US-APWRRAIsPEm Resource

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Sent: Monday, March 04, 2013 9:54 AM
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Subject: US-APWR Design Certification Application RAI 1001-6939 (18)
Attachments: US-APWR DC RAI 1001 COLP 6939.pdf

MHI,

The attachment contains the subject request for additional information (RAI). This RAI was sent to you in draft form. Your licensing review schedule assumes technically correct and complete responses within 30 days of receipt of RAIs. However, MHI is currently working to provide the NRC with a schedule of ongoing HFE work. The schedule will include dates for the submission of this RAI response. We will adjust the schedule accordingly.

Please submit your RAI response to the NRC Document Control Desk.

Thank you,

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U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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REQUEST FOR ADDITIONAL INFORMATION 1001-6939

Issue Date: 3/4/2013

Application Title: US-APWR Design Certification - Docket Number 52-021

Operating Company: Mitsubishi Heavy Industries

Docket No. 52-021

Review Section: 18 - Human Factors Engineering
Application Section: 18.10 Verification and validation

QUESTIONS

18-194

The applicant's HSI inventory is described in DCD, Section 18.10.2.2, "Design Verification." The DCD states that the scope of verification includes the HSIs associated with the scenarios identified through the operational condition sampling process.

The V&V IP, Section 4.1, "Operational Conditions Sampling," states, "The Operational Conditions Sampling (OCS) process will only be applied to the Validation tests. The Verification will not make use of the OCS process in that it will sample one hundred percent of the HSI." The V&V IP, Section 4.2.2, "HSI Task Support Verification," states. "The HSI Task Support Verifiaton will verify that the HSI inventory of components/displays/alarms/controls meets those identified by the task analysis. The inventory includes all HSI components associated with the personnel tasks based on the identified operational conditions." Since the inventory is limited by the operation condtions sampling it appears that the scope of the HSI task support verification is inconsistent with Section 4.1.

1. Please resolve the conflicting information.
2. Explain in more detail what is meant by sample 100% of the HSI.

   How are you using the term HSI in this context? Is it every interface in the control room (every alarm, display, control)? "Sample 100%" seems contradictory in that sampling would imply something less than 100%. Is a 100% verification of all HSI being accomplished?

18-195

MUAP-10012 is not referenced in the DCD.

Please provide reference so technical information needed to draw safety conclusion is associated with DCD.

18-196

MUAP-10012, Section 4.1 Operational Conditions Sampling, page 4, states. "The OCS will have a goal to drive the operator into causing errors that must be identified and recovered from."

The paragraph this sentence is embedded in appears to be talking about the goal of scenario

development. Since OCS is only identifying operating conditions that will be included in the sample it does not appear that the OCS by itself could accomplish the goal as stated.

Please verify this paragaph communicates the intended process. If the current description is accurate please explain how OCS is being defined so that its relationship with scenario development is clear.

18-197

MUAP-10012, revision 2, Section 4.2.2 HSI Task Support Verification, states that HEDs are written when the HSI design does not adequately supply the needed task interface. This statement does not provide sufficient specificity to conclude the acceptance criterion will be met.

For the HSI task support verification, specifically list the minimium requirements for writing an HED.

18-198

MUAP-10012 rev.2 provides a list of test objectives in Section 4.3.1 Objectives. The objectives listed in this section capture the intent of those listed in the review criterion with the following exceptions:

- From the second bullet, shift turnover is not addressed
- From the third bullet the concept of “adequate alerting, information, control, and feedback capability” has been disassociated from plant conditions and instead been associated with normal and degraded HSI conditions. Subsequent objectives state that “continued operation, accident management, and safe shutdown with a complete loss of all non-safety related HSI” will be validated. These objectives provide more detail on the HSI conditions being validated but lack the specificity that adequate alerting, information, control, and feedback capability is what is being sought.

Please address these exceptions.

18-199

The DCD, rev. 3, Section 18.10.2.3, “Integrated System Validation,” states that control locations outside the MCR are represented by part task or limited scope simulations meeting the guidelines of ANSI 3.5, Appendix D, or by mockups or analysis. No amplifying discussion is provided in MUAP-10012, rev. 2. This commitment does not differentiate between important and less important tasks and therefore does not provide the specificity needed to conclude this acceptance criteria is met.

Provide more detail on how operator actions outside the control room are addressed.

18-200

The V&V IP, MUAP-10012, rev. 2, Section 4.3.2, Test Beds, last bullet, states that the test facility is verified for conformance to the test facility characteristics identified earlier in section 4.3.2 before validations are conducted. It does not describe how this is done.

Describe how this verification will be accomplished.

18-201

NUREG 0711, rev. 2, section 11.4.3.2, ISV test objectives state that minimum and other staffing levels will be validated. The V&V IP, MUAP-10012, rev. 2, Section 4.3.3, “Plant Personnel,” defines the minimum staff as one Reactor Operator and one Senior Reactor Operator. The only other explanation of crew configuration is that crew size for the Validation Test will include a range of expected sizes to assure that the HSI supports operations and event management. With the exception of minimum staffing, this information does not address specific crew configurations and therefore does not provide the specificity needed to conclude this acceptance criteria is met.

Address all sizes and configurations identified in acceptance criterion 3 of NUREG 0711, section 11.4.3.2.3.

18-202

V&V IP, MUAP-10012, rev. 2, Section 4.3.5 contains information on how performance measures were sorted into objective and subjective categories but the remaining measurement characteristics identified in this criterion (NUREG 0711, rev. 2, section 11.4.3.2.5.1) are not addressed.

Address the applicability of all measurement characteristics identified in this criterion.

18-203

The response to RAI 796-5728, Question 18-161, dated 2/16/2012, is acceptable but has not been accurately reflected in the MUAP-10012, revision 2, October 2012. Specifically, the last sentence in the second paragraph of Section 4.4, “Test Design” does not make sense and is not consistent with the RAI response.

Please clarify the referenced sentence, "Only when areas outside of the control room are considered special environmental stressors such as temperature and radiation will also be included in the tests."

18-204

In general MUAP-10012, rev. 2, V&V IP, Sections 4.3.4 and 4.3.5 do not provide distinct explanations of the following concepts: Performance Measurement Characteristics, Performance Measures, and Performance Criteria. These concepts need to be separated and clearly explained within the implementation plan.

With respect to performance measures, there is general wording that implies both plant and personnel performance measures are being used. However, there is significant confusion about where these measures will be identified and what measures will actually be used. The following concerns are identified based on the revision 2 of the IP but additional reviews will be required once the concepts listed in the previous paragraph have been clarified.

· The last paragraph in Section 4.3.4 states that the sample scenarios will contain “Failure modes and detailed acceptance criterion, including Pass/Fail criterion. Measures and measurement tools to be used.” This seems to be contrary to the preceding paragraph which states, “In the case of plant performance measures, the evaluation criteria are shown, include a clear definition of the process parameter of interest as part of the test plan and included in the analysis of the test." Also the subsequent paragraph (starting section 4.3.5) states that

performance measures in general are identified in the test procedures. The inconsistency needs to be addressed and if inclusion of performance measures within test procedures is the intended path then the test procedures associated with the sample scenarios need to be submitted to demonstrate how performance measures are being selected.

· The second sentence in the first paragraph of Section 4.3.5 states that ISV observers will add additional measures to be collected prior to the start of a scenario. Please describe how scenario consistency is maintained using this practice. If the practice is retained explain the guidelines the observers will follow when identifying these measures, how and when acceptance criteria for the measures are identified, and how the additional measures will be controlled so they are integrated into the scenario performance and analysis.

· The first bullet in Section 4.3.5 identifies sources of measurements. The first five items on the list appear to be sources for obtaining actual plant and operator actions which would be compared to performance measurement criteria. Only the last bullet appears to be a source of Plant performance measurements.

· Section 4.3.4, Section entitled, “Scenario Human Performance Evaluation Criteria Development,” third paragraph provides a list of “Types of evaluation criteria.” This list appears to be a more complete list of sources used to develop performance measures and their acceptance criteria even though it is not clearly identified as such.

Plant Performance Measures: The V&V IP, section 4.3.4, “Scenario Definition,” states that evaluation criteria will be developed for global plant process parameters (e.g., process parameters maintained below safety system actuation, or within design limits.)” Section 4.3.5, “Performance Measures,” states that plant process data resulting from operator action, or in-action that includes plant process data (i.e., pressures, temperatures, flows, levels, radiation level), and component states (i.e., off / on; open / closed, as a function of time, at various vital locations in the plant simulation as is possible) is a source for performance measurements. While subject to some confusion on which plant performance measures are used and where they are documented the staff finds that there is clear intent to use plant performance measures to assess ISV performance.

Personnel Performance Measures: The V&V IP, Section 4.3.5, states that performance measures will include personnel tasks, situation awareness, and cognitive workload. The staff finds that personnel performance measure will be used to assess ISV performance.

Validation of Control Room anthropometric/physiological factors associated with layout and work station dimensions, and display characterization were completed as part of Phase 1and are included in the US-Basic HSI system described in the Topical Report. The Topical Report describes the US-Basic HSI System which serves as the foundation for the US-APWR HFE design. The staff approved this Topical Report for application to the US-APWR HFE design in Safety Evaluation (ML113250603). In RAI 796-5728, Question 18-161 the staff asked if there were anthropometric/physiological factors pertinent to the US-APWR HFE design that needed performance measures. The RAI response identified several factors (e.g., lighting, background noise) and proposed V&V IP changes the staff found acceptable. These changes have not been accurately reflected in the V&V IP. Specifically, the last sentence in the second paragraph of Section 4.4, “Test Design” does not make sense and is not consistent with the RAI response.

Performance Measure Hierarchy: In RAI 796-5728, Question 18-162 the staff requested clarification of how pass/failure criteria will be identified. The staff identified the following concerns with the response:

· The changes were not included in the V&V IP plan as the response indicated they would be.

· The first sentence of the response states, “As a general rule, in most cases objective, time dependent histories of specific plant parameters (temperature, pressure, flow rate,

radiation level, water level and environmental release), component position or operations (pump on or off, valve open or closed) and operator actions (assuming control of an automated action) will be used as pass fail measures." This sentence implies plant performance measures will be used but provides no specificity on how pass/fail criteria are identified. Every plant condition could fall into the general rule yet it is clear that not every plant condition would be used as a pass/fail criterion.
The last two sentences state, "In addition subjective measures of scenario specific significant factors, i.e., situation awareness that indicate a significant loss of awareness, may, in addition, be used as pass/fail performance measures for selected scenarios. This will be at the discretion of the test observers/administrators." While there is no problem with allowing discretion in determining pass/fail performance criteria, this statement provides no minimum guidance on what observers/administrators consider. Thus they could decide no conditions would be pass/fail regardless of their severity. Again there is insufficient specificity in these sentences to support a safety conclusion.

18-205

Specific plant performance measures have not been identified.
MUAP-10012, rev. 2, Section 4.3.5, page 17, last paragraph, provides the following definition of Pass/Fail plant performance indicators, "Pass/Fail indicators are defined as any violation of Technical Specifications, impacts on the conclusions of the PRA/HRA and the RIHAs, or impacts on the Chapter 15 transient and accident analysis." This creates the following questions:

· What does "Violation of Technical Specification mean? A condition outside of what Technical Specification's address? A limiting safety system setting is violated? A limiting Condition of Operation is not met?

· What does "Impacts on the conclusions" mean? This phrase does not provide sufficient specificity to understand what will constitute a failure. It also does not provide the specificity needed to serve as an ITAAC acceptance criterion. This question also applies to "impacts" Chapter 15 analyses.

In summary, the change provides more insight but still did not provide sufficient specificity to understand what will constitute a failure. It also did not provide the specificity needed to provide ITAAC acceptance criterion.
The response to RAI 796-5728, Question 18-163 indicated that specific plant performance measures would be identified in the sample scenarios. Each of the four scenarios provided in the V&V IP, Appendix 1 addresses performance measures in section 5 of the scenario. A matrix is provided under this section entitled "Objective Measures" that lists operator actions or behaviors. The staff concludes that the matrices contain operator action as would be found in an emergency procedure. They identify the tasks that need to be performed but do not consistently identify the performance measure to be applied. These tasks do not have sufficient specificity to be used as performance measures. They would serve to verify that the alarms, displays and controls existed but this action has already been accomplished as part of the verification activities.

18-206

Each of the sample scenarios from Appendix 1 of the V&V IP contains a matrix in the performance measures section of the scenario that identifies operator actions. The V&V IP, Section 4.3.5 defines primary and secondary tasks and states that the following measurements

are used:

- Time
- Operation and monitoring log
- Errors
- Amount achieved or accomplished
- Subjective report of participants
- Behavior categorization by observers

It is not clear whether these measurements are applied to all tasks or those that are chosen to be important as suggested by the last bullet in the criterion.
Two sentences later another list of measures is provided that applies to both primary and secondary tasks (the last sentence preceding the list doesn't make sense). Is this list intended to augment the first list or are the lists applied to different task groups?
The following sentences need to be clarified:

- In addition the "Time" to identify, decide and take action, data will be collected for both primary and secondary tasks:
- Range of plant parameter to their limit before actions take

Secondary tasks, while included in the text, did not appear in the sample scenarios. Specific performance measures also did not appear in the scenarios so it was not possible for the staff to assess whether there was an appropriate level of detail associated with any of the tasks.
Section 4.3.5 states that more detailed data will be collected for knowledge based tasks in order to assess the complexity of the crew actions. This sentence does not provide the specificity needed to understand how a "more fine grained analysis of complicated tasks" is actually performed. The intent of the guidance is also not fully met as complicated tasks has been limited to "Knowledge based tasks" which is only used as an example in the criterion.

18-207

V&V IP, Section 4.3.5 states that cognitive workload will be measured using 1) questions/rating scales administered to operators after each scenario, 2) scripted queries that operators respond to during a scenario and 3) qualitative information from observers. The combination of these three techniques, based on our initial review, appear to provide an acceptable method for assessing cognitive workload but the staff would like additional information describing how the methods are administered and/or how they compare with industry standard practices. Please address the following questions:
1. For the questions/rating scales administered to the operators after each scenarios, please describe the similarities and differences of this method with the NASA TLX, Subjective Workload Assessment Technique (SWAT), or other methods that have historically been used to assess cognitive workload. If these rating scales have been used in phase 1 testing please explain how that testing demonstrated the usefulness and validity of the questions/rating scales.
2. For the scripted queries administered during the scenario, please provide examples of the queries and explain how they are designed to address the following assumption associated with spare capacity measures:
One of the assumptions implicit in the use of spare capacity measures is that resource expenditure associated with the primary task is not changed by the introduction of the subsidiary task (e.g., the operator does not devote fewer resources to the primary task after the subsidiary task is introduced). (NUREG-CR-6396)
(Or in other words explain how the performance measure characteristic of intrusiveness applies to this measure. Other measures that apply should also be explained as part of addressing

NUREG-0711, Section 11.4.3.2.5.1, criterion 1)

18-208

The V&V IP, MJAP-10012, rev. 2, Section 4.3.4, “Scenario Definition,” 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. The types of “evaluation criteria” that will be developed by this group of experts include:

· Global plant process parameter criteria

· Timeliness of operator actions

· Operator performance with respect to teamwork, communications, execution of procedures

· Risk-based criteria derived from the PRA

· Operator’s understanding of the current plant state

· Lessons learned from Operating Experience

· Secondary task performance

This list captures the performance measures suggested in the previous acceptance criteria but does not provide the acceptance criteria being suggested by this criterion.

The V&V IP continues and states:

"Evaluation criteria related to human performance are defined and included in the description of each scenario. In the case of plant performance measures, the evaluation criteria are shown, include a clear definition of the process parameter of interest as part of the test plan and included in the analysis of the test."

This paragraph raises the following questions/observations:

- Specific acceptance criteria, as being suggested by the criterion, were not found in the sample scenarios provided in attachment 1.
- The second sentence is not clear – either the grammar is not correct, words are missing or phrases don’t modify each other properly – the staff is not sure of the intent.
- The second sentence refers to a test plan. We will need to review the test plans associated with the sample scenarios to verify the acceptance criteria meet the intent of this recommendation.

18-209

The initial submittal did not address this criterion. RAI 796-5728, Question 18-167 requested the identification of acceptance criteria and their bases for the performance measures used in the ISV scenarios. Additional information was not provided in MUAP-10012, V&V IP, rev. 2.

Address this criterion in the V&V IP or justify why the criterion is unnecessary.

18-210

The V&V IP, MUAP-10012, rev. 2, Section 4.4.1, “Coupling Crews and Scenarios,” states that the applicant will vary the scenario sequences used in the US-APWR validation testing. In order to control crew expectation bias the test scenarios will be neutral, random, and in different order for each test crew and scenario sequences will not follow “give away" sequencing. Scenario sequences will be varied between test crews to control sequence bias and the sequencing will be reviewed by an experienced HF test designer and HF engineer to assure any sequence bias is minimized and documented.
Please define the phrase, “test scenarios will be neutral, random.” Do you really mean, “Scenario sequencing will be neutral and random?” If so, does this mean something beyond “different order?”

18-211

The V&V IP, MUAP-10012, rev. 2, Section 4.4.2, “Test Procedures,” states that test procedures will be prepared to manage the test, assure consistency, control test bias, support repeatable results and focus the test on the specific scenario test objectives. The V&V Team will develop the Test procedures. The test observers/administrators will apply these procedures to set up each scenario, manage the scenario and analyze the test results, and the scenario developers will use the test procedure to build the scenario set. Please address the following issues:
1. The V&V IP states that the test procedures will contain all the elements listed in the acceptance criterion but in several cases the criterion has been summarized and thus lost some of the specificity of the criterion. The following elements need to more specifically describe what will be controlled by the test procedure.
· Specific criteria for conduct of specific scenarios – What criterion does this include?
· Instructions regarding when and how to collect and store data – Describe the minimum collection and storage techniques that will be used so the scope of the when and how questions is clear.
· Procedures for documentation of the Validation Tests – What are the minimum actions to be included in these procedures?
2. Use of the test procedures to support the analysis of test results is a function beyond the administrative controls addressed in this criterion. Actions and acceptance criterion associated with ISV analysis are reviewed by the staff to assure conformance with other criteria. Including this information in the test procedures will necessitate the submittal of the test procedures associated with each of the sample scenarios.
3. The paragraph indicates the “scenario developers will use the test procedure to build the scenario set.” Please explain what is meant by scenario set and how it is used. It seems contradictory to a previous statement that all test crews perform all scenarios. Similarly, the first bullet in this paragraph states that the test procedures will be used to identify which crews receive which scenarios. This also seems inconsistent.

18-212

The V&V IP, MUAP-10012, rev 2., Section 4.4, “Test Design,” states that control of bias is an objective of the test procedures but it does not explain how this is accomplished. It is understood that pilot testing will be performed to identify and reduce bias from the test procedure. Please address bias explicitly in the test procedure particularly with respect to tester expectancy bias and participant response bias. If these bias controls are unnecessary please

explain why.

Reviewer note: A thorough test plan in itself helps to reduce bias. This may be the thought behind the current test plan description. If it is then this response should point out how the organization and content of the test plan minimize bias.

18-213

MUAP-10012, rev 2., Section 4.4.3, Test Personnel Training," first paragraph contains inconsistent information. The first sentence states, "a minimum of three experts in the areas of HFE, plant operations, and operator training shall serve as test observers/administrators." Later in the same paragraph is states, "The observer/administrator team will include two HFE experts. ...The third member will have either a plant operations or training background." There are also what appear to be extraneous words in the paragraph (inter, same, specific).

18-214

The V&V IP, MUAP-10012, rev. 2, Section 4.5, “Data Analysis,” discusses the applicant’s general approach to data analysis. The analysis method uses a spread sheet to collect the subjective and objective measures being used to validate the Control Room HFE design. Input is divided into nine categories that include key concepts such as situational awareness, workload, and error tolerance. Pass/Fail measures that fail and HEDs identified by operators in post scenario questionnaires are entered directly into the HED tracking data base. Other performance information is collected in the spread sheet and frequency counts are used to identify the number of crews that fail to meet criteria in each of the performance categories. Since the frequency counts come from a variety of sources they provide converging evidence that the HSI meets plant safety goals, or identifies areas of the USAPWR HSI design that need to be improved.
The staff finds the general methods for data analysis acceptable but has the following questions related to how data is addressed. The V&V IP, Section 4.4.1, “Coupling Crews and Scenarios,” states that all three test crews will perform all scenarios. If consistent results are not achieved between the three crews, a fourth crew will be given the scenario to manage.
Please define the term “consistent results” so that it is specific and measurable.

· Section 4.5 states that one criteria being used to define problems from the collection of data entered on the spread sheet is “Categories where two or more crews exhibited the same problem are highlighted as requiring additional assessment.” Does “consistent result” equal “two or more crews exhibiting the same problem?” What does additional assessment mean – a fourth crew runs the scenario??

· When a fourth crew runs the scenario what failure rate constitutes a failure and why is this acceptable? From our current understanding a 2 of 4 failure rate could be acceptable and this seems high for the sample size we’re dealing with. The statement in Section 4.5 saying, “If three crews cannot meet the Pass/Fail Indicators it will be considered as a failure,’ seems to imply an even higher threshold for failure (3 out of 4).

· It is not clear howthe analysis method is considering both individual crew and overall performance. Please confirm that a single crew failure of a Pass/Fail performance criterion would still generate an HED. IF this is not the case, please provide a detailed discussion of why this practice is acceptable.

Please review the use of “HED” verses “HFE issue” in MUAP-10012. Based on your response to RAI 796-5728 Question 18-170 it is not clear the terms are used consistently. For example:

- Section 4.3.5 states, “open-ended HED entries in the operator feedback forms provide indication of specific HEDs that need to be addressed.” This implies Operators could write HEDs directly without screening or convergent analysis. Is this what is intended?
- Section 4.5 states, “The verbal debrief sessions provide rich contextual information that will be used to identify successful performance, as well as interpret the HEDs, understand their extent, and the broad cumulative effects and interrelationships that cross HEDs.” Are HEDs trended for common issues or are HFE issues evaluated for trends that should be documented in an HED?
- Section 4.5 states, “Such categories point to human performance areas of potential concern and indicate a need to examine the extent to which HEDs may have contributed to this human performance problem. Using the converging measures logic, HEDs that may have contributed to the human performance difficulties are identified based on review of validation team observations made during the scenarios as well as operator feedback obtained during the post-scenario debrief sessions, final debrief sessions, and HEDs that are submitted by the operators.” This is confusing. Is the intent that HFE issues are evaluated in each category and HEDs are written where the validation team and operators identify issues.

18-215

The RAI response to Quesion 18-171 (RAI 796-5728) stated that the V&V IP, MUAP-10012, rev 2., Section 4.6, would include a statement that “An independent panel of experts will be used to sample the validation results and verify the data analysis and the V&V results." This statement was not included in revision 2. If sampling is still intended how would the sample size and distribution be identified?

18-216

The RAI response to Question 18-172 (RAI 796-5728) indicated that the V&V IP, MUAP-10012, rev. 2, Section 4.5, would include a statement that provided additional examples of “computing descriptive statistics.” This statement was not included in revision 2. The response itself does not address the intent of the acceptance criterion in that the response is providing additional statistical analysis when the intent of the acceptance criterion is to adjust for the fact that real-world performance can only be inferred. Please describe how margins are established to allow for real world performance that can not be exactly determined by the ISV and the analysis of ISV results.

18-217

Throughout the V&V IP, MUAP-10012, rev. 2, it is clearly specified that HEDs will be generated by the test participants as well as the test personnel for any problem identified during the V&V activities. With one exception the document states that these HEDs are entered in the HED data base. Justification of discrepancies prior to HED generation is not presented as an element of the process. The only point of confusion is introduced in Section 4.3.5, “Performance Measures,” in the last paragraph on page 21. The statement is made, “These multiple sources of data are analyzed and the results are used to provide converging indications of human factors issues of primary concern, as well as to identify specific ‘HEDs’ that are entered into an HED database.” This statement could be interpreted to mean that some HEDs are not put into the HED database. If this interpretation is taken, then these HEDs could represent a screening which would need to be described in sufficient detail to address this criterion. Please clarify the intent of this sentence. If justification prior to entering the HEDs in the data base is intended, it needs to be much more clearly defined as part of the

HED process.

18-218

The V&V IP, MUAP-10012, rev. 2, Appendix 2, Section 2.3 addresses HED evaluation but provides no direction on how individual HEDs are evaluated. The first four bullets of this criterion address subjects that should be included in this evaluation. The current HED evaluation process only uses these areas as possible groupings to be used for trend analysis which is the subject of the last two paragraphs. Please provide specific direction within the V&V IP describing what is to be included in the individual HED evaluation.

The V&V IP, Appendix 2, Section 2.1, 2nd and 3rd paragraphs, state that each HED shall be evaluated by the HFE team. The 4th paragraph states that each HED shall be assessed by an expert Panel. Table 1 (HED workflow steps) says the expert Panel or the HFE team completes an evaluation. This same paragraph indicates the expert panel shall have the US-APWR HFE team available as technical consultants. Please clarify who is responsible for the HED evaluation.

Appendix A, Section 2.3.2, “HFE grouping,” states that, “To assist HED evaluation, resolution, and explanation it may be constructive to group HEDs by HFE classifications. Typical HFE classifications are HFE basic generic categories used for classifying discrepancies." These sentences do not provide the specificity needed to support ITAAC acceptance criteria. The statements make trending optional and there is no minimum set of parameters that will be trended against. Section 2.3.1, “NRC Grouping,’ contains the same lack of specificity. Please provide specific commitments on how cumulative effects and generic implications will be addressed.

18-219

The V&V IP, MUAP-10012, rev. 2, Appendix A, Section 2.4, “HED Classification,” states that there are two types of evaluation categories that can be used, Mitsubishi Significance Category and NRC Priority Category. At least one significance classification is applied to each HED or to a group of HEDs. The NRC priority categories agree with those described in this criterion. While significance categories are identified, it is unclear how they are used in the process. MUAP-09019, rev 2., Section 6.6 states that, “The US-APWR HSIS will be considered acceptable only when all testing is completed with no significant (i.e., no priority 1) HEDs generated.” The V&V IP, Appendix A, Section 2.6 has omitted any definition of what constitutes a “significant HED.”

- Explain how significance categories are used in the HED resolution process.
- Resolve the difference between MUAP-09019 and the V&V IP.

In addition, both priority scales use a generic description for the significance category associated with safety consequences. The Mitsubishi Significance category 5 is HEDs likely to lead to human error with safety consequences. The NRC priority 1 is direct or indirect consequences to safety. Neither category is sufficiently defined to provide the specificity needed for ITAAC acceptance criteria. NUREG-0711 guidance uses technical specification violations as an example of a condition that could be indicative of an HED with safety consequences. The Mitsubishi categories only address technical specifications as follows, “HEDs do not necessarily have a safety consequence, but are likely to have a Tech-Spec implication." This further confuses what would be contained within the category of “HEDs [that] are likely to lead to human error with safety consequences.” Similar lack of specificity is found

in many of the other Mitsubishi categories where the phrases, “do not necessarily have safety consequences,” “significant frequency,” and “likely to lead” do not provide a clear, specific significance definition that will support consistent prioritization.

- Provide specific definitions for the significance categories so there is consistent prioritization.
- Explain why Technical Specification violations are not included within the scope of Mitsubishi significant category 5 as the regulatory guidance would suggest.

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These items apply to MUAP-10012, rev. 2, Appendix 2, HED Process Description
Section 2.1, last paragraph: HED closure will occur when the requirements of the HED closure requirement are considered satisfied by the HFE team and by an independent documented review by the Expert Panel.
Section 2.5, Closure criteria 1, 2, 4, and 6 indicate only “expected” resolution is needed to close an HED
Section 2.6, 1st paragraph: “Where a documented test plan is required, HED closure does not require the test to be completed, since if the test is not successful, additional HEDs will be generated during that test. This HED closure process avoids keeping HEDs open for extended durations, since there may be several years between the time when an HED is first identified and when an actual retest will occur. The US-APWR HSI will be considered acceptable only when all testing is completed with no significant HEDs generated. An HED can be closed when the solution is documented and the closure requirements are met**,** as defined by the HED closure requirement. HED closure agreement must be reached between the HSI Design Team and the Expert Panel.”
Section 2.8.2, 1st paragraph: “When the HED closure requirements are documented, the HED may be closed. Otherwise an issue may remain with ‘Resolved’ status and closed when the required closure activities are complete.
These sections raise the following concerns:

- There appears to be no specificity in how the closure process occurs. Sometimes a test plan is required other time it is not, sometimes the HED is is closed, other times it is left in a “Resolved” status then closed when closure activities are complete. There is no discussion of the standards used to make these decisions.
- It is not clear how test plans would be tracked once the associated HEDs are closed.
- The process assumes the proposed action and subsequent testing will always address the original problem. It also assumes the proposed action and testing will maintain the priority of the original problem even after the HED is closed. In the staff’s experience, neither assumption holds true under the changing conditions of design and construction. From the staff’s perspective the current process misses the fundamental step of validating corrective actions have indeed resolved the original problem.

Please address these concerns.


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