July 10, 2009

Mr. Yoshiki Ogata, General Manager
APWR Promoting Department
Mitsubishi Heavy Industries, Ltd.
16-5, Konan 2-Chome, Minato-Ku
Tokyo, 108-8215 JAPAN

SUBJECT: MITSUBISHI HEAVY INDUSTRIES, LTD. – REVIEW STATUS OF THE SAFETY SYSTEM DIGITAL PLATFORM -MELTAC-, TOPICAL REPORT MUAP-07005 (TAC NO. MD6878)

Dear Mr. Ogata:

By letter UAP-HF-07026, dated March 2, 2007 (Agencywide Document Access and Management System (ADAMS) Accession Number ML070730349), Mitsubishi Heavy Industries, Ltd. (MHI) submitted for the U.S. Nuclear Regulatory Commission (NRC) staff review, MUAP-07005, "Safety System Digital Platform -MELTAC-." By letter dated May 21, 2008 (ADAMS Accession Number ML081220719), the NRC accepted this topical report for review.

The NRC's review of this topical report included two audits, a public meeting, and a set of requests for additional information. During its review, the staff identified several outstanding technical and licensing concerns which are documented in the enclosure. Due to the nature of the technical issues, particularly quality assurance, the NRC will not continue the review of MUAP-07005 for current operating reactors. Once the technical issues have been adequately addressed, MUAP-07005 may be re-submitted for current operating reactors.

MHI is being given an opportunity to review and discuss these issues with the NRC in order to inform the staff of its path forward in completing the Design Certification review. Specifically, MHI should consider the integration of MELTAC with the US-APWR Design Certification Application. MHI is requested to provide a response to this letter, within 30 days, outlining the proposed path forward. We are prepared to discuss the information contained in the attached enclosure at a future public meeting and answer any clarifying questions you may have on this subject at that time.

If you have any questions regarding this matter, please contact Michael Magee at 301-415-6988, or via e-mail at Michael.Magee@nrc.gov.

Sincerely,

/RA/

Paul Kallan, Acting Branch Chief
US-APWR Project Branch
Division of New Reactor Licensing
Office of New Reactors

Enclosure: As stated

cc w/encl: See next page

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SUMMARY OF THE NRC STAFF FINDINGS REGARDING
MUAP-07005, "SAFETY SYSTEM DIGITAL PLATFORM –MELTAC-," REVISION 3

BACKGROUND

By letter (UAP-HF-07026) dated March 2, 2007 (ML070730349), Mitsubishi Heavy Industries, Ltd. (MHI) submitted for U.S. Nuclear Regulatory Commission (NRC) staff review Topical Report (TR) MUAP-07005, "Safety System Digital Platform –MELTAC-", Revision 0 (ML070730354). The TR describes MHI's digital platform that is to be used in safety-related instrumentation and control (I&C) systems in its US-APWR nuclear power plant design and in current operating reactors. The MELTAC platform is developed by Mitsubishi Electric Co. and supplied to MHI. By letter dated May 21, 2008 (ML081220719) the NRC staff identified that it performed an acceptance review of the subject TR and accepted it for review.

On July 3, 2008, the NRC Staff issued an RAI (ML081930585) and MHI responded to the RAI by letter (UAP-HF-08145) dated August 22, 2008 (ML082390120). On July 1, 2009, the NRC staff issued a second RAI (ML091830607). Revision 3 (ML083659258), dated December 15, 2008, is the current revision.

KEY FINDINGS

In a telephone call on June 17, 2009, the NRC stated that TR MUAP-07005 could not be approved based on several key technical issues listed below. Additionally, the staff found the performance of audits to be difficult due to the fact that the majority of MELTAC documents are written in Japanese. As a result, the performance of audits is envisioned to take longer than normal to accommodate the language issue.

KEY FINDING EVALUATION SUMMARY

During the process of reviewing TR MUAP-07005, NRC staff noted the following technical and licensing issues. The identified issues are not a complete list of issues associated with the MELTAC platform, but highlight those that are most significant.

1. Quality Assurance of MELTAC

   MHI claims in MUAP-07005 that the basic software for the MELTAC platform meets quality assurance (QA) requirements of 10 CFR Part 50, Appendix B. However, MHI noted that MELTAC was developed under the Japanese Standard JEAG4101, which provides QA requirements for nuclear power plants but lacks guidance on independent software verification and validation (V&V). MHI addressed this deficiency by performing independent reviews at Japanese nuclear power plants, on software in use less than 1 plant operating fuel cycle and crediting operating experience for software with more than 1 cycle of operating time. Due to the breadth and depth of the corrective actions needed to address software quality assurance, the staff disagrees with MHI's claim that the MELTAC system was developed in accordance with 10 CFR Part 50, Appendix B, requirements. Consistent with the applicable Appendix B requirements, all computer-based systems used in safety-related applications must be designed, developed, tested, and undergo independent V&V. Therefore, MHI's proposed use of operating experience as a surrogate for independent V&V is not acceptable.

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. For example, MHI's audit team identified issues including: (1) Mitsubishi Electric Co. has not established a QA program based on 10 CFR Part 50, Appendix B; (2) configuration management weaknesses; (3) software design change weaknesses; (4) inadequate documentation of design activities; (5) software test control weaknesses; (6) record retention weaknesses; (7) lack of procedures to address 10 CFR Part 21; and (8) lack of processes (or failure to follow processes) for software obsolescence and retirement.

Due to the significance of the QA issues identified by MHI, the NRC staff does not plan to continue the review until the QA issues are satisfactorily addressed through well defined and documented corrective actions. In addition, 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.

Alternatively, MHI may provide objective evidence that the MELTAC platform has been dedicated in accordance with the requirements of 10 CFR Part 21 and 10 CFR Part 50, Appendix B.

2. Language Translation Issues

During the March 2009 audit, the staff experienced difficulty confirming information in documents since all engineering and quality assurance work is performed in Japanese. The staff anticipates that even with detailed audit plans, situations will arise where un-translated documents are needed to verify information. 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.

During the same audit, the staff also observed that equipment labels, technical manuals, and the engineering computer software for MELTAC were not translated into English. The staff considers this a significant human factors issue that needs to be addressed before the MELTAC TR could be approved.

3. Technical Issues

During the March 2009 audit, the staff identified the use of several field programmable gate arrays (FPGAs) in the MELTAC platform. FPGA firmware should be developed using an approved, QA-based development process similar to safety-related software. However, MHI did not address the quality of the FPGA firmware development process. MHI would need to address the quality-related aspects of the firmware development process prior to approval of the TR.

During the same audit, the staff observed the connection between the MELTAC platform and the engineering tool. The proposed design deviates from NRC's Digital I&C Interim Staff Guidance No. 4, "Highly Integrated Control Room – Communications," particularly Points 3 and 10 of Section 1. Specifically, MHI would 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.

MHI plans to use the MELTAC platform in safety-related and non-safety I&C applications. However, the topical report does not adequately address 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. This issue must be adequately addressed prior to approval of the TR.

CONCLUSION

The NRC staff identified several issues involving quality assurance and technical aspects of the MELTAC platform that need to be resolved prior to continuing review of the topical report. Additionally, since the MELTAC platform was originally developed for the Japanese nuclear industry, design documents are in Japanese which hinder the review efforts by the staff. MHI is requested to address the issues identified in this enclosure and provide their path forward including design information needed for the US-APWR design certification application.

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