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NUCLEAR REGULATORY COMMISSION
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May 8, 2008

Mr. Keith Paulson
Senior Technical Manager
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300 Oxford Drive, Suite 301
Monroeville, PA 15146

SUBJECT: MITSUBISHI NUCLEAR ENERGY SYSTEMS, INC. - REQUEST FOR
ADDITIONAL INFORMATION ON US-APWR TOPICAL REPORT
MUAP-07007-P, "HUMAN SYSTEM INTERFACE DESCRIPTION AND HUMAN
FACTORS ENGINEERING PROCESS"

Dear Mr. Paulson:

By letter dated July 3, 2007, Mitsubishi Nuclear Energy Systems, Inc. (MNES) submitted for NRC staff review Topical Report MUAP-07007-P, "Human System description and Human Factors Engineering Process." The NRC staff has reviewed this topical report and has determined that the following information is needed for the NRC staff to complete its review. The NRC staff plans to schedule a non-public (proprietary) meeting with MNES in order to discuss the response to this request for additional information.

Sincerely,

Stephen R. Monarque
Stephen Raul Monarque
USAPWR Projects Branch
Division of New Reactor Licensing
Office of New Reactors

Docket No. 52-021

Enclosure: As stated

cc: See next page

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OFFICIAL RECORD

MHI US-APWR Topical Report MUAP-07007-NP R1, "HSI System Description and HFE Process"

RAI Number (xx.yy-nn xx=chapt. yy=sect. nn=RAI)	Question Summary	Full Text
18.0-1	Clarify the applicability to operating plants.	<p>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:</p> <p style="padding-left: 40px;">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.</p> <p>On page 1 MHI states the following:</p> <p style="padding-left: 40px;">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...</p> <p>With respect to the human factors engineering (HFE) process, MHI states the following on page 87:</p> <p style="padding-left: 40px;">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.</p> <p>"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</p>

		<p>Request.”</p> <p>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.”</p> <p>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.</p>
18.0-2	Clarify the HSI system design aspects for which MHI seeks NRC approval.	<p>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.</p>

18.0-3	Clarification of HFE program goals.	<p>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?</p>
18.0-4	Detail on HFE program assumptions and constraints.	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
18.0-5	Clarification of the	<p>The scope of the topical report is for digital instrumentation and control (I&C), and includes the safety</p>

	applicable HSIs.	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.
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.
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.
18.0-8	Clarification of HFE team responsibilities.	<p>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.</p> <p>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."</p> <p>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.</p>
18.0-9	Clarification of the	The HFE team's organizational placement and authority is described in Section 5.1.2 of the topical

	HFE team's organizational placement and authority.	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?
18.0-10	Clarification on responsibilities, qualifications, and credentials for HFE team positions.	<p>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.</p> <p>Also, there is no discussion of the qualifications or credentials for positions within the HFE team.</p> <p>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.</p>
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.
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.
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.
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.
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.
18.0-16	Clarification of HFE	HFE documentation is discussed in Section 5.1.3.e. MHI describes what is documented, notably

	documentation process.	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.
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?
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.
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.
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.
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.
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.
18.0-23	Clarification of HFE requirements	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

	imposed on the design process.	process that are derived from these documents or from other sources. Please identify and describe the specific HFE requirements imposed on the design process.
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.
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 where specific exemptions are requested under 10 CFR 50.12. Please describe how the HFE plan will provide assurance that plant modifications meet current regulations.
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.
18.0-27	Clarification of OER implementation plan.	<p>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."</p> <p>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)</p> <p>This is not sufficiently detailed to evaluate. The NUREG-0711, Rev. 2 criteria for OER include a review</p>

		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.
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.
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.
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.
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 be addressed for functional analysis and allocation.
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.
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.
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?
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 <i>depends</i> 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.
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)?
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.
18.0-38	Clarify intention for operating staff analysis and how results will be used	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

	by Combined License applicants.	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?
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?
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.
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: <ul style="list-style-type: none"> • 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

		<ul style="list-style-type: none"> • if consequences of errors are different for operating plants than new plants. <p>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.</p>
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.
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.
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.
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?
18.0-46	Clarify basis for	Though MHI states the task analysis results will provide the basis and input for procedure development

	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.
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.
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.
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: <ul style="list-style-type: none"> • "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."
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.
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.
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.
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.
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.
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 06-13), but this NEI report contains very little detail on the design of a training program. There is very little detail on the approach to training that MHI will design for US-APWR. Please explain the overall training approach for US-APWR.
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.
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.
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.
18.0-59	Clarify qualification	While MHI provides some detail on qualification of training instructors, there is no detail on the

	<p>criteria for training program organizations and personnel.</p>	<p>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.</p>
<p>18.0-60</p>	<p>Clarify facilities and resources for training.</p>	<p>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.</p> <p>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?</p> <p>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.</p> <p>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.</p> <p>Please provide detail on the facilities and resources such as plant-referenced simulator and part-task</p>

		training simulators needed to satisfy training design requirements and the guidance contained in ANSI 3.5 and Regulatory Guide 1.149.
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.
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.
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.
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.
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.
18.0-66	Clarify process for identifying HSI requirements.	<p>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.</p> <p>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 identified from the OER, the functional requirement analysis and function allocation, the task analysis, and staffing/qualifications and job analyses. In addition, risk-</p>

		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.
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.
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.
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.
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.
18.0-71	Clarify the concept of operations.	<p>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.</p> <p>MHI provides no detail other than an overall description of computer display style guide topics. Please provide detail on the following:</p> <ul style="list-style-type: none"> • 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

		<p>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</p> <ul style="list-style-type: none"> • 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.
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.
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.
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.
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.
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.
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.

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.
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.
18.0-80	Clarify Situation Awareness and Cognitive Workload measurement methodologies.	<p>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:</p> <ul style="list-style-type: none"> • 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.

		<p>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:</p> <ul style="list-style-type: none"> • 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. <p>Please explain what state-of-the-art methodologies will be used in measuring Situation Awareness and Cognitive Workload in the Integrated System Validation.</p>
18.0-81	Clarification of design implementation plan.	<p>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.</p>
18.0-82	Clarify human performance monitoring program goals.	<p>The first sentence in the Human Performance Monitoring Plan section states the following:</p> <p style="padding-left: 40px;">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.</p> <p>'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.</p>
18.0-83	Clarification of human performance monitoring strategy.	<p>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.</p>
18.0-84	Clarify scope and	<p>Please clarify the role of the topical report in the US-APWR license application.</p>

	intent of topical report.	
18.0-85	Clarify which HFE program element implementation will be part of the DCD and which have been completed.	<p>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:</p> <ul style="list-style-type: none"> • Operating Experience Review • Functional Requirements Analysis and Function Allocation • Task Analysis • Human Reliability Analysis • HSI Design • Procedure Development • Human Factors Verification and Validation <p>It is unclear if MHI is stating that the implementation approach used for Japanese PWRs is adequate for US applications. For Staffing and Qualifications MHI states that "MHI proposes operation with one SRO and one RO in the MCR for compliance with 10 CFR 50.54." No other detail is provide that addresses whether other aspects of the Staffing and Qualifications element included in an implementation plan. MHI states that "Implementation plan is added" for the following HFE program elements:</p> <ul style="list-style-type: none"> • Training Program Development • Design Implementation • Human Performance Monitoring <p>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.</p>
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?
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

		<p>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.</p>
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