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NUREG-0800



U.S. NUCLEAR REGULATORY COMMISSION STANDARD REVIEW PLAN

18.0 HUMAN FACTORS ENGINEERING

REVIEW RESPONSIBILITIES

Primary - Organization responsible for the review of human performance

Secondary - None

AREAS OF REVIEW

The specific areas of review are as follows:

Human Factors Engineering (HFE) Program

The organization responsible for the review of human performance reviews the HFE programs of applicants (e.g., for a construction permit (CP); operating license (OL); standard design certification (DC); and combined license (COL)) and licensees (e.g., for modifications and changes to a licensee's design or licensing basis). The purpose of these reviews is to improve safety by verifying that acceptable HFE practices and guidelines are incorporated into the plant's design. The guidance provided in this document, and in the supporting documents referenced, is used to conduct these HFE reviews.

This SRP chapter will be used by the staff when performing safety evaluations of license applications submitted by applicants pursuant to 10 CFR Part 50 and 10 CFR Part 52. This SRP chapter describes a process for evaluating (1) designs, (2) design processes, (3) design reviews, and (4) operator actions submitted by applicants and licensees for the broad range of NRC review responsibilities. Specific applications are discussed in

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USNRC STANDARD REVIEW PLAN

This Standard Review Plan, NUREG-0800, has been prepared to establish criteria that the U.S. Nuclear Regulatory Commission staff responsible for the review of applications to construct and operate nuclear power plants intends to use in evaluating whether an applicant/licensee meets the NRC's regulations. The Standard Review Plan is not a substitute for the NRC's regulations, and compliance with it is not required. However, an applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria and evaluate how the proposed alternatives to the SRP acceptance criteria provide an acceptable method of complying with the NRC regulations.

The standard review plan sections are numbered in accordance with corresponding sections in Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)." Not all sections of Regulatory Guide 1.70 have a corresponding review plan section. The SRP sections applicable to a combined license application for a new light-water reactor (LWR) are based on Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)."

These documents are made available to the public as part of the NRC's policy to inform the nuclear industry and the general public of regulatory procedures and policies. Individual sections of NUREG-0800 will be revised periodically, as appropriate, to accommodate comments and to reflect new information and experience. Comments may be submitted electronically by email to NRR_SRP@nrc.gov.

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"Applications" below. The chapter identifies 12 areas of review that are needed for successful integration of human characteristics and capabilities into nuclear power plant design. These areas of review include:

- 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
- Design Implementation
- Human Performance Monitoring

While the process defines 12 areas of review, not all may be applicable to reviewing a particular applicant's or licensee's HFE program. This is discussed in "Graded Approach to Review" below.

- 2. <u>Inspection, Test, Analysis, and Acceptance Criteria (ITAAC)</u>. For DC and COL reviews, the applicant's proposed information on the ITAAC associated with the HFE areas related to this SRP section is reviewed in accordance with SRP Section 14.3, "Inspections, Tests, Analyses, and Acceptance Criteria Design Certification," and 14.3.9, "Human Factors Engineering." The staff recognizes that the review of ITAAC is performed after review of the rest of this portion of the application against acceptance criteria contained in this SRP section. Furthermore, the ITAAC are reviewed to assure that all systems, structures, and components (SSCs) in this area of review are identified and addressed as appropriate in accordance with SRP Section 14.3 and 14.3.9.
- 3. <u>COL Action Items and Certification Requirements and Restrictions</u>. For a DC application, the review will also address COL action items and requirements and restrictions (e.g., interface requirements and site parameters).

For a COL application referencing a DC, a COL applicant must address COL action items (referred to as COL license information in certain DCs) included in the referenced DC. Additionally, a COL applicant must address requirements and restrictions (e.g., interface requirements and site parameters) included in the referenced DC.

Applications

NRC HFE reviews in three application areas are described below:

1. Review of the HFE Aspects of a New Plant - This chapter describes the staff's review activities to verify that accepted HFE principles are incorporated during the design process and that the human-system interfaces (HSIs) reflect a state-of-the-art HFE design. If an applicant proposes to build a new plant under 10 CFR Part 50 requirements, an HFE review of the new license application is performed.

Nuclear power plant (NPP) designers and vendors may submit designs for new standardized NPPs to the NRC for review and approval under 10 CFR Part 50 or they may submit designs for new standardized NPPs under 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," (see Part 52 Subpart B, "Standard Design Certification"). To obtain a standard design certification under Part 52, applicants must submit technical information which is technically relevant to the design. The technical information should include the HFE program. However, since technology is continually advancing, details of the applicant's HFE design might not be complete before the NRC issues a design certification. In such cases, reviews under 10 CFR Part 52 would primarily focus on the HFE design process.

An applicant may obtain a COL to operate a standardized NPP that has already received a design certification under 10 CFR Part 52. Portions of the facility design not covered by the design certification are reviewed at the COL stage. Thus, for new NPPs, HFE reviews can occur at different points within the 10 CFR Part 52 application and licensing process. These reviews can include the following:

- Design documentation, such as design-specific HFE guidance documents and specifications
- Prototype designs
- Completed designs
- HFE-related ITAAC (to verify that an as-built plant will be built and will operate to the standard design certification)
- HFE-related design acceptance criteria (to verify that the applicant properly executes the design process after certification)

For new NPPs (under 10 CFR Part 52), some HFE program elements may be deferred to the COL application. However, all HFE review criteria will be addressed before plant startup.

2. Review of the HFE Aspects of Control Room Modifications - The NRC staff conducts reviews of license amendment applications involving voluntary modifications of HFE aspects of HSIs. This chapter can be used to review changes or modifications to the control room and other significant HSIs. Modifications may be extensive, such as a large-scale modernization of control room HSIs, using computer-based technology as part of a digital instrumentation and controls (I&C) upgrade program. Such a program can result in substantial modifications to alarms, controls, and displays that are associated with SSCs important to safety. The NRC may also review certain plant modifications involving changes to the FSAR as part of the change process described in 10 CFR 50.59. Guidance related to 10 CFR 50.59 is provided in Regulatory Guide (RG) 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," and Nuclear Energy Institute (NEI) publication 96-07, "Guidelines for 10 CFR 50.59 Implementation."

3. Review of the HFE Aspects of Modifications Affecting Risk-Important Human Actions -The NRC staff reviews modifications to ensure they are acceptable. This SRP chapter can also be used to review changes or modifications to licenses for nuclear power plants that include changes to human actions. While HSI modernization may be a large-scale modification, even smaller-scale modifications may be risk-important, especially when they affect operator actions that are credited in the safety analysis report (SAR). An HFE review is conducted if such a modification affects the role of personnel or the tasks they perform and is potentially significant to plant safety. Modifications affect the role or tasks of personnel if they impose new or different demands on them to operate or maintain the plant, or otherwise ensure safety. An example of such a modification would be substituting manual actions for automatic actions for performing design functions described in the SAR. The NRC may also review certain plant modifications involving changes to the SAR as part of the change process described in 10 CFR 50.59. Additional guidance related to 10 CFR 50.59 is provided in RG 1.187 and Nuclear Energy Institute (NEI) publication 96-07, "Guidelines for 10 CFR 50.59 Implementation."

Graded Approach to Review

The degree to which the NRC staff applies the review methodolgy in this SRP and evaluates an applicant's HFE design will reflect the specific circumstances of individual applications. For example, generally the review of the HFE aspects of a new plant will entail a comprehensive, detailed evaluation (see Section II.A), while the review of individual modifications to existing designs may be less extensive. In its complete form as applied to the review of the HFE aspects of a new plant, the review process provides a comprehensive, detailed evaluation (see Section II.A). However, the level of staff review of an applicant's HFE design should reflect the unique circumstances of the review. In addition, staff reviews should also reflect risk-informed regulation and considerations. The NRC, the nuclear industry, and the public have moved to a broader consideration of risk in many activities associated with NPPs. Therefore, risk importance is taken into account when deciding which particular items to review and the depth of review necessary. This aspect of grading the review is discussed in Section II.C below and can be applied to both risk-informed and non-risk-informed submittals

This chapter provides detailed examples of graded review criteria for several reviews:

- Control room modifications (see Section II.B)
- Modifications affecting human actions of high risk importance (see Section II.C.2)
- Modifications affecting human actions of moderate risk importance (see Section II.C.3)
- Modifications affecting human actions of lower risk importance (see Section II.C.4)

Within these graded review criteria, the guidance is further tailored each specific review. The areas of review with respect to an applicant's submittal are based on:

- An evaluation of the information provided by the applicant
- The similarity of the associated HFE issues to those recently reviewed for other plants
- The determination of whether items of special or unique safety significance are involved

Review Interfaces

Other SRP sections interface with this section as follows:

- 1. <u>Section 6.3 "Emergency Core Cooling System (ECCS)."</u> Section 6.3 addresses the review of ECCS. Section III.19 discusses the review of operator manual actions that may be necessary during ECCS operation in accident sequences up through the time of long-term core cooling. Chapter 18 addresses important manual actions under the HRA element. Thus, the reviews of Section 6.3 III.19 and Chapter 18 should be conducted in a coordinated manner.
- 2. <u>Chapter 7, "Instrumentation and Controls."</u> Descriptions of HSI components and characteristics are addressed by both Chapters 7 and 18 reviews. As appropriate, the review results of one chapter should be considered in the review activities for the other chapter.
- 3. <u>Section 13.1.1, "Management and Technical Support Organization."</u> Section 13.1.1 addresses review of the corporate-level management and technical organizations of the applicant and its major contractors. Section 13.1.1 addresses the need for clearly defined management and organizational responsibilities with regard to HFE considerations in plant design. Chapter 18, under Acceptance Criteria, requires a comprehensive summary of management's role in ensuring that HFE is adequately considered in new plant design and in the modification of an existing plant. The reviews of Section 13.1.1 and Chapter 18 should be conducted in a coordinated manner.
- 4. <u>Section 13.1.2-13.1.3, "Operating Organization."</u> Section 13.1.2-13.1.3 addresses the review for specific staffing requirements. In addition, Chapter 18 specifies a systematic analysis of staffing requirements that includes a thorough understanding of task requirements and applicable regulatory requirements. The Chapter 18 analysis addresses the requirements from Section 13.1.2-13.1.3 as an input. Reviewers should verify that staffing requirements addressed under Section 13.1.2-13.1.3 are properly considered in the Chapter 18 analysis.
- 5. Sections 13.2.1, "Reactor Operator and Requalification Program; Reactor Operator Training and 13.2.2, "Non-licensed Plant Staff Training." Sections 13.2.1 and 13.2.2 provide specific criteria for reviewing training programs for reactor operators and non-licensed plant staff. Chapter 18 contains an area of review titled "Training Program Development," which provides criteria for reviewing the process by which training programs are developed. It addresses the relationship between training development and the overall HFE design process. These reviews should be conducted in a coordinated manner. Topics from the SRP Chapter 18 area of review that are related to the review of Sections 13.2.1 and 13.2.2 are cross-referenced.
- 6. <u>Sections 13.5.1.1, "Administrative Procedures General" 13.5.1.2, "Administrative Procedures Initial Test Program", 13.5.2.1, "Operating and Emergency Operating Procedures, and 13.5.2.2, "Maintenance and Other Operating Procedures." Sections 13.5.1.1, 13.5.1.2, 13.5.2.1, and 13.5.2.2 provide specific criteria for the content of administrative procedures and operating and maintenance procedures. Chapter 18 contains an area of review titled "Procedure Development," which provides criteria for</u>

the review of the procedure development process rather than the actual procedures. These reviews should be conducted in a coordinated manner. Topics from the Chapter 18 review that are related to the review of Sections 13.5.1.1, 13.5.1.2, 13.5.2.1, and 13.5.2.2 are cross-referenced.

- 7. <u>Section 13.6.1, "Physical Security Combined License and 13.6.2, "Physical Security Design Certification."</u> Sections 13.6.1 and 13.6.2 provide criteria for review of the central alarm station (CAS) and secondary alarm station (SAS). Chapter 18 reviews the CAS and SAS from a human factors perspective.
- 8. Section 14.3.9, "Human Factors Engineering (Tier 1)." Section 14.3.9 addresses the review of an applicant's Design Control Document (DCD) specifically to assure the acceptability of Tier 1 information for the main control room (MCR) panels, remote shutdown (RSP) panel, and local control station (LCS) panels. The organization responsible for the review of human performance also has primary review responsibility for additional material applicable to multiple systems of the standard design in Tier 1 pertaining to human factors engineering, if such material is provided by the applicant. The organization responsible for the review of human performance is responsible for providing input to other technical review organizations regarding the minimum inventory of alarms, controls and indications appropriate for the MCR and RSP.
- 9. <u>Chapter 15, "Accident Analysis."</u> Many organizations have responsibility for the review of Chapter 15, which addresses anticipated operational occurrences and postulated accidents. Information from analyses conducted to address the criteria of Chapter 15 should be incorporated as input to the HFE design process.
- 10. Chapter 19, "Probabilistic Risk Assessment and Severe Accident Evaluation." Chapter 19 addresses probabilistic risk assessments for site-specific safety risks. The Chapter 18 review area "Human Reliability Analysis" addresses the relationship between HFE activities and probabilistic risk analysis/human reliability analysis (PRA/HRA) activities and the use of risk insights in the HFE program. These reviews should be conducted in a coordinated manner. Topics from the SRP Chapter 18 area of review that are related to the review of Chapter 19 are cross-referenced.

The specific acceptance criteria and review procedures are contained in the referenced SRP sections.

II. ACCEPTANCE CRITERIA

Requirements

Acceptance criteria are based on meeting the relevant requirements of the following Commission regulations¹:

¹For Part 50 applicants not listed in 10 CFR 50.34 (f), the provisions of 50.34(f) will be made a requirement during the licensing process.

- 1. 10 CFR 50.34(f)(1)(i)
- 2. 10 CFR 50.34(f)(2)
- 3. 10 CFR 50.34(f)(3)(i)
- 4. 10 CFR 50.34(f)(3)(vii)
- 5. 10 CFR 50.54 (i) to (m)
- 6. 10 CFR 50.120
- 7. 10 CFR 52.47
- 8. 10 CFR 52.79
- 9. 10 CFR 52.80
- 10. 10 CFR Part 55

The specific aspects of these requirements are detailed in the applicable SRP Acceptance Criteria discussion.

SRP Acceptance Criteria

Specific SRP acceptance criteria acceptable to meet the relevant requirements of the NRC's regulations previously identified follow for the review described in this SRP section. The SRP is not a substitute for the NRC's regulations, and compliance with it is not required. However, an applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria and evaluate how the proposed alternatives to the SRP acceptance criteria provide acceptable methods of compliance with the NRC regulations.

A. Review of the HFE Aspects of a New Plant

A.1 HFE Program Management

The objective of this review is to confirm that the applicant has adequately considered the role of HFE and the means by which HFE activities will be accomplished. The review should verify that:

- The applicant has identified plans to oversee design and construction of the nuclear facility in accordance with the requirements of 10 CFR 50.34(f)(3)(vii), as described in SRP Section 13.1.1, "Management and Technical Support Organization."
- The applicant has an HFE design team with the responsibility, authority, placement within the organization, and composition to ensure that the design commitment to HFE is achieved. There is, however, no assumption that HFE is the responsibility of a single organization or that there is an organizational unit called the HFE design team.

- The team is guided by an HFE program plan to ensure the proper development, execution, oversight, and documentation of the HFE program.
- The overall HFE program appropriately considers and address the deterministic aspects of the design, as discussed in RG 1.174.

The HFE program plan should describe the technical program in sufficient detail to ensure that all aspects of the HSIs, procedures, and training are developed, designed, and evaluated on the basis of a structured top-down systems analysis using accepted HFE principles.

The applicant's HFE program management should be evaluated in accordance with the review criteria of NUREG-0711, "Human Factors Engineering Program Review Model."

A.2 Operating Experience Review

The objective of this review is to verify that the applicant has identified and analyzed HFE-related problems and issues in previous designs so that these problems and issues may be avoided in the development of the new design. This review should also verify that the applicant has retained positive features of previous designs. The operating experience review (OER) should be evaluated in accordance with the review criteria of NUREG-0711 and should satisfy the requirements of 10 CFR 50.34(f)(3)(i) and 52.49(a)(21).

A.3 Functional Requirements Analysis and Function Allocation

Functional requirements analysis is the identification and analysis of those functions that must be performed to satisfy plant safety objectives; that is, to prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. Function allocation analysis is the analysis of requirements for plant control and the assignment of control functions to (1) personnel (e.g., manual control), (2) system elements (e.g., automatic control and passive, self-controlling phenomena), and (3) combinations of personnel and system elements (e.g., shared control, automatic systems with manual backup).

The objective of this review is to verify that (1) the plant's functions that must be performed to satisfy plant safety objectives have been defined, 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. Functional requirements analysis and function analysis should be evaluated in accordance with the review criteria of NUREG-0711.

A.4 Task Analysis

Task analysis is the analysis of human performance that results from the allocation of functions to personnel and the identification of HSI characteristics needed to support personnel task accomplishment. The objective of this review is to ensure that the applicant's task analysis identifies the specific tasks that are needed for function accomplishment and their information, control, and task-support requirements. The task analysis should be evaluated in accordance with the review criteria of NUREG-0711.

A.5 Staffing and Qualifications

The objective of this review is to verify that the applicant has analyzed the requirements for the number and qualifications of personnel in a systematic manner that includes a thorough understanding of task requirements and applicable regulatory requirements. The applicant's staffing and qualifications analyses should be evaluated in accordance with the review criteria of NUREG-0711 and should satisfy the requirements of 10 CFR 50.54 (i) through (m). If an exemption from these requirements is being sought, the analysis and justifications should be presented [see also NUREG/CR-6838, "Technical Basis for Regulatory Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m)" and NUREG-1791, "Guidelines for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operating Staff Requirements Specified in 10 CFR 50.54(m) — Final Report"]. The full staffing program is considered to be an operational program as discussed in SECY-05-197 and in RG-1.206 "Combined License Applications for Nuclear Power Plants (LWR Edition)". Section C.IV.4, "Operational Programs."

A.6 Human Reliability Analysis

Human reliability analysis (HRA) is an evaluation of the potential for and mechanisms of human error that may affect plant safety. The objectives of this review are to ensure 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 detect errors and recover from them; and (2) the HRA activity effectively integrates the HFE program and PRA. A design-specific PRA/HRA is required by 10 CFR 50.34(f)(1)(i), 52.47(b)(1) and 52.79, and is addressed in SRP Chapter 19 and RG 1.206 Section C.II.1. RG 1.206 Section C.II.1 specifies the purpose and objectives of the PRA, as well as the required scope and level of detail. In order to accomplish the above objectives, the HRA/PRA and the modeling of HAs must be of sufficient quality (see SRP Chapter 19 and RG 1.206 Section C.II.1).

Review of the HRA should be coordinated with SRP Section 6.3.III.19 and RG 1.206 Section C.I.6.3.2.8 as they relate to manual actions for ECCS.

The integration of the applicant's HRA with the HFE program should be evaluated in accordance with the review criteria of NUREG-0711.

A.7 Human-System Interface Design

The HSI design process represents the translation of function and task requirements into HSI characteristics and functions. The objective of this review is to evaluate 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. The applicant's HSI design process should be evaluated in accordance with the review criteria of NUREG-0711, and the final design evaluated in accordance with the review criteria of NUREG-0700, "Human-System Interface Design Review Guidelines."

The HSI design should address those subsections of 10 CFR 50.34(f)(2) that are applicable to the plant's design from the following list: 10 CFR 50.34(f)(2)(i), (iii), (iv), (v), (xi), (xii), (xii), (xv), (xvii), (xvii), (xix), (xxi), (xxiv), (xxv), & (xxvii). In addition to the HFE considerations discussed above, the following specific HSI design guidance should also be addressed:

- Safety parameter display system requirements, as described in 10 CFR 50.34(f)(2)(iv), NUREG-0835, NUREG-1342, and Supplement 1 of NUREG-0737.
- 2. Periodic testing of protection systems actuation functions, as described in Regulatory Guide 1.22.
- 3. Bypassed and inoperable status indication for NPP safety systems, as described in Regulatory Guide 1.47.
- 4. Manual initiation of protective actions, as described in Regulatory Guide 1.62.
- 5. Instrumentation for light-water-cooled nuclear power plants to access plant and environmental conditions during and following an accident, as described in Regulatory Guide 1.97.
- 6. Instrumentation setpoints, as described in Regulatory Guide 1.105.
- 7. Functional criteria for emergency response facilities, as described in NUREG-0696.
- 8. A minimum inventory of controls, displays and alarms.

The HSI design should describe the process, after the plant is in operation, by which (1) HSIs are modified and updated,(2) temporary HSI changes are made (such as set point modification) and (3) operator defined HSIs are created (such as temporary displays defined by operators for monitoring a specific situation).

The HSI design review should be coordinated with the instrumentation and controls review in SRP Chapter 7.

A.8 Procedure Development

The objective of this review is to confirm that the applicant's procedure development program incorporates HFE principles and criteria, along with all other design requirements, to develop procedures that are technically accurate, comprehensive, explicit, easy to utilize, validated, and in conformance with 10 CFR 50.34(f)(2)(ii). Because procedures are considered an essential component of the HFE design, they should be derived from the same design process and analyses as the other components of the HSI (e.g., displays, controls, operator aids) and subject to the same evaluation processes. The applicant's procedure development program should be evaluated in accordance with the review criteria of NUREG-0711. The review should be coordinated with the review of procedures described in SRP Section 13.5. The full procedures program is considered to be an operational program as discussed in SECY-05-197 and in RG-1.206 Section C.IV.4.

A.9 Training Program Development

The objective of this review is to ensure 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

The training program should be developed in accordance with 10 CFR 50.120, 10 CFR 52.79, and 10 CFR Part 55 to ensure that personnel's qualifications are commensurate with the performance requirements of their jobs. The applicant's training program should be evaluated in accordance with the review criteria of NUREG-0711 and should address applicable guidance provided in SRP Section 13.2, "Training." The full training program is considered to be an operational program as discussed in SECY-05-197 and in RG-1.206 Section C.IV.4.

A.10 Verification and Validation

Verification and validation (V&V) evaluations seek to comprehensively determine that the design conforms to HFE design principles and that it enables plant personnel to successfully perform their tasks to achieve plant safety and other operational goals. The overall scope for V&V should include the main control room, the remote shutdown panel, and local control stations (including the central alarm system (CAS) and secondary alarm system (SAS) associated with

the risk important HAs. The applicant's V&V activities include operational condition sampling, design verification, integrated system validation, and human engineering discrepancy (HED) resolution. The objectives of the staff review of each of these activities are identified in the following subsections.

A.10.1 Operational Conditions Sampling

The applicant's sampling methodology identifies the range of operational conditions that guide V&V activities. The objectives of the review are to ensure 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. The use of risk importance to help select failure events, transients, and accidents for use in V&V is appropriate. The applicant's operational conditions sampling should be evaluated in accordance with the review criteria of NUREG-0711.

A.10.2 Design Verification

The applicant's verification should demonstrate that the design meets task and human requirements. Verification activities require a characterization of the HSI. The staff's review of design verification has the following objectives:

- Inventory and Characterization Review The objective of this review is to evaluate whether 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.
- HSI Task Support Verification Review The objective of this review is to evaluate whether the applicant verifies that the HSI provides all alarms, information, and control capabilities required for personnel tasks.
- HFE Design Verification Review The objective of this review is to evaluate whether the applicant verifies that the characteristics of the HSI and the environment in which it is used conform to HFE guidelines.

The applicant's design verification should be evaluated in accordance with the review criteria of NUREG-0711.

A.10.3 Integrated System Validation

The objective of integrated system validation is to confirm that the integrated system design (i.e., hardware, software, and personnel elements) acceptably supports safe operation of the plant. Validation is based on performance-based tests. The applicant's integrated system validation should be evaluated in accordance with the review criteria of NUREG-0711.

A.10.4 Human Engineering Discrepancy (HED) Resolution

HED resolution is the process of evaluating and resolving issues that are identified in V&V evaluations. The objectives of the staff's review are to verify that the applicant's HED evaluation acceptably prioritizes HEDs in terms of their need for improvement and that design solutions and a realistic schedule for implementation is developed to address those HEDs selected for correction. The applicant's HED resolution should be evaluated in accordance with the review criteria of NUREG-0711.

A.11 Design Implementation

The objective of this review is to verify that the applicant's as-built design will conform to the verified and validated design that resulted from the HFE design process. The applicant's design implementation process should be evaluated in accordance with the review criteria of NUREG-0711. This review should also ensure the acceptability of the applicant's plans for determining the operability of the MCR, RSP, LCSs, Technical Support Center and Emergency Operations Facility.

A.12 Human Performance Monitoring

The objective of this review is to assure 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 verify that the conclusions that have been drawn from the evaluation remain valid over the life of the plant. The applicant's performance monitoring strategy should be evaluated in accordance with the review criteria of NUREG-0711.

B. Review of the HFE Aspects of Control Room Modifications

License amendments involving major changes to the HSIs, such as control room modernization, should be reviewed using the guidance contained in Section II.A of this SRP chapter. However, since the extent of such modifications can vary, the staff's review should be tailored using the additional guidance from NUREG-0711 and presented in this section.

B.1 HFE Program Management

The goals of the HFE program should address the need to consider the effects that the modification may have on the performance of personnel. The review should address the applications plan with respect to the following:

- Planning the installation to minimize disruptions to work of plant personnel
- Coordinating training and procedure modifications with implementing the modification to verify that both accurately reflect the characteristics of the modification

 Conducting training to maximize personnel's knowledge of and skill with the new design before its implementation

B.2 Operating Experience Review (OER)

The operating experience of the plant being modified and plants with similar modifications should be reviewed as part of the OER. The OER should provide information on past performance of predecessor designs or earlier designs on which the new plant is based.

B.3 Functional Requirements Analysis and Function Allocation

Functional requirements analysis and function analysis should consider the following:

- Functional requirements analyses for modifications that are likely to change existing safety functions, introduce new functions for systems supporting safety functions, or involve unclear functional requirements that may be important to safety.
- Function allocation analyses for modifications that are likely to change the allocation between personnel and plant systems of functions important to safety.
- A change in an operator's role due to a modification should be examined within the context of its effects on the operator's overall responsibilities.

B.4 Task Analysis

The following considerations should be addressed in the review of plant modifications that are likely to affect human actions (HAs) previously identified as risk-important, cause existing HAs to become risk-important, or create new actions that are risk-important:

- The tasks analyses should be revised and updated to reflect requirements of the modification; the scope should include tasks involving the modification and its interactions with the rest of the plant, including those resulting from functions addressed in the analyses of functional requirements and function allocation. For maintenance, tests, inspections, and surveillances, attention should be given to risk-important actions that are new or supported by new technologies (e.g., new capabilities for online maintenance).
- The task analysis should identify the design characteristics of the existing HSIs that support the performance of experienced personnel (e.g., support high levels of performance during demanding situations).

B.5 Human-System Interface Design

The following considerations should be addressed in the review of design modifications:

- The extent to which HSI modifications are consistent with users' existing strategies and the licensee's SAR and Chapter 18 commitments.
- The extent to which HSI modifications support crew coordination
- The degree to which the HSI reflects changes resulting from integration among plant systems

The final design modifications should be reviewed in accordance with the review criteria of NUREG-0700, as applicable.

B.6 Procedure Development

The review should evaluate whether procedures are modified and whether their content, format, and integration accurately reflect changes in the plant, human actions, and HSIs.

B.7 Training Program Development

The review should evaluate whether any changes in training content or frequency are warranted following plant modernization programs.

B.8 Verification and Validation

- Operational Conditions Sampling. V&V of the modification should reflect expected operational conditions and should address the potential effect of negative transfer of learning when the new and old components are different and impose different demands on personnel. The applicant's sampling should also consider any effects on performance of having both old and new versions of the same HSI components in place.
- 2. <u>HSI Task Support Verification</u>. HSI task support verification should focus on the HSIs that are relevant to the modification. For modifications to plant systems that do not include modifications of the HSIs, task support verification should identify any new demands for monitoring and control, and determine whether they are adequately addressed by the existing HSI design. HSIs for temporary configurations and situations where both old and new HSIs are left in place should be evaluated for their potential to negatively impact performance.
- 3. <u>HFE Design Verification</u>. HFE design verification should focus on the HSIs that are relevant to the modification. HSIs for temporary configurations and situations where both old and new HSIs are left in place should be evaluated for their potential to negatively impact performance.

4. Integrated System Validation. The applicant should perform an integrated system validation for all modifications that may (1) change personnel tasks; (2) change task demands, such as by changing task dynamics, complexity, or workload; or (3) interact with or affect HSIs and procedures in ways that may degrade performance. Integrated system validation may not be needed when a modification results in minor changes to personnel tasks such that they may reasonably be expected to have little or no overall effect on workload and the likelihood of error. 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. The applicant's test objectives and scenarios should be developed to address aspects of performance that are affected by the modification design, including personnel functions and tasks affected by the modification.

B.9 Design Implementation

The objective of this review is to verify that the applicant's implementation of plant changes considers the effect on personnel performance and provides the necessary support for safety of operations. The applicant's design implementation should be evaluated in accordance with the review criteria of NUREG-0711. The following aspects of the design process should be addressed.

- 1. <u>General Criteria</u>. The staff's review should address whether the applicant has provided assurance that:
- The reactor fuel is safely monitored during the shutdown time period while the physical modifications are being implemented in the control room.
- Operations and maintenance crews are fully trained and qualified to operate and maintain the plant prior to starting up with the new systems and HSIs in place.
- Modifications in plant procedures and training reflect changes in plant systems, crew roles and responsibilities, HSIs, and that procedures required for the testing and operation of new systems and HSIs are in place prior to the modification being placed into service.
- The applicant has a plan to monitor the system performance to identify and address any problems that arise.
- Modernization Programs Consisting of Many Small Modifications. The staff's review should address whether the applicant can verify that each modification follows an HFE program for the maintenance of standardization and consistency, and that modifications fulfill a clear operational need and do not interfere with existing systems.

- 3. <u>Modernization Programs Consisting of Large Modifications During Multiple Outages</u>. The staff's review should address whether the applicant can verify that:
- Task analysis is performed for each interim configuration to verify that the task demands that are unique to interim configurations are known.
- HRA addresses any unique tasks that may affect risk or any changes to existing tasks due to the interim configuration.
- The HSIs needed to perform important tasks are consistent and standardized.
- Procedures are developed for temporary configurations of systems and HSIs that are used by personnel when the plant is not shut down.
- Training is developed for temporary configurations of systems, HSIs, and procedures that are used by personnel when the plant is not shut down.
- Temporary operational configurations are evaluated using V&V.
- 4. <u>Modernization Programs Where Both Old and New Equipment Are Left in Place</u>. The staff's review should address whether the applicant can verify that the potential for negative effects on personnel performance has been evaluated.
- 5. Modernization Programs Where New Nonfunctional HSIs Are In Place In Parallel With Old Functional HSIs. The staff's review should address whether the applicant can verify that the potential for negative effects on personnel performance due to control room or HSI clutter arising from having both old and new HSIs available in parallel is evaluated and that the nonfunctional state of the HSIs is clearly indicated.
- C. Review of the HFE Aspects of Modifications Affecting Risk-Important Human Actions

The staff's review of license amendments and actions involving plant changes that affect important human actions (HAs) use a graded, risk-informed approach in conformance with Regulatory Guide (RG) 1.174. The staff's review uses a two-phase approach. The first phase is a screening analysis to determine the risk associated with the plant modification and its associated HAs using both quantitative and qualitative information (see Section C.1 below). This approach can be accomplished for submittals by licensees that are either risk-informed or non-risk-informed. Plan modifications and HAs are categorized into regions of high, medium, and lower risk. This categorization is used to determine the level of HFE review needed.

The second phase of the review is performed by the human factors analyst and consists of the HFE review. Changes that involve more risk-significant HAs receive a detailed review (see Section C.2.1 below), while those of moderate risk significance receive a less detailed review (see Section C.2.2 below). HAs in the lowest risk region receive minimal HFE review (see Section C.2.3 below).

C.1 Phase I - Risk Screening

C.1.1 Screening Process for Risk-Informed Change Requests

If the submittal is appropriately risk-informed, applicants should evaluate the risk associated with the proposed modification and the HAs associated with it. The applicant's risk screening should be evaluated in accordance with the review criteria of "Guidance for the Review of Changes to Human Actions" (NUREG-1764), as summarized in the four paragraphs below.

Determine the Risk of the Entire Modification. The first review step is to perform a risk-informed screening of the entire modification, including both equipment and HAs, in accordance with the review criteria of NUREG-1764, for both permanent and temporary changes. As part of this evaluation, the staff should determine whether the PRA information submitted as part of the risk-informed (R-I) submittal is suitable. The review criteria defined in RG 1.174 and SRP Chapter 19 should be used. If the staff determines that the information is not suitable, a generic method screening process should be used (see item C.1.2 below). RG 1.174 notes that licensee applications that lie in Region I of the acceptance guidelines for core damage frequency (or for large early release frequency) are generally not permitted. Proposed changes that are calculated to be in the Region I of three risk regions are identified as most risk significant. If the entire modification is in Region I, the staff determines whether the modification is rejected. If it is rejected, then no additional HFE review is needed. If it is not rejected, the staff determines whether the modification contains only HAs or if it includes both equipment and HAs. If the modification contains only HAs (no equipment modifications) and was determined to be in Region I, then the HA should be reviewed using the Level I criteria in Section C.2.1 below. If the modification contains equipment and HAs, then the risk importance of the HA should be evaluated (see item 2 below).

<u>Determine the Risk of the HAs</u>. The second review step is to perform a risk-informed screening of the HA portion of the modification in accordance with the review criteria of NUREG-1764. This is done by evaluating both the risk achievement worth (RAW) and the Fussell-Vesely (FV) risk importance measures. HAs will be preliminarily sorted into the three Levels.

<u>Perform Qualitative Screen of the HAs.</u> The third risk-screening step is to identify whether there are qualitative factors that should be taken into account when determining the risk importance of the HA. This step may be used to adjust the review level either up or down. This evaluation should be in accordance with the review criteria of NUREG-1764.

<u>Integrated Assessment of Human Actions Safety Significance</u>. This step provides guidance on how to integrate the results from Steps 1 through 3 of the screening process for risk-informed licensing basis change requests.

C.1.2 Screening Process for Non-risk-informed Change Requests

If the submittal is appropriately non-risk-informed, the NRC will perform the risk screening as follows:

Review of Non-Risk-Informed Submittals. In keeping with RG 1.174, a licensee submittal to the NRC may or may not be risk-informed) at the licensee's option. If it is not risk informed, then the staff may choose to use an Estimated Risk Method or a Generic Method to determine risk in accordance with the review criteria of NUREG-1764. These methods will result in a proposed Level (I, II, or III) for the review. Qualitative screening is then applied to the proposed level to see if it needs to be adjusted. Alternatively, the staff may choose to perform a deterministic review without using the risk screening methodology. Also, using guidance provided in SRP Chapter 19 and NRC Regulatory Issue Summary 2001-02, "Guidance on Risk-Informed Decision Making in License Amendment Reviews", the staff may determine that "special circumstances" exist that could result in the staff requesting the license to submit risk information.

<u>Integrated Assessment of Human Actions Safety Significance</u>. The integrated assessments of HA safety significance for non risk-informed applications is similar to that for risk-informed applications, but simpler because there are fewer inputs to integrate.

C.1.3 Determine the Level of HFE Review.

Based on the quantitative and qualitative information available, the staff should classify the HA into one of three HFE review levels in accordance with the review criteria of NUREG-1764.

- Level I HAs, high risk, are reviewed using the criteria in Section C.2.1
- Level II HAs, moderate risk, are reviewed using the criteria in Section C.2.2 below.
- Level III HAs, minimal risk, are reviewed using the criteria in Section C.2.3 below.

C.2 Phase II - HFE Review

C.2.1 Level I HFE Review

HAs in the high-risk category should be reviewed using the Level I review criteria provided below.

 General Deterministic Review Criteria. The applicant should provide adequate assurance that deterministic aspects of design, such as whether the change meets current regulations, does not compromise defense-in-depth, and maintains sufficient safety margins, as discussed in RG 1.174, have been appropriately addressed. The staff should evaluate the deterministic aspects of the design in accordance with the review criteria of NUREG-1764.

- 2. Operating Experience Review. The applicant should identify and analyze HFE-related problems and issues encountered previously in designs and human tasks that are similar to the planned modification so that issues that could potentially hinder human performance can be addressed. The OER should address the operating histories of plant systems, HAs, procedures, and HSI technologies related to the proposed changes to HAs. The staff's evaluation should be conducted in accordance with the review criteria of NUREG-1764.
- 3. Functional Requirements Analysis And Functional Allocation. The applicant should define any changes in the plant's safety functions (functional requirements analysis), and provide evidence that the allocation of functions between humans and automatic systems provides an acceptable role for plant personnel; i.e., the allocations take advantage of human strengths and avoid functions that would be negatively affected by human limitations (functional allocation). The staff's review should address all plant functions affected by the change in HAs, including changes to the functions and to their allocation between personnel and automatic systems in accordance with the review criteria of NUREG-1764.
- 4. <u>Task Analysis</u>. The applicant should identify the behavioral requirements of the tasks personnel are required to perform. The task analysis should form the basis for specifying the requirements for the HSI, procedures, and training. The task analyses should address HAs in their entirety, including all pertinent plant conditions, situational factors, and performance-shaping factors. While the primary focus is licensed operator tasks, tasks performed by other personnel (e.g.,emergency actions, maintenance, testing, inspection, and surveillance) that occur at the same time as the HAs and directly influence the actions are included in the task analysis. The staff should review the applicant's task analysis in accordance with the review criteria of NUREG-1764.
- 5. <u>Staffing and Qualifications</u>. The applicant should analyze the proposed change in HAs to determine the number and qualifications of personnel based on task requirements and applicable regulatory requirements. The analysis should addresses personnel requirements for all conditions in which the HA may be performed. The staffing and qualification review should be conducted in accordance with the review criteria of NUREG-1764.

- 6. Probabilistic Risk and Human Reliability Analysis. For risk-informed submittals, the applicant should (1) update the PRA model to reflect system, component, and HA changes that are necessary based on the proposed modification or HAs; (2) perform an analysis of the potential effects of the proposed changes upon plant safety and reliability, in a manner consistent with current, accepted PRA/HRA principles and practices, and (3) use the risk insights derived from the results in the selection of HAs and the development of procedures, HSI component lists, and training in order to limit risk and the likelihood of personnel error and to provide for error detection and recovery capability. The staff's HRA review should be conducted in accordance with the review criteria of NUREG-1764.
- 7. <u>Human-System Interface Design</u>. The applicant should translate function and task requirements into the detailed HSI design through the systematic application of HFE principles and criteria. The applicant's HSI design should be evaluated in accordance with the review criteria of NUREG-1764. The staff's review should address the design of temporary and permanent modifications to the HSI, including new HSI components and the modification of existing ones, for the proposed changes in the HAs. Where changes in HAs result in modifications to large portions of the HSI or in the use of HSI technologies that do not have proven operating histories, the review may also examine the HSI design process using the review criteria of NUREG-0711, Rev. 1. The review addresses aspects of the HSI and the work environment that affect the ability of the personnel to perform the HAs. The final design should be reviewed in accordance with the review criteria of NUREG-0700, as applicable.
- 8. Procedure Design. The applicant should modify applicable plant procedures and, where needed, provide guidance for the successful completion of the HAs. The procedures should adequately reflect changes in plant equipment and HAs. In the procedure development process, the applicant should apply HFE principles and criteria along with all other design requirements to develop procedure modifications that are technically accurate, comprehensive, explicit, easy to use, and validated. The applicant's procedure design should be evaluated in accordance with the review criteria of NUREG-1764.
- 9. <u>Training Program Design</u>. The applicant should develop and conduct adequate training for the HAs, including any changes in qualifications, as described in NRC Information Notice 97-78, "Crediting of Operation Actions In Place of Automatic Actions and Modification of Operator Actions, Including Response Times." The training program should include all licensed and non-licensed personnel who perform the changed HAs. The applicant's training program should be evaluated in accordance with the review criteria of NUREG-1764.

- 10. Human Factors Verification and Validation. The applicant should conduct V&V evaluations to (1) provide assurance that the HFE/HSI design provides all necessary alarms, displays, and controls to support plant personnel tasks (HSI task support verification); (2) provide assurance that the HFE/HSI design conforms to HFE principles, guidelines, and standards (HFE design verification); (3) provide adequate assurance that the HFE/HSI design can be effectively operated by personnel within all performance requirements applicable to the HA (integrated system validation); and (4) provide adequate assurance that the final product as built conforms to the verified and validated design that resulted from the HFE design process (final plant HFE/HSI design verification). The applicant's V&V should be evaluated in accordance with the review criteria of NUREG-1764.
- 11. Human Performance Monitoring Strategy. The applicant should have a human performance monitoring strategy to verify that no adverse safety degradation occurs because of the changes that are made, to provide adequate assurance that the conclusions that have been drawn from the evaluation remain valid over time, and to provide adequate assurance that personnel have maintained the skills necessary to accomplish the assumed actions. The applicant's human performance monitoring strategy should be evaluated in accordance with the review criteria of NUREG-1764.

C.2.2 Level II HFE Review

HAs in the medium-risk category should be reviewed using the Level II review criteria provided below.

- General Deterministic Review Criteria. The applicant should provide adequate assurance that deterministic aspects of design, as discussed in RG 1.174, have been appropriately addressed. The staff should evaluate the deterministic aspects of the design, including that the change meets current regulations and does not compromise defense-in-depth, in accordance with the review criteria of NUREG-1764.
- 2. <u>Analysis</u>. The applicant should analyze the changes to the HA in terms of OER, functional and task analysis, and staffing and qualifications, and should identify HFE inputs for any modifications to the HSI, procedures, and training that may be necessary. The applicant's HFE analyses should be evaluated in accordance with the review criteria of NUREG-1764.
- Design of HSIs, Procedures, and Training. The applicant should support the HA by appropriate modifications to the HSI, procedures, and training. The applicant's HSIs, procedures, and training design should be evaluated in accordance with the review criteria of NUREG-1764. Design modifications to the HSI should be reviewed in accordance with the review criteria of NUREG-0700.

4. <u>Human Action Verification</u>. The applicant should verify that the HA can be successfully accomplished with the modified HSI, procedures, and training. The applicant's verification should be evaluated in accordance with the review criteria of NUREG-1764.

C.2.3 Level III HFE Review

For an HA classified in third level, the staff review should verify that the action is, in fact, in Level III. Verification is accomplished by reviewing the licensee's analysis methods that show the placement of the action in that level. Typically no detailed HFE review is necessary. However, the staff may specify specific areas for review based on the results of the risk-screening process.

Technical Rationale

The technical rationale for application of these acceptance criteria to the areas of review addressed by this SRP section is discussed in the following paragraphs:

The NRC bases its HFE review on current regulatory requirements established in post-TMI orders and 10 CFR 50.34(f), "Additional TMI-Related Requirements." The NRC reviews HFE aspects of new control rooms (post-1982) 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. For plants licensed under 10 CFR Part 52, the requirements of 10 CFR 50.34(f) are incorporated under 10 CFR 52.47 and 10 CFR 52.79. Meeting these requirements provides evidence that plant design, staffing, and operating practices acceptable and that plant safety will not be compromised by human error or deficiencies in human interfaces with hardware and software. In addition, the staff relies on the SRP and post-TMI bulletins as guidance.

To support the review of an applicant's submittal for conformance to these 10 CFR requirements, the staff uses primarily three guidance documents: NUREG-0711, NUREG-0700, and NUREG-1764.

NUREG-0711 is (1) based upon currently accepted HFE practices, (2) well-defined, and (3) validated through experience with the development of complex, high-reliability systems in other industrial and military applications. The technical basis upon which the staff's HFE review guidance was developed was (1) general systems theory and engineering principles; (2) available NPP industry HFE guidance, standards, guidance, and recommended practices developed in the industry (e.g., IEC and IEEE); HFE guidance developed for complex systems in general (e.g., by groups such as DoD, NASA, and the Human Factors and Ergonomics Society). As part of the development process, the guidance and its associated technical reports were extensively reviewed by independent subject matter experts, professional organizations, and industry representatives. As a result the staff's guidance provides a technically valid basis upon which to review applicant HFE programs, processes, and designs.

NUREG-0711 identifies the important HFE elements in a system development, design, and evaluation process that are necessary and sufficient requisites to successful integration of human factors in complex systems. The review model also identifies aspects of each HFE element that are key to a safety review, and describes acceptance criteria by which the HFE elements can be evaluated. NUREG-0711 also serves as a technical basis for the review of ITAAC for plant HFE.

NUREG-0711 addresses the integration of HFE in the design process and was originally developed to support NRC reviews of submittals for certification of new plant designs under 10 CFR Part 52. However, because it updates the guidance of Appendix B of NUREG-0700, Revision 0, it should be used for HFE reviews of new plant designs licensed under both 10 CFR Part 50 and 10 CFR Part 52. Portions of NUREG-0711 should also be used, as appropriate, to support the NRC in its reviews of upgrades of current control rooms.

NRC guidance for a structured, top-down systems analysis of HFE was originally provided in NUREG-0700, Revision 0. This document provided a methodology for the review of existing control rooms. It recommended that additional analyses be conducted for new control rooms to optimize the allocation of functions to humans and machines and further examine advanced control system technologies. Appendix B of NUREG-0700, Revision 0, was provided as one source of guidance regarding these analyses.

NUREG-0700 now focuses on guidance for the review of plant HSIs. The guidance has been updated twice to reflect changes in HSI technologies.

NUREG-1764, addresses the human performance aspects of changes to HAs that are credited for safety, especially those involving changes in the licensing basis of the plant; e.g., use of manual action in place of an automatic action for safety system operations. Risk-informed guidance and acceptance criteria are provided for the review of licensee proposals addressing such modifications. The review method uses a graded, risk-informed approach and provides guidance for reviewing the human performance aspects of changes to plant systems and operations. Three HFE review levels are defined: high, medium, and low risk (called Levels I, II, and III). HAs are reviewed using human factors engineering criteria to evaluate whether the proposed HA can be reliably performed when called upon in the plant. HAs in the high-risk level receive a detailed review and those in the medium-risk level receive a less detailed review that is commensurate with their risk. For HAs falling into the low isk level, minimal (or no) human factors review is performed.

Thus, the HFE review process presented in this SRP chapter incorporates guidance from all three documents.

III. REVIEW PROCEDURES

The reviewer will select material from the procedures described below, as may be appropriate for a particular case.

These review procedures are based on the identified SRP acceptance criteria. For deviations from these acceptance criteria, the staff should review the applicant's evaluation of how the proposed alternatives provide an acceptable method of complying with the relevant NRC requirements identified in Subsection II.

The applicant should submit review materials for each review area. RG 1.206 provides guidance to DC and COL applicants for submitting review materials. The material submitted will vary depending on the completion status of each review element. Information may be submitted as part of a Design Control Document (DCD) by a DC applicant, in an FSAR by a COL applicant, and/or in separate reports described below. These separate reports may be submitted to the NRC or referenced in licensing documents as discussed in RG 1.206. The reports that the applicant may submit include:

The general types of reports that the applicant may submit are described in NUREG-0711. These include:

- 1. <u>Implementation Plan</u>. This submittal describes the applicant's proposed methodology for meeting the acceptance criteria of a particular HFE review 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 area. 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. An early review also provides advantages to applicants by obtaining early approval for the methodology when staff concerns can be more easily and more cost effectively addressed.
- 2. Results Summary Report. This submittal describes the results of the applicant's efforts related to a particular HFE review area. The NRC staff use the report as the main source of information for assessing the applicant's efforts using the review criteria contained in this document.

It is not intended that submittals necessarily be provided as separate reports. Rather it is important that information on methodology and results be available to the reviewer. In some cases an applicant may choose to provide this information as part of a DCD or FSAR, in a single report or, in the case of license amendments, in the form of a safety analysis. It is also possible that, for more complex areas of review, such as HSI design or V&V, more than two reports may be submitted in order to address all review criteria. In addition to these reports, the reviewer may review sample work products (e.g., analyses and implemented designs).

In addition to the implementation plans and results summary reports, additional submittals are identified, where appropriate, in each HFE review area in NUREG-0711. The following are descriptions of special submittals and review considerations for specific areas of review:

- HFE Program Management. The applicant should provide the following for staff review:
 HFE program plan describing the applicant's HFE goals/objectives, technical program to
 accomplish the objectives, a system to track HFE issues, the HFE design team numbers
 and their qualifications, and the management and organizational structure to allow the
 technical program to be accomplished.
- 2. <u>Operating Experience Review</u>. The reviewer may also audit the issue tracking system for examination of OER issue treatment.

- 3. <u>Human Reliability Analysis</u>. The reviewers should review the PRA/HRA report(s) to gain a better understanding of the analysis method and results.
- 4. <u>Human-System Interface Design</u>. Other design-related HSI documents may be reviewed, such as applicant-developed guidance documents, detailed trade-off studies, technology assessments, or test/experiment reports developed to support the HSI design. In addition, a variety of mockups, prototypes, or similar physical representations of the HSI design may be available for preliminary review of the design implementation.
- 5. <u>Procedure Development</u>. Generic technical guidelines and sample procedures should be available for review.
- 6. Verification and Validation. The HFE issues tracking system, described in NUREG-0711, should be reviewed. The actual HSI design or a high-fidelity prototype or simulator of the HSI should be available for the staff to examine in conjunction with the verification reviews. In addition, the staff may witness the integrated system validation evaluations. A documented description of the final HSI design that resulted from the HSI task support verification, HFE design verification, integrated system validation, and issue resolution verification activities should be reviewed. Finally, the installation of the completed design in the plant should be reviewed, if time and resources permit.
- 7. <u>Human Performance Monitoring</u>. Submittals for the staff's review of an applicant's human performance monitoring program should be made on a case-by-case basis.
- 8. <u>ITAAC</u>. For standard design certification reviews under 10 CFR Part 52, the procedures above should be followed, as modified by the procedures in SRP Section 14.3 and its subsections. SRP Section 14.3 contains procedures for the review of certified design material (CDM) for the standard design, including the site parameters, interface criteria, and ITAAC.

When determining the review material that should be submitted on the docket versus retained by the licensee for audit or review by NRC reviewers and inspectors, the key aspect is that the amount of information submitted on the docket must be sufficient to support the staff's safety determination. That is, the final safety analysis report includes information at a level sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before a COL is issued.

For a DC application there is some variability in the number and type of reviews conducted depending on the completion status of the HFE. A key determining factor for the review is the applicant's desired approval status for each of the 12 HFE elements in Section II.A previously cited. The elements could be approved at a <u>programmatic level</u>, at an <u>implementation plan level</u>, or at a <u>completed element level</u>. It is also possible that some elements may be partially, but not completely approved. The approval status for each element should be determined early in the review process since it affects the amount and type of material to be submitted by the applicant and reviewed by the NRC. Elements approved at the <u>programmatic level</u> typically would only require summary information in the DCD or Tier 2 information (information in the DCD that is approved but not certified). Elements approved at the <u>implementation plan level</u> would require summary information in the DCD and a more detailed implementation plan to be submitted on the docket. These implementation plans typically would become Tier 2*

information (information in the DCD that is subject to NRC approval before it can be changed by an applicant or licensee). Completed elements would require summary information in the DCD and would also need a results summary report. In some cases the plans and results summary reports may be referenced (see RG 1.206 for the element by element discussion). SRP Section 14.3.9 contains a discussion of the DCD Tier 1 information (the portion of the DCD that is approved and certified).

The HFE reviewer may also need to review and close out COL action/information items that were identified in the final safety evaluation report for a design certification review and also documented in the DCD associated with the design certification. Submittals requesting the closure of these items may occur at various times post-DC. These items are mentioned in SRP Section 14.3.9.1. The review should be done in accordance with the wording of the COL item itself and will most likely require the review of a full or partial results summary report for a particular HFE element from NUREG-0711. As appropriate, the reviewer should use the acceptance criteria from the corresponding element of NUREG-0711, as amplified in Section II.A of this Chapter. There will also be HFE-related ITAAC that need closure at some time in the life cycle of a COL process. The closure process for these will be detailed in the NRC construction inspection program, and will also involve the use of the acceptance criteria from the corresponding element of NUREG-0711.

A new COL application that does not reference a DC will generally need to be complete, in that all elements should be fully addressed and reviewed by the staff. However, as noted in RG 1.206, the Design Implementation element will not be completed until the plant is constructed and the Human Performance Monitoring element, will continue after plant startup. For a COL application that references a DC, each element will have been addressed in the DC to some level of detail, as discussed previously. The COL application will then need to address, and the staff must review, any elements not already completed and certified. This may require review of an implementation plan and a results summary report, or just the results summary report.

For HFE reviews of control room modernizations, the staff's review should be tailored as described in Section II.B above. For HFE reviews of modifications that affect risk-important human actions, the staff's review should be tailored as described in Section II.C above.

IV. EVALUATION FINDINGS

The reviewer verifies that the applicant has provided sufficient information and that the review and calculations (if applicable) support conclusions of the following type to be included in the staff's safety evaluation report. The reviewer also states the bases for those conclusions.

- 1. The reviewer's determination that all review criteria are satisfied, using the methods described in the SRP.
- 2. The reviewer's determination that alternative means of satisfying review criteria are acceptable.
- 3. The reviewer's determination that acceptable justification for deviations from review criteria exist. The justifications may be based upon such evidence as analyses of recent literature, analyses of current practices and operational experience, tradeoff studies, and the results of engineering experiments and evaluations.

An overall review conclusion is determined by comparing the goals of the HFE review, which are based on the type and purpose of the HFE review, to the evidence provided in the applicant's submittals. Important considerations include:

- 1. Did the reviewer examine all relevant areas of review?
- 2. Did the reviewer evaluate each area of review at the appropriate level (e.g., program description level, implementation plan level, and completed-area-of-review level)?
- 3. Were the reviewer's findings for each area of review acceptable?

If the evidence provided by the review does not satisfy the goal of the HFE review, then additional analysis and design activities may be performed by the applicant to address the staff's concerns. These may include: (1) additional analysis and review for areas that have not been examined at the completed-area-of-review level, (2) completion of the design or correction of design deficiencies identified through the review, and (3) appropriate testing or V&V.

For DC and COL reviews, the findings will also summarize the staff's evaluation of requirements and restrictions (e.g., interface requirements and site parameters) and COL action items relevant to this SRP section.

In addition, to the extent that the review is not discussed in other SER sections, the findings will summarize the staff's evaluation of the ITAAC, including design acceptance criteria, as applicable.

V. IMPLEMENTATION

The staff will use this SRP section in performing safety evaluations of DC applications and license applications submitted by applicants pursuant to 10 CFR Part 50 or 10 CFR Part 52. Except when the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the staff will use the method described herein to evaluate conformance with Commission regulations.

The methods described in this chapter will be used in evaluations of: (1) submittals in connection with applications for construction permits, design certifications, operating licenses, and combined licenses; (2) submittals from operating reactor licenses who voluntarily propose to initiate system modifications if there is a clear nexus between the proposed modifications and this guidance.

The provisions of this SRP section apply to reviews of applications submitted six months or more after the date of issuance of this SRP section, unless superseded by a later revision.

VI. REFERENCES

- 1. 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."
- 2. 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants."

- 3. 10 CFR Part 55, "Operator's Licenses."
- 4. NUREG-0654, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants."
- 5. NUREG-0696, "Functional Criteria for Emergency Response Facilities."
- 6. NUREG-0700, Revision 2, "Human-System Interface Design Review Guidelines."
- 7. NUREG-0711, Revision 2, "Human Factors Engineering Program Review Model."
- 8. NUREG-0737 and Supplement 1, "Clarification of TMI Action Plan Requirements."
- 9. NUREG-0835, "Human Factors Acceptance Criteria for the Safety Parameter Display System."
- 10. NUREG-1342, "A Status Report Regarding Industry Implementation of Safety Parameter Display Systems."
- 11. NUREG-1764, "Guidance for the Review of Changes to Human Actions."
- 12. NUREG-1791, "Guidelines for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operating Staff Requirements Specified in 10 CFR 50.54(m) Final Report"
- 13. NUREG/CR-2300, "PRA Procedures Guide: A Guide to the Performance of Probabilistic Risk Assessments for Nuclear Power Plants."
- 14. NUREG/CR-2815, "Probabilistic Safety Analysis Procedures Guide."
- 15. NUREG/CR-3485, "PRA Review Manual."
- 16. NUREG/CR-6838, "Technical Basis for Regulatory Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m)."
- 17. NUREG/CR-6400, "HFE Insights for Advanced Reactors Based Upon Operating Experience."
- 18. Regulatory Guide 1.9, "Selection, Design, Qualification, and Testing of Emergency Diesel Generation Units Used as Class 1E Onsite Electric Power Systems at Nuclear Power Plants."
- 19. Regulatory Guide 1.22, "Periodic Testing of Protection System Actuation Functions."
- 20. Regulatory Guide 1.47, "Bypassed and Inoperable Status Indication for NPP Safety Systems."
- 21. Regulatory Guide 1.62, "Manual Initiation of Protective Actions."

- 22. Regulatory Guide 1.81, "Shared Emergency and Shutdown Electrical Systems for Multi-Unit NPPs."
- 23. Regulatory Guide 1.97, "Instrumentation for Light-Water-Cooled Nuclear Power Plants To Assess Plant and Environmental Conditions During and Following an Accident."
- 24. Regulatory Guide 1.105, "Instrumentation Setpoints."
- 25. Regulatory Guide 1.174, "An Approach to Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis."
- 26. Regulatory Guide 1.177, "An Approach for Plant-Specific, Risk-Informed Decision Making: Technical Specifications."
- 27. Regulatory Guide 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments."
- 28. Regulatory Guide 1.206, Combined License Application for Nuclear Power Plants (LWR Edition) currently DG-1145.
- 30. Information Notice 95-48, "Results of Shift Staffing Study."
- 31. Information Notice 97-78, "Crediting of Operator Action In Place of Automatic Actions and Modification of Operator Actions, Including Response Times."
- 32. NRC Regulatory Issue Summary 2001-02, "Guidance on Risk-Informed Decision Making in License Amendment Reviews."
- 33. NRC Regulatory Issue Summary 2002-22, "Use of EPRI/NEI Joint Task Force Report, Guideline on Licensing Digital Upgrades: EPRI TR-102348, Revision 1, NEI01-01:a Revision of EPRI TR-102348 to Reflect Changes to the 10CFR 50.59 Rule."

PAPERWORK REDUCTION ACT STATEMENT

The information collections contained in the Standard Review Plan are covered by the requirements of 10 CFR Part 50 and 10 CFR Part 52, and were approved by the Office of Management and Budget, approval number 3150-0011 and 3150-0151.

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