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TOKYO, JAPAN

August 28, 2009

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-09418

**Subject: MHI's Response to Summary of the NRC Staff Findings regarding MUAP-07005, "Safety System Digital Platform –MELTAC-, Revision 3"**

**Reference: 1)** "MITSUBISHI HEAVY INDUSTRIES, LTD. – REVIEW STATUS OF THE SAFETY SYSTEM DIGITAL PLATFORM -MELTAC-, TOPICAL REPORT MUAP-07005 (TAC NO. MD6878)," dated July 10, 2009.

With this letter, Mitsubishi Heavy Industries, Ltd. ("MHI") transmits to the U.S. Nuclear Regulatory Commission ("NRC") a document entitled "Response to Summary of the NRC Staff Findings regarding MUAP-07005, "Safety System Digital Platform –MELTAC-, Revision 3"."

Enclosed is the response to the NRC findings regarding Topical Report "Safety System Digital Platform –MELTAC-, MUAP-07005, Revision 3" 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. Response to Summary of the NRC Staff Findings regarding MUAP-07005, "Safety System Digital Platform –MELTAC-, Revision 3"

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



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Docket No. 52-021  
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Enclosure 1

UAP-HF-09418  
Docket Number 52-021

Response to Summary of the NRC Staff Findings regarding  
MUAP-07005, "Safety System Digital Platform –MELTAC-, Revision 3"

August 2009

**Response to Summary of the NRC Staff Findings regarding MUAP-07005,  
“Safety System Digital Platform –MELTAC-, Revision 3”**

This is in response to “SUMMARY OF THE NRC STAFF FINDINGS REGARDING MUAP-07005, “SAFETY SYSTEM DIGITAL PLATFORM –MELTAC-,” REVISION 3” dated July 10, 2009.

In the above document, the NRC staff has identified significant issues in the following areas:

1. Quality Assurance
2. Language Translation
3. Technical

1. Quality Assurance

- a) *... the staff disagrees with MHI's claim that the MELTAC system was developed in accordance with 10 CFR Part 50, Appendix B, requirements.*

It was never our intention to imply that MELTAC was developed in complete accordance with 10 CFR Part 50, Appendix B. The MELTAC Topical Report, MUAP-07005, attempts to describe the US Conformance Program (UCP), which compared the original Japanese development program to 10 CFR Part 50, Appendix B, requirements. The UCP included compensatory actions for the deficiencies discovered (i.e. additional independent V&V). The Topical Report revision 4 will be clarified to remove any implication that MELTAC was developed in complete accordance with 10 CFR Part 50, Appendix B. The Topical Report revision 4 will also describe the re-evaluation of the MELTAC development process, as described at the end of this letter in the section entitled “Overall Quality Assurance”. In accordance with 10CFR21, the reevaluation will provide reasonable assurance that MELTAC is equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. MELTAC Topical Report revision 4 will be issued by the end of September 2009.

- b) *MHI's proposed use of operating experience as a surrogate for independent V&V is not acceptable.*

The MELTAC Topical Report describes software with insufficient operating experience, designated Category 1 software, and software that we considered to have sufficient operating experience, designated Category 2 software. It is noted that Category 2 software, includes firmware that resides in supporting modules, such as I/O and communications modules. Based on our UCP assessment, which was based on Annex C of IEEE 7-4.3.2, operating experience was credited to compensate only for the lack of independence in the original V&V for Category 2 software; additional independent V&V was provided only for Category 1 software, where operating experience was not considered sufficient. MELCO will now conduct the same additional independent V&V activities for Category 2 software, as conducted previously for Category 1 software. The MELTAC Topical Report revision 4 will modify the description of the UCP to reflect this change. The technical documentation for these additional UCP activities for Category 2

software will be available for NRC audit by the end of March 2010. A UCP report (written in English) will be submitted, also by the end of March 2010.

*c) ...MHI and Mitsubishi Electric Co. need to provide objective evidence of a QA program that satisfactorily implements the requirements of 10 CFR Part 50, Appendix B, and demonstrates how the MELTAC platform was developed against that criteria.*

This issue is addressed at the end of this letter in the section entitled "Overall Quality Assurance".

*d) During the March 2009 audit, MHI's QA audit team identified several issues with Mitsubishi Electric's Co. QA practices that impact the staff's approval of the platform.*

MELCO has initiated corrective actions that will resolve the "findings" and "concerns" identified in the MHI QA report from the March 2009 QA audit. These "findings" and "concerns" relate to the MELTAC development program and are therefore directly applicable to the MELTAC Topical Report. MHI will audit MELCO's revised Quality Assurance Program (QAP), including procedures and training. MHI's supplemental QA audit report will be submitted by the end of December 2009.

In addition, MELCO will expand the QAP to address production, operations and retirement phases of the MELTAC product life cycle. MHI will audit MELCO's expanded Quality Assurance Program (QAP), including documentation and training. MHI's QA audit report of the expanded phases will be submitted by the end of June 2010.

## 2. Language Translation

*a) The staff's expectation is that all documents needed during an audit should be properly translated into English so that the staff can perform an effective and efficient review of the documents.*

We will translate additional documents that are relevant to an audit. These documents are identified in our response to RAI-23[UAP-HF-09393]. This documentation will be available for NRC audit by the end of January 2010.

*b) Equipment labels, technical manuals, and the engineering computer software for MELTAC were not translated into English.*

It has always been our plan that the equipment labels, technical manuals, and the engineering tool displays for MELTAC would be translated into English. This will be clearly stated in the MELTAC Topical Report revision 4. These activities will be completed and available for NRC audit by the end of June, 2010.

## 3. Technical

*a) FPGA firmware should be developed using an approved, QA-based development process similar to safety-related software.*

The original UCP evaluated the FPGAs as hardware devices, not software. We will further expand the UCP to evaluate the life cycle process for the FPGAs based on the same criteria as for safety-related software. This is also noted in our response to RAI-24[UAP-HF-09393]. The MELTAC Topical Report revision 4 will modify the description of the UCP to reflect this change. The Topical Report revision 4 will also clarify the applicability of the software life cycle process to FPGAs, and will identify any unique aspects for FPGAs. The technical documentation for these additional UCP activities for FPGAs will be available for NRC audit by the end of May, 2010. A UCP report (written in English) will be submitted, also by the end of May 2010.

*b) Need to address in the TR, the basis for a permanent connection between the non-safety engineering tool and the safety-related MELTAC system, and the adequacy of a software-based communication control versus a hardware-based control.*

Please refer to our response to RAI-12[UAP-HF-09393]. In summary, we believe the current design complies with ISG-04 and is consistent with other previously approved digital platforms. We will submit a Software Safety Analysis Report by the end of September 2009, which addresses communication requirements and potential failures, as defined in ISG-04. In addition, we encourage the NRC staff to conduct a special technical audit where we will present the details of the design and demonstrate this compliance. This technical audit can be conducted after completion of the Software Safety Analysis report. The Software Safety Analysis Report will be referenced in the MELTAC Topical Report revision 4.

*c) Need to address in the TR, compliance to 10 CFR 50.55a (h) and 10 CFR Part 50, Appendix B, requirements regarding the identification of safety-related components versus those used in non-safety applications.*

Safety and non-safety components of MELTAC are uniquely identified. This includes hardware, software and documentation. Please refer to our response to RAI-01 and RAI-05[UAP-HF-09393]. The identification method will be described in the MELTAC Topical Report revision 4. Components with unique identification will be available for NRC audit by March 2010.

#### Overall Quality Assurance

As explained in item 1(a) above, the purpose of MELCO's original UCP program was to compare the original MELTAC development to US NRC technical and quality requirements, and to compensate for any gaps. MELCO implemented the UCP in accordance with NPD Procedure Q-4102 "Safety System Digital Platform Quality Assurance Program" which was the basis for compliance to 10CFR50 Appendix B. However, the MHI QA audit of March 2009 identified deficiencies in MELCO's QAP, which has now raised NRC questions about the quality of the original UCP. To resolve this issue, we are taking the following actions:

1. MELCO is resolving all "findings" and "concerns" from MHI's QA audit as explained in item 1(d), above. This includes revision of the QAP, training of MELCO personnel, and re-audit by MHI.
2. After item 1(d) is completed, MELCO will re-evaluate the MELTAC

development process, in accordance with the new QAP. This re-evaluation will be conducted by MELCO personnel and management, that are independent of the MELTAC development team and UCP teams. The re-evaluation will be consistent with a commercial grade dedication (CGD) process, in that it will contain the two major components of CGD:

- (1) assessment of critical characteristics
- (2) assessment of built-in quality

The assessments will be documented using the format of Table 6-4 from EPRI TR-106439. For item 1, the critical characteristics are defined by the MELTAC Topical Report. Independent verification will confirm these critical characteristics through review of original design, testing and UCP documentation. For item 2, the assessment will be based on the scope and methods defined in Table 6-4c from EPRI TR-106439, and Section 7 of EPRI TR-107330, including documentation review, thread audits and assessment of experience applicability. However, items related to production, operations and maintenance will be excluded, since MELCO will have a 10CFR50 Appendix B compliant QAP in place for all post-development activities, as explained in Item 1(d), above.

The re-evaluation will consider the original MELTAC design activities and all UCP efforts, including the expanded UCP, as explained in items 1(b) and 3(a), above. Therefore, it will be conducted in three phases:

- Phase 1 will re-evaluate the original MELTAC development and the original UCP. This encompasses all hardware and software with the exception of Category 2 software and FPGAs, which are addressed in subsequent phases, below. Phase 1 will begin upon completion of the QAP corrective actions, item 1(d) above. The technical documentation for the re-evaluation activities will be available for NRC audit by the end of March 2010. A re-evaluation report (written in English) will be submitted, also by the end of March 2010.
- Phase 2 will re-evaluate the original development and UCP related to Category 2 software. This phase will begin upon completion of item 1(b), above. The technical documentation for the re-evaluation activities will be available for NRC audit by the end of May 2010. A re-evaluation report (written in English) will be submitted, also by the end of May 2010.
- Phase 3 will re-evaluate the original development and UCP related to FPGAs. This phase will begin upon completion of item 3(a), above. The technical documentation for the re-evaluation activities will be available for NRC audit by the end of June 2010. A re-evaluation report (written in English) will be submitted, also by the end of June 2010.

MELTAC Topical Report revision 4, which will be available by the end of September 2009, will describe the complete re-evaluation program and will reference the re-evaluation reports.

The complete re-evaluation of MELTAC development will be conducted under MELCO's new QAP, which will include the re-evaluation procedure. MELCO's new QAP will also include the production, operations and retirement phases of the MELTAC product life cycle. MHI will audit MELCO's new QAP, and the associated

activities to confirm compliance to 10CFR50 Appendix B by December 2009. However, it is important to emphasize that MHI will not be a commercial dedicator for MELTAC.

Figure 1 clarifies the relationship between the MELTAC development activities conducted under their QAP to date, and the non-recurring re-evaluation activities and the recurring project activities which will be conducted under their new QAP (which will be fully comply with 10CFR50 Appendix B).

#### Path Forward

Based on the activities described above, we will address, in the near term, all quality assurance, language and technical issues highlighted as "most significant" in the staff's letter of July 10, 2009. Figure 2 shows the integrated schedule for these activities. The plan described above is detailed in the Topical Report revision 4. Other issues are addressed in RAI responses.

Although MHI and MELCO are disappointed in NRR's decision to not continue the review of MUAP-07005 for operating reactors, we understand this decision and plan to resubmit the topical report for operating reactors after all activities described above have been completed and approved by NRO for the US-APWR.

To ensure the schedule for the MELTAC activities described above does not delay the SER for the US-APWR, MHI proposes the following:

- The staff's current schedule for the MELTAC Topical Report SER should be maintained. That SER would contain Application Specific Action Items (ASAI) for all outstanding MELTAC review activities.
- The next revision of the US-APWR DCD, which will be submitted by the end of October 2009, will include an ITAAC, which addresses closure of all MELTAC ASAs.

The intent of the MELTAC ITAAC for the US-APWR is to take completion of the MELTAC review off the critical path for the US-APWR SER. However, MHI and MELCO are still hopeful that adherence to the schedule presented above will allow the requirements of the MELTAC ITAAC to be completed in a timely manner, and thereby allow the MELTAC ITAAC to be eliminated from the final US-APWR DCD revision.

We request a meeting with the staff to discuss the details of this plan, including the process for ITAAC closure.

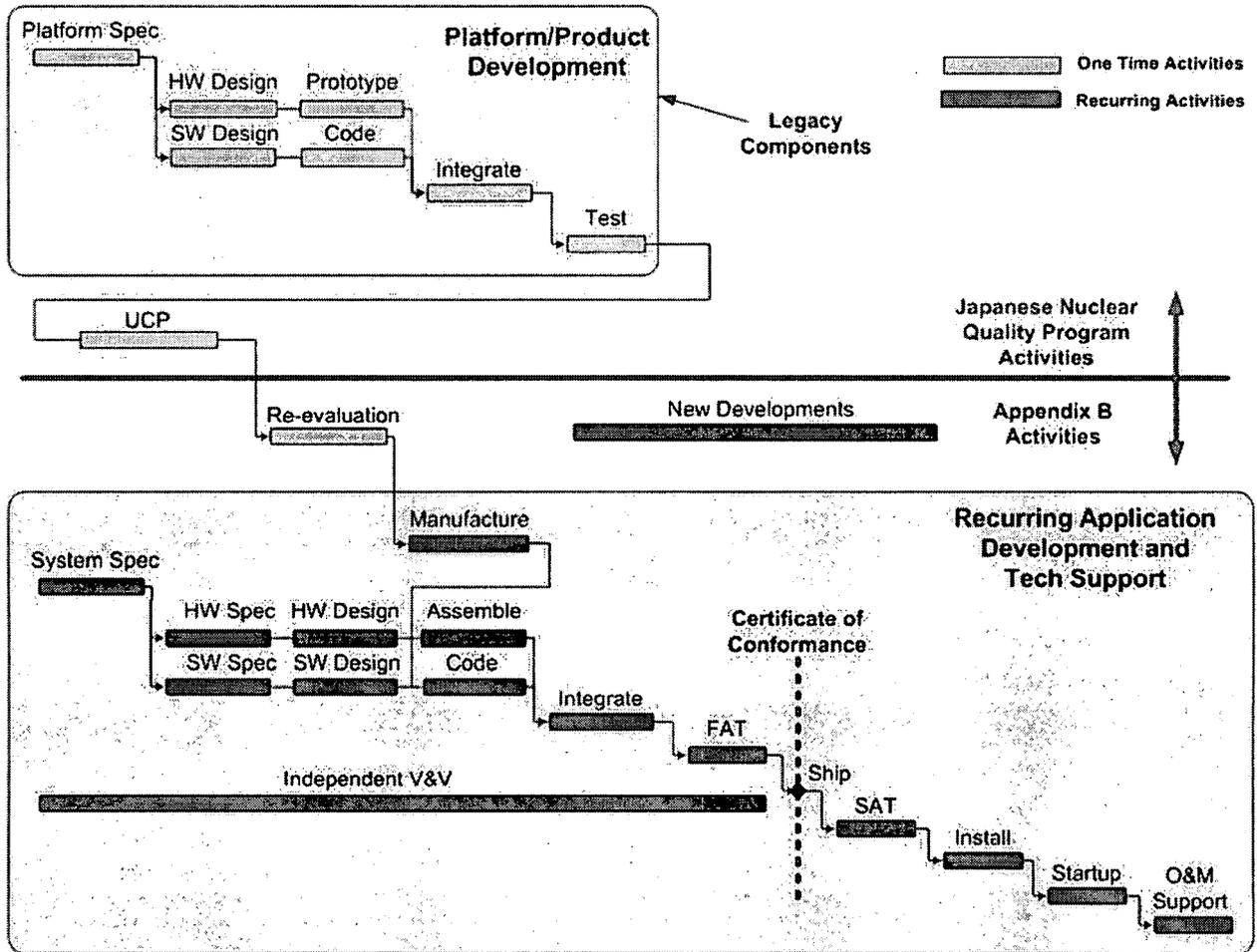


Figure 1 – Japanese Nuclear Quality Program vs. Appendix B Activities