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US-APWR TOPICAL REPORT

HFE Process and HSI System Design MUAP-07007-P(R2)

Mitsubishi Heavy Industries, Inc.

Docket No. 52-021

COLP Branch

2nd round MHI US-APWR Topical Report MUAP-07007-P R2, "HSI System Description and HFE Process"

The following are the NRC Follow-up Requests for Additional Information (RAI), based on original RAI's and Applicant responses:

Follow-up RAI to RAI 18.0-**1**

Regarding the topical report's applicability of its description to both US-APWR, a new design, and operating, non-US-APWR plants, MHI states the following on page iv:

> This report distinguishes between the descriptions applicable to the US-APWR and those relevant to operating plants, where there is a clear need for such a distinction. Where there are no distinctions, the description is generically applicable to the US-APWR and a broad range of operating plants, although not necessarily all operating plants. When this topical report is referenced in a plant-specific Licensing Amendment Request, the Plant Licensing Documentation will identify any areas of this topical report that are not applicable.

On page 1 MHI states the following:

> The design process described in this report is applicable to the MHI Human System Interface [HSI] designs for both new and existing operating plants. The system descriptions are directly applicable to the MHI US-APWR. For operating plants the basic design features that ensure regulatory compliance are maintained, as described in this report. However, due to plant differences, specific changes in implementation detail will be described in Plant Licensing Documentation…

With respect to the human factors engineering (HFE) process, MHI states the following on page 87:

> The applicability to operating plants is dependent on the scope of the HSI upgrade. For operating

plant upgrades Plant Licensing Documentation identifies the specific sections of this document that are applied and any deviations from the methods described in this report.

“Plant Licensing Documentation” is defined on page 2 of the topical report as “plant level documentation that is specific to a group of plants or a single plant, such as the Design Control Document (DCD), Combined Operating Licensing (COL) Application, Final Safety Analysis Report, or License Amendment Request.”

There are two items described specifically for being addressed in the HSI in operating plants. One HSI design item is specifically described by MHI in the HSI design description section as relating to changes to operating plants. In the description of aspects of the design, MHI indicates that the sizes and locations of the large display panel’s screen may vary in operating plants based on physical limitations of the operating plant. Staffing and qualification requirements results are described in HFE process section. The described “minimum and maximum staffing” (minimum operating staff located in and outside the MCR; maximum operating staff located in the main control room (MCR)) “may … be applied to operating plants with an appropriate level of plant modernization. Staffing and analysis for modernized operating plants is described in Plant Licensing Documentation.”

The wording in topical report sentences quoted above, “For operating plants the basic design features that ensure regulatory compliance are maintained, as described in this report.” and “The applicability to operating plants is dependent on the scope of the HSI upgrade.” makes it unclear what aspects of the HFE process and the HSI system design described in this report apply to operating plants. It is unclear what might differ “basic design features” from those that are not “basic design features.” The second sentence leaves the specification of the applicability of the topical report’s HFE process and HSI system design description completely indeterminate. Please provide clarity on the applicability of the topical report to operating plants.

MHI Response:
Based on the following statements, all sections of this topical report are applicable to operating plants:

Section 1.0 - "The purpose of this Topical Report is to describe the Mitsubishi Heavy Industries (MHI) Human System Interface (HSI) System (HSIS) design and the Human Factors Engineering (HFE) design process used by MHI for that system. MHI seeks approval from the US Nuclear Regulatory Commission for the use of the MHI HSI System for new nuclear plants and for operating nuclear plants."

Abstract - "When this topical report is referenced in a plant-specific Licensing Amendment Request, the Plant Licensing Documentation will identify any areas of this topical report that are not applicable.

This topical report describes the Basic HSI System design, and the HFE design process. Both are applicable to new and operating plants. Within the design process section, this document defines the "Plant Licensing Documentation" that MHI will generate for either application. The "Plant Licensing Documentation" that has been generated, and will continue to be generated, for the US-APWR exemplifies the "Plant Licensing

Documentation" that will be generated for operating plants.

For example, for the US-APWR, the "Plant Licensing Documentation" is fulfilled by the US-APWR DCD and the ITAACs. The DCD contains the US-APWR plant specific plans for each HFE Program Element. In addition, the DCD, references HFE reports that will be submitted for NRC review during the DCD review process. The ITAACs in Tier 1 define the plant specific HFE reports that will be available for NRC review later in the licensing process. It is noted that for the US-APWR, there are very few site specific HFE activities. Therefore, most "Plant Licensing Documentation" is generically applicable to all sites. Site specific "Plant Licensing Documentation" is defined as COL actions, and is described in the COLA. Therefore, the words "Plant Licensing Documentation", as used in the TR, or "plant specific" as used in many RAI responses, do not refer to documentation in a specific COL Application, but rather to documentation in the US-APWR DCD or associated generic US-APWR ITAAC reports.

For an operating plant upgrade, MHI plans to use a similar approach. A license amendment request (LAR) would define all plant specific HFE program element plans to a level of detail that is comparable to Chapter 18 of the US-APWR DCD. The scope of each HFE program element plan would be tailored to reflect the extent of change from the current plant condition, and any changes from the generically approved HSI System design, if any. The LAR would also include the schedule for generating all of the plant specific HFE reports, required by this HSI Topical Report (MUAP-07007).

Follow-up RAI:
MHI's response does not provide the information requested by the staff.

The RAI states that it is unclear in the Topical Report what distinguishes "basic design features" from those design features that are not "basic". The response to the RAI introduces the statement that the "topical report describes the Basic HSI System design," which does not adequately address the RAI. Please provide detailed clarifying information describing those parts of the HSI system design that are "basic," from those that are not. In addition, please provide detailed clarifying information describing which design features "ensure regulatory compliance."

It is unclear to the staff what the word "maintained" in the sentence "For operating plants the basic design features that ensure regulatory compliance are maintained, as described in this report." means. Please clarify the meaning of the word "maintained" within the context of the statement.

To assist the staff in understanding those aspects of the HSI design that shall be applicable to operating plants apart from those that are not, the staff requests that MHI:

- clarify what is meant by the term "basic design features" with enough specificity so that the definition can be used to systematically distinguish basic design features from those that are not,
- indicate specific design features as being basic or not basic, or
- revise the wording of the topical report to clearly indicate which design features will be applicable to

operating plants.

Also, the distinction between “plant specific” and “site specific” in the response is difficult to understand. A common interpretation of “plant specific” items are those items that are particular to an individual plant, and “site specific” items are those items that are particular to an individual site (which could include more than one plant). It is unclear why “plant specific” items are addressed in more generically applicable licensing documents than “site specific” items. The text in the response to RAI 18.0-2 states that “the HSI design for local controls and HFE design process for local controls is plant specific and is therefore not included as part of the generic HSI System design or design process description,” suggests that “plant specific” items are not included in more generically applicable licensing documents – this appears to be inconsistent with the response to the current RAI. Please clarify the usage of “plant specific.”

Follow-up RAI to RAI 18.0-**3**

HFE program goals are discussed in Section 5.1.1.1 and are an almost exact restatement of NUREG-0711, “Human Factors Engineering Program Review Model,” Rev. 2 criteria 2.4.1(1). These are generic goals that would be expected of well-designed systems. MHI should show a plan for how these goals will be further defined into objectives that are testable or able to be evaluated and how achievement of these objectives will be tested and/or evaluated. What is the plan for how the HFE activities will meet the HFE Program Goals, how will the HFE Program Goals be further defined into testable or verifiable objectives, and how will achievement of these objectives be tested and/or evaluated?

MHI Response:
Section 5.1 provides an overview of the HFE Program Plan. Each element of the plan is described in sections 5.2 through 5.12. Each section describes the objectives of that specific element and how those objectives are accomplished.

Section 5.10 describes the Human Factors Verification and Validation plan. This section describes how the HFE program goals are further defined into testable or verifiable objectives and how those objectives are evaluated. As stated in Section 5.0 "This section describes the generic HFE design process. Any portions of the HFE design process that are not complete for a specific plant and therefore may require future commitments, such as Design Acceptance Criteria or licensing conditions for operating plants, are described in Plant Licensing Documentation."

The Topical Report is intended only to describe the key aspects of the program plan for each HFE program element. The detailed HFE program plan and the schedule for executing that program plan are described in Plant Licensing Documentation. Chapter 18 of the DCD for the US-APWR provides that detailed program plan for the US-APWR, and therefore exemplifies this approach. Attachment-1 shows MHI's planned schedule for generating all reports for the US-APWR HFE program.

Follow-up RAI:
MHI's response does not address the information requested by the RAI. Also, the US-APWR DCD document does not give sufficient detail to sufficiently address the criterion in NUREG-0711, section 2.4.1(1). Please provide:

1. The generic HFE program goals of the program
2. The plan for **how** these goals will be further defined into objectives that are testable or able to be evaluated
3. **How** achievement of the objectives will be tested and/or evaluated.

Follow-up RAI to RAI 18.0-**6**

Though MHI seeks NRC approval of the topical report for replacement of current HSI systems in operating plants, the topical report does not discuss the part of this criterion that addresses plant modifications. Please provide detail on how plant personnel will be involved in the HFE program for plant modifications.

MHI Response:
As stated in the response to RAI 18.0-04, MHI plans to engage US utility operators in each element of the US HSI System development. This is applicable to new plants or operating plant modifications. The detailed plan for the HFE program for a plant modification will be described in plant licensing documentation.

The following will be added to Section 5.11: "Facility design changes are documented and analyzed for their potential impact on HSIs. Those design implementation issues that negatively impact human performance are identified as HEDs and are tracked and dispositioned. HFE design modifications are documented in a periodic status report."

Follow-up RAI:
The RAI asks for detail on how plant personnel will be used in the HFE program for plant modifications. MHI states in the response to RAI 18.0-1 that “The detailed plan for the HFE program for a plant modification will be described in plant licensing documentation.” Please provide clarification on what this statement means.

Is the HFE program plan for plant modifications described in the Topical Report a general version of a HFE program plan described in other licensing documentation?

Please provide clarification on the relationship between the HFE program plan described in this document and detailed program plans for plant modifications that will be described in other licensing documentation.

Follow-up RAI to RAI 18.0-**7**

Even though MHI seeks NRC approval for replacement of current HSI systems in operating plants, this document does not address the criteria for Effect of Modifications on Personnel Performance. For replacements of current HSI systems in operating plants with the US-APWR HSI, please provide detail how the HFE program plan address the effects of these modifications on personnel performance.

MHI Response:
HFE program elements 2 thru 6 consider the Effect of Modifications on Personnel performance. The goal of each element is to ensure the HSI design maintains or improves current human performance levels. This is confirmed initially through HFE program element 10 and then throughout the life of the plant in HFE program element 12. Program element 6 specifically identifies risk significant tasks and activities conducted in each HFE program element to minimize the potential for human performance errors. As stated in Section 5.11 "For any HSI change to a licensed design the potential impact on Human Actions is assessed and a risk significance level is assigned in accordance with the criteria in NUREG-1764. The risk significance considers the scope of the change as well as the potential impact on plant safety functions." The detailed HFE plan for plant specific HSI modifications will be described in plant licensing documentation. In general, the HFE plan for any plant HSI upgrade would be comparable to Chapter 18 of the US-APWR DCD. However, each HFE Plan would be tailored to the modification, with focus on what is actually changing. For example, if we are simply changing the HSI but there are no changes to Function Allocation, there would be a minimal effort (and plan description) for the FRA/FA program element.

Follow-up RAI:
NUREG-0711 Rev. 2 cites documents that give guidance for evaluating modifications to plants, specifically I.G. 1.187 and NEI 96-07. NEI 96-07 contains the methodologies that are acceptable to the staff for complying with the provisions of 10 CFR 50.59, which addresses plant modifications. There is not enough detail provided to assess whether or not MHI's HFE program plan is consistent with the guidance given by NEI 96-07. Please provide enough detail so the staff can verify that MHI's resulting HFE program plan for the effects of modifications on personnel performance will conform to the intent of the methodology.

Also, please provide clarification as to what "comparable to" means in the sentence "In general, the HFE plan for any plant HSI upgrade would be comparable to Chapter 18 of the US-APWR DCD."?

Follow-up RAI to RAI 18.0-**8**

In Section 5.1.2.2, MHI addresses responsibilities of the HFE team by describing the HFE team roles. There is no discussion of the HFE team's responsibility for developing the HFE plans and procedures or review of HFE activities. Please provide a discussion of the HFE team's responsibility for developing the HFE plans and procedures or review of HFE activities.

MHI states that the Project Manager is responsible for making sure aspects of the HFE activity follow the HFE Implementation Plan. MHI states that the Design Team Manager is responsible for "phasing of activities." It is unclear what "phasing of activities" includes -- does "phasing" include scheduling the activities

and milestones? Also, since there is a separate V&V Team Manager it is unclear if the Design Team Manager is responsible for scheduling of verification and validation (V&V) -- both seem to report to the Project Manager, but not to each other. Please clarify the intent of “phasing of activities.”

The team described is called the "HFE Design Team." However, there is no discussion of who is responsible for carrying out the operating experience review, the functional requirements and function allocation analysis, the task analysis, the staffing and qualifications analysis, the human reliability analysis, procedure development, the training program development, the design implementation, or human performance monitoring. It is unclear if the HFE team will be responsible for developing HFE plans and procedures, reviewing HFE activities, and scheduling all HFE activities and milestones. Please clarify the HFE team's responsibilities with respect to the development of all HFE plans and procedures; oversight and review of all HFE design, development, test, and evaluation activities; and scheduling of activities and milestones.

MHI Response:
The following will be added to the responsibility of the HFE Design Team Manager:
"Development of HFE plans and procedures, conducting HFE activities for all elements except Verification and Validation (V&V), and review of V&V results."

The following will be added to the responsibility of the HFE V&V Team Manager:
"Development of HFE plans and procedures for V&V. Review of HFE plans, procedures and results for all elements except V&V."

The following will be added to Section 5.1.2.2: "The Design Team Manager's responsibility of "phasing of activities" includes planning the schedule for all HFE activities and milestones, including the high level scheduling of V&V activities and milestones. However, the detailed scheduling of V&V activities and milestones is the responsibility of the V&V Team manager."

The following will be added to Section 5.1.2.2: "The HFE Design Team is directly responsible for developing plans, procedures and schedules, and carrying out the HFE activities for the operating experience review, the functional requirements and function allocation analysis, and the task analysis. The HFE Design Team reviews the plans, procedures and schedules, and provides oversight for the staffing and qualifications analysis, the human reliability analysis, procedure development, V&V, the training program development, the design implementation, and human performance monitoring".

Follow-up RAI:
MHI’s response gives a general description of the HFE Teams responsibilities. However, it does not detail **how** the HFE team goes about carrying out those responsibilities which are the staffing and qualifications analysis, the human reliability analysis, procedure development, V&V, the training program development, the design implementation, and human performance monitoring. The response seems to be a restatement of the NUREG-0711 criterion. Please provide detailed clarifying information so that the staff can assess how the

HFE Team carries out the various activities highlighted in the NUREG-0711 Section 2.4.2 criterion 1.

Follow-up RAI to RAI 18.0-**9**

The HFE team's organizational placement and authority is described in Section 5.1.2 of the topical report. However, there is no description of how the HFE team relates to the organization of the US-APWR's total program and its authority within the US-APWR's total program. Other than MHI's statement that the HFE V&V Team Manager has the "authorities to ensure V&V activities are not adversely affected by commercial and schedule pressures" there is no further discussion of the HFE Team's authority to assure that its responsibilities are accomplished, to identify problems in overall plant design implementation, or to control processing, delivery, installation, of use of HFE products when a problem has been identified. How does the HFE Team relate to the organization of the US-APWR's total program and what is its authority within the total program? What is the HFE Team's authority to assure that its responsibilities are accomplished, to identify problems in overall plant design implementation, and to control processing, delivery, installation, of use of HFE products when a problem has been identified?

MHI Response:
The HFE Design Team is one of the engineering branches in the US-APWR project organization and responsibility for HFE aspect of the US-APWR total program.

The HFE Design Team is responsible for identifying HFE problems in overall plant design implementation, controlling HFE processing, delivery, installation, of use of HFE products. Section 5.1.3 describes the "The process through which the HFE Design team executes its responsibilities..." The placement of the HFE Design Team Manager within the overall organization is defined in the HFE Program Implementation Procedure, which is a plant specific document."

The plant specific documentation for the US-APWR is the HFE Program Implementation Procedure, described in Section 18.1.3.1 of the DCD. This procedure governs all generic US-APWR HFE activities (i.e. those activities covered by the DAC/ITAAC). This procedure will be in place for all US-APWR HFE activities (i.e. OER, FRA/FA, HRA, TA, etc). In addition, this procedure governs how the HFE Team interacts with other design organizations for the US-APWR.

For the few site specific HFE Program activities, the COL applicant will either adopt the same HFE Program Implementation Procedures or write their own.

Follow-up RAI:
MHI’s response simply indicates that this is a plant specific issue; the DCD section referred to indicates the generic responsibilities, but the issue of authority to assure appropriate HFE is not addressed. Please give clarifying detailed information on what the HFE Team's authority is to assure that its responsibilities are accomplished, to identify problems in overall plant design implementation, and to control processing, delivery, installation, of use of HFE products when problems have been identified.

Follow-up RAI to RAI 18.0-**10**

The HFE team's composition is described in Section 5.1.2.2 of the topical report. While MHI states that the Design Team Manager is responsible for "phasing of activities" it is unclear if the Design Team Manager or anyone else will have the specific responsibility of developing and maintaining the HFE design process schedule. Other typical contributions of the Technical Project Management functions include being a central point of contact for management of the HFE design and implementation process – MHI does not discuss who is responsible for this function.

Also, there is no discussion of the qualifications or credentials for positions within the HFE team.

Please provide explanation for who is responsible for developing and maintaining the HFE design process schedule, who is the central contact for management of the HFE design and implementation process, and the qualifications and credentials for positions within the HFE team.

MHI Response:
The following will be added to Section 5.1.2.2: "The Design Team Manager is responsible for developing and maintaining the HFE design process schedule. The Design Team Manager is the central point of contact for management of the HFE design and implementation process".

The technical skills encompassed by the aggregate of all HSI Design Team Members are described in Section 5.1.2.2 2).

The following will be added to Section 5.1.2.2 2): "The HFE design team conducts all design activities for HSIs. The HFE design team consists of a multi-disciplinary technical staff. The team is under the leadership of an individual experienced in the management of the design and operation of complex control technologies. The specific individuals and qualifications of those individuals, who are responsible for each HFE program element are documented within the implementation procedure for that HFE program element."

Follow-up RAI:
Qualifications and credentials (per NUREG-0711, Appendix A) for the technical staff in various skill areas are not addressed.

Experts on each program element do not necessarily correlate to the HFE team members. If there is correlation it needs be stated explicitly so there is a basis for describing the qualifications and credentials within individual sections of the implementing procedure.

Please provide the necessary qualifications and credentials for the HFE design team’s technical staff.

Follow-up RAI to RAI 18.0-**11**

Except for the Project Manager, the HFE Design Team Manager, and the HFE V&V Team Manager, there is no discussion of the job descriptions or assignments of HFE team personnel. Please provide detail on the job descriptions and assignments of the complete HFE team.

MHI Response:
The job descriptions of the HFE Design Team and V&V Team personnel are encompassed in the descriptions of the HFE program elements. Specific job assignments are the responsibility of the Design Team and V&V Team managers. These assignments change frequently and are therefore not appropriate for licensing documentation.

Follow-up RAI:
What skills with members of the HFE Team have and how will the HFE Team members employ these skills for the various tasks performed for design, evaluation, issue tracking, work scheduling, etc. More detail is necessary describing the specific job activities in the program elements and what category of personnel (HF engineer, nuclear engineer) etc will be performing that function. Also, see Follow-up RAI to RAI 18.0-10.

Follow-up RAI to RAI 18.0-**12**

The general process procedures are described in Section 5.1.3.a. MHI makes reference to a flow diagram (Figure 5.1-2) that illustrates the general process procedures, but there is little detail provided to explain the process flow diagram. There is very little detail explaining general process procedures particulars in the text. There is no discussion of what the "Design Section" or the "Review Section" is. There is no discussion of the sheets, logs, and documents in the figure. There is no description of what the responsibilities of the Review Manager are and what the relationship between the HFE Team and the Review Manager is. There is no description of what the responsibilities of Open Review Committee are and what the relationship between the HFE Team and the Open Review Committee is. Please provide detail, to address the deficiencies identified, on the 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, and design team review of HFE products.

MHI Response:
Figure 5.1-2 will be revised, as follows:

"Review Manager" will be replaced with "HFE V&V Team Manager"

"Review Section" will be replaced with "HFE V&V Team"

"Review Committee Member" will be replaced with HFE V&V Team Member".

Text will be added to generally explain the interaction of the HFE review process with the rest of the plant, as follows:

An HFE Design Team representative will be assigned to review every plant document that contains

requirements or descriptions of safety significant human-machine interfaces. This includes documentation for local controls, maintenance activities, periodic testing activities, etc. HEDs identified by the HFE Design Team reviewer will be entered in the HFE Issues Tracking System database and tracked to closure.

The details of this interaction process are included in the HFE Program Implementation procedure.

Follow-up RAI:
The details requested are summarized in a two sentence paragraph, which the response states will be elaborated in a program implementation procedure. The adequacy of a process cannot be evaluated without details on how the general HFE process works. Please provide these details for staff review.

Follow-up RAI to RAI 18.0-**17**

Subcontractor HFE efforts are described in Section 5.1.3.f. MHI states that HFE requirements are included in each subcontract and that "HFE requirements are periodically verified by review of the subcontractor's HMI design and manufacturing guidelines by the HFE Team." There is no detail on the verification process of subcontractor HFE efforts – what are the criteria for determining if a subcontractor is compliant with HFE requirements?

MHI Response:
The following will be added to Section 5.1.3.f: "The V&V Team is responsible for this verification review. Verification will be conducted to the same standards as designs created by the Design Team. For example if the supplier is intended to conform to the Basic HSI System Style Guide, the V&V Team will verify the supplier's products against the Style Guide. Verification procedures are plant specific documents".

Follow-up RAI:
Is the V&V team involved in verifying supplier products at the design stage?

How are Design Team standards determined?

How are the Design Team standards communicated to the V&V team?

In the response, please clarify what “is intended to” mean in the sentence “For example if the supplier is intended to conform to the Basic HSI System Style Guide, the V&V Team will verify the supplier's products against the Style Guide.”?

Follow-up RAI to RAI 18.0-**18**

Little detail is given on the HFE Issues Tracking System other than it is the same system as that is used for the rest of the US-APWR design effort -- no description is given of this system. Please describe the tracking system including how it will help provide reasonable assurance that HFE issues that need to be addressed before the design process is completed are not overlooked.

MHI Response:
The following will be added to Section 5.1.2.2 (3): "The V&V Team shall ensure all items in the HFE Issues Tracking System have been completed at the appropriate phase of the design process".

The following will be added to Section 5.1.2.2 (4). "The QA Organization shall conduct period audits of the design and V&V processes, which include disposition of items in the HFE Issues Tracking System".

Follow-up RAI:
MHI's response states who is responsible for issues tracking but does not provide detail on the tracking system including **how** it will help provide reasonable assurance that HFE issues that need to be addressed before the design process is completed are not overlooked.

Please provide in greater detail **how** the tracking system will help provide reasonable assurance that HFE issues that need to be addressed before the design process is completed are not overlooked.

Follow-up RAI to RAI 18.0-**20**

MHI states that the HFE issues are entered into the HFE Issues Tracking Systems as well as actions taken to address the issues, resolutions of issues, and the design team's acceptance of the resolutions. MHI states that issues are entered into the HFE Issues Tracking System if they meet or exceed "the threshold of significance established by the design team." It follows that if a significance threshold is too high an issue that needs to be addressed at a later date will not be entered into the tracking system and there may be no assurance that the issue will be attended to. Please define how the threshold of significance value for deciding to enter HFE issues into the HFE Issues Tracking System is determined.

MHI Response:
The document will be revised as follows: There is no significance threshold for issue entry into the tracking system. Each issue or concern entered into the system is evaluated for its significance to human performance. The basis for the disposition of all entries is included in the database.

Follow-up RAI:
The response given by MHI does not clarify the criteria for which issue (or concern) is entered into the issues tracking system or not. Please clarify, in greater detail, the methodology MHI will use to evaluate the significant human performance issues or concerns.

Follow-up RAI to RAI 18.0-**24**

MHI states that "static and dynamic models" will be developed to evaluate the HSI design and a part-task simulator that is used for HFE activities. There is no definition of what static models and dynamic models are and little detail on how they will be used in the HFE program. Please explain static models and dynamic models and how they will be used in the HFE program. Little detail is provided on the tools and techniques used to develop the hardware and software interfaces for US-APWR, such as graphic user interfaces (GUIs), panel layouts, procedure design, etc. Please provide further explanation about the tools and techniques used to develop the hardware and software interfaces for US-APWR, such as GUIs, panel layouts, procedure design, etc. There is discussion of a part-task simulator, a "complete control room full scope simulator," and a simulator facility, but little detail is provided about these and how they will be used in the HFE program. Please explain the use of the different simulator types. Two images of a facility used for HFE verification and validation in Japan are shown in Appendix B, but no explanation is given for how the facilities depicted in these images related to the design of US-APWR. Please explain how the facilities relate to the US-APWR design.

MHI Response:
The document will be revised as follows: "The HSI design implementation activities include the development of static graphic displays, and dynamic graphic displays driven by high fidelity plant model simulators... Static graphic displays are used for the following verification activities: (1) Conformance to NUREG0700 design criteria (2) Confirmation of HSI inventory with operating procedures (3) Confirmation of usability with task analysis. The dynamic graphic displays driven by high fidelity plant model simulators are used to... Verification activities, using static graphic displays are conducted prior to verification and validation activities, using dynamic displays driven by high fidelity plant models."

The process for creating computer based procedures is described in Section 4.8. Another similar section will be added to the Topical Report that describes the process for creating static displays (e.g., display icon library, conformance to HIFE style guide) and then converting them to dynamic displays (e.g., linking to live points in the 1/0 database).

As described in Section 5.1.5, part-task simulators are used at the early design stage, for verification of the graphic displays for each plant system. The following will be ' added: "A Full scope simulator is used for integrated validation testing." A description of the use of full scope simulators during each phase of HSI development will be added to the Topical Report, as described in the response to RAI-4.

These pictures show the Japanese HSI System. As explained in the Abstract of this Topical Report, the Japanese HSI System is the basis (reference design) for the US HSI System, which will be applied initially to the US-APWR.

Follow-up RAI:
The staff reviewed MUAP-07007-P Revision 2 (September 2008) and did not find the text quoted in the response. Please clarify where this text can be found in the topical report. Additionally, please clarify the

meaning of the last sentence of the first paragraph.

Also, please give detailed information to satisfy the criteria for specifying HFE facilities, equipment, tools, and techniques to be used for the HFE program.

Follow-up RAI to RAI 18.0-**25**

MHI seeks NRC approval of the HSI system design for "replacement of current HSI systems in operating plants" but there is no discussion in the topical report of how MHI will address plant modifications. The HFE plan should provide assurance that plant modifications meet current regulations, except were specific exemptions are requested under 10 CFR 50.12. Please describe how the HFE plan will provide assurance that plant modifications meet current regulations.

MHI Response:
As stated in the Abstract: "For applications in the US, this report demonstrates conformance of the HSI System design and design process with all applicable US Codes and Standards." Conformance to current regulations is assured through Staff approval of this Topical Report and the LAR that will reference this topical report and provide supplemental plant specific documentation. MHI is not planning any exemption requests.

Follow-up RAI:
MHI's response asserts that the Topical Report provides information demonstrating that the HSI design and design process meets relevant US Codes and Standards. Moreover, the response asserts that the staff assures compliance to current regulations by approving the Topical Report and the LAR used for plant modifications. The Topical Report does not demonstrate conformance of the HSI System design and design process with all applicable US Codes and Standards. The information provided by MHI in the Topical Report and the response to the RAI is unacceptable in satisfying the criteria for providing assurance in the HFE plan that a plant modification meets current regulations.

Please provide detailed information describing how the HFE plan will provide assurance that plant modifications meet current regulations.

Follow-up RAI to RAI 18.0-**27**

The Operating Experience Review (OER) is described in Section 5.2. According to NUREG-0711, Rev. 2, the OER "should provide administrative procedures for evaluating operating, design and construction experience and for ensuring that applicable important industry experiences will be provided in a timely manner to those designing and construction the plant."

MHI states in the topical report "MHI has examined and addressed the issues and causes of the events in the past commissioning and/or the present operating plants, both domestic and overseas, and improved the in-service plant facilities and the construction plant designs if necessary in order to avoid the issue again." (p. 99)

This is not sufficiently detailed to evaluate. The NUREG-0711, Rev. 2 criteria for OER include a review of predecessor or related plants and systems, review of recognized industry issues and related HFE technology, interviews with plant personnel, and identification of risk-important human actions. The topical report does not describe the scope of the OER, or the review process, or address any of the aforementioned criteria. Please provide detail on the plan to implement the OER, including methods and how other NUREG-0711, Rev. 2 OER criteria will be addressed.

MHI Response:
The following will be added to Section 5.2: "Each application of MHI's HSI System will build upon previous applications. For example, the first US-APWR will build upon the application of the HSI System to Japanese plants. The first application of the HSI System to an operating plant, will build upon the application to the US-APWR. Therefore the scope of OER and the specific plan for that OER is described in plant specific licensing documentation."

Follow-up RAI:
The response simply states that the OER implementation plan will build upon previous applications of the HSI System to operating plants and, because of this, will be described in other licensing documentation. A review of the operating experience of a similar HSI is necessary of any OER, and the response does not specify detail for a plan of **how** an OER will for the US-APWR HSI design be implemented. An OER is a necessary precursor to a design. Please provide a plan for **how** the OER will be implemented for staff review.

Follow-up RAI to RAI 18.0-**28**

MHI states that they have "examined and addressed the issues and causes of events in the past commissioning and/or present operating plants," and improved designs if necessary to avoid the issue again. This implies that an OER has already been performed, but no results are presented. There is no discussion of whether or not the past commissioning and the present operating plants that were examined are considered predecessor plants – predecessor plants are those that have designs upon which the US-APWR design will be based. It is unclear if the issues identified in this examination have been incorporated into the issues tracking system of the US-APWR HFE program. Table 5.2-1, almost illegible, and it does not appear to address any human factors issues. Please provide detail on what predecessor designs or highly similar plants or plant systems have already been examined for the OER, what methodologies were used to review them, and how the issues identified from this review were/are/will be documented and tracked for the US-APWR HFE program. Also, MHI should clarify the status of the OER and indicate when the results will be available for review.

MHI Response:
As described in Section 4.0 "This topical report describes the HFE elements that were encompassed in the development program in Japan. Table 4.0-1 compares the NUREG-0711 HFE program elements to the elements in the HFE program implemented for Japanese PWRs." Section 5.2 describes the OER process

that has been completed for the Japanese HSI System. This same OER process is applicable to future applications. As stated above, each application builds upon the OER from each previous application of the HSI System. Therefore, the scope of OER and the specific plan for that OER is described in plant specific licensing documentation.

The Japanese HSI System design reflects the resolution of all OER issues that were identified. Since the Japanese HSI System is considered the predecessor design for the US-APWR, these issues do not exist in the US-APWR issues tracking database. The US-APWR issues tracking database will include only new issues, which are identified during the US-APWR OER activity, as described in the US-APWR DCD. Again, the US-APWR OER builds upon the work previously conducted for the predecessor reference design. The US-APWR OER will include a review of the corrective actions database for CPNPP 1 &2, to identify issues that may be generically applicable to all US applications. The US-APWR OER will be completed 12/2008. The resolution of any HEDs identified by that OER will be reflected in the final Basic HSI System which will be documented in a revision to this Topical Report, by 06/2009. The basis for all changes to the Basic HSI System currently documented in this Topical Report will be explained.

Follow-up RAI:
The response does not provide details describing what kind of findings were obtained in the Japanese OER, or how they were resolved. The Japanese HFE process, including the OER, has not been certified as a process that can be referenced in a US application.

The information provided by MHI in the Topical Report and the response to the RAI is unacceptable in addressing the information requested by the staff for RAI 18.0-28. Please provide the detailed information describing what kind of findings were obtained in the Japanese OER and how they were resolved.

Follow-up RAI to RAI 18.0-**30**

Functional Requirements and Functional Allocation is described in Section 5.3 of the topical report. NUREG-0711, Rev. 2 states that “Functional requirements analysis and function allocation should be performed using a structured, documented methodology reflecting HFE principles.” The topical report illustrates the hierarchical structure of plant functions and describes some rules for the application of automation (pp. 100 – 103), but no detail is provided on the methodology employed to perform the functional analysis and allocation and there is no explanation of the basis for developing the rules. Please provide detail on the methodology that was employed to perform the functional analysis and allocation and the basis for developing rules used for function allocation.

MHI Response:
As stated in Section 5.3 " ...the functions and allocations are based primarily on historical practices ... Therefore the focus of this HFE effort is to identify any changes from historical practices (i.e., a detailed evaluation of unchanged practices is not ... conducted)." Therefore, the following will be added to Section 5.3: "The report for this element identifies all function allocation changes from the reference plant, including the

reason for those changes and technical justification regarding human performance in accordance with the methodology and criteria described in Sections 5.3.1 and 5.3.2." MHI plans to complete the FRA/FA of the US-APWR by the 6/2009 as shown in Attachment-I.

For an operating plant, the FA will start with what exists at the plant today. This HFE program element will only analyze changes, which may be none. New HSI does not always result in function allocation changes.

Follow-up RAI:
The response indicates that FRA/FA has not been completed for the US plant, and simply stating that FRA/FA is based on "historical practices" does not allow evaluation of **how** the FRA/FA was completed for the Japanese reference plant. The Japanese HFE process, including the FRA/FA, has not been certified as a process that can be referenced in a US application. The information provided by MHI in the Topical Report and the response to the RAI is unacceptable in addressing the information requested by the staff for RAI 18.0-30.

Will the completed FRA/FA technical information include both the Japanese (reference plant) FRA/FA, and the differences between that plants FRA/FA and the US-APWR's FRA/FA?

Follow-up RAI to RAI 18.0-**31**

NUREG-0711, Rev. 2 states that plant functions and systems be described in detail, including the technical basis for all function allocations (see NUREG 0711 Functional Requirements and Functional Allocation criteria 3 – 6). Please detail the implementation plan for the types of content that will addressed for functional analysis and allocation.

MHI Response:
See response 18.0-30

Follow-up RAI:
RAI response 18.0-30 is unacceptable and is not a satisfactory response for RAI 18.0-31. Please detail the implementation plan for the types of content that will be addressed for functional analysis and allocation.

Follow-up RAI to RAI 18.0-**32**

NUREG-0711, Rev. 2 states that the allocation analysis consider the responsibility of personnel to monitor automatic functions and to assume control in the event of an automatic system failure (p. 22, criterion 8). The general rules for automation articulated on pages 100 – 101 of the topical report emphasize task frequency, repetitiveness, workload and accuracy. There is no discussion of the need for operators to maintain situational awareness of automated system performance. Please describe the plan for analysis of this issue.

MHI Response:
MHI uses the function analysis element to define the allocation between manual operations and automation.

For critical automated functions, situation awareness is assured through the identification of the Minimum Inventory of SDCV indications and alarms, as described in section 4.12.d. The SDCV Minimum Inventory is identified through the Task Analysis, as stated in Section 5.4.2 "...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".

Follow-up RAI:
While SDCV indications and alarms can potentially be one way to support situation awareness, information should be provided that details a plan for analyzing situation awareness, a property of the human operators, not a property of the technology in the control room. For instance how, with MHI, do situational awareness analyses provide information about how operators could dynamically infer the proper functioning of automated systems that may not have exceeded alarm threshold limits? Please provide detailed clarifying information describing the plan for operator situational awareness of automated system performance.

Follow-up RAI to RAI 18.0-**37**

The Detailed level Task Analysis Method is described, based on the goals, operators, methods, and selection rules (GOMS) model (p. 107 – 108). This model provides useful distinctions between perception, cognition and motion, but the staff is unclear as to the value of the timing analysis. If applied to the range of tasks required for full analysis of the plant design, it seems that this could easily overwhelm the human factors team, and it is not clear how the analysis is related to the NUREG-0711, Rev. 2 criteria. Please clarify the value provided by the GOMS timing analysis, how the resulting data will be used, and how it fulfills the NUREG-0711, Rev. 2 criteria for Task Analysis.

MHI Response:
The following descriptions to Section 5.4.3.2 will be added; GOMS is used only for tasks that meet all of the following criteria:

1. Significant changes from the reference design or tasks where there is no operating history in the reference design.
2. Where the tasks are identified as risk significant through the HRA element.
3. Where the task is time critical.

GOMS is a technique similar to operational sequence diagrams. The GOMS analysis is based on preliminary operating procedures.

MHI plans to execute all task analysis for the US-APWR based on differences from the Japanese standard PWR. The GOMS analysis assumes the number of crew members to be one licensed-SRO and one licensed-RO and based on the minimum staffing for the US-APWR. Cognitive workload can be estimated to determine the HSI inventory of alarms, displays, and controls necessary to perform crew tasks.

Follow-up RAI:
MHI's response does not address the information requested by the staff. Please give detailed information clarifying the value provided by the GOMS timing analysis, and how it fulfills the NUREG-0711, Rev. 2 criteria for Task Analysis.

Follow-up RAI to RAI 18.0-**38**

MHI states in the Staffing and Qualifications section that the "Final Staffing and Qualification requirements depend on the operating utility's applications; therefore it is a Combined License applicant responsibility." While it is appropriate that the COL applicant be responsible for the final staffing and qualifications analysis and results, MHI does define minimum and maximum operating staff in this topical report. The discussion of numbers of operating staff in Section 5.5.2 bases the minimum and maximum numbers on NRC regulations – there is no analysis described to determine the numbers of operating staff needed to operate a US-APWR plant safely in a full range of plant conditions, which could conceivably be higher than that required by NRC regulations. Will MHI conduct a full staffing analysis for operating staff? Does MHI expect that the operating staff analysis carried out by COL applicants must comply with the results for minimum and maximum operating staff presented in this report?

MHI Response:
The following will be added to Section 5.5: "The plant specific report for the Staffing and Qualifications program element will define the staffing and qualifications for personnel that perform operations or maintenance tasks directly related to plant safety. The report will define the basis for the staffing numbers and qualification requirements, with justification for changes from the reference plant. Staffing will be confirmed through Task Analysis and V&V program elements."

MHI expects applicants to comply with the minimum and maximum operating staffing defined in this report, or to conduct additional Task Analysis and V&V to justify the changes.

Follow-up RAI:
MHI's response refers to providing justification for changes to staffing numbers and qualification requirements from the reference plant. What is the reference plant?

MHI's response does not provide information that addresses the staff's request. Was an operating staff analysis carried out to determine the minimum and maximum staff defined in the Topical Report? If so, please describe the operating staff analysis methodology that was used.

Follow-up RAI to RAI 18.0-**40**

MHI provides no discussion of how risk-important human actions will be identified from the probabilistic risk analysis (PRA)/HRA and how these risk-important human actions will be used as input to the HFE design. There is a process flow figure (Figure 5.6-1) that shows PRA and HRA as individual items in the process flow and both PRA and HRA appear to have inputs into the gross-level task analysis, but there is no explanation of this figure, so any conclusions about how PRA and HRA fits into the overall HFE process are uncertain. Please provide detail on how risk-important human actions will be identified in a way that will provide reasonable assurance that important actions are not overlooked and how results of the PRA/HRA will be used as input into the HFE design process.

MHI Response:
Risk important human actions are identified in the PRA. The methods used by the PRA analysis to identify these actions is not within the scope of this HFE element, and therefore not explained in this Topical Report. MHI would expect the NRC to conduct a thorough review of each plant specific PRA to ensure risk significant human actions are appropriately identified.

The scope of this HFE element is to ensure that for those human actions that are identified in the PRA as risk significant, the appropriate probability of human error is defined. As stated in Section 5.6.4 "HRA sheets are prepared for tasks corresponding to risk important HAs." In addition, this element ensures that these risk-significant human actions are considered in each HFE program element to ensure the HSI design has minimized the probability of human error for these risk significant human actions. Risk-important human error analysis has been done in the US-APWR PRA, and will be evaluated internally with the modifications of the design.

The HRA for the US-APWR will be completed by 6/2009.

Follow-up RAI:
The information provided by MHI in the Topical Report and the response to the RAI is unacceptable in clarifying the HRA plan.

The response indicates that the methods for identifying risk-important human actions from the PRA are not within the scope of the HRA element. Per NUREG-071, Rev. 2 Section 7.4(1), risk-important human actions should be identified from the PRA/HRA and used as input to the HFE design effort. The methodology used by the PRA/HRA analysis to identify these risk-important HAs is within the scope of this HFE element.

Please provide sufficient detail on **how** results of the PRA/HRA will be used as input into the HFE design process.

Follow-up RAI to RAI 18.0-**42**

There is some discussion of how risk-important HAs and associated tasks and scenarios as identified by the PRA/HRA will be addressed during function allocation analyses, task analyses, HSI design, procedure development, and training. MHI does state that a human factors engineer and systems safety engineer will be members of the procedure development team and will provide PRA/HRA results and that the procedure content will incorporate "important human actions." MHI also states that HAs that have been identified as risk-significant by the PRA will be considered in the task analysis, however there is no discussion of how the identified HAs will be used as part of the task analysis. In addition, MHI states that the results of the PRA and HRA will be used as inputs to the HSI design process but no detail is provided on how the PRA/HRA results will be used for HSI design. Please provide detail on how risk-important Has and associated tasks and scenarios as identified by the PRA/HRA will be addressed during function allocation analyses, task analyses, HSI design, procedure development, and training.

MHI Response:
During functional allocation, automation is evaluated for risk significant HAs.

For tasks that remain allocated to human actions, the Task analysis assesses the workload for these HAs. In order to reduce the workload, staffing changes, HSI design improvement, operation procedure improvement and/or training improvement are assessed in subsequent program elements. The result of HSI design and staffing changes are confirmed during HSI V&V activities. V&V activities also confirm the assumptions made during preparation of the HRA sheets. Risk significant HAs are specifically tracked and discussed in each program element report. This is ensured through the HFE implementation procedure and the QA review process.

Follow-up RAI:
MHI's response does not provide sufficient detail in describing **how** risk-important HAs and associated tasks and scenarios as identified by the PRA/HRA will be addressed during other HFE program elements. For instance, how will automation be evaluated for risk-important HAs in the function allocation analysis? Also, for instance, how does the task analysis assess workload for risk-important HAs?

Follow-up RAI to RAI 18.0-**43**

There is little discussion of how HSI design, procedure development, and training design will be used to address risk-important HAs, as identified by PRA/HRA results, to minimize the likelihood of operator error and provide for error detection and recovery capability. MHI does state that the HRA will be used as an input to the training development program to reduce the likelihood and consequences of errors from risk-important HAs, but there are no specifics on how the HRA will be used for this. Please provide detail on how the HFE process for HSI design, procedure development, and training design will be used to address risk-important HAs, as identified by PRA/HRA results, to minimize the likelihood of operator error and provide for error detection and recovery capability.

MHI Response:
Please see response on RAI 18.0-42.

Follow-up RAI:
MHI's response simply refers to the response to RAI 18-42. The response to RAI 18.0-42 does not address the information requested by the staff for RAI 18.0-43. Please provide detailed information describing **how** the HFE process for HSI design, procedure development, and training design will be used to address risk-important HAs, as identified by PRA/HRA results, to minimize the likelihood of operator error and provide for error detection and recovery capability.

Follow-up RAI to RAI 18.0-**44**

There is no discussion of how identified HRA assumptions will be validated. HRA assumptions may be validated by walkthrough analyses with personnel with operational experience using a control room mockup or simulator. Please provide detail on how identified HRA assumptions will be validated.

MHI Response:
HRA assumptions will be validated in the V&V stage. In the early design stage, they are verified using a static display navigation system with walkthrough and display selections analyses. In the final design stage, they are validated through operability testing using a US-APWR simulator with licensed plant operations personnel.

Follow-up RAI:
The staff does not understand MHI's response. MHI states that HRA assumptions will be validated in the V&V stage and MHI states the HRA assumptions will be validated in the Design stage. Are the HRA assumptions validated in both the Design and V&V stages?

The response does not provide sufficient detail. The methodology for HRA assumption validation in the V&V stage is not described. The methodology for HRA assumption validation in the design stage does not significantly describe the methodology used.

Follow-up RAI to RAI 18.0-**45**

MHI does not state that procedures for US-APWR will address applicable requirements of NUREG-0800, "Standard Review Plan for Review of Safety Analysis Reports for Nuclear Power Plants," Section 13.5. What is MHI's plan for making sure that procedures will address applicable requirements of NUREG-0800, Section 13.5?

MHI Response:
This element ensures appropriate HFE principals and HFE Design Team engagement in the development of operating procedures. Conformances to the specific requirements of NUREG-0800 are assured through HFE Design Team participation in the development of the procedure writer's guide, and verification of the

operating procedures by the HFE V&V Team.

Follow-up RAI:
The response does not significantly describe the methodology used to ensure that procedures will address applicable requirements of NUREG-0800, Section 13.5. Please clarify in greater detail what MHI's plan is for making sure that procedures will address applicable requirements of NUREG-0800, Section 13.5.

Follow-up RAI to RAI 18.0-**46**

Though MHI states the task analysis results will provide the basis and input for procedure development (Sections 5.4.1, 5.4.2) and that members of the procedures development team will be responsible for providing tasks analysis results and results from the PRA/HRA on risk-important human actions (Section 5.8.2), there is no detail on what the basis for procedure development will include. Please provide detail on what will provide the basis for procedure development.

MHI Response:
Procedures are based on the procedures from the reference plant. Changes to those procedures are technically justified based on plant design documentation. Procedures are an integral part of the HSI system, therefore they are included in the V&V process.

Follow-up RAI:
The response indicates that procedures are based on procedures from the reference plant, but there is no definition of what the reference plant is. Procedures from a plant referenced by US-APWR licensing documentation shall be approved by the NRC. The information provided by MHI in the Topical Report and the response to the RAI is unacceptable in clarifying the basis for procedure development. Please provide detailed information describing what will provide the basis for procedure development.

Follow-up RAI to RAI 18.0-**50**

In the discussion of emergency operating procedures (EOPs) in Section 5.8.1.b, MHI list two types of procedures: event-based and symptom-based. There is no explanation given for event-based versus symptom-based procedures other than the types of events and safety functions they address. Typically, event-based procedures use entry conditions that are based on the origin of an event, while symptom-based procedures use entry conditions that are based on indirect, observable effects of an event. Please detail how entry conditions for EOPs will be determined and, if there are different kinds of entry conditions for event-based procedures versus symptom-based procedures, please explain what the differences are.

MHI Response:
This document does not explain "event based" and "symptom based" since these are well understood terms in the nuclear industry. MHI does not intend to change these philosophies for the US-APWR or for operating plants. Reference plant procedures will be modified only to accommodate the new HSI, not to change the approach to event mitigation

Follow-up RAI:
The information provided in the response does not address the RAI. Entry conditions for EOPs should be symptom-based. The information provided by MHI in the Topical Report and the response to the RAI is unacceptable in clarifying the entry conditions for EOPs.

Have Generic Technical Guidelines (GTGs) been developed for the reference plant? Information should be described here… are these available for review? What are the differences between reference plant and US-APWR?

Follow-up RAI to RAI 18.0-**51**

Little detail is given on how procedures will be verified and validated. MHI states that the procedures will be validated in an integrated system validation, but there is no description of an integrated system validation as described in NUREG-0711, Rev. 2 Section 11, which should involve the use of a simulator or other representation of the integrated system. Please explain how the process to verify and validate procedures will address how procedures will be verified that they are correct and can be carried out, how the final validation of procedures will be realized using an integrated system simulation, and how modified procedures will be verified with respect to content, format, integration, and effect on personnel tasks significant to plant safety.

MHI Response:
Section 5.8.2 states "The procedures are ... validated and finalized in the integrated system validation described in section 5.10." Section 5.10.2.1.b describes the personnel tasks that are included in the Integrated validation, including "... tasks that are well defined by normal, abnormal, emergency, alarm response, and test procedures". Section 5.10.2.2.4.b states "The validation test facility ... is a full scale HSI mockup with a full-scope simulator." Section 5.10.2.2.2 will be clarified as follows: "5.10.2.2.2 HSI task support verification confirms that the HSI provides all alarms, information, control and procedures required for personnel tasks."

Follow-up RAI:
The response does not provide sufficient detail to give the staff reasonable assurance that the HFE process will address how procedures will be verified that they are correct and can be carried out, how the final validation of procedures will be realized using an integrated system simulation, and how modified procedures will be verified with respect to content, format, integration, and effect on personnel tasks significant to plant safety.

Please provide the detailed information requested in RAI 18.0-51.

Follow-up RAI to RAI 18.0-**52**

In the topical report, MHI describes a computer-based operating procedure (CBP) system for use in the US-APWR HSI design. There is no description of the process used to derive and evaluate the computer-based procedure system. Please explain the process through which the impacts of providing procedures by computer will be identified, how justifications for the use of CBPs over paper-based procedures will be documented, and how an analysis of the loss of CBPs will be performed and documented.

MHI Response:
The process for developing the computerized procedure system was the same as the process for all other features of the Japanese HSI System. The computerized procedures are evaluated through the HSI V&V process using a full-scale plant simulator, as explained above. The V&V encompasses use of the computer based procedure system during normal and abnormal plant conditions and all degraded HSI conditions, including loss of the electronic procedures. As stated in Section 5.8.1.b "Emergency procedures consider the degraded HSI conditions described in Section 4.11. Section 4.11.3 states "The criteria based on the operational needs are mainly defined by determining the minimum information and controls required to execute paper-based Emergency Operating Procedures (EOP)."

Follow-up RAI:
The response does not provide sufficient detail to give the staff reasonable assurance that the HFE process will identify the impacts of providing procedures by computer, document justifications for the use of CBPs over paper-based procedures, and analyze and document impact of the loss of CBPs.

Please provide the detailed clarifying information requested in RAI 18.0-52.

Follow-up RAI to RAI 18.0-**54**

No description is given of a plan for evaluating physical means through which procedures will be accessed and used. Please detail a plan for evaluating physical means through which procedures will be accessed and used.

MHI Response:
MHI plans both computer-based procedures, and backup paper based procedures for degraded HSI conditions. As described in Section 4.8, computer based procedures may be accessed from links on the Alarm VDU or Operational VDU. They may also be accessed directly through the Index window as shown in Figure 4.8-1 and Table 4.8-1. The following will be added to Section 4.8 "Backup paper procedures for the degraded HSI conditions described in Section 4.11 will be easily accessed from storage facilities in the MCR and RSR."

Follow-up RAI:
MHI's response should give more specific detail on how procedures will be accessed and used. 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. The description in Section 4.8 and 4.11 does not give sufficient detail to address how procedures will be accessed and used.

Follow-up RAI to RAI 18.0-**55**

MHI mentions IAEA's Systematic Approach to Training, but it does not follow from the wording "is introduced" that this is the training program that will be adopted for US-APWR. MHI states that the training program for the HSI system will be developed in accordance with the NEI technical report "Template for an Industry Training Program Description" (NEI 06-13), but this NEI report contains very little detail on the design of a training program. There is very little detail on the approach to training that MHI will design for US-APWR. Please explain the overall training approach for US-APWR.

MHI Response:
The following change will be made to Section 5.9.1: "The IAEA's Systematic Approach to Training (SAT) program will be followed and the following points are clarified ..." Since the training program is developed in cooperation with the training department of the COL or existing applicant, the details of the training program will be provided in plant licensing documentation.

Follow-up RAI:
The response references a training program “developed in cooperation with the training department of the COL or existing applicant.” The Topical Report does not specify that the training program will be developed in cooperation with the training department of the COL applicant. What is meant by the “existing applicant?”

Follow-up RAI to RAI 18.0-**58**

While MHI does state that HFE Design Team will provide input to training program's learning objectives, there is no description of what organizations will be responsible for the development and implementation of the training program. Please explain the roles of the organizations responsible for the training program development and implementation.

MHI Response:
The training program is developed in cooperation with the training department of the COL or existing applicant. MHI provides all plant documentation which establishes the basis for the training program. This includes Electrical and Mechanical Flow Diagrams, Functional Diagrams, Tech Manuals, Design Bases Documents, Setpoint and operating range documents, and accident analysis. The actual division of responsibility for development and presentation of the training material will be documented in the plant specific training program report.

Follow-up RAI:
The response adequately clarifies roles of organizations in the training program.

The items identified in the response that are cited as basis for the training program are inadequate as a basis. The basis for the training program should also include Licensing Basis, the OER, the FRA/FA, the Task Analysis, the HRA, the HSI Design, Plant Procedures, and V&V (c.f. NUREG-0711, rev. 2, 10.4.3(1) on Learning Objectives). Please clarify the basis for training program.

Follow-up RAI to RAI 18.0-**59**

While MHI provides some detail on qualification of training instructors, there is no detail on the qualification required of organizations and personnel for training program development. While MHI lists some of qualifications required for instructors, the detail provided is not very specific. It is unclear what is meant by some of the required skills and qualifications that are listed and how would these be used to ensure that an instructor had the required qualifications. For example, one of the qualifications listed is "working experience," but there is no explanation of type of work the instructor should have had experience. Also, for example, are the listed "assessment" items assessments that the instructor should be able to do or assessments that will be used to make sure the instructor is qualified? If these are assessments of the instructor qualifications, qualifications should include the acceptance criteria for the assessments. Qualifications for personnel and organizations should be verifiable criteria for experience, education (for personnel), skills, and capabilities for the development and conduct of training. Please detail the qualification criteria for the organizations and personnel involved in the development and conduct of training.

MHI Response:
The NEI 06-13A Template for training program describes qualification criteria for the organizations and personnel involved in the development and conduct of training. Since the training program is developed in cooperation with the training department of the COL or existing applicant, the details of the training program will be provided in plant specific documentation.

Follow-up RAI:
The staff reviewed the Reference COL applicant's FSAR which references the US-APWR design. The Training Program element of the COL was incorporated by reference with no departures (IBR). Information on the development of the training program was not provided in the COL applicant's application.

MHI states that the training program is developed in cooperation with the training department of the COL applicant, and that the details of the training program will be provided in plant specific documentation. Please clarify which aspects of the training program will be developed by MHI and which will be developed by the COL applicant.

Follow-up RAI to RAI 18.0-**60**

The section on the operator training simulator fidelity (5.9.2) does not address the guidance contained in Regulatory Guide 1.149 “Nuclear Power Plant Simulation Facilities for Use in Operator Training and License Examinations,” Revision 3. ANSI/ANS 3.5 does not provide requirements on simulator fidelity only but also provides requirements for simulator functional capabilities, performance, and scope. MHI does not address many of the requirements stated in ANSI/ANS 3.5-1998.

It is unclear what is meant by the statement "Simulator's MCR and RSS console and their HSI system does not deviate from those of the reference." What does not deviate from the reference?

ANSI/ANS 3.5-1998 requires that many PWR parameters match reference unit data with 1% of the reference unit instrument loop range. MHI states that “The major PWR parameter (RCS flow, SG steam flow, SG feed flow, Charging flow, etc.,) match reference unit data within 2% of the reference unit instrument loop range." While this satisfies ANSI/ANS 3.5-1998 requirements for the specific parameters listed, use of "etc." does not sufficiently qualify which parameters will be will not be within a 1 percent tolerance of the reference.

MHI states that the "Instructor is able to use training simulator's basic functions (initialization, switch, check, freeze/run, snapshot, slow time/fast time, recorder power off, emergency power off, backtrack, record/replay, annunciator control, etc.,)." This list does not include all the instructor capabilities the simulator should support under ANSI/ANS 3.5-1998 requirements, including, for instance, the capabilities to replicate malfunctions and reproduce operator actions. Use of "etc." does not sufficiently qualify which instructor capabilities the training simulator will support.

Please provide detail on the 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 Regulatory Guide 1.149.

MHI Response:
The following will be added to Section 5.9.2: "The training simulator meets the requirements of Regulatory Guide 1.149 "Nuclear Power Plant Simulation Facilities for Use in Operator Training and License Examinations,"

The statement "Simulator's MCR and RSS console and their HSI system does not deviate from those of the reference." is simply restating the ANS 3.5 requirement that the simulator replicate the reference unit. Section 5.9.2 will be revised as follows:
"The following parameters will match the reference unit data within 1%:

- Temperature (T) average
- T-hot
- T-cold
- MWe
- Power range nuclear instrumentation readings

- Reactor coolant system pressure
- Steam generator pressure
- Pressurizer level.

The following parameters will match the reference unit data within 2%:

- Steam generator feeds flow
- Reactor coolant system flow
- Steam generator level
- Letdown flow
- Charging flow
- Steam flow
- Turbine first stage pressure."

Subsection 5.9.2 is not intended to be a specification for the training simulator fidelity. It is only intended to exemplify the fidelity that will be included. Subsection 5.9.2 will be revised as follows: Training simulator satisfies the requirements addressed in ANSI/ANS 3.5, including: .... Instructor is able to use training simulator's basic functions, such as ... "This is not intended to be a simulator specification" (see response above).

Follow-up RAI:
The RAI asked MHI to provide detail on the-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 Regulatory Guide 1.149. The response describes the training simulator only. Please clarify if there are other facilities and resources for training besides the training simulator referred to in the topical report. If there are other training facilities and resources, please identify and define them.

Follow-up RAI to RAI 18.0-**64**

MHI does not describe a plan for the evaluation and modification of training. Please detail a plan for the evaluation and modification of training.

MHI Response:
Section 5.9.6 "Training Program Modifications" will be added, as follow: "Training program modifications include development of new or revised training material, changes in instructing techniques or changes in the frequency of training. Modifications to the training program, may result from: (1) HEDs identified during validation, as discussed in Section 5.10.2.2.5, (2) design changes, which are addressed in Section 5.11, or (3) from the evaluation of human performance, which is addressed in Section 5.12. Training program changes will be implemented using the same process as the development of the original training program."

Follow-up RAI:
MHI’s response does not provide adequate detail. The response states: “Training program changes will be

implemented using the same process as the development of the original training program." Since a level of detail on the original training that is adequate for staff review is not provided, the staff cannot evaluate the training modification plan.

Please clarify, what is the “original training plan?”

Follow-up RAI to RAI 18.0-**65**

MHI does not describe a plan for periodic retraining. Please detail a plan for periodic retraining of personnel, including how the potential necessity of changes or increases in retraining will be evaluated following replacement of HSI systems in operating plants.

MHI Response:
See the response to 18.0-64.

Follow-up RAI:
The response simply refers to the response to RAI 18.0-64. Please provide detailed information describing the periodic retraining plan.

Follow-up RAI to RAI 18.0-**66**

There seems to be conflicting information in the report about what analyses will be used to identify HSI requirements. Though it is stated in a section titled "Scope of HSI Design" that the OER, functional analysis and function allocation, task analysis, and staffing analysis stages of the HFE process will be used to identify HSI requirements, in a section entitled "Input Information to HSI Design Process" MHI states, "The output of the preceding process is input for the HSI design process. Input information includes functional requirement of operation, result of PRA, result of HRA, performance requirement for personnel, various regulatory requirement." It is unclear what is being referred to by the "preceding process" – i.e. what is the "preceding process"? In HFE process flow figure presented in the HRA section of the report (Figure 5.6-1), the only HFE program element feeding into the HSI design element is the Staffing & Qualification element – though it may be that this figure was not intended to provide detail on inputs into the HSI design.

Because of these conflicting statements and the lack of detail on the process through which HSI requirements will be identified, it is unclear how MHI intends to identify HSI requirements. Requirements for the HSIs should be identified from the OER, the functional requirement analysis and function allocation, the task analysis, and staffing/qualifications and job analyses. In addition, risk-important human actions, as identified by the PRA/HRA, should be addressed by the HSI design. Please provide detail on how requirements for the HSIs will be identified from the OER, the functional requirement analysis and function allocation, the task analysis, staffing/qualifications and job analyses, and risk-important human actions identified from the PRA/HRA.

MHI Response:
Section 5.7.2 "Scope of HSI Design" will be revised as follows: "The HFE program encompasses the HSI used by operators and operations support personnel in the MCR, RSR, TSC and EOF. In addition, the program encompasses HSI in local areas of the plant which supports:

- On-line testing, radiological protection activities, and required chemical monitoring supporting technical specifications
- Maintenance required by technical specifications
- Emergency and abnormal conditions response"

The sources of input to the HSI design process currently in Section 5.7.2 will be moved to 5.7.3.1, with clarification that all previous HFE program elements provide input to the HSI design. In addition, the following will be added to Section 5.7.3.1:
"Issues from all program elements that may impact the basic HSI design features, as described in Section 4, are entered into the HFE Issues Tracking System. These issues are tracked to closure through completion of the HSI design process. Other outputs of previous program elements provide input to development of the plant specific HSI inventory (i.e., alarms, indications, controls, and procedures)."

The detailed HSI design plan is a plant specific document. For example, for the US-APWR the HSI Design Program element is described in DCD Section 18.7. This plan includes generation of an HSI Design Report, which summarizes the HSI design process and design description. For the US-APWR this report is an ITAAC commitment.

Follow-up RAI:
Little detail is provided in the response on the process the MHI will use for identifying requirements for each of the previous analyses. Please provide greater detail on how requirements for the HSIs will be identified.

Follow-up RAI to RAI 18.0-**67**

Analysis of personnel task requirements is described in Sections 5.7.2 and 5.7.3.1. There is nothing added in the topical report over the high-level criteria provided in NUREG-0711, Rev. 2 for MHI's plan for implementing personnel task requirements analysis. Please provide details on how identified task requirements will be used to identify HSI requirements.

MHI Response:
The task analysis generates the HSI inventory, including the HSI design characteristics of that inventory, necessary to support personnel task requirements. See the response to 18.0-36.

Follow-up RAI:
Personnel task requirements should be identified from the OER, the FRA/FA, the Task Analysis, and staffing/qualifications and job analyses. Please clarify how the task analysis generates the HSI inventory and its design characteristics, and how the HSI inventory support personnel task requirements.

Follow-up RAI to RAI 18.0-**68**

MHI states in Section 5.7.2 that constraints imposed by the overall I&C system will be considered throughout the design process, but no detail is provided on how the overall I&C system constraints will be considered throughout the design process. Please provide detail on how the constraints imposed by the overall I&C system will be considered throughout the design process.

MHI Response:
This section will be revised as follows: "Constraints imposed by the overall instrumentation and control (I&C) system are considered throughout the HSI design process. These constraints are understood by the HSI design team based on the interdisciplinary skills and training identified in Section 5.1.2.2." The following will be added to Section 5.1.2.2: "The Design Team and V&V Team are trained in the constraints of the overall I&C design."

Follow-up RAI:
There is no detail provided in the response on the process used to consider how constraints imposed on the overall I&C system will be considered. The response addresses the capability of the HSI design team, but not the processed used. Please provide detailed clarifying information on the process used to consider how constraints imposed on the overall I&C system will be considered.

Follow-up RAI to RAI 18.0-**69**

MHI states in Section 5.7.2 that applicable regulatory requirements will be identified for HSI design inputs, but no detail is provided on how applicable regulatory requirements will be identified or which regulatory requirements are relevant for HSI design inputs. Please provide detail on how applicable regulatory requirements will be identified and which regulatory requirements are relevant for HSI design inputs.

MHI Response:
The applicable regulatory requirements are described in Chapter 3 of the topical report. As stated in Section 5.1 "The overall goal of the HFE program management is to ensure the HSI system ... satisfies all of the required regulatory requirements." Conformance to these requirements is assured through the interdisciplinary technical skills of the HFE Design Team and V&V Team.

Follow-up RAI:
There is no detail provided in the response on the process used to identify applicable regulatory requirements. Chapter 3 contains a listing of regulatory documents, codes, and standards with short descriptions of potentially relevant content. Please clarify in greater detail what design process MHI will use to identify and incorporate specific regulatory requirements.

Follow-up RAI to RAI 18.0-**70**

MHI states in Section 5.7.2 that other requirements will be identified for HSI design inputs, but no detail is provided on how other requirements will be identified or which requirements, other than those provided by other analyses in the design process, constraints imposed by the overall I&C system, and regulatory considerations, will be relevant for HSI design inputs. Please provide detail on how HSI design requirements other than those provided by other analyses in the design process, constraints imposed by the overall I&C system, and regulatory considerations will be identified.

MHI Response:
The following will be added to Section 5.7.2: "The concept of operations is encompassed by the functional requirements report and staffing report which are the output of Sections 5.3 and 5.5, respectively. These reports focus on changes from the reference design(s), which are determined primarily from the OER in Section 5.2. The Task Analysis from Section 5.4 is the primary input to design of the HSI inventory. That inventory is implemented within the HSI features, described in Section 4 and in accordance with the design details documented in the Style Guide. The style guide is developed based on historical practices, changes as needed per the OER, and in conformance to the guidance of NUREG-0700. HRA identifies the portion of the HSI design that requires special attention during all phases of the HFE program, including V&V. The HSI design is documented as described in Section 5.7.3.3. Testing and evaluation of the HSI design is described in the Verification and Validation phase of the HFE program, as described in Section 5.10."

Follow-up RAI:
There seems to be no direct treatment in MHI's response of how HSI design requirements other than those provided by other analyses in the design process, constraints imposed by the overall I&C system, and regulatory considerations will be identified. The response given is more programmatic than implementation plan level.

Please provide greater detail describing ***how*** HSI design requirements other than those provided by other analyses in the design process, constraints imposed by the overall I&C system, and regulatory considerations will be identified.

Follow-up RAI to RAI 18.0-**71**

Section 5.7.2, "Scope of HSI Design," is a restatement and précis of much of the detailed NUREG-0711, Rev. 2 review criteria for HSI design process. NUREG-0711, Rev. 2 provides detailed review criteria on a number of issues with respect to the HSI design process.

MHI provides no detail other than an overall description of computer display style guide topics. Please provide detail on the following:

- how a concept of operations will be developed and what it will describe,
- how functional requirements for the HSIs will be developed and which issues and HSI systems they will address,
- how the HSI designs will address functional requirements,

- how HSI concept designs will be developed, evaluated, and used to identify HSI design performance requirements,
- how detailed HSI designs will be specified through the use of a style guide, consideration of HSI design principals, risk-important HAs, and the many factors, conditions, analyses, tasks, etc. significant for HSI designs, as explained in the NUREG-0711, Rev. 2 review criteria
- how the style guide contents will be developed, what its overall content will be and how it will be used for HSI design,
- how design modifications will be addressed,
- how HSI designs will be tested and evaluated, including through trade-off evaluations and performance-based tests, and
- how the HSI designs will be documented.

MHI Response:
As stated in Section 5.3 "... the focus of functional requirements analysis is to identify any changes from historical practices (i.e., a detailed evaluation of unchanged practices is not ...conducted)." The following will be added to Section 5.3: "The function analysis and allocation report will document the function allocation for major plant functions, with the primary focus on functions of safety significance. Where the function allocation is different than historical practices the change is justified based on change drivers, the function allocation hierarchy described in Section 5.3.1, and the function allocation principles described in Section 5.3.2. Function allocation changes from historical practices are emphasized in all aspects of the HFE program, including V&V.

Follow-up RAI:
The response does not address concept of operations. The response focuses on the use of the functional allocation analysis, but not concept of operations. Please provide the necessary detailed information to satisfy the original 18.0-71 RAI.

Please specify which “historical practices” are being considered for FRA/FA, as referred to in the response.

Follow-up RAI to RAI 18.0-**72**

Functional requirements specification is described in Section 5.7.2. The description is a restatement of the high-level NUREG-0711, Rev. 2 criteria. Please provide detail on the process for specifying functional requirements for HSIs.

MHI Response:
Section 5.7.2 is intended only to explain how the functional requirements are used in development of the HSI design. The process for developing the functional requirements is described in Section 5.3.

Follow-up RAI:
Section 5.3 of the topical report describes functional requirements analysis (FRA) process, not the

specification of functions that the HSIs must support, which is different from the FRA. The FRA identifies functions that must be performed to satisfy plant safety. If the Function Allocation process allocates a function completely to system (i.e. totally automated) resources, that function does not need to be addressed by the HSI. Functional requirements specification of the HSI is a process of identifying the functionality that various types of HSIs (e.g. instrumentation, controls, and alarms) should provide. The topical report or the response to the RAI does not provide detail on the process for identifying the functionality that various types of HSIs should provide.

Please provide detail on the process for specifying the functional requirements for HSIs.

Follow-up RAI to RAI 18.0-**73**

Very little of the HSI concept design process is discussed in the topical report. Please provide detail on the HSI concept design process that satisfies the NUREG-0711, Rev. 2 criteria for review of an implementation plan.

MHI Response:
The following will be added to Section 5.7.3.2: "The specific alarms, indications, controls and procedures, which compose the HSI system, are designed based primarily on the HSI inventory requirements resulting from the Task Analysis and the HSI styled guide. The integrated components of the HSI system are verified and validated, as described in Section 5.10. Verification activities utilize static HSI simulation tools. Validation activities employ full scale dynamic simulators."

Follow-up RAI:
The response does not address the HSI concept design process. The RAI asked MHI to provide detail on the HSI concept design process that satisfies NUREG-0711, Rev. 2 criteria for review of an implementation plan.

Please address the NUREG-0711, Rev. 2 review criteria for an HSI concept design process implementation plan in greater detail.

Follow-up RAI to RAI 18.0-**74**

Except for a description of a style guide in Section 5.7.3.2, the HSI detailed design and integration process is not discussed in the topical report. Please provide detail on the HSI detailed design and integration process that satisfies the NUREG-0711, Rev. 2 criteria for review of an implementation plan, including criterion (10), considerations for review of design modifications.

MHI Response:
The following will be added to Section 5.7.3.2 "The specific alarms, indications, controls and procedures, which compose the HSI system, are designed based primarily on the HSI inventory requirements resulting from the Task Analysis and the HSI styled guide. The integrated components of the HSI system are verified and validated, as described in Section 5.10. Verification activities utilize static HSI simulation tools. Validation

activities employ full scale dynamic simulators."

Follow-up RAI:
The response does not address the HSI detailed design and integration process. The RAI asked MHI to provide detail on the HSI detailed design and integration process that satisfies NUREG-0711, Rev. 2 criteria for review of an HSI detailed design and integration process implementation plan.

Please provide detail information on the HSI detailed design and integration process that satisfies the NUREG-0711, Rev. 2 criteria for review of an implementation plan, including criterion (10), considerations for review of design modifications.

Follow-up RAI to RAI 18.0-**75**

In the topical report, MHI describes the general types of guidelines that the style guide for displays contains. MHI states "The style guide conforms to NUREG-0700." -- it is unclear what MHI means by this statement. Does this mean that the contents of the style guide is consistent with NUREG-0700, “Human System Interface Design Review Guidelines,” Revision 2, but could be a subset of the NUREG-0700 guidance? Are the style guide contents completely inclusive of NUREG-0700 guidance? Which revision of NUREG-0700 is referred to in this section of the topical report? Please provide detail on how the style guide will be developed, addressing criterion (1) in the HSI Detailed Design and Integration section of 0700, including, but not limited to, how the style guide will address HSI modifications.

MHI Response:
Section 3.5 references NUREG-0700. Section 3.0 states "Unless specifically noted, the latest version of the codes and standards issued as of the date of this document is the applicable one." Therefore, NUREG-0700 Revision 2 is the applicable reference. The following will be added to Section 5.7.3.2:

"The style guide encompasses the subset of NUREG-0700 guidance that is applicable to the HSI features described in Section 4." The following will be added to Section 5.11. "HSI modifications to a licensed design will utilize the HSI features described in Section 4. If there are changes to the basic HSI features described in Section 4, those changes will undergo a complete evaluation to determine what portions of the HFE program must be repeated. Effects on the HSI style guide will be included in this evaluation."

Follow-up RAI:
The response does not address how the style guide will be developed.

The response refers to NUREG-0700 Rev 2 as a code or standard -- it is neither a code nor standard. NUREG-0700 Rev 2 provides review guidelines used to evaluate HSI designs or design-specific HFE guidelines documents or style guides in accordance with NUREG-0800. It does not follow from the statement in Section 3.0 of the topical report that "Unless specifically noted, the latest version of the codes and standards issued as of the date of this document is the applicable one." applies to the NUREG-0700 version.

The information provided by MHI in the Topical Report and the response to the RAI is unacceptable in addressing the information requested by the staff for RAI 18.0-75. Please provide detailed clarifying information describing **how** the style guide will be developed, addressing criterion (1) in the HSI Detailed Design and Integration section of NUREG-0700, including, but not limited to, how the style guide will address HSI modifications.

Follow-up RAI to RAI 18.0-**76**

HSI tests and evaluations are described in Section 5.7.3.3. The NUREG-0711, Rev. 2 review criteria for HSI tests and evaluations are generally not addressed in the topical report. Please provide detail on the HSI test and evaluation methodologies, addressing the criteria in the HSI Tests and Evaluations section of NUREG-0700, including, but not limited to, how the HSI test and evaluation methodologies will address HSI modifications.

MHI Response:
HSI tests and evaluations are part of the V&V program described in Section 5.10. The V&V procedures and reports are plant specific documents which describe the test and evaluation details. The US-APWR DCD Section 18.10 exemplifies a plant specific V&V plan. That plan requires generation of V&V procedures and reports, which are plant specific documents.

Follow-up RAI:
HSI tests and evaluations should be carried out iteratively throughout the HSI design phase. Verification and validation is performed on a 'final', integrated design. The response does not address HSI tests and evaluation. The information provided by MHI in the Topical Report and the response to the RAI is unacceptable in addressing the information requested by the staff for RAI 18.0-76.

Please provide the detail on the HSI test and evaluation methodologies, addressing the criteria in the HSI Tests and Evaluations section of NUREG-0711, including, but not limited to, **how** the HSI test and evaluation methodologies will address HSI modifications.

Follow-up RAI to RAI 18.0-**77**

HSI design documentation is described in Section 5.7.3.3. The content of the topical report for HSI design documentation restates the NUREG-0711, Rev. 2 criteria. Please provide detail on the HSI design documentation process, addressing the criteria in the HSI Design Documentation section of NUREG-0700.

MHI Response:
The detailed HSI description including its form, function and performance characteristics are documented in the HSI design style guide. 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 are documented in the OER report, the HFE Design Report and the V&V Report.

Records for the basis of the design changes are documented in the HFE Issue Tracking system.

Follow-up RAI:
The response indicates that the HSI description is documented in the HSI design style guide. A HSI design style guide provides guidelines for the design but does not document a description of specific, detailed HSI design's form, function, and performance characteristics or the outcomes of tests and evaluations in support of HSI design. An OER analysis does not include literature analyses, tradeoff studies, engineering evaluations and experiments, and benchmark evaluations unless they refer to work done or issues identified related to the past performance of predecessor designs. Similarly, the V&V does not contain operating experience and literature analyses, tradeoff studies, engineering evaluations and experiments, and benchmark evaluations unless they refer to work done or issues identified related to the V&V. Please further clarify the HSI design documentation process as an activity that is part of the HSI design process.

Follow-up RAI to RAI 18.0-**78**

MHI's discussion of their Human Factors Verification and Validation plan is almost entirely a restatement and précis of much of the detailed NUREG-0711, Rev. 2 review criteria. NUREG-0711, Rev. 2 provides detailed review criteria on a number of issues with respect to the Human Factors Verification and Validation process. The NUREG-0711, Rev. 2 review criteria provides the detailed standards that will be used by NRC staff to verify that the applicant's proposed verification and validation methodologies include evaluations that determine if the final design will conform to HFE design principles and will enable personnel to successfully and safely achieve operational goals. The NUREG-0711, Rev. 2 review criteria indicate the verification and validation issues that the applicant's methodology must address, but does not explain or stipulate the methodologies the applicant will use. MHI should provide a detailed implementation plan that describes the human factors verification and validation methodologies that will be used for the US-APWR design. Please provide a plan for human factors verification and validation that describes the process and methodologies that will be used to determine if the final US-APWR design will conform to HFE design principles and will enable personnel to successfully and safely achieve operational goals.

MHI Response:
The V&V program is largely determined based on the extent of changes from the reference design. Therefore, the plan for human factors verification and validation is a plant specific licensing document. For example, the V&V plan for the US-APWR, which consists of two phases, is described in Section 18.10 of the DCD. Plant specific documents also include V&V procedures and reports. US-APWR Phase 1a V&V procedures are currently in use for the Phase 1 a portion of the V&V program. The US-APWR Phase 1 a V&V report will be issued by 12/2008. The Phase lb V&V report will be issued 6/2009.

Follow-up RAI:
The information provided by MHI in the Topical Report and the response to the RAI is unacceptable in clarifying the V&V plan.

The response indicates that the V&V program is based on changes from a reference design. A V&V program should be carried out on the final design and should not only include changes from a reference design. If a reference design is used, the V&V program should be carried out on the reference design and the V&V implementation plan and results for the reference design should be described. If the reference design is a design that has been certified by the NRC then the V&V program and results can be referenced by the applicant in addition to providing a description of the V&V program and results on the changes from the reference design.

Please provide a detailed plan for human factors verification and validation that describes the process and methodologies that will be used to determine if the final US-APWR design will conform to HFE design principles and will enable personnel to successfully and safely achieve operational goals.

Follow-up RAI to RAI 18.0-**79**

MHI lists some variables to be measured for Integrated System Validation but there is no explanation of the necessary detail required to address NUREG-0711, Rev. 2 review criteria. For the Performance Measurement activity of the Integrated System Validation, please explain what aspects of plant and personnel performance will be evaluated using the proposed measures, what the quality characteristics of these measures are, which of these measures will be used as "pass/fail" criteria for validation, which will be used for more thorough understanding and analysis of performance and errors, which measures will be sufficient for assessment of primary tasks, and which measures will be sufficient for assessment of secondary tasks.

MHI Response:
Performance measures are based primarily on the validation event scenarios, therefore these are documented in the plant specific validation procedure. For example, for the US-APWR a key performance measure will be the operator response time for time critical manual actions in response to plant Anticipated Operation Occurrences and Postulated Accidents with concurrent common cause failure of digital I&C systems.

Follow-up RAI:
The “plant specific validation procedure” referred to in the response is not identified and its role in the V&V program is not explained.

Based on the MHI response the “plant specific validation procedure” contains details of the performance measurement characteristics, selection, and criteria, detail. Therefore, please provide the “plant specific validation procedure” or provide the detailed information that is in the procedure to address RAI 18.0-79 for staff review.

Follow-up RAI to RAI 18.0-**80**

For Integrated System Validation measures of Situation Awareness and Cognitive Workload should reflect the current state-of-the-art. MHI states that video data and interviews of participants will be used for analysis of Situation Awareness and Cognitive Workload, but there is no explanation of how this data will be used and what specific measures will be derived from this data to assess Situation Awareness or Cognitive Workload. The reviewers are unaware of any general use of video data or interview data for Situation Awareness or Cognitive Workload measurement (with the exception of the use of eye movement video for measuring Cognitive Workload). Measures of Situation Awareness should reflect the state-of the-art, such as those found in the following references:

- Collier, S. G. & Folleso, K. (1995). SACRI: A measure of situation awareness for nuclear power plant control rooms. Proceedings of an International Conference: Experimental Analysis and Measurement of Situation Awareness (pp. 115-122). Daytona Beach, FL.
- Endsley, M. R. & Garland, D. J. (Eds.) (2000). Situation awareness analysis and measurement. Mahwah, NJ: Lawrence Erlbaum Associates.

Measures of Cognitive Workload should reflect the state-of-the-art, as well. Recent overviews of cognitive workload measurement techniques are found in the following:

- Megaw,,E.D., (2005) The definition and measurement of mental workload. In: J.R. Wilson and E.N. Corlett, Editors, Evaluation of Human Work (third ed), London, Taylor & Francis.
- Young, M. S. & Stanton, N. A. (2005) Mental workload. In N. A. Stanton et al (Eds.), Handbook of Human Factors and Ergonomics Methods, Boca Raton, FL, CRC Press.

Please explain what state-of-the-art methodologies will be used in measuring Situation Awareness and Cognitive Workload in the Integrated System Validation.

MHI Response:
Video will not be used for the evaluation of situation awareness or cognitive workload. Section 5.10.2.2.4e "Situation Awareness" will be modified as follows "As described in Section 4.1d, the primary purpose of the Large Display Panel (LDP) is to provide Spatially Dedicated Continuously Visible (SDCV) information to operation personnel to enhance situation awareness. One purpose of the Safety VDUs is to provide SDCV displays for accident monitoring, as described in Section 4.6.1. The content of the SDCV information on the LDP and Safety VDUs is determined based on industry and NRC guidance for SDCV Minimum Inventory, as described in Section 4.12d. The content and display style guide of the LDP and Safety VDUs will be verified and validated. Therefore, since the purpose of SDCV HSI is to achieve adequate situation awareness, and the HSI design meets the best available industry and NRC guidance for SDCV HSI, situation awareness will not be measured." Section 5.10.2.2.4e "Cognitive Workload" will be revised as follows "Cognitive workloads evaluated based on the method described in subsection 5.4.3.2."

Follow-up RAI:
The information provided by MHI in the Topical Report and the response to the RAI is unacceptable in addressing the information requested by the staff for RAI 18.0-80.

MHI states in the response that the “HSI design meets the best available industry and NRC guidance for SDCV HSI.” The LDP for the US-APWR has not been reviewed or certified by the NRC.

Also, the information provided with regards to the operational personnel’s situation awareness is not adequate. Please provide detailed information clarifying the V&V program methodology for measuring situation awareness.

Follow-up RAI to RAI 18.0-**81**

The MHI topical report provides very little detail concerning design implementation of the HFE aspects of the plant. NUREG-0711, Rev. 2 lists general and specific criteria associated with plant modernization and final plant HFE design verification. MHI simply states that ITAAC will be used to verify the HSI system, and that the criteria are to be included in the DCD submittal, and briefly addresses impact on Human Actions. Please detail the overall plan for design implementation for new and modernized plants. The information provided should address the specific criteria listed in NUREG-0711, Rev. 2, including, but not limited to, those addressing modernization programs.

MHI Response:
As stated in Section 5.11 "For new plants [such as the US-APWR] the ITAAC is used to confirm that the implemented HSI System is consistent with the validated HSI System. Inspections, Tests, Analysis, and Acceptance Criteria (ITAAC) are included in the DCD submittal. The Design Implementation Plan element of the HFE Program Model also applies to operating plant modernization." To clarify this point, the following will be added to Section 5.11: "Design implementation is addressed in plant specific licensing documentation."

Follow-up RAI:
The response is adequate for the US-APWR design, but not for modernization of existing plants. Please provide details describing how the HSIs will be implemented in existing plants.

Follow-up RAI to RAI 18.0-**83**

NUREG-0711, Rev. 2 describes five specific criteria for a human performance monitoring program. The MHI topical report does not specifically describe a human performance monitoring program – it simply describes the high-level criteria that the human performance monitoring program should address. Please provide detail on overall strategy for human performance monitoring. The information provided should address the specific criteria listed in NUREG-0711, Rev. 2.

MHI Response:
The following will be added to Section 5.12: "The human performance monitoring program is developed in cooperation with the training department of the COL or existing applicant. The human performance monitoring program will be described in plant licensing documentation."

Follow-up RAI:
The response uses the phrase “existing applicant.” What is meant by “existing applicant”?

Follow-up RAI to RAI 18.0-**85**

Table 4.0-1 lists "identifies additional program plan activities conducted for US applications" that were not" elements in the HFE program implemented for Japanese PWRs" (p. 11). For HFE Program Management MHI states that "MHI's design process conforms to NUREG-0711 normally. Additional documentation is required." It is unclear what is meant by "normally" in this sentence. MHI states that "Approach is same as Japanese PWR" for the following HFE program elements:

- Operating Experience Review
- Functional Requirements Analysis and Function Allocation
- Task Analysis
- Human Reliability Analysis
- HSI Design
- Procedure Development
- Human Factors Verification and Validation

It is unclear if MHI is stating that the implementation approach used for Japanese PWRs is adequate for US applications. For Staffing and Qualifications MHI states that "MHI proposes operation with one SRO and one RO in the MCR for compliance with 10 CFR 50.54." No other detail is provide that addresses whether other aspects of the Staffing and Qualifications element included in an implementation plan. MHI states that "Implementation plan is added" for the following HFE program elements:

- Training Program Development
- Design Implementation
- Human Performance Monitoring

MHI will need to provide evidence that all HFE program elements comply with US regulations. Please clarify which HFE program element implementation plans will be included as part of the DCD for US-APWR and replacement of current HSI systems in operating plants. Please indicate which of the plans have been completed.

MHI Response:
Table 4.0-1 will be revised as follows "MHI's design process conforms to NUREG-0711. However, additional documentation is required."

The intent of Table 4.0-1 is to identify for which program elements the HFE program for US applications will use the same design process as was previously conducted for the Japanese HSI System, or where there are differences. Where the approach is the same, MHI considers the design process used for the Japanese HSI

System to be adequate for US applications. This does not mean that the all Japanese program elements are directly applicable. All program elements are reassessed as described in the plant specific HFE program plan.

Table 4.0-1 provides only an applicability summary. The Staffing and Qualifications program element is described in Section 5.5.

As exemplified by Chapter 18 of the US-APWR DCD, plant specific licensing documentation will include program plans for all HFE program elements. The content of the plans will be focused on development of the plant specific HSI inventory and on changes from the Basic HSI System reference design, if necessary. The HFE program documentation for development of the Japanese HSI system is available for audit. However, as shown in Table 4.0-1, the Japanese program was not documented to the level of detail suggested in the guidance of NUREG071 1. Phase 1 of the US-APWR HFE program compensates for this documentation deficiency by conducting additional V&V for the Basic HSI System with US HFE experts and US operators. Additional V&V will be conducted in Phase 2 for the completely integrated US-APWR HSI System.

Follow-up RAI:
In the response MHI proposes adding the following text to Table 4.0-1:
"MHI's design process conforms to NUREG-0711. However, additional documentation is required."

NUREG-0711 is guidance for NRC reviewers and MHI's assertion that the "design process conforms to NUREG-0711" does not reflect the current findings of reviewing staff. It is also unclear what is meant by "MHI's design process" – does this refer to the design process used for the Japanese design, the US-APWR design, or both?

MHI states in the response that the HFE program used for the Japanese design "was not documented to the level of detail suggested in the guidance of NUREG0711" and that "Phase 1 of the US-APWR HFE program compensates for this documentation deficiency by conducting additional V&V for the Basic HSI System with US HFE experts and US operators." but there is no explanation of how the additional V&V in Phase 1 compensates for documentation deficiencies in the HFE program used for the Japanese design. Moreover, it is unclear what "compensates" means in this context – will MHI provide complete documentation of the HFE program for the US-APWR at a level of detail that will allow the NRC to review the methodologies used for the HFE program or will MHI provide documentation that addresses items not sufficiently addressed by the documentation of the HFE program used for the Japanese design?

Follow-up RAI to RAI 18.0-**86**

What aspects of MHI's HFE program will be COL items?

MHI Response:
The aspects of the HFE program that are outside the scope of approval for the DCD are documented in the Tier 1 ITAACs. ITAACs related to the Basic HSI System design will be completed during the DCD review process by MHI; these ITAACs will be removed. ITAACs related to the analysis that supports the development of the US-APWR HSI Inventory design (ie. FA, HRA and TA) will also be completed during the DCD review process; these ITAACs will also be removed. The ITAACs related to the remaining HFE analysis and design program elements will be completed during the first COL application review. ITAACs related to V&V of the completely integrated HSI System will be completed prior to fuel load. MHI is responsible for completing all ITAACs. However, some of these ITAACs are based on design assumptions for the portion of the site specific design which is outside the scope of the DCD (e.g., switchyard connections, ultimate heat sink). It is the responsibility of the COL applicant to verify these assumptions or implement a design change process for any assumptions that are not applicable to the site specific application. Site specific COL applicant actions are identified within each section of Chapter 18 of the US-APWR DCD.

Follow-up RAI:
This RAI requires clarification of the appropriateness of submitting the “Basic HSI System design” as part of the US-APWR design certification.

MHI states in the response “The ITAACs related to the remaining HFE analysis and design program elements will be completed during the first COL application review.” It is unspecified which HFE program elements MHI states are “remaining.” The response should provide more clarity about which HFE program elements are “remaining” for a COL application. Also this statement seems to be inconsistent with the statement that “MHI is responsible for completing all ITAACs.” Please provide additional clarifying information describing those aspects of MHI’s HFE program that will be COL items and those that are not.