REQUEST FOR ADDITIONAL INFORMATION 796-5728 REVISION 3

8/3/2011

US-APWR Design Certification

Mitsubishi Heavy Industries

Docket No. 52-021

SRP Section: 18 - Human Factors Engineering
Application Section: 18.10

QUESTIONS for Operating Licensing and Human Performance Branch (AP1000/EPR Projects) (COLP)

18-150

SRP 14.3.9, II, Acceptance Criterion 2 states “If an implementation plan, rather than a completed HFE element, was accepted as part of the design certification process, then ITAAC should address the completion of the HFE program element.” This RAI has two parts.

Part 1: The applicant’s Verification and Validation (V&V) program is described in DCD, Tier 2, Section 18.10. The DCD references MUAP-07007, HSI System Description and HFE Process, for detailed information the US-APWR V&V program. Information about V&V is also presented in the V&V Implementation Plan (MUAP-10012, R0). However, this document is not referenced by either the DCD or MUAP-07007. The NUREG-0711 Compliance Roadmap (MUAP-09024, R0) indicates that a detailed Phase 2b V&V procedure describes the design verification. Which document is this referring to? V&V is addressed in DCD, Tier 1, Section 2.9, Table 2.9-1, Design Commitment 10. The commitment is to conduct the V&V program in accordance with the V&V Program Implementation Plan. However, no specific plan is referenced, thus there is some ambiguity over which document (07007 or 10012) is the plan. Please clarify which document is the implementation plan, the relationship between the documents, and reference it in the Tier 1 and Tier 2 portions of the DCD.

Part 2: DCD, Section 18.10, the V&V IP, and the US-APWR NUREG-0711 Compliance Roadmap, Sec. 11, V&V, refer to various other documents, containing various amounts of detail on V&V. These include MUAP-07007-P(R3), MUAP-08014-P(R0) [NOTE: Revision 1 was issued 5/31/2011, after this question was written], and MUAP-09019-P(R0). From the review performed by staff to date, it appears that all of these documents are needed to obtain the full commitment to the NUREG-0711 criteria and to understand the details of the US-APWR V&V program. If this “diffuse” structure is maintained, they should all be referenced in the DCD. Also NRC and MHI will need to agree whether all these should be designated as Tier 2*. Further, the staff has concerns whether the applicant V&V team can adequately construct and implement an Integrated System Validation that will effectively address regulatory guidance, when the program commitments are so diffuse over many documents. Please address.

18-151

The NRC is reviewing V&V at an implementation plan level of review. Per NUREG-0711, an implementation plan gives the applicant's proposed methodology for meeting the

acceptance criteria of the element. Since the implementation plan is the basis of the NRC's safety finding for HFE activities that are yet to be completed, the staff must understand in detail how the methodology will be implemented; and must be confident that it can be reliably conducted by design personnel and that it will provide acceptable results.

Many aspects of MHI's V&V plan are not at a sufficient level of detail. For example, the staff expects to see the detailed scenario descriptions, the exact performance measures to be collected for each scenario, and the specific acceptance criteria for each performance measure. These details are not provided. Many of the more specific RAIs request these details. The current V&V documentation rests heavily on Phase 1 tests that serve as an illustration of how V&V will be conducted. However, that is not an implementation plan as described above. Please provide an implementation plan for US-APWR V&V at the level of detail necessary for staff review.

18-152

The various MHI documents discuss four versions of the MHI HSI. It appears that the Generic US-APWR HSI is the version that will receive the V&V that is being described in the DCD and in the V&V IP. However neither the DCD nor the V&V IP specifically state that. Further, the compliance roadmap frequently refers to the US-APWR plant specific V&V, rather than the Generic US-APWR V&V. Please clarify which version of the HSI will be the subject of the V&V for the US-APWR design certification.

18-153

The DCD and MUAP-07007 indicate that V&V is a phased activity and that the results from earlier V&V activities will not be repeated. For example, DCD Revision 3, Section 18.10.2, Methodology, states, "The US-APWR HSI and procedures are based on the Japanese APWR HSI and procedures. The changes to HSI and procedures are described in Sections 18.7 and 18.8, respectively. Therefore, the US-APWR HFE V&V program focuses on these changes."

MUAP-07007, revision 3, section 5.10 states that:
The V&V program is conducted in multiple phases, as described at a high level in Appendix C, and in more detail in the each plant specific V&V Implementation Plan… The V&V program activities conducted during Phase 1, which applies to the Basic HSI System, is generically applicable to all applications of the US Basic HSI System (i.e. to the US-APWR and operating plant upgrades). Phase 1 V&V will not be repeated.

The staff V&V review is conducted on the V&V activities performed for the final design (the Generic US-APWR HSI in this case). The staff typically does not consider interim tests and evaluations that are performed during the design process as the V&V. As noted in NUREG-0711, section 11.1:
"Many design documents (e.g., ISO 11064) recommend conducting V&V throughout the design process. This document <NUREG-0711> agrees with that recommendation, with these activities called "HSI Tests and Evaluations" (see the HSI Design element, Section 8.4.6). … V&V is considered a test that final design requirements are met."

The staff's V&V review for a DCD application is directed at the final design that is to be certified. Please clarify the relation between Phases 1a/1b and Phase 2. Confirm that the Phase 2 V&V will be complete. If not complete, describe how you plan to "take credit" for Phases 1a/1b, especially considering the fact that the HSI tested will be different between the Phases.

18-154

MUAP-07007, revision 3, section 5.10 states that plant specific V&V activities will be conducted.

> The V&V program is conducted in multiple phases, as described at a high level in Appendix C, and in more detail in the *each plant specific V&V Implementation Plan*.
>
> The V&V program activities conducted during Phases 2/3, as described in Appendix C for the US-APWR, will be uniquely repeated for all plant/site specific applications. *Phases 2/3 are carried out on final plant/site specific HSI design*.

This appears to state that Phase 2/3 V&V activities will be conducted for each site using a site specific V&V implementation plan.

The Generic US-APWR HSI Design will have been verified and validated in Phase 2. Please explain what will be verified and validated in Phase 3 and how complete this V&V will be.

18-155

NUREG-0711, Criterion 11.4.1.2.2, Identification of Scenarios, and 11.4.3.2.4, Scenario Definition, address the Integrated System Validation (ISV) scenarios. As summarized in the Compliance Roadmap, the MHI V&V documents do not specifically address all of the review criteria for the scenarios. Rather the documents refer to the Phase 1a and 1b V&V testing done on the US-Basic HSI and generally state that the results reports for this earlier V&V provide an illustration of the V&V to be done for the US-APWR. This general reference to earlier V&V does not provide a sufficient commitment to allow design certification of the US-APWR.

Further, based on a brief review of the Phase 1a and 1b scenarios, they do not seem to address all of the sampling dimensions of NUREG-0711, item 11.4.1.2.1.

18-156

Section 5.0 of the V&V IP (MUAP-10012) is References. Reference 6 is referred to on page 8 of the IP as the training simulator standard (ANS 3.5), however the reference citation in Section 5.0 appears to have mixed together two ANS standards into one reference, ANSI/ANS 3.5 1998 and ANSI/ANS 3.1 1993, reaffirmed 1999. Please correct.

18-157

NUREG-0711, Section 11.4.1.2.1, includes plant conditions, personnel tasks, and situational factors known to challenge personnel performance and that should be included in the Operational Conditions Sampling (OCS) for V&V.

Section 4.3.4 of the V&V IP provides only a high level commitment to these OCS criteria. More detailed OCS specifics (but not all that is in the NUREG-0711 criteria) are given in MUAP-07007, Section 5.10.2.1. MHI should provide an appropriate commitment to the added details from the criteria.

18-158

NUREG-0711, item 11.4.1.2.2(1) specifies that the results of the OCS should be combined to identify a set of scenarios. The V&V IP, Section 4.1 provides an overview of the OCS process. However, MHI needs to either define in some detail the process for identifying the scenarios based on the OCS process, or present the list of scenarios to be used, together with a justification or table that shows how they satisfy the OCS criteria. Currently neither has been done, rather scenarios selected for the earlier Phase 1a and 1b V&V testing are generally refered to. This set of scenarios is not sufficiently complete to serve as the Phase 2 (US-APWR generic HSI). On the other hand, Section 4.3.4 of the IP states that scenarios will include all normal evolutions and malfunctions per ANSI/ANS 3.5. This appears to be a larger number than typically used for ISV. Please provide this information.

18-159

NUREG-0711, item 11.4.3.2.4(1) specifies information that should be defined for each scenario. The US-APWR HFE Program NUREG-0711 Compliance Roadmap (MUAP-09024) refers to the Phase 1a and 1b summary results for an illustration of the level of detail for test scenario definitions. However, the Phase 1a and 1b summaries do not provide all of the information in the criterion. Please provide a satisfactory commitment to the detailed information needs of this criterion. In addition provide a sample of at least 3 completed scenarios.

[eRAI question ID 20935]

18-160

Per NUREG-0711, Section 11.4.3.2.5.1, Review Criterion 1, MHI does not discuss the characteristics of the performance measures to be used in ISV. The DCD states that the ISV methodology will address measurement characteristics but does not provide any information. Nor is the information provided in any of the following documents: MUAP-07007; MUAP-10012, R0; MUAP-09019; or MUAP-08014-P, R0. The NUREG-0711 Compliance Roadmap (MUAP-09024, R0) states that measurement characteristics are “satisfied” by the use of “converging measures logic.” The Roadmap references MUAP-08014-P, R0, Part 1 for an explanation of the approach. We do agree with the importance of converging measures to the validation and HED evaluation process. In fact, that is addressed in NUREG-0711, Section 11.4.3.2.7, Data Analysis and

Interpretation. Criterion 3 states that “the degree of convergent validity should be evaluated, i.e., the convergence or consistency of the measures of performance.” However, it does not address the measurement characteristics of the measures. To illustrate, assume there are three measures of workload and the results of the ISV testing does not indicate a workload problem on any of the three measures. Thus, a converging measures logic leads to the conclusion that workload is acceptable. However, if the three measures have poor construct validity (that is, do not provide good measures of workload), then the conclusion may be false. A converging measures logic should only be used when the measures have acceptable measurement characteristics. Otherwise, misleading or incorrect conclusion may result.

The staff recognizes that most of the measurement characteristics identified in Review Criterion 1 in NUREG-0711, Section 11.4.3.2.5.1 will not be applicable to many of the measures, but MHI should minimally identify and address the characteristics that are applicable. For example, the applicant should explain how a questionnaire used to assess workload or situation awareness was developed and why the approach to measuring these variables in this way is a good one.

18-161

The DCD, section 18.10.2.3 references MUAP-07007, Section 5.10.2.2.4, Integrated System Validation, Part e, Performance Measurement, for information on performance measure. It states that a hierarchal set of performance measures will be used; however, there is no discussion of anthropometric/physiological factors. The NUREG-0711 Compliance Roadmap (MUAP-09024, R0) indicates that anthropometric/physiological factors were measured in the Phase 1 tests and that a “concrete illustration” of them are in MUAP-08014-P (R0) and the measures will be used in the US-APWR ISV test. However, their absence from the DCD and from MUAP-07007 leaves the status of these measures unclear. Please identify how these factors will be addressed.

18-162

The DCD references MUAP-07007, Section 5.10.2.2.4, Integrated System Validation, Part e, Performance Measurement, for information on performance measure. There is no discussion of pass/fail measures in the DCD or MUAP-07007. Pass/fail measures are discussed in the V&V Plan (MUAP-10012, R0), Section 4.3.5, “Performance Measures. However, MHI does not specifically identify which measures are pass/fail and which are used for performance analysis. Please identify which specific measures are to be used as pass/fail measures.

18-163

Please identify the specific plant performance measures that will be used for the specific scenarios being used in the tests. In lieu of the complete set of measures for each ISV scenario, the staff will accept a sample of three detailed scenarios, as per the previous RAI question ID number 20935.

18-164

Please identify the specific personnel task measures that will be used for the specific scenarios being used in the tests. In lieu of the complete set of measures for each ISV scenario, the staff will accept a sample of three detailed scenarios, as per RAI question ID 20935.

18-165

MUAP-07007, section 5.10.2.2.4 Part e, indicates that situation awareness measure will not be used (p. 159), yet the V&V Implementation Plan (MUAP-10012, R0) and the NUREG-0711 Compliance Roadmap (MUAP-09024, R0) indicates SA measures will be used. Please clarify.
To the extent that these measures are scenario specific, please identify the specific measures that will be used for the specific scenarios being used in the tests. In lieu of the complete set of measures for each ISV scenario, the staff will accept a sample of three detailed scenarios, as per RAI question ID 20935.

18-166

MUAP-07007, Section 5.10.2.2.4, Integrated System Validation, Part e, Performance Measurement, states that cognitive workload will be measured by methods described in Section 5.4.3.2. However, in that section, the use of a human information processing model to evaluate workload as part of task analysis is described. We do not see how this is applicable to measuring workload as part of dynamic scenarios during ISV. The NUREG-0711 Compliance Roadmap (MUAP-09024, R0) references MUAP-07007, but identifies the use of multiple converging measures of workload, based on operator and observer ratings, as was used in the Phase 1 evaluation. The V&V Implementation Plan (MUAP-10012, R0), Section 4.3.5, indicates workload will be measured using rating scales administered to operators after each scenario. The V&V Implementation Plan also states that workload will be assessed by expert observer evaluations. This description is consistent with the Roadmap, but not with MUAP-07007 which is referenced by the DCD. Please clarify the approach to workload measurement in the ISV tests.

18-167

The NUREG-0711 Compliance Roadmap (MUAP-09024, R0) identifies criteria, but does not reference the DCD or MUAP-07007. Instead it discusses the Phase 1 evaluation described in MUAP-08014-P, R0 [Revision 1 was received after the question was written.] and MUAP-09019-P, R0. The Roadmap states that the same approach will be used in US-APWR ISV. An examination of the Phase 1b criteria found in MUAP-09019-P, R0, Part 3, Appendix 8.4, revealed that specific plant and operator action criteria were identified for each scenario along with the basis for each is identified. No criteria for other types of performance measures are provided. Section 4.3.4, Scenario Definition, of the V&V Implementation Plan (MUAP-10012, R0) discusses the applicant's general approach to defining acceptance criteria. The Plan states that performance criteria are established for each scenario in terms of plant and human performance. The criteria are

defined by operations subject matter experts and make use of industry standards and guidelines, such as those established by INPO and the NRC.

Page 9 of the Plan references “Appendices of this plan” for examples. However, MUAP-10012, R0 does not include any appendices.

Therefore, please identify the specific performance criteria and bases for the measures that will be used for the specific scenarios being used in the US-APWR ISV tests. In lieu of the complete set of measures for each ISV scenario, the staff will accept a sample of three detailed scenarios, as per RAI question ID 20935.

18-168

NUREG-0711 criterion 11.4.3.2.6.2 (1) states that detailed, clear, and objective procedures should be available to govern the conduct of the ISV tests. A number of sub-criteria are given, and sub-criterion (2) notes one added area. MUAP-07007P (R3), Section 5.10.2.2.4.f, Test Design, states that test procedures are prepared that meet these criteria. However, details are not provided. The MHI Roadmap states that such procedures were available and used for the Phase 1a and 1b validation testing. If credit is to be taken for this earlier set of test procedures, they will need to be made available for staff audit. Please provide the information on how the criterion is met.

18-169

MUAP-10012, R0 indicates that the analysis of pass/fail measures addresses objective quantitative measures and will be accomplished in two stages. The first is the comparison of performance of each crew to the acceptance criteria to determine whether the crew has passed or failed. The second analysis combines the results across crews to determine the proportion of crews that passed to the total number of crews. The former is based on criteria established for individual measures (see RAI Question #20943). However, the acceptance criteria for combining data across crews are not presented. The Plan only provides an example. Information is needed as to the precise criteria that will be used to determine the acceptability of the design. Please provide these criteria.

18-170

MUAP-10012, R0, page 20, indicates that the analysis of non-pass/fail measures will be used to identify HEDs. The results will be assessed across measures to identify HEDs using the converging measures logic. However, additional information is needed to identify when an HED is identified, e.g., how is the convergence of measures used to identify HEDs. Please provide the criteria.

18-171

MUAP-07007, revision 3, HSI System Description and HFE Process, 5.10.2.2.4 part g, provides a commitment for independent verification of the data analysis, but no

methodology for achieving the commitment is presented in the documentation reviewed. Please provide a methodology to accomplish this commitment.

18-172

MUAP-07007, revision 3, HSI System Description and HFE Process, 5.10.2.2.4 part g, provides a commitment for use of a margin-of-error in the analysis, but no methodology for achieving the commitment is presented in the documentation reviewed. Please provide a methodology to accomplish this commitment.

18-173

NUREG-0711 Section 11.4.4.2, Criterion 1, states that discrepancies may be acceptable if sufficient justification exists. The V&V IP Section 4.7, V&V HED Resolutions, is brief and merely states that HEDs will undergo the same evaluation program as described in MUAP-08014 and MUAP-09019. The compliance roadmap refers only to MUAP-09019, Sections 6 & 7. The justification per this criterion appears to be in MUAP-09019, Section 6.5, HED Resolution, Item 8, but this does not explain what would be a sufficient “basis” for such closure. Also, Section 6.6, HED Closure, states that closure does not require demonstration of a successful solution. This does not appear appropriate. Please clarify and provide sufficient information to address Criterion 1.

18-174

NUREG-0711, Section 11.4.4.2, provides several criteria for HED resolution. An area in two criteria, (2) and (5), of 11.4.4.2 that appeared not to be contained in the MHI documentation was the evaluation of possible cumulative effects and interrelations of multiple HEDs or when HEDs are potentially indicative of a broader problem. Please address.

18-175

This RAI has two parts.

Part 1 - HFE V&V of the US-APWR is identified as Design Commitment 10 in Table 2.9-1 of Section 2.9 in the Human Factors Engineering Design Control Document for the US-APWR, Tier 1, MUAP-DC020, Revision 3 (March 2011). The commitment is to conduct the V&V program in accordance with the V&V Program Implementation Plan. However, there is some ambiguity over which document is the plan. The DCD Tier 2 description references MUAP -07007, HSI System Description and HFE Process for “a description of the US-APWR HFE V&V program. However, MUAP-10012, R0 is identified as the V&V Implementation Plan, yet it is not referenced in the Tier 2 description. The V&V Implementation Plan referenced in the ITAAC design commitment should be specifically identified. Please clarify which document is the implementation plan.

Part 2 - In addition, the Acceptance Criterion simply states that a results summary report exists and concluded that the V&V program was conducted in accordance with the V&V

IP. More detailed acceptance criteria are needed to support ITAAC inspections. Please provide more explicit acceptance criteria design commitment 10.

18-176

Different methodologies for conducting HFE Design Verification are described in DCD (Section 18.10.2.2, Design Verification), MUAP-07007 (Section 5.10.2.2.3, HFE Design Verification), and Section 4.2.3, Design Verification, of the V&V Implementation Plan (MUAP-10012, R0). The DCD describes the use of the style guide and NUREG-0700 to review actual HSI, MUAP -07007 describes the use of NUREG-0700 to review the style guide; and the IP describes the use of the style guide to verify HSIs in a training simulator. Please clarify the methodology to be used for HFE Design Verification. Also, please clarify the use of the style guide for the U.S. APWR Design.

18-177

DCD Section 18.10.2.2 states that “Unique US-APWR HFE verification activities are not required for the basic HSI design characteristics of control, alarms, and indications, since this verification activity was conducted during Japanese human factors (HF) V&V program activities. HF verification is conducted for any changes to the Japanese HSI design.” The V&V Implementation Plan (MUAP-10012, R0), Section 4.2.3, Design Verification, states that 100% of the HSI will be evaluated. Please clarify the scope of the design verifications.