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TOKYO, JAPAN

April 28, 2011

Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Mr. Jeffrey A. Ciocco

Docket No. 52-021
MHI Ref: UAP-HF-11125

Subject: MHI's Responses to US-APWR DCD RAI No. 728-4534 REVISION 2 (SRP 18)

Reference: 1) "Request for Additional Information No. 728-4534 REVISION 2, SRP Section: 18 - Human Factors Engineering, Application Section: 18.1" dated April 4, 2011.

With this letter, Mitsubishi Heavy Industries, Ltd. ("MHI") transmits to the U.S. Nuclear Regulatory Commission ("NRC") a document entitled "Responses to Request for Additional Information No. 728-4534 Revision 2."

Enclosed are the responses to the RAI contained within Reference 1.

Please contact Dr. C. Keith Paulson, Senior Technical Manager, Mitsubishi Nuclear Energy Systems, Inc. if the NRC has questions concerning any aspect of the submittals. His contact information is below.

Sincerely,

Yoshiki Ogata,
General Manager- APWR Promoting Department
Mitsubishi Heavy Industries, LTD.

Enclosure:

1. Responses to Request for Additional Information No. 728-4534 REVISION 2

D081
NRO

CC: J. A. Ciocco
C. K. Paulson

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Docket No. 52-021
MHI Ref: UAP-HF-11125

Enclosure 1

UAP-HF-11125
Docket No. 52-021

Responses to Request for Additional Information No. 728-4534
REVISION 2

April 2011

RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

04/28/2011

US-APWR Design Certification

Mitsubishi Heavy Industries

Docket No. 52-021

RAI NO.:	**NO. 728-4534 REVISION 2**
SRP SECTION:	**18.1 - HUMAN FACTORS ENGINEERING**
APPLICATION SECTION:	**18.01 – 18.1 PROGRAM PLAN**
DATE OF RAI ISSUE:	**04/04/2011**

QUESTION NO. : 18-106

NUREG-0711 Criterion 2.4.1(2) states: "Assumptions and Constraints - An assumption or constraint is an aspect of the design, such as a specific staffing plan or the use of specific HSI technology that is an *input* to the HFE program rather than the result of HFE analyses and evaluations. The design assumptions and constraints should be clearly identified."

The US-APWR DCD does not clearly communicate that the US-Basic HSI design, as described in Topical Report MUAP-07007, is used as the basis for the US-APWR configuration. For example:

- DCD, Section 18.1.1.1 states that, "The design assumptions and constraints of the Basic HSI System are clearly identified in Section 5.1.1.2 of Reference 18.1-1." This statement seems too limiting as the entire US-Basic HSI design is the assumed starting point for the US-APWR. The staff believes this relationship needs to be stated explicitly in the DCD so the scope of the associated SER is clear.

- DCD, Section 18.1.1.1 states that, "Reference 18.1-1 describes the US-APWR HSIS design and the HFE design process." The staff believes this is incorrect and should say that Reference 18.1-1 describes the US-Basic HSI design. The reference to the HFE design process is irrelevant as a generic reference since section 5 will not be approved in the SER associated with MUAP-07007 (see last bullet below).

- Many sections of the DCD and the supporting technical reports use the terms "Japanese APWR design", "Basic HSI System", "Japanese standard HSI design", and "reference plants." These terms need to be used consistently and where appropriate replaced with a reference to the US-Basic HSI Design so there is no confusion in which configuration supports the US-APWR design configuration. The staff has reviewed the interface between the Japanese APWR and the US-Basic HSI Design as part of the Safety Evaluation of Topical Report MUAP-07007. As discussed during a public meeting on February 20, 2011, staff will be approving section 4 of MUAP-07007 in its SER. Given approval of section 4 of the Topical Report, the DCD should explicitly

address the translation of the US Basic HSI design configuration to the US-APWR configuration.

- References are made to the processes described in section 5 of Topical Report, MUAP-07007, which will not be approved in the Safety Evaluation associated with that report, as discussed during a public meeting on February 20, 2011. For example, "Reference 18.10-2, Subsection 5.10.2.2.4, describes the process for the integrated system validation methodology." Typically such references are not going to be sufficient as the Topical Report provides a program level description verses an implementation plan level description. These references should be to the detailed Implementation Plan that translates the US-Basic HSI Design to the US-APWR Design.

The following actions are requested:

1. Revise the DCD so it explains that the US-Basic HSI design is the starting point for the US-APWR HSI design.
2. Revise terminology in the DCD and supporting documents so that terms are used consistently.
3. Reference the Topical Report and/or supporting documents consistently.

ANSWER:

DCD, Section 18.1 will be revised as shown below. The MUAP-09019 US-APWR HSI Design Technical report, Part 1 HFE Overall Implementation procedure will be referred as a US-APWR HFE process instead of section 5 of the Topical Report, MUAP-07007.
MHI agrees to, in addition, do a complete review and to revise the terminology of "Japanese APWR design", "Basic HSI System", "Japanese standard HSI design", and "reference plants" in the next revision (revision 4) of the DCD to make their use consistent accross all sections.
MHI also agrees to revise, in revision 4 of the DCD to refer to the MUAP-09019 as a US-APWR HFE process (See RAI 18-114 response).

Impact on DCD

The first paragraph of DCD 18.1.1.1 will be replaced:

"The assumptions and constraints of the design, such as a specific staffing plan or the use of specific HSI technology ~~inherent in~~ are inputs to the HFE program rather than the result of HFE analyses and evaluations. The US-Basic HSIS is the starting point for the US-APWR HSIS, therefore it is considered a constraint of the US-APWR HSIS. The inventory of controls, indications, alarms and procedures needed to operate the US-APWR will be implemented using the HSI components of the US-Basic HSIS. These HSI components include the large display panel, operational visual display units (VDU), alarm VDUs, computer based procedure VDUs, safety VDUs and conventional HSI. The HSI components encapsulate the HSI design bases and methods for control, indication, alarm and procedures. In a broader sense, the US-Basic HSIS encapsulates the general arrangement and integration of these HSI components. These aspects of the US-Basic HSIS will not be changed for the US-APWR HSIS unless something unique for the US-APWR plant requires a change. The design assumptions and

constraints of the US-Basic HSI System are clearly identified in Section 5.1.1.2 of Reference 18.1-1."

Paragraph 2 of 18.1.1.1 should be changed as follows:

"A fundamental design constraint of the US-Basic HSIS, that also applies to the US-APWR HSIS, ~~HFE design assumption~~ is that ~~it is possible to operate~~ the plant can be operated with just one reactor operator ..."

The third paragraph of DCD 18.1.1.1 will be revised as follows:

"Reference 18.1-1 describes the US-Basic ~~US-APWR~~ HSIS design and Reference 18.1-12 describes the US-APWR HFE design process. ~~The HSIS has been developed and tested for application in both new and existing operating plants in Japan. The functional requirement specification for the Japanese Advanced Pressurized Water Reactor (APWR) HSIS design serves as the initial source of input to the HSIS design effort.~~ The US-~~APWR~~-Basic HSIS design is an ~~direct~~ evolution of~~from~~ the predecessor ~~standard~~ Japanese PWR to which screen based digital HSIS has been applied. The US-Basic HSIS has been verified and validated by US licensed operators using a HFE verification and validation process appropriate for the HSI design basis and methods of the US-Basic HSIS, such as the operator console and large display panel layout, console ergonomic design, alarm presentation system, display navigation, software control functions, and layout of operational display configuration, as described in Section 4 of Reference 18.1-1.

The US-APWR HFE process is conducted based on the US-Basic HSIS as a foundation and is performed for the US-APWR plant-specific application as described in Reference 18.1-12 (Part 1).
~~However, due to differences between existing Japanese nuclear plants and the US-APWR, and the potential for cross-cultural HFE issues, specific changes in the design are addressed in the US-APWR design.~~

The fourth paragraph of DCD 18.1.1.1 will be revised as follows:

"The ~~development of the~~ integrated US-APWR HSIS~~,~~ is developed in accordance with the HFE Program Elements ~~as~~ described in Sections 18.2 through 18.12~~18.7, 18.8, and 18.9, ("Human System Interface Design," "Procedure Development," and "Training Program Development"), are conducted in an HFE development facility~~. Each section references summary report for OER, FRA/FA, TA, and HRA (Reference 18.1-12, and 18.1-13 (Part 2)), and a detailed Implementation Plan which governs the activities conducted for the other HFE Program Element (Reference 18.1-14, 18.1-15, 18.1-16, 18.1-17, 18.1-18 and 18.1-19.) ~~In addition to HSIS development and testing (Reference 18.1-1, Subsection 5.7.3.3, "HSI Tests and Evaluations"), the verification and validation (V&V) process described in Section 18.10 are conducted in this facility (Reference 18.1-1, Subsection 5.10.2.2.4.b, "Integrated System Validation", "Validation Test Facility"). This facility provides the updated proof of concept testing and "factory testing" described in Reference 18.1-3, Subsection 2.3.2, "Advanced Pressurized Water Reactor.~~"

DCD, Section 18.1.2.4, the last sentence in the second paragraph;

"The roles and responsibilities for the key sections of the organization are described in ~~Reference 18.1-1 Subsection 5.1.2.2~~ Reference 18.1-12, Part 1 Section 3.2. "

DCD, Section 18.1.3.4;

"HFE milestones are identified so that evaluations of the effectiveness of the HFE effort can be made at critical checkpoints and the relationship to the integrated plant sequence of events is shown. A relative program ~~schedule~~ process of HFE tasks showing relationships between HFE elements and activities, products, and reviews has been developed (Reference 18.1-12, Part 1, Section 5). The schedules and milestones are shown in the Reference 18-1 Figure 4.0-2."

DCD, Section 18.1.3.6;

"HFE requirements are included in each subcontract for HFE support and the subcontractor's compliance with HFE requirements is periodically verified. HFE work performed by subcontractors is controlled as described in Reference 18.1-12, Part 1, Section 5 and 18.1-6."

DCD, Section 18.1.4, the last paragraph;

"The process through which the HFE design team executes its responsibilities is described in Reference 18.1-12, Part 1 Section 6 and Section 7."

The following references are added in DCD Section 18.1.7:

"

18.1-12	US-APWR HSI Design, MUAP-09019-P (Proprietary) and MUAP-09019-NP (Non-Proprietary), Revision 0, June 2009.
18.1-13	US-APWR Human System Interface Verification and Validation (Phase 1a), MUAP-08014-P (Proprietary) and MUAP-08014-NP (Non-Proprietary), Revision 0, December 2008
18.1-14	US-APWR HSI Design Implementation Plan, MUAP-10009, Revision 0, April 2010
18.1-15	US-APWR Procedure Development Implementation Plan, MUAP-10010, Revision 0, April 2010
18.1-16	Training Program Development Implementation Plan, MUAP-10011, Revision 0, April 2010
18.1-17	Verification and Validation implementation plan, MUAP-10012, Revision 0, April 2010
18.1-18	Design Implementation, MUAP-10013, Revision 0, April 2010
18.1-19	Human Performance Monitoring Implementation Plan, MUAP-10014, Revision 0, April 2010"

Impact on R-COLA

There is no impact on the R-COLA

Impact on S-COLA

There is no impact on the S-COLA

Impact on PRA

There is no impact on the PRA

RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

04/28/2011

US-APWR Design Certification

Mitsubishi Heavy Industries

Docket No. 52-021

RAI NO.:	**NO. 728-4534 REVISION 2**
SRP SECTION:	**18.1 - HUMAN FACTORS ENGINEERING**
APPLICATION SECTION:	**18.01 – 18.1 PROGRAM PLAN**
DATE OF RAI ISSUE:	**04/04/2011**

QUESTION NO. : 18-107

NUREG-0711 criterion 2.4.1(3) states: "Applicable Facilities—The HFE program should address the main control room, remote shutdown facility, technical support center (TSC), emergency operations facility (EOF), and local control stations (LCSs)."
DCD section 18.1.1.2 states: "Local control stations (LCSs) - consideration of HFE activities for LCSs are limited to those control stations that support:

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

How are risk important human actions addressed with respect to LCSs?

ANSWER:

All risk important human actions(HAs) that have been identified in the PRA, have been evaluated in the "Human Reliability Analysis" HFE program element. The results of that program element are documented in Part 2 Section 2 of the HSI Design Technical Report (MUAP-09019,R0), which was submitted June 2009. This document reflects the risk significant HAs identified in the US-APWR Probabilistic Risk Assessment (MUAP-07030, Rev.0). As part of the US-APWR philosophy for the current design phase, as explained in MUAP-10009 page 15, all risk important HAs that were identified and that have been typically located outside the MCR for previous generation plants, were moved into the MCR for the US-APWR. Therefore risk important HA list contained in the attachment to MUAP-09019 Part 2 section 2 only contains HAs within the MCR.

As explained in the response to RAI No. 664-5046 18-95, MUAP-09019 will be updated to reflect the latest PRA report MUAP-07030, but to date no HAs identified for LCSs have been identified as risk important human actions. However, the HFE process, as described in MUAP-09019 Part 1, is iterative. If additional risk important HAs are identified in the future, these will be

similarly evaluated, with preference, as practical based on the design status, given to location within the MCR.

All risk important HAs at LCS (should they be identified in the future), and all HAs located at LCS that fall into the limited categories identified below (risk important or not), will be evaluated and designed in accordance with the remaining HFE Implementation Plans listed below:

- MUAP-09019, US-APWR HSI Design, Part 1 HFE Overall Implementation Procedure Section 2.2 defines the scope of the HFE program as including the LCSs. Part 2 Section 2, HRA Section 2.4.2.2.1 included LCSs in the analysis and 2.4.2.2.2 describes the inclusion of the communications between the MCR and LCSs.

- MUAP-10009, HSI Design, page 10 discusses LCSs included in the functional requirement development. Page 15 describes the process noted above that moved the LCS HAs identified to date for normal and accident conditions into the MCR.

- MUAP-10011, Training, Section 4.1 indicates that LCSs are included in the training element.

- MUAP-10012, V&V, The Abstract, states that LCSs are included in the program. The Scope, Section2, lists the LCSs as within the scope of the V&V program.

- MUAP-10014, Human Performance Monitoring states in Section 2.0 that LCSs are within the scope.

Impact on DCD

Section 18.6.1 of the DCD will be revised to state;
The Scope of the HRA/PRA incorporation into the HFE ~~design~~ effort encompasses risk-important HAs as described in Reference 18.1-12, Part 2 Section2. The iterative...

The last bullet of Section 18.6.2 of the DCD will be revised to state;

- HRA Assumptions such as decision making and diagnosis strategies for dominant sequences are validated by walk through analysis with personnel with operational experience using ~~a plant-specific control room~~ mock ups or simulator.

The following will be added to the end of Section 18.6.3;
All risk important human actions (HAs) that have been identified in the PRA, have been evaluated in the "Human Reliability Analysis" HFE program element. The results of that program element are documented in Part 2 Section 2 of Reference 18.1-12. This document reflects the risk significant HAs identified in the US-APWR Probabilistic Risk Assessment (Reference 18.1-20). As part of the US-APWR philosophy, all risk important HAs that were identified and that have been typically located outside the MCR for previous generation plants, were moved into the MCR for the US-APWR. Therefore the risk important HA list contained in the attachment to Reference 18.1-12 Part 2 Section 2 of Reference 18.1-12 only contains HAs within the MCR.

However, the HFE process, as described in Reference 18.1-12 Part 1, is iterative. If additional risk important HAs are identified in the future, these will be similarly evaluated, with preference, as practical based on the design status, given to location within the MCR.

All risk important HAs at LCS (should they be identified in the future), and all HAs located at LCS that fall into the categories identified in Section 18.1.1.2 (risk important or not), will be evaluated and designed in accordance with the remaining HFE Implementation Plans ((Reference 18.1-14, 18.1-15, 18.1-16, 18.1-17, 18.1-18 and 18.1-19.).

The following references are added in DCD Section 18.1.7:

18.1-20 US-APWR Probabilistic Risk Assessment, US-APWR HSI Design, MUAP-07030-P (Proprietary) and MUAP-09030-NP (Non-Proprietary), Revision 2, December 2009.

Impact on R-COLA

There is no impact on the R-COLA

Impact on S-COLA

There is no impact on the S-COLA

Impact on PRA

There is no impact on the PRA

RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

04/28/2011

US-APWR Design Certification

Mitsubishi Heavy Industries

Docket No. 52-021

RAI NO.:	**NO. 728-4534 REVISION 2**
SRP SECTION:	**18.1 - HUMAN FACTORS ENGINEERING**
APPLICATION SECTION:	**18.01 – 18.1 PROGRAM PLAN**
DATE OF RAI ISSUE:	**04/04/2011**

QUESTION NO. : 18-108

NUREG-0711 Criterion 2.4.1(3) states: "Applicable Facilities - The HFE Program should address the main control room, remote shutdown facility, technical support center (TSC), emergency operations facility (EOF), and local control stations (LCSs)."

MHI has responded to RAI 295-2341, questions 18-7 and 18-8. Both questions deal with the HFE design of the EOF/TSC. The responses have not resolved the staff's questions. Further confusion exists because NUREG-0711 is not clear as to which elements are to be applied to the EOF/TSC. The staff requests responses for the following questions and has provided best practices observed from other design centers that represent what the staff feels is a reasonable compromise from 100% application of all NUREG-0711.

EOF/TSC HFE design responsibilities are unclear.

- DCD Section 18.1.1.2 states the DCD scope is limited to identification of information requirements and includes SPDS, Meteorological displays, off-site radiation monitoring, and post accident monitoring.

- DCD Section 18.1.1.2 States, "The site specific HFE team is to design the EOF, in accordance with the HFE program. The site specific HFE team is to specify the communication system requirements; ..."

- MUAP-09019, US-APWR HSI Design, section 2.3 states, "The license holder shall also create implementation procedures for the EOF..."

Concerns:

- MUAP-09019 increases the scope of the COL applicant's responsibility. The MUAP is not referenced in the DCD.

- The COL applicant's responsibility for design responsibilities is not communicated to the applicant via a COL information item. The MHI response to question 18-7 indicated that

the additional COL information item was deleted because the DCD section now described the division of responsibility between the HFE team and COL applicant. This is not consistent with NUREG-0800 guidance which states that interface requirements are identified as COL information items. Also the additional ITAAC added did not contain specific, measurable acceptance criteria. The acceptance criteria were the same as the design commitment.

- The DCD does not provide a complete list of what the COL applicant is responsible for. For example, anthropometric design and room layout are not addressed.

- The MHI response to question 18-8 stated that the same approach as the NUREG-0711 program is applied to the process for the EOF/TSC but then took immediate exception to that by stating that processes other than the task analysis were very clear and therefore needless to analyze for the EOF/TSC. No basis was provided to support this position.

The staff believes the following actions should be taken:

- Reestablish the COL information item to communicate the interface requirement associated with EOF/TSC design. Specify in the COL information item that the COL applicant should complete the EOF/TSC design in accordance with NUREG-0696. This provides approved acceptance criteria for the design of these centers and avoids questions about what the phrase, "in accordance with the HFE program" means.

- Complete the OER, Functional analysis/functional allocation, and task analysis elements for the EOF/TSC HFE design. V&V is accomplished via the site specific ITAAC that require a full participation exercise followed by the periodic drills required by the COL applicants emergency.

Reference: MHI's Responses to US-APWR DCD RAI No. 295-2341;
MHI Ref: UAP-HF-09225; dated April 28, 2009; ML091210213.

ANSWER:

The HFE analysis in the OER of MUAP-08014 Human System Interface Verification and Validation (Phase 1a), Part 2, and the FRA/FA/HRA/TA in MUAP-09019 HSI Design, encompass the TSC and EOF. The remaining US-APWR HFE Implementation Plans also encompass the TSC. However, the application of the US-APWR HFE Implementation plans to the EOF is limited to the communication and information requirements for the EOF, as previously defined in Section 18.1.1.2. The EOF facility, itself, will be designed in accordance with NUREG-0696.

Since the scope of the DCD licensing basis will be changed to encompass the complete EOF, as explained above, a COL Action item is not needed.
To clarify the HFE design process for the EOF, the document revisions shown below will be made.

Impact on DCD

DCD Section 18.1.1.2;

(The fifth bullet in the first paragraph)
• Emergency operations facilities (EOFs) ~~(communications and information requirements only)~~

(The third paragraph)
The ~~site specific HFE team is to design the~~ communications and information requirements of the EOF, will be designed in accordance with the US-APWR HFE program.
~~The site specific HFE team is to specify the communication system requirements; however, the~~ The US-APWR HFE team determines the EOF information that must be transmitted, in accordance with regulatory requirements and guidance, and incorporates this information in the HFE design (Sections 18.7, 18.8, and 18.9) and the V&V process (Section 18.10). The EOF facility itself, is outside the scope of the US-APWR HFE Implementation Plans. The EOF facility is designed in accordance with NUREG-0696. The EOF design process specifies the complete EOF facility design, including the method of incorporating the communications and information requirements established by the US-APWR HFE program. The HSI displays at the EOF include the following:

MUAP-09019, Part 1 Section 2.3;

This Implementation Plan~~rocedure~~ is applicable to all HFE program elements, as defined in DCD Chapter 18, with the exception of Human Performance Monitoring (HPM). HPM is the responsibility of the license holder and ~~are~~is, therefore, governed by the license holder's own HPM implementation procedure, which is written in accordance with the strategy developed in the HPM ~~program~~ implementation plan ~~referenced in the COL application~~. It is noted that most US-APWR COL applicants are expected to reference the HPM program plan in Section 18.12 of the US-APWR DCD, but this is not required.
~~The license holder shall also create implementation procedures for the EOF, since the scope of the EOF encompassed by the US-APWR HFE team is limited to the design if the information displays and specification of the communication requirements.~~

The license holder shall also create implementation procedures for any HFE program elements that must be re-evaluated due to facility design changes.
The communications and information requirements of the EOF, will be established in accordance with the US-APWR HFE Implementation Plans; therefore this Implementation Procedure is applicable. However, the EOF facility itself, is outside the scope of the US-APWR HFE Implementation Plans; therefore this Implementation Procedure is not applicable.

MUAP-09019, Part 1 Section 8, the first paragraph;

The US-APWR HFE Program used for the MCR also ~~MCR development~~ applies to the Remote Shutdown Room (RSR) ~~and~~ the Technical Support Center (TSC), the communications and information requirements of the Emergency Operations facilities (EOF), and local stations since they are derivatives of the MCR.

MUAP-09019, Part 1 Section 8.2.2.3, the last sentence in the third paragraph;

The simulator shall be adaptable to encompass V&V for the Remote Shutdown Console and the information displays used at the Technical Support Center. It is noted that the HFE design team defines the information displays requirements and communication requirements for the EOF in accordance with the US-APWR HFE Implementation Plans, but the design and V&V is ~~of the~~

~~EOF is the responsibility of the COL applicant~~ outside the scope of the US-APWR HFE Implementation Plans.

MUAP-09019, Part 1 Section 8.3.1,

The scope of the Phase 3a site-specific activaties includes all facilities addressed in Phase 2, including the information and communication requirements for the EOF. The site specific design and V&V of the EOF is ~~the responsibility of the licensee~~ outside the scope of the US-APWR HFE Implementation Plans.

Impact on R-COLA

There is no impact on the R-COLA

Impact on S-COLA

There is no impact on the S-COLA

Impact on PRA

There is no impact on the PRA

RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

04/28/2011

US-APWR Design Certification

Mitsubishi Heavy Industries

Docket No. 52-021

RAI NO.:	**NO. 728-4534 REVISION 2**
SRP SECTION:	**18.1 - HUMAN FACTORS ENGINEERING**
APPLICATION SECTION:	**18.01 – 18.1 PROGRAM PLAN**
DATE OF RAI ISSUE:	**04/04/2011**

QUESTION NO. : 18-109

NUREG-0711 Criterion 2.4.2(2) states, "... The team should have the authority and organizational placement to provide reasonable assurance that all areas of responsibility are accomplished and to identify problems in the implementation of the overall plant design. The team should have the authority to control further processing, delivery, installation, or use of HFE products until the disposition of a nonconformance, deficiency, or unsatisfactory condition has been achieved."

The diagram in DCD Figure 18.1-1 does not show how the HFE design team fits into the larger design team and the US-APWR project.

MUAP-09019, Section 3.2, Figure 1 provides an organization chart which includes both organizational and functional relationships but only shows the organization up through project manager positions. It is unclear how they fit in the larger engineering organization. RAI 295-2341, Question 18-9 requested this information. The response (UAP-HF-09225) stated the organization placement and authority of these teams is controlled by the "Quality Assurance Program . . . (PQD-HD-19005)." This document shows the high level organization but does not connect that organization with the organization described in MUAP-09019.

- Describe the management levels between the project manager described in MUAP-09019, Figure 1 and the management position described in the QA program.
- Include or reference within the DCD the information in MUAP-09019 and this RAI response so more detailed organizational information is available to illustrate how this criterion is met.

ANSWER:

MUAP-09019 Part 1, Section 3.2 will be revised as shown below.

MUAP-09019, Part 1, Section 3.2;

" The HFE project organization and the position of the HFE project manager (HFE manager) are shown in Figure 1. The HFE manager has overall responsibility for the US-APWR HSIS project, which includes HSIS design, and HSIS V&V activities directly controlled by the HFE Implementation Plans. ~~shall be the lead organization for the US-APWR HSIS project, HSIS design, and HSIS V&V activities.~~ The HFE manager shall assure that all HFE program elements are appropriately implemented in accordance with the respective HFE implementation plan. Through matrixed responsibilities, the HFE manager is also responsible for the oversight of designs and activities from other engineering departments, that affect risk significant human performance, as shown in Figure 2. The HFE manager is responsible for organizing the HFE team, oversight of the HFE processes, and controlling HFE resources including those outside of his direct line organization.

The HSIS design group shall be separate from the HSIS V&V group. The ~~Project~~ MHFE manager, the HSIS Design Manager, and the HSIS V&V Manager shall be from MHI. Subcontractors ~~(such as URS)~~ to the HSIS design group and HSIS V&V group shall perform work at the direction of MHI.

The HFE team shall conduct HFE activities under the MHI Engineering Management Department's work protocol ("4FC-UAP-20070007"), which shall comply with MHI Quality Assurance Program (PQD-HD-19005).

Figure 2 shows the matrixed HFE team positions in relationship to the other MHI engineering organization team members which are controlled under the MHI QA program.

The HFE manager assigns HFE activities to the HFE team members according to each subject matter organization's responsibilities. The HFE manager is the functional manager of the HFE team members. The HFE team members are assigned from each engineering organization according to HFE manager requests.

The HFE team has a responsibility to identify and oversee the correction of HFE problems implementation of the overall plant design.
The HFE team shall coordinate with other plant organization to identify and resolve HFE issues by the following approach:

- Organize design review meetings with plant design and HFE experts to identify and discuss solution of HFE issues
- Define the responsible design organization to lead issues resolution. Generally, the plant design organizations are responsible for resolving HFE design issues, by improving their plant design specifications.
- Follow up with the assigned design organizations to complete their actions
- Verify the HFE issues resolved through technical review, and/or conducting verifications using prototype models or simulators"

Figure 1 of MUAP-01019 will be revised as per shown in Attachment 1, and Attachment 2
Figure 2 of HFE team organization in the MHI engineering and design organizations will be added to MUAP-09019 Part 1, Section 3.2, showing the HFE team organization in the MHI engineering and design organizations.

Impact on DCD

DCD, Section 18.1.2.2;
The first sentence of the first paragraph will be revised as follows:

"The primary HFE organization within the US-APWR program is identified below. The organizational structure to manage the HFE ~~design~~ team is shown in Figure 18.1-1."

DCD Figure 18.1-1 will be replaced with Figure 1 in MUAP-09019 Part 1 to clarify the organization.

The second paragraph in the DCD Section 18.1.2.2 will be revised as follows:

"

- Engineering Management Director (EMD)
  The EMD is responsible for controlling engineering resources/organizations and directing responsible organizations to resolve critical design or engineering issues which includes human factor engineering issues.

- HFE manager (project manager~~PM~~)
  The HFE ~~Project~~ Manager assures that all HFE elements are appropriately ~~the process of design, V&V, and quality assurance (QA) is appropriately~~ implemented in accordance with the HFE implementation plan.
  The HFE manager is responsible for organizing the HFE team, oversight of the HFE processes, and controlling HFE resources.

- HSIS Design team manager (DTM)
  The DTM is responsible for implementing all of the HFE elements. The design team conducts all design activities for hardware and software. The
  DTM assures that the design team correctly performs design activities based on the technical requirements and the development process in accordance with Reference 18.1-6. The DTM is also responsible for the following:
  - Initiation, recommendation, and provision for resolutions of problems identified during the implementation of the HFE activities
  - Verification of the effectiveness of the solutions provided to problems
  - Assurance that HFE activities comply with HFE plans and procedures
  - Scheduling of activities
  - Methods for identification, closure, and documentation of human factors issues
  - HSI design and HFE documentation configuration controls

- QA Organization
  The QA organization conducts the QA in accordance with the QA plan (Reference 18.6-1), which includes conformance to the supplier's overall QA program.

The HFE team's role and position of the other MHI engineering organizations is described in Reference 18.1-12, Part 1, Section 3.2."

Impact on R-COLA

There is no impact on the R-COLA

Impact on S-COLA

There is no impact on the S-COLA

Impact on PRA

There is no impact on the PRA

Attachment-1

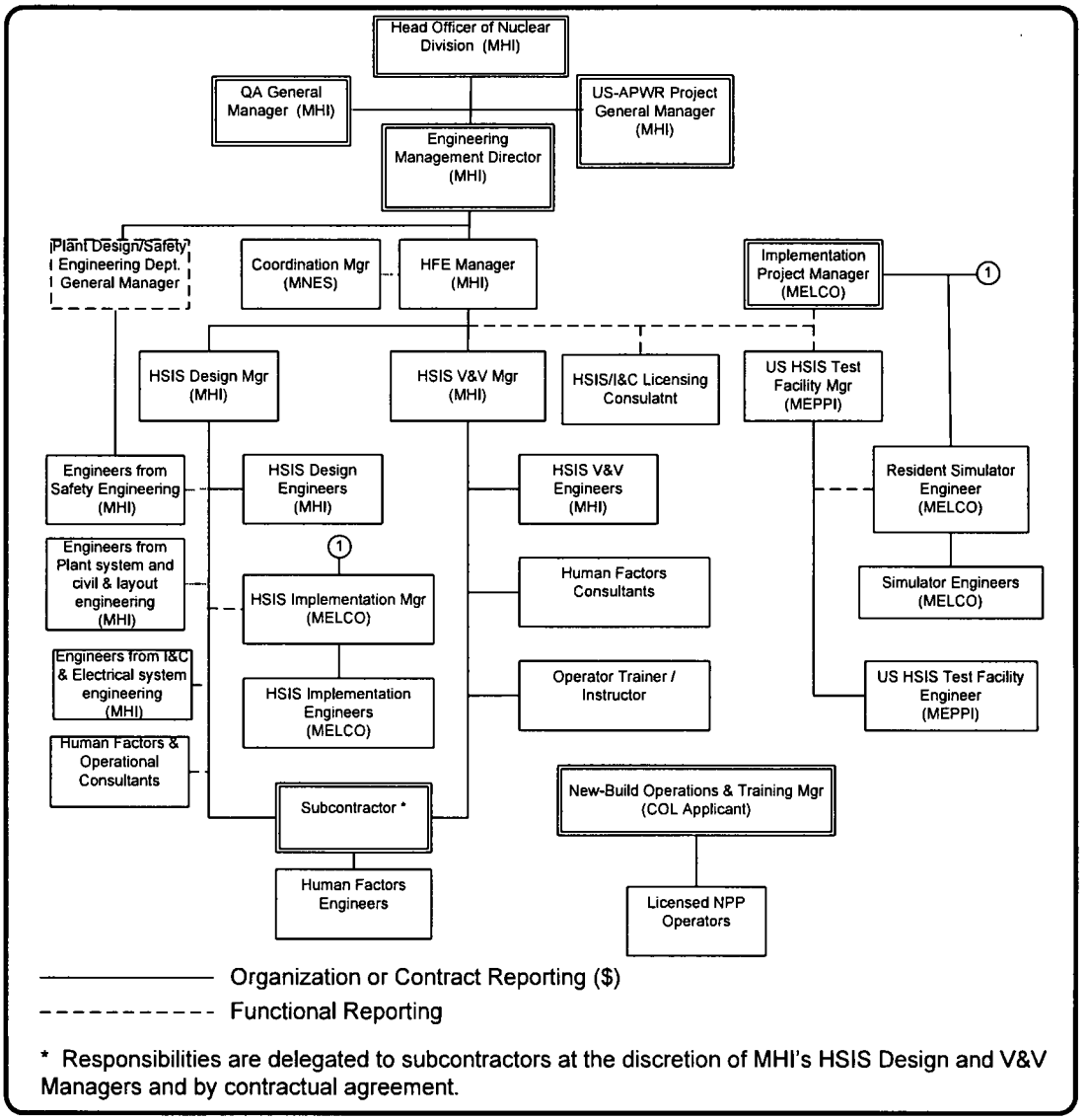

Figure 1 HFE Team ~~Project~~ Organization

Attachment-2

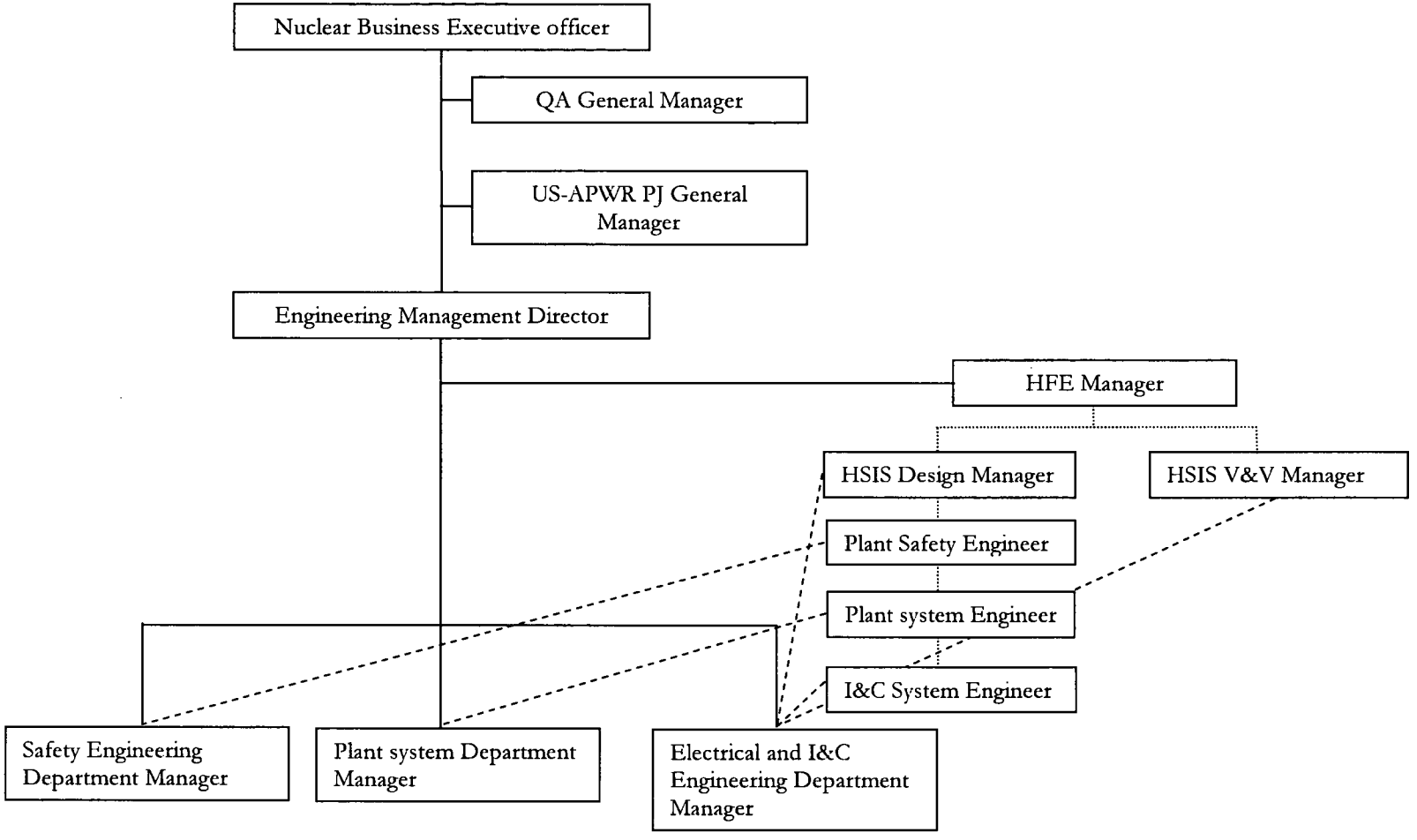

Figure 2 HFE team organization in the MHI engineering and design organizations

RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

04/28/2011

US-APWR Design Certification

Mitsubishi Heavy Industries

Docket No. 52-021

RAI NO.:	**NO. 728-4534 REVISION 2**
SRP SECTION:	**18.1 - HUMAN FACTORS ENGINEERING**
APPLICATION SECTION:	**18.01 – 18.1 PROGRAM PLAN**
DATE OF RAI ISSUE:	**04/04/2011**

QUESTION NO. : 18-110

NUREG-0711, Criterion 2.4.1(4) states: "Applicable HSIs, Procedures and Training – The applicable HSIs, procedures, and training included in the HFE program should include all operations, accident management, maintenance, test, inspection and surveillance interfaces (including procedures)."

Topical Report MUAP-07007, section 5.1.1.4 uses the same words as the NUREG. The DCD section 18.1.1.3 replaces the term "accident management" with "emergency response."

Please clarify the difference in wording. (note: emergency response could mean emergency operating procedures and/or the procedures used to implement the emergency plan).

ANSWER:

The activities associated with "emergency response" were intended to be the same activities associated with "accident management." In order to provide consistency between MUAP-07007 and the DCD, MHI will revise DCD section 18.1.1.3 will be revised as shown below.

Impact on DCD

The DCD section 18.1.1.3;

The applicable HSIs, procedures, and training developed and evaluated by the HFE program includes operations, ~~emergency response~~ accident management, maintenance, test, inspection, and surveillance interfaces (including procedures and training provided to operations and maintenance personnel to maintain plant safety and respond to abnormal plant conditions).

MHI will replace the word "emergency response" to "accident management" in the DCD section 18.1.1.3.

Impact on R-COLA

There is no impact on the R-COLA

Impact on S-COLA

There is no impact on the S-COLA

Impact on PRA

There is no impact on the PRA

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DATE OF RAI ISSUE:	**04/04/2011**

QUESTION NO. : 18-111

NUREG-0711 Criterion 2.4.3(1) states: "General Process Procedures - The process through which the team will execute their responsibilities should be identified. The process should include procedures for:

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

From the MHI response to RAI 295-2341, Questions 18-12 and 18-16, and DCD section18.1.3.1, the staff understands that the QA Program describes generic quality standards applicable to the above activities.

Please provide the title of the working level documents that control these activities and a summary of what each document requires relative to the areas listed in the NUREG-0711 criterion above.

ANSWER:

The HFE manager responsibilities include following responsible;

- 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

MUAP-09019, Part 1, Section 3.2 and Section 3.3 will be revised to incorporate the summary of the HFE work process as shown below.

MUAP-09019, Part 1, Section 3.2;

See the markup of the RAI 18-109 response.

MUAP-09019, Part1, Section 3.3;

3.3.1 HFE project manager (HFE Manager)
The HFE ~~project~~ manager shall be responsible for management decisions regarding the HFE program. The HFE ~~project~~ manager shall assign work responsibilities to the technical disciplines. The technical managers and their staffs shall implement the assigned work responsibilities.

The HFE manager shall assure that all HFE program elements are appropriately implemented in accordance with the respective HFE implementation plan.
The HFE manager is responsible for making HFE design decisions and controlling HSIS design changes. Plant design authorities (i.e., engineering divisions) are required to change the plant design based on HFE design decisions. HFE members consist of multi-disciplined engineers dispatched from each engineering division. HFE members are responsible for resolving HFE issues in accordance with their engineering responsibilities. The HFE manager is responsible for organizing the HFE team, oversight of the HFE processes, and controlling HFE resources including those outside of his direct line organization.

In addition, MUAP-09019, Part 1, Section 3.2 and Section 3.3 will be revised to incorporate the summary of following HFE design decisions process in a part of plant design control as shown below and also addressed in a part of RAI 18-111 response above.

- making HFE design decisions
- governing equipment design changes
- design team review of HFE products

MUAP-09019, Part 1, Section 3.2;

The HFE team has a responsibility to identify and oversee the correction of HFE problems implementation of the overall plant design.
The HFE team shall coordinate with other plant organization to identify and resolve HFE issues by the following approach:

- Organize design review meetings with plant design and HFE experts to identify and discuss solution of HFE issues
- Define the responsible design organization to lead issues resolution. Generally, the plant design organizations are responsible for resolving HFE design issues, by improving their plant design specifications.

- Follow up with the assigned design organizations to complete their actions
- Verify the HFE issues resolved through technical review, and/or conducting verifications using prototype models or simulators

The plant design organizations are responsible for resolving design issues which are identified by the HFE program, by improving their plant design specifications.
The HFE team is responsible for controlling HFE issues tracking, i.e., initiating human factor discrepancies (HEDs), tracking HEDs, coordinating with experts and plant design organizations to resolve HEDs, verifying HFE issues are addressed going through all HEF activities.

Impact on DCD

Refer to the RAI Question No.18-109 DCD impact.

Impact on R-COLA

There is no impact on the R-COLA

Impact on S-COLA

There is no impact on the S-COLA

Impact on PRA

There is no impact on the PRA

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QUESTION NO. : 18-112

NUREG-0711 Criterion 2.4.3(2) states: "Process Management Tools - Tools and techniques (e.g., review forms) to be utilized by the team to verify they fulfill their responsibilities should be identified."

The MHI response to RAI 295-2341, Question 18-13, describes the HED process. The staff acknowledges this as one process management tool but this tool does not address the responsibilities listed in criterion 2.4.3(1).

MHI is requested to:

- Provide the title of working level procedures that control work flow, work priority, work review, describe interfaces with project management, and describe interfaces with supporting technical groups.
- List the key data bases, forms, and other tools contained in these procedures that are used to facilitate proper implementation of the procedure.
- Provide a flow chart of the engineering process that includes process feedback, issue disposition, independent reviews, and supporting technical reviews.

Include this material in the DCD or in documents referenced by the DCD (The staff is looking for more detail than QA Program control contained in the previous response).

ANSWER:

Attachment-3 describes working level procedures based on the NUREG-0711 Criterion 2.4.3 (2). MUAP-09019 HSI Design, Part 1 Section 5 will be revised to attach the Attachment-3.

Impact on DCD

There is no impact on the DCD

Impact on R-COLA

There is no impact on the R-COLA

Impact on S-COLA

There is no impact on the S-COLA

Impact on PRA

There is no impact on the PRA

(1) Integration of HFE and Other Plant Design Activities with Management tool & processes

During HFE activities, if there are any HFE issues identified that may impact plant design engineering or if it found to be necessary to track completion of the required actions, Attachment 4, HFE Review Form is used to document the item/action. Anyone in the HFE team can initiate a HFE Review Form for problems identified during the HFE activities. The completed forms are reviewed by HFE team members and are approved by the HFE manager; approved forms are tracked by unique sequential identification codes and maintained either in hard copy binders, or electronically in the HFE tracking database which captures all information in the form. The forms are tracked as a QA record.

Review and resolution meetings with design engineers are organized by the HFE manager or assigned individuals to agree on resolutions which include design changes, if needed.

If issues are addressed by design changes, the form is closed by assigned team member's signature, and the form is revised/annotated indicating the basis for closure. The HFE manger confirms and approves the review form by verifying that was closed.

(2) HFE Program Milestones

Once each HFE activity is completed, the HFE team verifies that activity meets its Implementation Plan and produces a summary document to summarize and/or consolidate each activity. Critical check points in conjunction with plant design progresses are performed and when issues are found during these checks of each HFE program element action is taken to resolve the issue.

Figure 2 shows the HFE milestone and critical checkpoint in embedded in the plant design, procurement, constructions and operation. Figure 3 show engineering work processes and integrations with plant design organizations. Arrow shows critical checkpoint which indicates each activities milestones and relations with other HFE elements.

Attachment-3

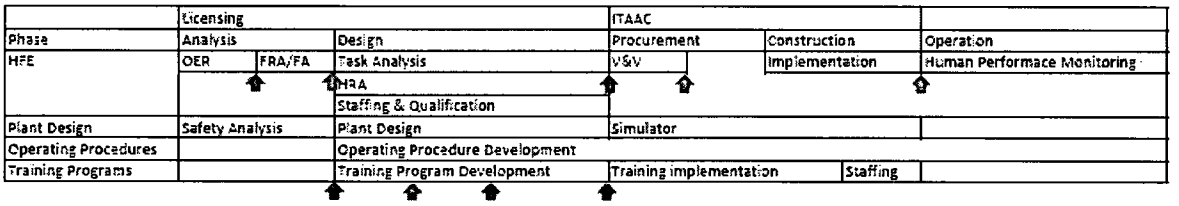

Figure 2 HFE program milestones embedded in the plant design, procedure, construction and operation

(3) Subcontractor HFE Efforts – If a subcontractor is involved in HFE activities, the HFE team verifies the subcontractor complies with the HFE requirements. HFE manager requires that subcontractors shall work under MHI's QA programs and HFE implementation plans & procedures MHI developed and documented as licensing document and/or internal MHI's work procedures. The MHI QA organization verifies subcontractors to conduct their work.

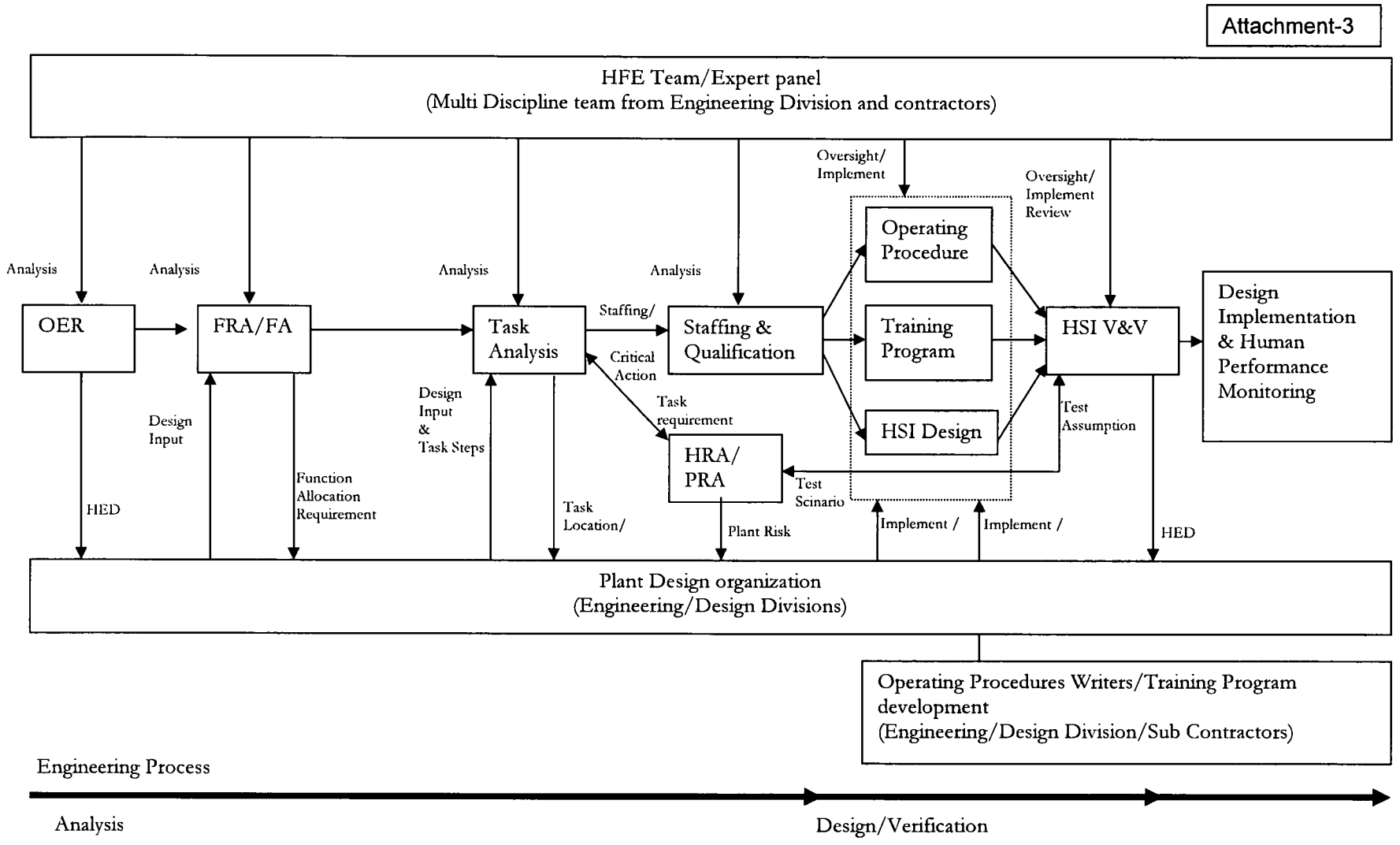

Figure 3 Engineering work process and integrations flow between HFE team and plant design organizations

Attachment 4

HFE Review Form	
HFE Category:	Issue Date:
Title:	Issuer Name:
Description: (Issue/discussion)	
Resolution: Review Meeting Necessities & Decision: (Yes/No) Description: Incorporated Engineering Documents:	
Assigned engineering organization: (Title/Print Name/Signature/Date)	
HFE team organization: (Title/Print Name/Signature/Date) HFE Manager Approval: (Title/Print Name/Signature/Date)	

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Mitsubishi Heavy Industries

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QUESTION NO. : 18-114

DCD, Chapter 18, Section 18.1,"HFE Program Management," does not reference MUAP-09019, "US-APWR HSI Design," yet part 1 of that document contains additional detail on the program management plan.

The documents are not always consistent. For example:

MUAP-09019, Section 3.1 provides a minimum experience level of 10 years. Minimum experience is not addressed in the DCD.

MUAP-09019, Section 6.1 says an "expert panel" shall formulate discrepancy resolution. The DCD, Section 8.1.4 says the HSI design team will do this. From the explanation in MUAP-09019 the "expert Panel" appears to contain membership outside the HFE design and V&V teams.

MUAP-09019, Section 6.2 provides information on the threshold being used for HEDs. This is not addressed in the DCD.
Within the Program Management section, the staff has used MUAP-09019 to clarify material in the DCD and/or demonstrate that review criteria have been met. For example:

- DCD, Section 18.1.1.2 – to clarify HFE application to local control stations
- DCD, Section 18.1.1.2 – to clarify EOF responsibilities
- DCD, Section 18.1.2.2 – to clarify project organization
- DCD, Section 18.1.3.3 – to clarify work process
- DCD, Section 18.1.4 – to clarify HED processing (MUAP-09019, sections 6&7)
- DCD, Section 18.1.5 – to clarify phased approach (MUAP-09019, section 8)

Consolidate or reference information within the DCD as appropriate. Resolve differences between the documents.

ANSWER:

DCD Section 18.1 will be revised as shown below:

Impact on DCD

Reference of MUAP-09019, "US-APWR HSI Design," Part 1 in the DCD and HFE organization qualification mismatch will also be eliminated referring to the MUAP-09019 Part 1, Section 3.1 and Section 6.1 for HFE expert panel in the DCD Section 18.1.2.4, the HED threshold will also be incorporated reffering to the MUAP 09019 Part 1, Section 6 and 7 in the DCD 18.1.4:

DCD, Section 18.1.2.4, the first sentence in the first paragraph;

"The HFE team staffing is described in terms of minimum qualifications and job descriptions of team personnel. The minimum qualifications and job descriptions of team personnel are documented in Reference 18.1-12, Part 1, Section 3.1 and Section 6.1 for HFE expert panel, and controlled as required by Reference 18.1-6."

DCD, Section 18.1.2.4, the last sentence in the second paragraph as also addressed in RAI-18-106 response above;

"The roles and responsibilities for the key sections of the organization are described in ~~Reference 18.1-1 Subsection 5.1.2.2~~ Reference 18.1-12, Part 1 Section 3.2. "

DCD, Section 18.1.3.3;

"The integration of design activities identifies, the inputs from other plant design activities to the HFE program and the outputs from the HFE program to other plant design activities. The iterative nature of the HFE design processes is addressed. HFE design controls are as described in Reference 18.1-6. The work process how HFE team interact with other plant design organization, are described in Reference 18.1-12, Part 1 Section 5."

DCD, Section 18.1.3.4 as also addressed in RAI-18-106 response above;

"HFE milestones are identified so that evaluations of the effectiveness of the HFE effort can be made at critical checkpoints and the relationship to the integrated plant sequence of events is shown. A relative program ~~schedule~~ process of HFE tasks showing relationships between HFE elements and activities, products, and reviews has been developed (Reference 18.1-12, Part 1, Section 5). The schedules and milestones are shown in ~~the~~ Reference 18-1-12, Part, Section 5, Attachment ~~Figure 4.0-2~~."

DCD, Section 18.1.3.6 as also addressed in RAI-18-106 response above;

"HFE requirements are included in each subcontract for HFE support and the subcontractor's compliance with HFE requirements is periodically verified. HFE work performed by subcontractors is controlled as described in Reference 18.1-12, Part 1, Section 5 and 18.1-6."

DCD, Section 18.1.4, the last paragraph as also addressed in RAI-18-106 response above;

"The process through which the HFE design team executes its responsibilities is described in Reference 18.1-12, Part 1 Section 6 and Section 7."

DCD Section 18.1.1.2 for EOF and local control stations applicability;

See the response to Question 18-107 and RAI 18-108 for EOF and local control stations applicability.

DCD, Section 18.1.2.2 – to clarify project organization;

See the response to Question 18-109 for project organization;

DCD, Section 18.1.3.3 – to clarify work process;

See the response to Question 18-112 for project organization;

DCD, Section 18.1.4 – to clarify HED processing (MUAP-09019, sections 6&7);

See above changes for DCD Section 18.1.4;

DCD, Section 18.1.5 – to clarify phased approach (MUAP-09019, section 8);

"The HFE technical program is performed in accordance with the HFE process specified in the US-APWR HFE implementation plan ~~NUREG-0711~~ (Reference 18.1-~~7~~12, Part 1, Section 8).
The US-APWR HFE process is divided into three phases.

1. Phase 1 yields the generic US Basic HSIS.
2. Phase 2 combines the US-APWR Inventory with the US Basic HSIS to yield the generic US-APWR HSIS.
3. Phase 3 makes minor site specific changes to the US-APWR HSIS to yield a site specific HSIS

The general development process ~~of each of the elements of the HFE technical program, including the associated implementation plans, analyses, and evaluation,~~ is shown ~~identified and described~~ in Figure 18.1-4.

In Phase 1, US Basic HSI is verified and documented in Reference 18.1-13, Part 1 and Reference 18.1-12, Part 3.
In Phase 2, US-APWR HFE implementation process is developed and documented in the Reference 18.1-12, Part 1. Also the HFE analysis which includes OER, FRA/FA, TA (for risk important human actions), and HRA, are performed and documented in Reference 18.13, Part 1 (OER) and Reference 18.1-12, Part 2.
Implementation plans for the other HFE elements for phase 2, which include site-specific assumptions for phase 3, are developed and documented in References 18.1-14, 18.1-15, 18.1-16, 18.1-17, 18.1-18 and 18.1-19."

DCD, Section 18.1.5 Figure 18.1-4 will be replaced with Figure 5 of MUAP-09019.

And following reference will be added in DCD, Section 18.1.7;

18.1-12	US-APWR HSI Design, MUAP-09019-P (Proprietary) and MUAP-09019-NP (Non-Proprietary), Revision 0, June 2009.
18.1-13	US-APWR Human System Interface Verification and Validation (Phase 1a), MUAP-08014-P (Proprietary) and MUAP-08014-NP (Non-Proprietary), Revision 0, December 2008
18.1-14	US-APWR HSI Design Implementation Plan, MUAP-10009, Revision 0, April 2010
18.1-15	US-APWR Procedure Development Implementation Plan, MUAP-10010, Revision 0, April 2010
18.1-16	Training Program Development Implementation Plan, MUAP-10011, Revision 0, April 2010
18.1-17	Verification and Validation implementation plan, MUAP-10012, Revision 0, April 2010
18.1-18	Design Implementation, MUAP-10013, Revision 0, April 2010
18.1-19	Human Performance Monitoring Implementation Plan, MUAP-10014, Revision 0, April 2010

For "expert panel" position in the HSIS design team:

MUAP-09019, Section 6.1, the second paragraph;
"The HSIS Design Manager is responsible for evaluating and closing HEDs. HEDs may be caused from broad engineering fields and plant operational experiences. In order to evaluate the HEDs, the HSIS Design manager organizes a multi disciplined expert team in a HSI Design team as an "Expert Panel". The ~~HSIS Design "Each discrepancy~~ HEDs shall be evaluated by the "Expert Panel." The Expert Panel shall comprise selected HSI Design and V&V Team members, I&C experts, and nuclear plant process, systems, and operations experts. As stated before experts shall have at least 10 years of nuclear experience in their expert field and an education background that supports their expert credentials. The Expert Panel shall have available technical consultants from the HSI Implementation Team."

Impact on R-COLA

There is no impact on the R-COLA

Impact on S-COLA

There is no impact on the S-COLA

Impact on PRA

There is no impact on the PRA

This completes MHI's responses to the NRC's questions.