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X/XX/2008

**US-APWR Design Certification**

**Mitsubishi Heavy Industries**

**Docket No.52-021**

**RAI NO.: NO.X REVISION X**

**SRP SECTION: 18 – Human Factors Engineering**

**APPLICATION SECTION: 18.0**

**DATE OF RAI ISSUE: X/XX/2008**

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**QUESTION NO. : 18.0-1**

**Clarify the applicability to operating plants.**

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.

#### **ANSWER:**

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.

#### **Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**Question No. : 18.0-2**

**Clarify the HSI system design aspects for which MHI seeks NRC approval.**

It is unclear what aspects of the HSI system MHI seeks approval for and what MHI means by "HSI system." In the Abstract of the topical report on page iii, MHI states that they seek approval of the US-APWR HSI system design. On page iv of the Abstract it is stated that "MHI specifically seeks NRC approval" of the HSI System design in the areas of multi-channel operator stations, HSI System's ability to accommodate reduced operator staffing, operation under degraded conditions, common cause failure modes for Defense-in-Depth and Diversity (D3) analysis, minimum inventory of HSI, and computer based procedures, while HSI system design description in the topical report describes much more than these items alone. MHI also states on page iii that the HSI system includes "an operator console, a supervisor console, and a Large Display Panel." On page 1, MHI states that the HSI system is "the complete set of safety and non-safety HSI components." The topical report also indicates that the operator supervisor consoles are part of the MCR and a large display panel is part of the both the MCR and the Technical Support Center (TSC). MHI states in Section 4.2 that the HFE program includes the MCR, the TSC, the remote shutdown room, the emergency operations facility (EOF), and local control stations (LCS). There is no clear description in the topical report of what aspects of the HSI system MHI seeks approval from the NRC for – the description is inconsistent and imprecise. Please provide clarity on what aspects of the HSI system design MHI seeks approval from the NRC.

**ANSWER:**

As defined in the Abstract "This topical report describes the functional design of the MHI Human System Interface (HSI) System and the Human Factors Engineering

(HFE) process used to create this system ... MHI seeks NRC approval of the HSI System design and its design process...”

The “significant innovations” on page iv of the Abstract are identified only to bring special attention to “... aspects of the system may not be readily familiar to those acquainted with previous analog designs” and “conformance to codes and standards” for those innovations. The NRC should not take this to mean that MHI is seeking approval only for these items and the design process related to these items. MHI is seeking approval for the entire HSI System and the design process for that complete system.

The scope of the HSI system is an operator console, a supervisor console, and a Large Display Panel in the MCR, RSC, TSC and EOF including associated HSI methods for alarms, indications, controls and procedures.

The HSI System also includes requirements for the applicability of local controls. However, 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. The design of local controls will be addressed in plant licensing documentation.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-3**

**Clarification of HFE program goals**

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?

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-4**

**Detail on HFE program assumptions and constraints.**

Assumptions and constraints are discussed in Section 5.1.1.2. MHI states that "Program must conform to regulations and rules related to safety and human factors design." (p. 87) MHI provides a fairly long list of regulatory and standards documents that apply to the HSI system design in Section 3.0. The list is not a comprehensive listing of all applicable regulatory or standards documents – for instance, even though changes to HSI systems in operating plants is an issue addressed in the topical report, it does not list NUREG/CR-6637, "Human Systems Interface and Plant Modernization Process: Technical Basis and Human Factors Review Guidance" as applicable regulatory guidance.

MHI also states that "Program must meet the requirements of utility operators" and goes on to specify the means that these requirements will be met (pp. 87-88), though there is no explanation of how utility requirements will be communicated and integrated into the HFE program and how the means specified will serve to meet these requirements. Please provide an explanation of how utility requirements will be communicated and integrated into the HFE program and how the means specified will serve to meet these requirements.

MHI states that "Human system interface requirements are to be met [sic] the plant system of the US-APWR and operating plants." and that "...hardware restrictions are taken into account in the human system interface design." (p. 88) There is no description of which HSI requirements or hardware restrictions are being referred to or how such HSI requirements or hardware restrictions might be derived. Please

provide a description of which HSI requirements or hardware restrictions are being referred to or how such HSI requirements or hardware restrictions might be derived.

MHI states that the approach for many of the NUREG-0711 program elements is the same as that for Japanese pressurized water reactors (PWR) MCRs implemented by MHI and Japanese utilities. (pp. 11-13) It is unclear whether MHI will employ the methodologies and results used in the development of Japanese PWR MCRs as inputs for the US-APWR HFE program and HSI design. Please clarify whether MHI will employ the methodologies and results used in the development of Japanese PWR MCRs as inputs for the US-APWR HFE program and HSI design.

**ANSWER:**

NUREG/CRs are not "rules or regulations". The NUREGs MHI has used as guidance for the development of the HSI design and HFE process are defined in Section 3.5. MHI has used and will continue to use NUREG/CRs as additional sources of guidance on human factors issues. For any areas where the Staff finds deficiencies in the HSI design or the HFE design process, MHI will consult the guidance in additional NUREGs to resolve those deficiencies.

Utility requirements have been and will continue to be communicated and integrated into the HFE program through several activities: The Abstract states "The HSI System has been evaluated by Japanese utility operators using a prototype main control board driven by a plant simulator." Appendix A describes the "History of Development of Japanese PWR Main Control Room by Mitsubishi and Japanese PWR Power Utilities". Appendix B describes the Japanese V&V activities: "more than one hundred operators participated in the dynamic validation, which enabled operation practices to be implemented in the design from the development phase." Section 4.0 states "This HSI System has been designed in a joint project between MHI, MELCO and Japanese PWR Owner Group utilities (See Appendix A)... HFE elements E01, E02, E03, E04, E05, E06, E07, E08, E10 and E11 were included in the design process with Japanese utilities... Table 4.0-1 compares the NUREG0711 HFE program elements to the elements in the HFE program implemented for Japanese PWRs. This table also identifies additional program plan activities conducted for US applications." As was the case for the Japanese HSI System development, MHI plans to engage US utility operators in each element of the US HSI System development.

The capability of the HSI hardware is a design constraint, which is considered in all aspects of the HSI System design. Hardware capability restrictions are most significant in two key areas:

- 1 - MHI uses Safety VDUs for safety related HSI. To meet the software quality requirements, the software for these devices must be kept very simple. As a result, these devices have primitive graphics and navigational capabilities.
- 2 - To meet the D3 (Defense-In Depth and Diversity) requirements, MHI uses conventional HSI components, such as analog indicators, status lights, alarm tiles and switches. These devices do not have the same dynamic capabilities as digital VDU HSI devices.

The Abstract states "MHI seeks NRC approval of the HSI System design ... The HSI System is essentially the same as the HSI System developed by MHI and MELCO for nuclear power plants in Japan." Table 4.0-1 describes "...HFE Program Plan for Japanese PWRs and Additional HFE Program Plan Activities for US Applications".

For each HFE program element MHI plans to employ the methodologies and results used in the development of the Japanese HSI System as the initial starting point for the US HSI System. HFE program element reports are plant specific documents. The report for each HFE program element will explain the applicability of the Japanese input and what additional activities were conducted for the US program. The first US application will be for the US-APWR. Subsequent US applications will use the US-APWR methodologies and results as the initial reference plant starting point. For each subsequent plant the report for each HFE program element will explain the applicability of the US-APWR reference plant input and what additional activities were conducted for the new specific plant application.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**Question No. : 18.0-5**

**Clarification of the applicable HSIs**

The scope of the topical report is for digital instrumentation and control (I&C), and includes the safety and non-safety HSI systems. (p. 1) .Not specifically included in the scope are non-I&C systems that can include manual valves and specific LCSs. While the report does indicate "manual controls" will be located in the LCSs and the MCR (p. 20), the report does not state that non-I&C systems will be addressed by the HFE program. It is the staff's position that any HSI, I&C or non-I&C, should be addressed by the HFE program. Please clarify the relationship between the HFE program and non-I&C HSIs.

**ANSWER:**

Non-I&C HSIs relevant to safety functions (e.g., Function allocation for plant safety functions, Task analysis for significant operations and Human actions from PRA, etc.) is within the scope of the overall HFE program. However, as stated in response to RAI-02, 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. The design of local controls will be addressed in plant licensing documentation.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**Question No. : 18.0-6**

**Detail on involvement of plant personnel in plant modifications.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**Question No. : 18.0-7**

**Detail on effects of modifications on personnel performance.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-8**

**Clarification of HFE team responsibilities.**

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.

**ANSWER:**

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

The following will be added to the responsibility of the 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".

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-9**

**Clarification of the HFE team's organizational placement and authority.**

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?

**ANSWER:**

The HFE 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 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 Team Manager within the overall organization is defined in the HFE Program Implementation Procedure, which is a plant specific document."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-10**

**Clarification on responsibilities, qualifications, and credentials for HFE team positions.**

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.

**ANSWER:**

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).

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-11**

**Clarification on team staffing.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

**18.0-22**

**Draft**

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**QUESTION NO. : 18.0-12**

**Clarification of general process procedures.**

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.

**ANSWER:**

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 explain the interaction of the HFE review process with the rest of the plant.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-13**

**Clarification of process management tools.**

Process management tools are described in Section 5.1.3.b. MHI states that "Review Record Sheet" is used to implement the HFE review process, but there is very little description of this process management tool. There is no description of any other process management tool/techniques or any other HFE process, besides the review process, that is addressed by process management tools/techniques. Please explain how Review Record Sheets will be used in the HFE process, what other tools/techniques, if any, are used in the HFE process, what processes these tools/techniques address, and how these tools/techniques address the processes.

**ANSWER:**

Section 5.1.3 is intended to describe the key components of the HFE program management process. The HFE Program Implementation Procedure is a plant specific document.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

**18.0-25**

**Draft**

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**QUESTION NO. : 18.0-14**

***Clarification of integration of HFE and other plant design activities.***

Integration of HFE and other plant design activities is described in Section 5.1.3.c. Review Committee Meetings and discrepancy reports appear to be the means of integration between HFE design activities and other plant design activities, but these means of integration are not described. While there is some mention of the iterative nature of elements of the HFE process, such as the use of a part-task simulator for iterative evaluations, making the task analysis more detailed as the HFE process progresses, and how the human reliability analysis (HRA) is developed further as the task analysis progresses, there is no discussion of the iterative nature of the overall HFE design process, i.e. how the HFE design process proceeds iteratively based on interaction with non-HFE design activities throughout the design process. Please provide detail on discrepancy reports, review committee meetings, and any other methods for integration of design activities, including what they are and how they, along with any other methods, serve to integrate HFE design activities with other plant design activities and proceed throughout the design process. This detail should also describe the inputs (or processes to provide inputs) from HFE to other subsystem design specialties and the inputs (or processes to provide inputs) from other specialties HFE program.

**ANSWER:**

Section 5.1.3 is intended to describe the key components of the HFE program management process. The HFE Program Implementation Procedure is a plant specific document. This document describes the interaction with non-HFE design activities throughout the design process. The iterative nature of the HFE process is shown in Figure 5.1-3 and Figure 5.4-1.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-15**

**Clarification of HFE program milestones.**

HFE program milestones are described in Section 5.1.3.d. MHI shows a flow diagram (Fig. 5.1-3) of the HFE process and states that the Program Milestones as well as a relative schedule are shown in this diagram, but it is unclear which elements of the diagram are milestones and if the diagram represents a schedule. MHI also shows a Gantt chart (Fig. 4.0-2) that illustrates what is described as a "typical schedule of HSI design for the US-APWR" but there is no reference to this schedule in the text. It is unclear if and how this schedule relates to the HFE process described in this report. The schedule does not clearly show milestones or how the HFE efforts related to other concurrent efforts other than regulatory submittals and construction. No products are shown as resulting, and the feedback loops are so extensive as to convey that all the work is done in parallel. Please provide detail, to address the discrepancies identified, on the HFE program milestones, what the schedule of the HFE program tasks will be, and how HFE activities, products, and reviews will relate to each other in time and to other non-HFE events in the overall plant design.

**ANSWER:**

This document is intended to describe the HFE process, which is depicted in Figure 5.1-3. The schedule and milestones are plant specific documents. Figure 4.0-2 will be deleted from this document.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

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There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-16**

**Clarification of HFE documentation process.**

HFE documentation is discussed in Section 5.1.3.e. MHI describes what is documented, notably deviations from evaluation criteria, but not what types of documents are developed and used. MHI does not describe how the documents are accessed and retained. Please explain what documents will be developed and used in the HFE process, how they will be accessed and retained, and what will be documented in the HFE process other than deviations from evaluation criteria.

**ANSWER:**

The typical documents to be generated will be added to the sections describing each program element. Actual document commitments will be identified in plant licensing documentation. Document access and retention is covered in the specific QA program for each plant

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-17**

**Clarification of HFE requirements for subcontractors.**

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?

**ANSWER:**

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. Verification procedures are plant specific documents".

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-18**

**Clarification of HFE issues tracking system.**

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.

**ANSWER:**

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".

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-19**

**Clarification of HFE issues tracking method.**

Little detail is given on the method used to document and track HFE issues. Please explain the method used to document and track HFE issues.

**ANSWER:**

A detailed description of the HFE Issues Tracking System is provided in the HFE Program Implementation Procedure, which is a plant specific document.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-20**

**Clarification of HFE issue threshold of significance.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-21**

**Clarification of HFE issues tracking responsibility.**

There is no detail on who within the HFE Design Team is responsible for the various stages of issues tracking. Please explain who within the HFE Design Team will be responsible for the various stages of issues tracking.

**ANSWER:**

A detailed description of the HFE Issues Tracking System is provided in the HFE Program Implementation Procedure, which is a plant specific document.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-22**

**Clarification of HFE technical program general development.**

No detail is given on the general development of implementation plans, analyses, and evaluations of the HFE Program Elements. A figure is provided (Fig. 5.1-3) that appears to show a general process flow for the HFE Program Elements, but no explanation is given for the figure's contents in the report text. Another figure is provided (Fig. 4.0-1) that shows a general process flow, presumably for past MHI PWR HSI design processes (this figure's caption is "HFE Design Process of Past Mitsubishi PWR HSI"), but no description of this figure is provided in the text and no description is provided of how this process flow relates to the HFE process for US-APWR. Please explain the general development of HFE implementation plans, analyses, and evaluations of HFE program elements.

**ANSWER:**

~~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."~~

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-22**

**Clarification of HFE technical program general development.**

No detail is given on the general development of implementation plans, analyses, and evaluations of the HFE Program Elements. A figure is provided (Fig. 5.1-3) that appears to show a general process flow for the HFE Program Elements, but no explanation is given for the figure's contents in the report text. Another figure is provided (Fig. 4.0-1) that shows a general process flow, presumably for past MHI PWR HSI design processes (this figure's caption is "HFE Design Process of Past Mitsubishi PWR HSI"), but no description of this figure is provided in the text and no description is provided of how this process flow relates to the HFE process for US-APWR. Please explain the general development of HFE implementation plans, analyses, and evaluations of HFE program elements.

**ANSWER:**

The HFE program plan, procedures and reports for each program element are plant specific documents. For the US-APWR the HFE program plan is documented in Chapter 18 of the DCD. Specific procedures and reports are identified in the ITAACs.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-23**

**Clarification of HFE requirements imposed on the design process.**

Standards, specification, and regulatory guidance documents that are sources of HFE requirements are listed in Section 3.0 but little detail is provided on the specific HFE requirements imposed on the design process that are derived from these documents or from other sources. Please identify and describe the specific HFE requirements imposed on the design process.

**ANSWER:**

Most of the references in Section 3 impose requirements on the HSI System design, which is described in Section 4. Requirements imposed on the HFE design process are primarily from the program elements of NUREG-0711. The key requirements of NUREG-0711 are captured in the program element descriptions in Section 5.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-24**

**Clarification of HFE facilities, equipment, tools, and techniques.**

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.

**ANSWER:**

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 HFE style guide) and then converting them to dynamic displays (e.g., linking to live points in the I/O 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."

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.

#### **Impact on DCD**

There is no impact on DCD.

#### **Impact on COLA**

There is no impact on COLA.

#### **Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-25**

**Description of assurance that plant modifications meet current regulations.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. :** 18.0-26

**Clarification of assurance that plant modifications will not compromise defense-in-depth.**

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 assure that plant modifications will not compromise defense-in-depth. Please provide detail how the HFE plan will provide assurance that plant modifications will not compromise defense-in-depth.

**ANSWER:**

As stated in the Abstract "The complete MHI digital instrumentation and control (I&C) design is described in four Topical Reports:

- Safety I&C System Description and Design Process
- Safety System Digital Platform - MELTAC -
- HSI System Description and HFE Process (Human Factor Engineering) Process (this report)
- Defense in Depth and Diversity"

An LAR that references this topical report will also reference the three other reports. In addition the LAR will reference the D3 Coping Analysis which is a plant specific licensing document.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. :** 18.0-27

**Clarification of OER implementation plan.**

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.

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-28**

**Detail and clarification of the OER.**

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.

**ANSWER:**

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 NUREG0711 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. MHI will meet with the Staff to discuss the schedule for all US-APWR HFE activities.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-29**

**Clarification of OER plan for plant modifications.**

MHI seeks NRC approval of the HSI system design for "replacement of current HSI systems in operating plants" but the topical report has no description of how MHI plans to address the operating experience of a plant for which the HSI systems will be replaced. Please provide detail on the plan for addressing an OER for replacement of HSI systems in operating plants.

**ANSWER:**

The following will be added to Section 5.2: "When the HSI system is applied to an operating plant, the Corrective Actions Program for that plant will be reviewed to identify any plant specific human performance issues that have not already been accommodated in the Basic HSI System or that may be applicable to the specific HSI Inventory for that plant."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**Docket No.52-021**

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**QUESTION NO. : 18.0-30**

**Clarification of functional analysis and allocation methodology.**

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.

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-31**

**Clarify functional analysis and allocation content.**

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.

**ANSWER:**

See response 18.0-30.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-32**

**Clarify plan to analyze situational awareness.**

NUREG-0711, Rev. 2 states that the allocation analysis consider the responsibility of personnel to monitor automatic functions and to assume control in the even 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.

**ANSWER:**

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".

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-33**

**Clarify intention to conduct functional analysis and allocation analysis.**

The topical report implies that automation levels will be modified on a case-by-case basis, using the operating experience review as a guide (p. 102). This seems to suggest that functional analysis and allocation will not be performed to meet the NUREG-0711, Rev. 2 criteria, but instead simply a review of existing plants. Please clarify the intention to conduct a full functional analysis and allocation analysis.

**ANSWER:**

The Staff's understanding is correct. The function analysis will be limited to changes from the reference plant. When the HSI system is applied to an operating plant, there may be no allocation changes. For the US-APWR the functional structure is essentially the same as the conventional PWR plant. The US-APWR functional requirement analysis and allocation element will conduct additional FRA/FA for the discrepancy from that of conventional plant.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-34**

**Clarify what will be task analyzed.**

The topical report describes the scope of the task analysis in words that are almost the same as NUREG-0711, Rev. 2. The same is true for the methodology. Please describe the MHI implementation plan for task analysis in specific terms: which tasks will be analyzed, which operating modes, specific Human Actions that have been found to affect plant safety, and the specific critical functions that have been automated. What specifically will be task- analyzed?

**ANSWER:**

The purpose of the Topical Report is to define the plan for each HFE program element. Function based task analysis is performed collecting important tasks in functional requirement analysis and allocation and specific Human Action which affects plant safety in the HRA analysis. Operational sequence task analysis is performed during the operation procedure development stage. The plan provides sufficient guidance for the selection of tasks to be analyzed. The specific tasks that are analyzed for each plant are described in the plant specific Task Analysis report.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

**18.0-53**

**Draft**

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**QUESTION NO. : 18.0-35**

**Clarify intention and plan to conduct iterative and detailed task analysis.**

The topical report states "Although detail level task analysis can be considered as a part of Human Factors V&V process, its methodology is described in this section." (p. 105). This is inconsistent with NUREG-0711, Rev. 2, which indicates that task analysis should be "iterative and progressively more detailed over time." (criterion 3) Further, V&V depends on having a precisely defined task set in order to sample from a range of tasks and operating conditions to carry out V&V (NUREG-0711, Rev. 2, p. 57). Please clarify the intention and plan to conduct iterative and detailed task analysis as the design activity progresses.

**ANSWER:**

MHI's approach is consistent with NUREG0711. As stated in section 5.4.3 "High level Task Analysis is performed in the early design stage and detail level Task Analysis is performed in later design stage (after HSI Design and Procedure Development phase)."

Section 5.4.3.2 states "The task analysis is iterative and becomes progressively more detailed over the design cycle." MHI's iterative approach is shown in Figure 5.4-1. As for other HFE program elements, Task Analysis will be focused and more detailed for the changes from the reference design.

MHI plans to complete the final detailed analysis by the end of 2009.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-36**

**Clarify method for gross and narrative task analysis.**

The Method for Gross and Narrative Task Analysis is described (pp. 107 – 108), but there is no indication, either in the written description or the sample data sheets, that the results can be used for the detailed specification of information and control requirements. How will this method capture and represent specific information requirements for task performance that can be used for specification of alarms, displays, data processing and controls for human task accomplishment (NUREG-0711, Rev. 2, p. 26, criterion 3)?

**ANSWER:**

Table 5.4-2 and 5.4-3 show the sample data sheets.

The method to use these sheets are described in pp. 107 – 108.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

**18.0-56**

**Draft**

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**QUESTION NO. : 18.0-37**

**Clarify GOMS timing analysis.**

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.

**ANSWER:**

The following descriptions to Section 5.4.3.2 will be add;

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 similar technique of operational sequence diagrams. It is based on the preliminary operating procedure.

MHI plans to execute iteratively from the Japanese standard PWR to change that of US-APWR base operation. It is also executed for difference to the modification of HSI design.

GOMS assume the number of crew members to be one licensed-SRO and one licensed-RO and based on the basic function allocation of the US-APWR and cognitive workload can be estimated and addresses a minimum inventory of alarms, displays, and controls necessary to perform crew tasks.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-38**

**Clarify intention for operating staff analysis and how results will be used by Combined License applicants.**

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?

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-39**

**Clarify how staffing and qualification analyses will be able to be used by MHI in the function allocation, HSI design, and procedure development processes.**

MHI states the operating staffing numbers are considered in the function allocation analysis (Section 5.3.2.1). MHI also depicts in Figure 5.4-1 that the staffing and qualifications element will serve as an input to HSI Design and Procedure Development elements. In Section 5.7.2 MHI states that staffing analyses are used to identify requirements for the HSIs. In Section 5.10.2.2.4 MHI states the shift staffing will be validated in the integrated system validation. If staffing and qualifications analyses and the validation of results from such analyses are to be carried out by COL applicants, how will the HFE elements described in the topical report that depend on staffing and qualifications analysis results be completed?

**ANSWER:**

The staffing and qualifications defined in the plant specific report for the Staffing and Qualifications program element, establishes the basis for all other program elements. While applicants are ultimately responsible for staffing, applicants who reference the US-APWR DCD, can reference the staffing report generated for the certified design. Changes to the staffing defined in the US-APWR staffing report, and any impact on related program elements, will be justified by the applicant.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-40**

**Clarify the HRA plan.**

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.*

**ANSWER:**

Risk important human actions are indentified 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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-41**

**Clarify HRA impact for operating plants.**

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 document of how MHI will take into account how the effects of such replacements will have on the HRA. It is unclear whether or not the HRA produced by the methodology described in the report applies to new plants and/or operating plants. To consider whether the HRA for new plants is appropriate for operating plants MHI will need to have a process to determine if:

- such modifications invalidate the assumptions of the HRA for new plants,
- the human errors analyzed in the HRA for new plants are relevant for operating plants,
- if the human error probabilities will be different for operating plants,
- if human errors may be introduced in operating plants that are not relevant for new plants, and
- if consequences of errors are different for operating plants than new plants.

As described by MHI, the Design Implementation Plan element applies to operating plant HSI changes and changes in human actions (HAs) are reviewed using NUREG-1764, "Guidance for the Review of Changes to Human Actions," Revision 1 criteria. NUREG-1764 is silent on how changes to risk-important HAs identified through such a review relate to an existing HRA. Please provide detail on how MHI will take into account the impact operating plant characteristics on the HRA.

**ANSWER:**

MHI does not intend to apply the HRA for the US-APWR to operating plants. As stated in Section 18.11 "For any HSI change to a licensed design the potential impact on Human Actions is assessed".

The HRA element for an operating plant ensures the new HSI system does not introduce increased human error probability compared to the predecessor HSI system. This is through the use of HRA sheets, as described in Section 5.6.4. If the design change does not affect the HSI for risk significant Human Actions new HRA sheets are not prepared.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-42**

**Clarify process for addressing risk-important HAs.**

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.

**ANSWER:**

*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 reprogramming 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 document QA review process.*

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. :** 18.0-43

**Clarify the process for addressing errors from risk-important HAs.**

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.

**ANSWER:**

Please see response on RAI 18.0-42.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-44**

**Clarify HRA assumption validation process.**

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.

**ANSWER:**

HRA assumptions will be validated in the V&V stage. In the early design stage, they are verified or validated using a representative simulator and/or 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 plant operation experience personnel.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-45**

**Clarify procedures will address NUREG-0800, Section 13.5 requirements.**

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?

**ANSWER:**

This element ensures appropriate HFE principals and HFE team engagement in the development of procedures. Conformances to the specific requirements of NUREG-0800, Section 13.5, are addressed in plant licensing documentation (e.g., Chapter 13 of the US-APWR DCD).

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-46**

**Clarify basis for procedure development.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

**18.0-72**

**Draft**

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**QUESTION NO. : 18.0-47**

**Clarify procedure development writer's guide.**

MHI restates the NUREG-0711, Rev. 2 criteria for what overall guidance the procedures writers guide should give for developing procedures. There is no detail on what the procedures writers guide's guidance will be and how the guidance will be used to implement procedure development. Please provide detail on what procedure development guidance the procedure writers guide will contain and how it will be used to guide procedure development.

**ANSWER:**

This topical report provides the plan for this program element. The actual procedure writer's guide will provide the guidance details.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**Docket No.52-021**

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**QUESTION NO. : 18.0-48**

**Clarify elements of procedures.**

MHI restates the NUREG-0711, Rev. 2 criteria for overall elements for procedure content. MHI provides no detail on the types of content for specific procedure elements. Please provide detail on what the elements of procedures will be.

**ANSWER:**

See response 18.0-47

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-49**

**Clarify meaning of statements in Section 5.8.2.**

MHI makes the statement that "contents of the procedures incorporate the following elements as existing procedures of Japan and US" and then goes on to list procedure elements. Immediate after the list of procedure elements MHI states "The most of operator experience is reflected present operation procedure of Japanese and US." It is not clear what these statements means. Does it mean that the procedures are already developed? Are there any differences between the procedures of the Japanese APWR and the procedures of the US-APWR. Please clarify what is meant by the following statements in Section 5.8.2:

- "contents of the procedures incorporate the following elements as existing procedures of Japan and US."
- "The most of operator experience is reflected present operation procedure of Japanese and US."

**ANSWER:**

See response 18.0-46

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

**18.0-75**

**Draft**

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**QUESTION NO.:** 18.0-50

**Clarify entry conditions for EOPs.**

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.

**ANSWER:**

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

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-51**

**Clarify procedure V&V process.**

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.

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

**MUAP-HF-08104**

**18.0-77**

**Draft**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-52**

**Clarify CBP system process.**

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.

**ANSWER:**

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)."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. :** 18.0-53

**Clarify procedure maintenance process.**

No plan for procedure maintenance and control of updates, including how modifications to individual procedures will be integrated across the full set of procedures, is described. Please detail the plan for procedure maintenance and control of updates, including how modifications to individual procedures will be integrated across the full set of procedures.

**ANSWER:**

As stated in Section 4.8 "The procedure is manually created ...The procedure is manually reviewed and approved through appropriate plant administrative quality assurance (QA) procedures." Therefore, the process for assuring modifications to individual procedures will be integrated across the full set of procedures is no different than for paper procedures. Procedure changes are evaluated for risk significance as described for the Design Implementation process in Section 5.11.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-54**

**Clarify procedure access and use evaluation.**

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.

**ANSWER:**

MHI plans both computer-based 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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-55**

**Clarify overall training approach.**

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 06-13A), 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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

**18.0-83**

**Draft**

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**QUESTION NO. :** 18.0-56

**Clarify training scope.**

MHI provides little detail on the overall scope of training that will be addressed. There is no statement on which personnel will be trained, what plant conditions and operational activities will personnel be trained for, and the HSIs for which personnel will be trained. Please detail the scope of training that will be designed for US-APWR.

**ANSWER:**

Section 5.9.3 describes the scope of classroom training for operators and technicians. The following will be added to Section 5.9.2 to define the scope of simulator training: "Simulator training is provided in accordance with industry guidance for licensed operators including NEI 06-13A". 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 later.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-57**

**Clarify how training will assure personnel qualification.**

MHI provides no description of how the US-APWR training program will provide reasonable assurance that trained personnel will be qualified adequately for their jobs' performance requirements. Please explain how the US-APWR training program will provide reasonable assurance that trained personnel will be qualified adequately for their jobs' performance requirements.

**ANSWER:**

NEI 06-13A provides the template to ensure personnel are adequately trained for their job's performance requirements. 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 later.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO.: 18.0-58**

**Clarify roles of organizations in training program**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

**18.0-86**

**Draft**

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**QUESTION NO. : 18.0-59**

**Clarify qualification criteria for training program organizations and personnel.**

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.

**ANSWER:**

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 later.

**Impact on DCD**

There is no impact on DCD.

**MUAP-HF-08104**

**18.0-87**

**Draft**

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-60**

**Clarify facilities and resources for training.**

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.

**ANSWER:**

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).

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-61**

**Clarify learning objectives derivation.**

While MHI lists the inputs provided by the HFE Design Team to the training development program, the listed inputs are a restatement of the NUREG-0711, Rev. 2 criteria for what the basis is for a learning objectives analysis. However, it is not clear what the listed inputs from the HFE Design Team will be used for in the training program development. Please clarify how the learning objectives for the training program will be derived.

**ANSWER:**

The following will be added to Section 5.9.5: "The HFE Design Team provides the following input to the training development program to identify the areas where training is required and for the development of the training material."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

**18.0-91**

**Draft**

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**QUESTION NO. : 18.0-62**

**Clarify how learning objectives address K&As.**

MHI does not state a plan that specifies how learning objectives will address the knowledge and skills relevant for trainees' jobs. Please detail a plan for how learning objectives will address the knowledge and skills relevant for trainees' jobs.

**ANSWER:**

The NEI 06-13A Template for the training program specifies how learning objectives will address the knowledge and skills relevant for trainees' jobs.

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 later.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-63**

**Clarify plan for designing the training program's content.**

MHI does not describe a plan for designing the content of the training program. Please detail a plan for designing the training program's content. The plan should address the criteria listed in the Content of Training Program section of NUREG-0711, Rev. 2.

**ANSWER:**

See the response for 18.0-56 for the scope of the training program. The NEI 06-13A Template defines the content of the training program.

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 later.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-64**

**Clarify training evaluation and modification plan.**

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

**ANSWER:**

Section 5.9.6 "Training Program Modifications" will be added, as follow: "Training program modifications including 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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-65**

**Clarify periodic retraining plan.**

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.

**ANSWER:**

See the response to 18.0-64.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-66**

**Clarify process for identifying HSI requirements.**

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.

**ANSWER:**

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)."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-67**

**Clarify analysis of personnel task requirements process.**

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.

**ANSWER:**

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

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-68**

**Clarify how system requirements will be considered in HSI design.**

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.

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-69**

**Clarify how regulatory requirements will be addressed in the HSI design.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-70**

**Clarify how other HSI design requirements will be identified.**

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.

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-71**

**Clarify the concept of operations.**

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.

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-72**

**Clarify functional requirements specification process.**

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.

**ANSWER:**

As stated in the Abstract "The HSI System is essentially the same as the HSI System developed by MHI and MELCO for nuclear power plants in Japan." Figure 4.0-1 shows the HFE Design Process used in the development of the HSI System, including the "Concept Design of Main Control Room". Appendices A and B describe the design process for the reference Japanese HSI System from initial conceptual design.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-73**

**Clarify HSI concept design process.**

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.

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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QUESTION NO. : 18.0-74

**Clarify HSI detailed design and integration process.**

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.

**ANSWER:**

~~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."~~

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

MUAP-HF-08104

18.0-107

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**QUESTION NO. : 18.0-75**

**Clarify the style guide development process.**

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.

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

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QUESTION NO. : 18.0-74

**Clarify HSI detailed design and integration process.**

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.

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**Impact on COLA**

There is no impact on COLA

**Impact on PRA**

There is no impact on PRA

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**QUESTION NO. :** 18.0-76

**Clarify HSI test and evaluation methodologies.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-77**

**Clarify HSI design documentation process.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. :** 18.0-78

**Clarify overall V&V plan.**

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.

**ANSWER:**

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 1 V&V procedures are currently in development. The US-APWR Phase 1 V&V report will be issued later this year.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-79**

**Clarify performance measurement process.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

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**QUESTION NO. : 18.0-80**

**Clarify Situation Awareness and Cognitive Workload measurement methodologies.**

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.

**ANSWER:**

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. 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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-81**

**Clarification of design implementation plan.**

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.

**ANSWER:**

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."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**Mitsubishi Heavy Industries**

**Docket No.52-021**

**RAI NO.: NO.X REVISION X**

**SRP SECTION: 18 – Human Factors Engineering**

**APPLICATION SECTION: 18.0**

**DATE OF RAI ISSUE: X/XX/2008**

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**QUESTION NO. : 18.0-82**

**Clarify human performance monitoring program goals.**

The first sentence in the Human Performance Monitoring Plan section states the following:

The goal of this element is to ensure that plant personnel have maintained the skills necessary to accomplish human actions within the time and performance criteria confirmed during the HSI validation program.

'Maintaining' skills implies that performance is dependent on personnel retention of skills. Performance could conceivably degrade because of design changes that negatively impact performance, perhaps so badly that the time and performance criteria are simply unachievable. Criterion (1) in the Human Performance Monitoring section of NUREG-0711, Rev. 2 states that reasonable assurance should be provided that "The design can be effectively used by personnel" and that "Changes made to the HSIs, procedures, and training do not have adverse effects on personnel performance." The goals of the human performance monitoring program should not be limited to ensuring plant personnel skill maintenance. Please clarify the goals of the human performance monitoring program.

**ANSWER:**

The following change will be made to Section 5.12 "In addition, the Human Performance Monitoring Plan ensures that no significant safety degradation occurs because of any changes that are made in the plant, including changes to HSI designs, procedures and training."

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION**

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**QUESTION NO. : 18.0-83**

**Clarification of human performance monitoring strategy.**

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.

**ANSWER:**

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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

**MUAP-HF-08104**

**18.0-121**

**Draft**

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**QUESTION NO. : 18.0-84**

**Clarify scope and intent of topical report.**

Please clarify the role of the topical report in the US-APWR license application.

**ANSWER:**

The topical report serves two purposes:

- 1 – Section 4 provides a detailed description of the Basic HSI System features, which are based on the Basic Japanese HSI System. These Basic HSI System features are not described in the US-APWR DCD. The Basic HSI System description is the starting point for the US-APWR Basic HSI System. Phase 1 of the US-APWR HFE design process generates the final US-APWR Basic HSI System. This phase is described in Section 18.10 of the US-APWR DCD. Phase 1a includes verification and validation, by US operators and HFE experts, to identify HEDs. Phase 1b evaluates these HEDs, generates required design changes, with additional V&V as may be necessary. Phase 1b will be completed and documented by mid 2009. MHI submitted this Basic HSI System description to obtain NRC comments. MHI planned to factor NRC comments into Phase 1 of the US-APWR HFE design process. MHI is very pleased to see that the NRC has no comments on the Basic HSI System.
- 2 – Section 5 describes the HFE design process as the basis for the plant specific HFE Program Plan, which is described in plant licensing documentation. For example, the HFE Program Plan for the US-APWR is described in Chapter 18 of the DCD. This plan will be executed through detailed plant specific implementation procedures, which are developed for each program element. MHI submitted the HFE design process description to obtain NRC comments. MHI plans to factor NRC comments into Chapter 18 of the US-APWR DCD, Rev 1.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-85**

**Clarify which HFE program element implementation will be part of the DCD and which have been completed.**

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 provided 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.

**ANSWER:**

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. 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 NUREG0711. 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.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. :** 18.0-86

**Clarify which aspects of the HFE program will be COL items.**

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

**ANSWER:**

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. ITAACs related to the US-APWR HSI Inventory design will be completed during the first COL application review. ITAACs related to the completely integrated HSI System will be completed prior to fuel load. MHI is responsible for completing post DCD ITAACs. However, some of these post DCD ITAACs are based on design assumptions for the portion of the plant 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. Plant specific COL applicant actions are identified within each section of Chapter 18.

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

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**QUESTION NO. : 18.0-87**

**Clarify ambiguous terminology.**

A variety of verb tenses are used throughout the topical report. The inconsistent use of verb tense makes it difficult to determine if certain aspects of an HFE review area's implementation plan or results have been completed, are in process, or will be completed in the future. For example, the sentence on page 138, "The validation test facility used to perform validation evaluations satisfies the following requirements." implies that validation has already been completed. A few sentences later, "The validation test facility is planned to be constructed at MELCO's factory in the US." implies that the test facility does not exist yet so validation could not have been completed. The next sentence, "The test facility is a full scale HSI mockup with a full-scope simulator." implies that the test facility currently exists. Also, the use of the verb "should," though not used frequently, makes it difficult to determine if a commitment is made. Please update the topical report's use of verb tense and clarify where commitments are made.

**ANSWER:**

This topical report describes the HFE process used for the Japanese HSI System development. This is the same process that is currently being used for the US-APWR and will be used in the future for plant specific applications. Therefore, where present tense is used the statement is applicable to past, present and future activities. For example, on page 138, "The validation test facility used to perform validation evaluations satisfies the following requirements" and "The test facility is a full scale HSI mockup with a full-scope simulator" are statements applicable to the facility used for the Japanese HSI System development in Kobe, Japan and to the facility used for HSI V&V in the US. However, the statement "The validation test facility is planned to be constructed at MELCO's factory in the US" refers specifically to the facility built for the US-APWR at Pittsburg in April 2008.

MHI will confirm the consistent use of verb tenses for the next topical report revision. MHI will replace all uses of "should" with an appropriate verb (per the discussion, above) which reflects commitments, such as "shall", "is" or "are".

**Impact on DCD**

There is no impact on DCD.

**Impact on COLA**

There is no impact on COLA.

**Impact on PRA**

There is no impact on PRA.

This concludes MHI's responses to the NRC's RAIs.