May 21, 2008

Mr. Keith Paulson
Senior Technical Manager
Mitsubishi Nuclear Energy Systems, Inc.
300 Oxford Drive, Suite 301
Monroeville, PA 15146

SUBJECT: REVIEW OF TOPICAL REPORTS RELATED TO THE US-APWR DIGITAL INSTRUMENTATION AND CONTROLS: MUAP-07004-P, REVISION 1, "SAFETY INSTRUMENTATION AND CONTROLS SYSTEM DESCRIPTION AND DESIGN PROCESS," AND MUAP-07005-P, REVISION 1, "SAFETY SYSTEM DIGITAL PLATFORM-MELTAC."

Dear Mr. Paulson:

By letter dated December 18, 2007, the NRC staff informed Mitsubishi Heavy Industries, Inc. (MHI) that additional information was needed before the NRC staff could begin its detailed review of Topical Reports MUAP-07004-P, Revision 1 "Safety Instrumentation and Controls System Description and Design Process," and MUAP-07005-P, Revision 1 "Safety System Digital Platform-MELTAC." Specifically, MHI was requested to provide additional information contained in NUREG-0800, "Standard Review Plan," Branch Technical Position 7-14, 'Guidance on Software Reviews for Digital Computer-Based Instrumentation and Control Systems.'

Subsequent to this letter, MHI submitted the following documents to the NRC staff related to the review of these two topical reports: Q-4102-P, "Safety System Digital Platform Quality Assurance Program," Q-6403-P, "Safety System Digital Platform Cyber Security Program," and Q-7302-P, "Safety System Digital Platform Software V&V Procedures," on March 31, 2008; and Technical Report, "Software Program Manual" on December 31, 2007.

The NRC staff reviewed these two topical reports, as well as the supplemental information provided to the NRC staff on December 31, 2007, and March 31, 2008, and determined that the material presented in these topical reports is sufficient to begin our comprehensive review in support of the US-APWR design certification application and possible reference by the current operating fleet. The NRC staff expects to issue a request for additional information during the month of June 2008. Contingent upon a reasonable assurance of safety, the NRC staff estimates issuing a safety evaluation for the Safety System Digital Platform-MELTAC and Safety Instrumentation and Controls System Description and Design Process topical reports by June 15, 2009, for both the US-APWR design certification application and the current operating fleet. This schedule assumes a 30-day response from MHI for any requests for additional information. However, the NRC staff may limit its review of these topical reports to the US-APWR design certification application in the event the NRC staff's review for the operating fleet would result in a delay to the review schedule for the US-APWR design certification.

As noted in the December 18, 2007, letter, the NRC staff's review of MHI's assessments performed (including the US Conformance Program) on the original MELTAC system software development process against the current Safety System Digital Platform Quality Assurance Program is of particular interest. In order to facilitate a timely review of these topical reports, the NRC staff plans to perform an inspection of MHI's documents related to the MELTAC digital platform at the Arlington, VA office during the month of August 2008. The enclosure provides a

list of topics the NRC staff intends to review during this site visit. As such, MHI should make available an English translation of these documents shown in the enclosure.

In addition, the NRC staff requests that the Safety System Digital Platform-MELTAC be revised to include the new references provided by the March 31, 2008 letter. The Table, in Enclosure 2 of the March 31, 2008 letter, provides where the quality assurance functions, described in Section 6.1.1 of this topical report, can be found in these documents that now comprise the Software Quality Assurance Program. This Table should be used as a guide for updating this topical report.

By letter dated January 29, 2008, MHI stated that the Software Program Manual will be revised "because this document has generic applicability to all MHI safety systems, MHI plans to revise this document to clearly indicate its generic applicability." Currently, the Software Program Manual exists as a technical report supporting the US-APWR design certification application and is applicable to application software for the US-APWR. The NRC staff intends to review the Software Program Manual as part of the US-APWR design certification application and any NRC staff conclusions to the Software Program Manual would only be applicable to the US-APWR application.

Finally, the NRC staff estimates that the review of both topical reports will require approximately 2,500 staff hours, including contractor and project management time. Section 170.21 of the Title 10 of the *Code of Federal Regulations* requires topical reports to be subject to fees based on the full cost of the review. You did not request a fee exemption; therefore, NRC staff hours will be billed accordingly.

Sincerely,

/RA/

Larry Burkhart, Chief
USAPWR Projects Branch
Division of New Reactors Licensing
Office of New Reactors

Docket No. 52-021

Enclosure: "List of Mitsubishi Heavy Industries' Documents to be Inspected"

cc: See next page

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Finally, the NRC staff estimates that the review of both topical reports will require approximately 2,500 staff hours, including contractor and project management time. Section 170.21 of the Title 10 of the *Code of Federal Regulations* requires topical reports to be subject to fees based on the full cost of the review. You did not request a fee exemption; therefore, NRC staff hours will be billed accordingly.

Sincerely,
/RA/
Larry Burkhart, Chief
USAPWR Projects Branch
Division of New Reactors Licensing
Office of New Reactors

Docket No. 52-021
Enclosure: "List of Mitsubishi Heavy Industries' Documents to be Inspected"
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List of Mitsubishi Heavy Industries' Documents to be Inspected

The NRC staff has scheduled an inspection of the MELTAC-related documents during the month of August 2008. In support of this inspection, Mitsubishi Heavy Industries is requested to provide an English version of these documents, listed below, to the NRC staff during this inspection.

1. Quality Assurance

Comparison between NRC and Japanese Life Cycle Process Requirements and Guidance (Similar to March 7, 2007, letter comparing 10 CFR 50 Appendix B/ NQA-1 and JEAG4101)

JEAG4101 and other Japanese requirements and guidance used in developing the MELTAC Platform

Q-7104, "Guideline for Creating Safety System Digital Platform Project Plan"

Current MELTAC project plan

MELTAC Software Development Plan; including a MELTAC U.S. Conformance Program (UCP) assessment (Section 6.1.4 of MUAP-07005-P, Revision 1)

MELTAC Platform Specification and Requirements Traceability Matrix (in accordance with Q-4102 per Section 6.1.7.1 of MUAP-07005-P, Revision 1)

MELTAC Software Specification; including the regression analysis for the UCP (Section 6.1.7.2 of MUAP-07005-P, Revision 1)

MELTAC Hardware Specification, original conformance to U.S. standards (Section 6.1.7 of MUAP-07005-P, Revision 1)

Category -1 Assessments for Software Units (Section 6.1.7.3 of MUAP-07005-P, Revision 1)

Category - 2 Assessments for Software Units (Section 6.1.7.3 of MUAP-07005-P, Revision 1)

Final V&V report following new Integration Tests for UCP (Section 6.1.7.4 of MUAP-07005-P, Revision 1)

2. Configuration Management

Q-7302.1 "Safety System Digital Platform V&V Detailed Procedures and Checklists"

Q-7302.2 "Safety System Digital Platform Configuration Management Detailed Procedures"

The assessments done for the UCP under configuration management (Section 6.1.5.7 of MUAP-07005-P, Revision 1)

A completed project Configuration Management Report
Configuration Management of the Engineering Tool

List of Mitsubishi Heavy Industries' Documents to be Inspected

3. Equipment Qualification

Environmental Qualification Program Technical Report (To be submitted December 2008)

Confirm these MELTAC documents will be part of this submittal; or separately submitted:

Environmental Test Plan, Procedure & report
Seismic Test Plan, Procedure & report
Surge/Isolation Test Plan, Procedure & report
EMI/RFI Test Plan & Procedure
EMC test report for the MELTAC Platform; JEXU-1016-0010
ESD Test Plan, Procedure & report