NEDO-33276, Revision 1, Sections 3.4 and 4.4.2, describe the objectives of the validation program. The seven objectives include validation of the operator role, specific personnel tasks, crew transitions between HSIs, and the other considerations identified in the staff's review criterion. Accordingly, the staff finds the V&V Plan 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 GEH clarify its integrated system validation simulator and the simulation of remote actions. This RAI has two parts:

1. Regarding the testbed to be used for integrated system validation, Section 3.4 of NEDO-

33276 states that integrated system validation is performed using dynamic HSI prototypes and high-fidelity simulators. Section 4.3.4 describes a variety of test beds that are to be used to address the different objectives of the validation program. Three of the main simulation facilities to be used in this program are the GEH Test System, Baseline Simulator (BS), and the Full Scope Simulator (FSS), described in [NEDO-33276,] Sections 4.3.5.2, 4.3.5.3, and 4.3.5.4, respectively. These simulators provide incremental levels of fidelity, and the BS and FSS models are ANSI/ANS-3.5 compatible. While ANSI/ANS 3.5 compatibility provides an acceptable basis for an integrated system validation testbed as described in NUREG-0711, the BS does not provide the full control room HSI. Thus, based on the staff's validation testbed criteria in NUREG-0711, Section 11.4.3.2.2, only the FSS is suitable for implementing integrated system validation. While the other simulators can provide valuable information to GEH during their test and evaluation program, the final validation addressed in NUREG-0711 should be performed using the FSS. The staff requested that GEH clarify the role of the FSS in the final validation. In addition, in response to RAI 18.10-1 GE submitted the Attachment to MFN 07-625 in which simulation capabilities are defined, including a Part Task Simulator, Full-Scope Simulator, and Site Specific Training Simulator. The BS is not included in this response. GEH is requested to describe how these descriptions correspond to those provided in NEDO-33276 and provide any changes to descriptions in NEDO-33276 that may be necessary to reconcile the two documents.

2. Regarding the simulation of remote actions, Section 4.3.4.1 indicates that actions at local system control stations are evaluated using drawings or mockup panels, but no information as to what evaluations are performed or how the actions will be analyzed. This statement is in the HFE Design Verification section rather than an integrated system validation section. Beyond this statement, no information about the treatment of local actions is provided. The staff requested that GEH identify what remote actions are needed for the scenarios to be used in validation testing and provide information as to how these actions will be modeled and evaluated for validation.

RAI 18.11-19 is being tracked as an open item.

Criteria 1-8 below for the Validation Testbeds review topic will be addressed as part of this open item.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-19.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-19.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-19.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-19.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-19.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-19.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-19.

(8) For important actions at complex HSIs remote from the main control room, where timely and precise human actions are required, the use of a simulation or mockup should be considered to verify that human performance requirements can be achieved. (For less risk-important HAs or where the HSIs are not complex, human performance may be assessed based on analysis such as task analysis rather than simulation.)

Evaluation of Criterion (8)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-19.

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

Evaluation of Criterion (9)

NEDO-33276, Revision 1, Section 4.3.5.5, addresses test bed verification. Test beds are compared to the plant design as it develops and modified for consistency. Accordingly, the staff finds the V&V Plan 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)

NEDO-33276, Revision 1, Section 4.4.3, identifies the participants in the validation exercises. V&V teams include GEH personnel, GEH subcontractors, and COL holder personnel. The teams include individuals in training to be ESBWR operators and SROs. Accordingly, the staff finds the V&V Plan 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)

In RAI 18.11-21, the staff requested that GEH clarify the selection of participants in validation exercises. NEDO-33276, Revision 1, Section 4.4.3, generally discusses participants in validation exercises. However, several aspects of participant selections are not identified in the plan:

- participants will account for human variability,
- how minimum and normal crew configurations will be assembled and what they will consist of, and
- how sampling bias will be prevented.

NEDO-33276 should be revised to provide the information or indicate that the detailed V&V implementation plan will address these participant sampling considerations. **RAI 18.11-21 is being tracked as an open item.**

Criteria 3-4 below for the Plant Personnel review topic will be addressed as part of this open item.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-21.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-21.

18.11.3.1.3.4 Scenario Definition

In RAI 18.11-22, the staff requested that GEH address the Scenario Definition review criteria. In RAI 18.11-4, the staff asked how the selected operational conditions were developed into scenarios. This RAI addresses the detailed definition of the scenarios so they can be run on the validation testbed. GEH's response to the original RAI indicated that specific scenario details are not included in the implementation plan as they will be developed as a part of the ESBWR design process. While in the context of a programmatic review, the staff agreed that this level of detail would be premature at this point in the process. The staff requested that GEH provide this information if the staff is to conduct an Implementation Plan level review. The descriptions should provide sufficient detail so they can be reviewed using the criteria in NRUGE-0711, Section 11.4.3.2.4. **RAI 18.11-22 is being tracked as an open item.**

Criteria 1-3 below for the Scenario Definition review topic will be addressed as part of this open item.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-22.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-22.

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

Evaluation of Criterion (3)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-22.

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)

NEDO-33276, Revision 1, does not discuss the measurement characteristics, such as reliability and validity. For measures that are new or unique to the ESBWR V&V, the applicant should provide information on measurement characteristics that are relevant to that type of measure.

In RAI 18.11-23, the staff requested that GEH address the review criteria for measurement characteristics. GEH's response to the RAI indicated that the level of detail in the implementation plan was not intended to discuss measurement characteristics. The staff requested that GEH provide this information on applicable measurement characteristics, such as reliability and validity, for all performance measures identified in response to RAI 18.11-24 so the staff is able to conduct an Implementation Plan level review (consistent with NUREG-0711, Section 11.4.3.2.5.1). **RAI 18.11-23 is being tracked as an open item.**

18.11.3.1.3.5.2 Performance Measure Selection

In RAI 18.11-24, the staff requested that GEH identify performance measures. For the staff to perform an implementation plan review, GEH is requested to identify the hierarchal set of performance measures (including plant/system level performance, operator task performance, situation awareness, operator workload, and anthropometric/physiological factors) that will be used in validation tests. The response should provide a clear picture of the range of measures to be used (consistent with NUREG-0711, Section 11.4.3.2.5.2). GEH's response to this RAI should consider the specific issues identified in the original RAI in RAI Letter 74.

The staff also requested that GEH consider questions on specific performance measures based on the RAI response in MFN 06-446, dated November 11, 2006:

- Operator task measures: The response addresses how operator tasks for validation will be selected. The staff requested that GEH address how performance on selected tasks will be measured.

- Situation awareness: The response discusses how situation awareness will be measured. The Situation Awareness Control Room Inventory (SACRI) method is discussed in NEDO-33276, Revision 1 but not in the RAI response. The staff requested that GEH discuss the performance measures that will be used with the SACRI method.

- Operator Workload: The response indicates that workload rating scales will be used and will be integrated by converting the ratings into a "fraction of the time involved over the simulated event." How will such a conversion be performed?

RAI 18.11-24 is being tracked as an open item.

RAI 18.11-25, the staff requested that GEH the clarify procedures and displays aspects of automation. The V&V plan discusses two additional areas of evaluation—procedures and displays—and identifies performance measures. It is not clear whether these represent two areas of performance measurement or two aspects of the design that will be evaluated. Regardless, the staff requests the following additional information.

- Procedures— NEDO-33276, Revision 1, Section 4.4.4.8, discusses the validation of operating procedures. The section indicates that the validation is completed during operator training phases. The applicant should specify the training phases that are being referred to in this statement. Section 4.4.7.8 on performance measures for operating procedures states that it "refer[s] to operator performance measures regarding situation awareness." The applicant should explain this statement. Based on the earlier discussion of situation awareness, the questions asked of operators appear to relate to the awareness of plant status. It is not clear how they can then be used to validate procedures.

- Displays—The first paragraph of NEDO-33276, Revision 1, Section 4.4.7.9, states that there are no human performance measures for graphical displays. The applicant should explain this statement.

RAI 18.11-25 is being tracked as an open item.

Criteria 1-6 below for the Performance Measure Selection review topic will be addressed as part of the open items for RAIs 18.11-24 and 18.11-25.

(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)

This criterion will be evaluated when GEH provides the information requested in RAIs 18.11-24 and 18.11-25.

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

Evaluation of Criterion (2)

This criterion will be evaluated when GEH provides the information requested in RAIs 18.11-24 and 18.11-25.

(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)

This criterion will be evaluated when GEH provides the information requested in RAIs 18.11-24 and 18.11-25.

(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)

This criterion will be evaluated when GEH provides the information requested in RAIs 18.11-24 and 18.11-25.

(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)

This criterion will be evaluated when GEH provides the information requested in RAIs 18.11-24 and 18.11-25.

(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)

This criterion will be evaluated when GEH provides the information requested in RAIs 18.11-24 and 18.11-25.

18.11.3.1.3.5.3 Performance Criteria

In RAI 18.11-26, the staff requested that GEH identify specific acceptance criteria for performance measures. For the staff to perform an implementation plan review, GEH is requested to identify the criteria to be used for performance measures (consistent with NUREG-0711, Section 11.4.3.2.5.3). The specific criteria that are used for decisions as to whether the

design is validated or not should be specified and distinguished from those used to better understand the results. In addition, the staff requested that GEH identify the basis for the criteria established. Note that the question of acceptance criteria is related to the discussion in RAI 18.11-29. **RAI 18.11-26 is being tracked as an open item.**

Criteria 1-2 below for the Performance Criteria review topic will be addressed as part of this open item.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-26.

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

Evaluation of Criterion (2)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-26.

18.11.3.1.3.6 Test Design

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.

In RAI 18.11-27, the staff requested that GEH address the Test Design review criteria and provide the detailed test design methodology. In NEDO-33276, Revision 1, GEH added a new section 4.4.9 to present a high level description of test design. However, GEH is requested to provide the detailed information requested if the staff is to conduct an Implementation Plan level review. The staff requested that GEH provide descriptions of the following aspect of test design (consistent with NUREG-0711, Section 11.4.3.2.6):

- presentation of scenarios to crews
- test procedures
- training of test conductors
- training of test participants
- pilot studies.

RAI 18.11-27 is being tracked as an open item.

The nine criteria below for the Test Design review topic (including the two criteria for Coupling Crews and Scenarios, the two criteria for Test Procedures, the criterion for Test Personnel Training, the two criteria for Participant Training, and the two criteria for Pilot Testing), will be addressed as part of this open item.

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 GEH address the reuse of scenarios during validation. NEDO-33276, Revision 1, Section 4.4.9, provides a high-level description of test design. Section 4.4.9.1 discusses the presentation of scenarios to crews but does not address how scenarios will be assigned to crews or scenario sequencing. Section 4.4.4.1 states the following:

> The reuse of a scenario for the same crew for MMIS validation is used to capture the improvement in the use of the MMIS. The data is not being collected to evaluate crew capabilities, but rather to validate that the MMIS can be used to effectively manage the normal operation and accident situations. If information is available to the crew and it is not understood initially, then the second run provides a second look at the MMIS.

The staff agrees that data are being collected to evaluate the design and not the crew. In addition, the approach described in the response seems appropriate for confirming that there is a problem with the HSI in a particular area. However, it may not be appropriate for use in deciding on the acceptability of the HSI design. For example, during the first trial, the crew may fail to recognize a component failure during an event because of poor HSI design, leading to a serious situation. On the second trial of the same scenario, the crew will know the second failure is coming and will not need to look at the HSIs to realize that the component has failed. Therefore, the applicant should further clarify the use of the second trial and address the issue of scenario sequencing. **RAI 18.11-28 is being tracked as an open item.**

This criterion will be evaluated when GEH provides the information requested in RAIs 18.11-27 and RAI 18.11-28.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-27.

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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-27.

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

Evaluation of Criterion (2)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-27.

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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-27.

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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-27.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-27.

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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-27.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-27.

18.11.3.1.3.7 Data Analysis and Interpretation

In RAI 18.11-29, the staff requested that GEH address the Data Analysis and Interpretation review criteria. To support the staff's review of the implementation plan, GEH is requested to describe (consistent with NUREG-0711, Section 11.4.3.2.7):

- what methods will be used to analyze data and to assess performance criteria
- how HEDs will be identified
- how consistency across different measures will be evaluated
- how data analysis will be verified for correctness

NEDO-33276, Revision 1, Section 4.4.8, contains high-level information about data analysis. The staff requested that GEH clarify the following information in Section 4.4.8:

> The methods for analyzing the simulation results will draw from experience in EPRI OER program as summarized in EPRI NP-6560L, which provides estimates of the median response time and the standard deviation associated with different types of cue response as measures of consistency between crews and individuals. Acceptability of the MMIS clarity is that standard deviation falls within the ranges of responses demonstrated in existing plant simulations for multiple crews. For larger deviations between crews an examination of the MMIS for improvement is documented in an HED.

This does not seem to be an appropriate means of analyzing validation data. Assuming there will be sufficient data to generate reliable statistics, the analysis is based on response variability and a comparison of that variability to the range of responses demonstrated in existing plant simulations. The approach seems to focus on variability alone, and not the acceptability of performance, e.g., are required tasks performed within an acceptable time for plant safety.

It would seem the approach to analyzing data should focus on whether observed integrated system performance (as defined by the set of performance measures selected for use in validation) is acceptable (as defined by the acceptance criteria for each of the performance measures). GEH is requested to provide an explanation of the approach to data analysis in light of the staff's concern.

Note that the question of acceptance criteria is related to the discussion in RAI 18.11-26. **RAI 18.11-29 is being tracked as an open item.**

The five criteria below for the Data Analysis and Interpretation review topic and criterion 2 for the Validation Conclusions review topic, will be addressed as part of this open item.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-29.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-29.

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

Evaluation of Criterion (3)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-29.

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

Evaluation of Criterion (4)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-29.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-29.

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)

NEDO-33276, Revision 1, Section 4.4.10, 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 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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-29.

18.11.3.1.4 Human Engineering Discrepancy Resolution

(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)

In RAI 18.11-32, the staff requested that GEH clarify the HED resolution methodology. NEDO-33276, Revision 1, Section 4.6, describes the resolution process for addressing HFE issues identified in V&V. The process is depicted graphically in [NEDO-33276, Revision 1,] Figure 4. GEH's process considers the impact on human performance and risk importance of issues from both quantitative (PRA) and qualitative perspectives. Where issues are found to qualitatively impact risk, the methodology seeks to determine if they can be addressed in PRA. While the methodology appears generally complete, the staff requests clarification regarding three points:

(1) Is there a provision for justifying a discrepancy, e.g., deviation from the style guide with justification?

(2) Figure 4, decision point 4, "Does Issue Meet Style Guide Requirements," describes actions for answering the question as "yes" or "no." However, meeting the style guide requirements is irrelevant for some issues. For example, integrated system validation may identify as an issue that a task could not be completed in time because of operator workload. In this case, the style guide requirements are not likely to be related to the issue. Instead, task reallocation to other personnel or automation may be the solution.

There should be a path to follow when the analyst concludes the issue is not related to style guide compliance.

(3) The final solutions identified appear to be overly restrictive. For example, if an issue cannot be addressed in PRA, the analyst is guided to consider changing training, procedures, or staffing/qualifications. However, as in the example above, task redesign or increased automation may be warranted. The proposed solutions should not be limited to those shown in the figure.

RAI 18.11-32 is being tracked as an open item.

Criteria 2-6 below for the Human Engineering Discrepancy Resolution review topic will be addressed as part of this open item.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-32.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-32.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-32.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-32.

(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)

This criterion will be evaluated when GEH provides the information requested in RAI 18.11-32.

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 3, Section 3.3, Table 3.3-1, Item 9, contains the Tier 1 ITAAC for HFE V&V. Table 3.3-1 contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall “MMIS and HFE Implementation Plan” rather than the implementation plan for the specific pertinent elements. In RAI 14.3-211, the staff requested that GEH change the 11 design descriptions to refer to the applicable implementation plans. In the case of V&V, the applicable implementation plan may be developed by the COL applicant, depending on the response to RAI 18.11-36, discussed above. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

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

In RAI 18.11-35, the staff requested that GEH ensure the DCD is consistent with NEDO-33276. Human factors V&V activities are mainly described in DCD Tier 2, Section 18.11. However, the material in Section 18.11 is not completely consistent with NEDO-33276, Revision 1. For example, the DCD discusses “HED identification and resolution,” while NEDO-33276 uses no such language. In addition, the DCD does not reference the V&V Plan. The staff requested that GEH revise the DCD to be consistent with NEDO-33276 and any changes that are identified in the RAI responses. **RAI 18.11-35 is being tracked as an open item.**

In RAI 18.11-37, the staff requested that GEH reference NEDO-33276 in the DCD. DCD Revision 4, Section 18.11, Human Factors V&V does not reference the V&V implementation plan (NEDO-33276) in the discussion of V&V implementation in Section 18.11.1. NEDO-33276 should be referenced in Section 18.11.1. NEDE 33217P should not be referenced. Note that NEDO-33276 is included in the references listed in Section 18.11.4. (The issue of referencing the implementation plans existed with the earlier version of the DCD and has been corrected in the other HFE program elements.) **RAI 18.11-37 is being tracked as an open item.**

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.11.4 Conclusions

Because of the open items still to be resolved for Human Factors V&V, the staff was unable to finalize its conclusions regarding acceptability.

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. [ITAAC are used to accomplish this goal. The following are the bases for the required ITAAC.]

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

18.12.2 Summary of Technical Information

The ESBWR Design Implementation is described in DCD Tier 2, Revision 3, Section 18.12, "Design Implementation." DCD Tier 2, Revision 3, Section 18.9 incorporates by reference NEDE-33217P, Revision 3, and NEDO-33278, Revision 2, "ESBWR Human Factors Engineering Design Implementation Plan."

The staff also reviewed the following GEH ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 3
- GEH responses to RAIs 18.12-1 though 18.12-6 (MFN 06-447)

18.12.3 Staff Evaluation

The staff performed an implementation plan 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 3 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 2, Section 1.1, "Purpose," 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 main control room.

Section 3.3 describes the methodology, and Section 4.3 describes its implementation. Methodology clarifications are identified below. Section 3.3 outlines an acceptable scope of what aspects of the design are included in this verification. Accordingly, the staff finds the Design Implementation Plan 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)

According to NEDO-33278, Revision 2, 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. Related to the methodology to be used, GEH needs to clarify several aspects, identified below, before the staff can complete its review of the methodology.

In RAI 18.12-2, the staff requested that GEH clarify the source document for the design verification acceptance criteria. In GEH's response, they indicated the criteria are derived from the "ESBWR style guide," which is included in the "HF Guidance manual." NEDO-33278, Revision 2, Section 3.3.1, states that the criteria for final design verification will be derived from an "HSI Report." The applicant should clarify what specific document will be used for the criteria to determine that the as-built design is acceptable. **RAI 18.12-2 is being tracked as an open item.**

In RAI 18.12-3, the staff requested that GEH clarify the methodology for as-built verification. GE's response to RAI 18.12-2 indicates that the style guide will provide acceptance criteria. The staff expects these criteria to be applied by verifying that the as-built design conforms to these criteria. The staff expected the verification to be made using the HFE Style Guide. Yet GEH's response to this RAI discusses procurement documents and the HSI Report. The staff requested that GEH explain in more detail the HSI Report and the acceptance criteria for the final design implementation verification.

NEDO-33278, Revision 2, describes a final design verification methodology that appears to be based on a review of documentation rather than a review of the actual as-built design. Section 3.1.4, "General Approach" indicates that the review is conducted on documents. The individual implementation sections are all consistent with this general approach and focus on documents, not the implemented design. As per NUREG-0711, Section 12.4.6, Criterion 2, it should be the design itself, as-built that is verified against the design documentation. Verifying documents with documents only establishes that the documents are in agreement, not that the controls and displays in the control room are in agreement with the design documentation. The staff requested that GEH provide justification of the proposed approach to address this concern. **RAI 18.12-3 is being tracked as an open item.**

In RAI 18.12-4, the staff requested that GEH clarify the role of the COLOG and as-built design verification for subsequent COLs. GEH's RAI response acceptably addressed the role of the COL holder and GEH as part of the HFE team. However, in reviewing NEDO-33278, Revision 2 of the plan two follow up questions were identified.

(1) Section 1.2 of the plan describes a somewhat different organization than was identified in the RAI response. It states that the verifications are the responsibility of the COLOG. Will the COLOG be the COL license applicant?

(2) Section 1.2 of the plan indicates that the verifications described for the plan "apply to the initial COL plants associated with the ESBWR design effort." The staff's position is that "as-built" verifications are needed for every new plant construction. The staff requested that GEH explain why only the initial plants will be verified.

This is RAI 18.12-4 is being tracked as an open item.

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

Evaluation of Criterion (3)

NEDO-33278, Revision 2, 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, and Section 4.4 describes its implementation.

The methodology described by GEH involves confirmation that items entered into the HFEITS have been closed. Long-term, outstanding HEDs and open items from HFEITS not addressed by GEH are turned over to the COL applicant for action, tracking, and final disposition. These items will be identified in a results summary report. Accordingly, the staff finds the Design Implementation Plan treatment of issue tracking system verification 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 3, Section 3.3, Table 3.3-1, Item 10, contains the Tier 1 ITAAC for design implementation. Table 3.3-1 contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall "MMIS and HFE Implementation Plan" rather than the specific pertinent elements implementation plan. In RAI 14.3-211, the staff requested that GEH update the 11 design descriptions to refer to the applicable implementation plans. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

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

In RAI 18.12-7, the staff requested that GEH ensure that the DCD is consistent with NEDO-33278. Design implementation activities are described in DCD Tier 2, Revision 3, Section 18.12. The Tier 2 description is not fully consistent with NEDO-33278, Revision 2, and should be revised. Note that the resolution of other remaining open RAIs for DCD Tier 2, Section 18.12 may necessitate additional revisions to the DCD. **RAI 18.12-7 is being tracked as an open item.**

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.12.4 Conclusions

Because of the open items still to be resolved for Design Implementation, the staff was unable to finalize its conclusions regarding acceptability.

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 their problem identification and corrective action program.

To review GEH's human performance monitoring, the staff used the review criteria in NUREG-0711, Section 13.4.

18.13.2 Summary of Technical Information

The ESBWR Human Performance Monitoring is described in DCD Tier 2, Revision 3, Section 18.13, "Human Performance Monitoring." DCD Tier 2, Revision 3, Section 18.13 incorporates by reference NEDE-33217P, Revision 3, and NEDO-33277, Revision 2, "ESBWR Human Factors Engineering Human Performance Monitoring Implementation Plan."

The staff also reviewed the following GEH ESBWR documents:

- ESBWR DCD Tier 1, Section 3.3, "Human Factors Engineering," Revision 3
- NEDO-33276, "ESBWR HFE Verification and Validation Implementation Plan," Revision 1
- GEH response to RAIs 18.13-1 through 18.13-5 (MFN 06-470)

18.13.3 Staff Evaluation

The staff performed an implementation plan 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 5 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.

- Human actions 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 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. DCD Tier 2, Revision 3, Section 18.13, addresses this item at a high level. NEDO-33277, Revision 2, Section 1.2, addresses it more specifically, noting the various locations for personnel actions.

DCD Tier 2, Revision 3, Section 18.13 states that the HPM program provides reasonable assurance of the following:

- Acceptable levels of performance established during the integrated HSI validation are maintained.

- Changes made to the initial HSIs, procedures, and training do not have adverse effects on personnel performance (e.g., a change interferes with trained skills).

NEDO-33277, Revision 2, Section 3, references the V&V portion of the design phase and describes how that provides the baseline that shows the effective use of the various HSIs by personnel. It also 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, and training are screened for generic final SAR impact and consistently applied at all ESBWRs in a timely manner.

- Changes made to the HSI are tested in the FSS before implementation in the plant.

NEDO-33277, Revision 2, 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 final SAR.

In view of the forgoing, the staff finds the HPM Plan 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 2 and DCD Tier 2, Revision 3, 18.13 provide the overview of a detailed plan for HPM during the design, V&V, and operational phases of the ESBWR. It includes activities for the nuclear steam supply system designer, the COLOG, and the COL holder. 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 corrective action program (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

- human actions are monitored commensurate with their safety importance
- feedback of information and corrective actions are accomplished in a timely manner
- degradation in performance can be detected and corrected before plant safety is compromised (e.g., by use of the plant simulator during periodic training exercises)

Evaluation of Criterion (3)

NEDO-33277, Revision 2, 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. It 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 FSS. 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. The overall structure of the program is outlined in NEDO-33277, Revision 2, Figure 2. 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 COLOG, and ESBWR licensees. Accordingly, the staff finds the HPM Plan 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 FSS, data analysis, and the involvement of the ESBWR vendor, the licensee, and the COLOG. This combination should provide for data and experience that are as close to actual demand conditions as is reasonably achievable. NEDO-33277, Revision 2, Chapter 3 lists the portions of the program that show its breadth. Accordingly, the staff finds the HPM Plan 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 2, Section 3.2.3, notes that the CAP screens adverse conditions and trends for potential generic applicability. NEDO-33277, Revision 2, Section 3.3.4, states that the program addresses the significance of the failure through application of precursor analysis and PRA/HRA importance measures. The COLOG 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 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 3, Table 3.3-1, Item 7, contains the Tier 1 ITAAC developed by GEH for HPM. Table 3.3-1 contains 11 items, one for each element of NUREG-0711 (except HFE program management) and the corresponding ESBWR element implementation plan. However, the Design Commitment column for each element refers to the overall "MMIS and HFE Implementation Plan" rather than the implementation plan for the specific pertinent elements. In RAI 14.3-211, the staff requested that GEH change the 11 design descriptions to refer to the applicable implementation plans. **RAI 14.3-211 addresses this generically and is being tracked as an open item.**

In addition, the staff has requested more explicit acceptance criteria in Column 3 of the HFE ITAAC. **RAI 14.3-271 addresses this generically and is being tracked as an open item.**

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

HPM implementation activities are mainly described in DCD Section 18.13. This provides a reasonable summary of the HPM program, including the purpose, the strategy, and the key elements of the HPM process. The HPM Plan provides more details on the HPM program.

As noted in RAI 18.2-18, the Tier 2 material should reference the detailed implementation plan. **RAI 18.2-18 is being tracked as an open item.**

18.13.4 Conclusions

Because of the open items still to be resolved for Human Performance Monitoring, the staff was unable to finalize its conclusions regarding acceptability.

18.14 Generic Issues Related to Human Factors Engineering

Generic issues determined to be applicable to the ESBWR design and related to human factors engineering are evaluated below.

18.14.1 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 "Operating Organization," SRP Section 18 and the referenced 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 1, the "ESBWR Human Factors Engineering Staffing and Qualifications Plan." This review is addressed in Section 18.6 of this report. As noted in Section 18.6.4 of this report, there are a few applicable open items in the staffing area. Therefore, Issue HF1.1 is still open for the ESBWR.

Section 13.1 of this report evaluates the organizational structure of the applicant as described in DCD Tier 2, Revision 3, 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," 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 1, Section 3.3, Design Commitment 7, and Tier 2, Sections 13 and 18.9, address procedures. DCD Section 18.9 incorporates by reference NEDO-33274, Revision 2, "ESBWR Human Factors Engineering Procedures Development Implementation Plan." Section 18.9 of this report provides the staff's review of this material. Section 18.9 of this report identifies several applicable open items and the EPGs have not yet been developed for ESBWR. Additionally, the methodology for the development of plant procedures, as described in DCD Tier 2, Revision 3, Chapter 13, is evaluated in Section 13.5 of this report. Therefore, Issue HF4.1 is still open for the ESBWR design.

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 IN 86-64, "Deficiencies in Upgrade Programs for Plant Emergency Operating Procedures." In addition, Element 8, "Procedures Development," of NUREG-0711, "Human Factors Engineering Program Review Model" covers this item.

As noted above for HF Issue 4.1, since Section 18.9 of this report contains several open items, Issue HF4.4 remains open 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 control room and remote shutdown room are sufficient and appropriate for their intended use. Control room crew activities should be analyzed to establish and describe communication and control links between the control room and the auxiliary control stations. Additionally, the potential impact of the actions of auxiliary personnel on plant safety should be analyzed.

This generic issue was resolved by NRC and no new requirements were established. In DCD Tier 2, Table 1.11-1 for HF 5.1, GEH stated that its on-going program for the design of I&C systems and MMI systems incorporates all applicable HFE requirements.

DCD Tier 1, Revision 3, Section 3.3, Design Commitment 6, and DCD Tier 2, Revision 3, Sections 13 and 18.8, Human-System Interface Design, address HSI Design. DCD Tier 2, Revision 3, Section 18.8 incorporates by reference NEDO-33268, Revision 2, "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 control stations (LCSs). However, Section 18.8 of this report identifies several applicable open items. Therefore, Issue HF5.1 is still open 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&Cs, in particular with respect to plant annunciators. The then-existing human engineering guidelines for control rooms 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 control room alarms. The staff stopped work on this issue when the Office of Nuclear Regulatory Research (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, Human-System Interface Design Review Guidelines, which includes HFE guidance for a variety of advanced HSIs, including advanced alarm systems.

In DCD Tier 2, Revision 3, Table 1.11-1 for HF 5.2, GEH stated that its on-going program for the design of I&C systems and MMI systems incorporates all applicable HFE requirements. DCD Tier 1, Revision 3, Section 3.3, Design Commitment 6, and DCD Tier 2, Revision 3, Section 18.8, Human-System Interface Design, address HSI Design. DCD Tier 2, Revision 3, Section 18.8 incorporates by reference NEDO-33268, Revision 2, "ESBWR Human-System Interface Design: Implementation Plan." Section 18.8 of this report provides the staff's review of this material. The design and the documents include an advanced alarm systems and computer-based procedures. These can be acceptably reviewed using NUREG-0711 and NUREG-0700. Thus, 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.

18.14.2 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 (SROAs), including a determination of whether automatic actuation is

necessary. Current plant designs call for the operator to take action 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 SROAs. There is much less of a need for such automation in the new passive plants, such as the ESBWR.

The American National Standards Institute (ANSI) and American Nuclear Society (ANS) issued ANSI/ANS 58.8-1984, "Time Response Design Criteria for Nuclear Safety Related Operator Actions," providing criteria to 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 3, Table 1.11-1, for Item B-17, GEH states 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 to the operator the alarms and information needed so that plant conditions can be monitored and the performance of both passive systems and the 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 3, Section 3.3, Design Commitment 2, and DCD Tier 2, Revision 3, Sections 18.4, addresses functional requirements analysis and function allocation. DCD Tier 2, Revision 3, Section 18.4 incorporates by reference NEDO-33219, Revision 1, "ESBWR System Functional Requirements Analysis Implementation Plan;" and GEH, NEDO-33220, Revision 1, "ESBWR Allocation of Functions Implementation Plan." Section 18.4 of this report provides the staff's review of this material and identifies several applicable open items. Therefore, Item B-17 is still open for the ESBWR design.

18.14.3 TMI 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 control room using human factors engineering (HFE) techniques and guidelines to identify and correct design deficiencies. This issue was clarified in NUREG-0737 and NUREG-0700, "Guidelines for Control Room Design Reviews," (1981), provided review guidance. This issue was considered resolved for operating plants with completion of the Detailed Control Room Design Reviews (DCRDRs).

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

The ESBWR DCD Tier 1, Revision 3, Section 3.3 and DCD Tier 2, Revision3, Section 18, address the HFE design of the control room. DCD Tier 2, Revision 3, Section 18.2 incorporates by reference NEDE-33217P (proprietary), Revision 3, "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. However, the question of timing to ensure that the final details of the design are submitted for Commission review prior to committing to fabrication has not been resolved. **This is being tracked as RAI 14.3-210, which is being tracked as an open item.**

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 control room operators. Supplement 1 to NUREG-0737 provides guidance for accomplishing improved 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. 10 CFR 50.34(f)(2)(iv) requires a plant SPDS console to provide such a display to operators, and to be capable of displaying a full range of important plant parameters and data trends on demand and capable of indicating when process limits are being approached or exceeded. Regulatory guidance for implement this requirement is provided in SRP Chapter 18.II.A.7, and other documents referenced therein (including NUREG-1342).

ESBWR DCD Tier 2, Revision 3, 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 control room design as part of the overall HFE design process. Table 1A-1 states that the ESBWR control room 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 18.8.3.3.1 of this report provides the staff's review of the SPDS design and identifies two confirmatory items. Pending the verification of the confirmatory items, Issue I.D.2 is considered resolved for the ESBWR.

18.14.4 Generic Letters

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

GL 81-04 states that the NRC 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 a SBO event. The USI has subsequently been completed and an SBO rule (10 CFR 50.63) issued. Thus, this GL is encompassed by the SBO rule and related guidance documents.

Per ESBWR DCD Appendix 1C, Table 1C-1, the ESBWR does not need emergency AC power to achieve safe shutdown in an SBO event. Therefore, GEH concluded that this issue (GL 81-04) is not applicable to the ESBWR Standard Plant design. A similar statement is made in Section 1.11 with regard to Task Action Plan Item A-44, Station Blackout. Chapter 8 of this report provides the staff's review of the need for emergency AC power and identifies an applicable open item. Therefore, GL 81-04 is open for the ESBWR design.

GL 83-05: Safety Evaluation of “Emergency Procedure Guidelines (EPGs)” Revision 2, NEDO-24934, June 1982

This GL addresses the NRC review and approval of EPGs for the operating fleet of BWRs and the subsequent development of EOPs based on the EPGs. This area is addressed above in the section on Issue HF4.1.

GL 89-06: Task Action Plan Item I.D.2 – Safety Parameter Display System

This GL 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. This is fully addressed in TMI Issue I.D.2 above.