

December 18, 2007

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-07005-P, "SAFETY SYSTEM DIGITAL PLATFORM-MELTAC," AND MUAP-07004-P, "SAFETY INSTRUMENTATION AND CONTROLS SYSTEM DESCRIPTION AND DESIGN PROCESS

Dear Mr. Paulson;

By letters dated March 7, 2007, Mitsubishi Heavy Industries, Inc. (MHI) submitted for Nuclear Regulatory Commission (NRC) staff review Topical Reports MUAP-07004-P, "Safety Instrumentation and Controls System Description and Design Process," and MUAP-07005-P, "Safety System Digital Platform-MELTAC." In response to the NRC staff's comments raised at a non-public (proprietary) meeting on June 12, 2007, MHI submitted Revision 1 for both of these topical reports on July 3, 2007. In its submittals, MHI requested NRC staff approval to use these topical reports in support of the US-APWR design certification application as well as the current operating fleet.

The NRC staff has reviewed Topical Reports "Safety System Digital Platform-MELTAC," and "Safety Instrumentation and Controls System Description and Design Process," and has determined that additional information is needed before the NRC staff can begin its review of these topical reports. Therefore, MHI is requested to provide to the NRC staff the requested information shown in Enclosure 1. Until MHI submits this requested information, the NRC staff will not begin its review of these two topical reports. When the NRC staff receives this requested information, the NRC staff will issue a subsequent letter that provides an acceptability determination. If the topical reports are found to be acceptable, we will also provide you with schedule milestones and resource estimates.

K. Paulson

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These acceptability issues, as described in the previous paragraphs, were discussed with you on December 4, 2007. 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/

Stephanie M. Coffin, Acting Chief
USAPWR Projects Branch
Division of New Reactors Licensing
Office of New Reactors

Project No. 0751

cc: See next page

These acceptability issues, as described in the previous paragraphs, were discussed with you on December 4, 2007. 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.

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Stephanie M. Coffin, Acting Chief
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REQUESTED INFORMATION FOR

MUAP-07005-P, “SAFETY SYSTEM DIGITAL PLATFORM-MELTAC” AND

MUAP-07004-P, “SAFETY INSTRUMENTATION AND CONTROLS SYSTEM DESCRIPTION AND DESIGN PROCESS”

Mitsubishi Heavy Industries (MHI) is requested to provide the information which is described in NUREG-0800, “Standard Review Plan,” Branch Technical Position 7-14, ‘Guidance on Software Reviews for Digital Computer-based Instrumentation and Control Systems.’ This branch technical position (BTP) provides guidelines for evaluating software life-cycle processes for digital computer-based instrumentation and control (I&C) systems.

Particularly, Section B.2 of BTP 7-14, “Information to be Reviewed” identifies the documents which typically contain the information necessary. The information the Nuclear Regulatory Commission staff will review is subdivided into two topic areas: planning, listed in Subsection B.2.1; and implementation, listed in Subsection B.2.2.

1. Software Life Cycle Process Planning

MHI is requested to submit the following documents to the NRC staff:

- Software Management Plan (SMP)
- Software Development Plan (SDP)
- Software Quality Assurance Plan (SQAP)
- Software Integration Plan (SIntP)
- Software Installation Plan (SInstP)
- Software Maintenance Plan (SMaintP)
- Software Training Plan (STrngP)
- Software Operations Plan (SOP)
- Software Safety Plan (SSP)
- Software Verification and Validation Plan (SVVP)
- Software Configuration Management Plan (SCMP)
- Software Test Plan (STP)

2. Software Life Cycle Process Implementation

MHI is requested to submit the following documents to the NRC staff:

- Safety analyses
- Verification and validation analysis and test reports
- Configuration management reports
- Testing Activities

One or more sets of these reports should be available for each of the following activity groups:

- Requirements
- Design

Enclosure 1

- Implementation
- Integration
- Validation
- Installation
- Operations and maintenance

System requirements and a Requirements Traceability Matrix should also be examined to provide context for the review.

Supplemental documents which may be necessary based on preliminary review of the MELTAC Topical Report

The NRC staff's preliminary review of the information contained in the Safety System Digital Platform-MELTAC topical report found that the original quality assurance (QA) program used for the development of the MELTAC platform was based on the Japanese Electric Association Guideline 4101. MHI intends to use MELTAC platform components (hardware or software) developed under the original QA program for U.S. nuclear applications. MHI's overall plan is to apply a new QA program that does address U.S. requirements, based on an assessment of the original QA program and resulting justification of the differences between the Japanese Electric Association and 10 CFR Part 50, Appendix B. As such, the NRC staff will need to review software development under the original QA program and the new proposed software QA plan.

Acceptance Criteria

BTP 7-14 subdivides the acceptance criteria for this information into the three areas or topics where the information should be found, as noted above. This document also explains partial or complete (unqualified) conformance to regulatory guides. It is recommended that MHI provide an evaluation describing the level of conformance to the regulatory guides. The guidelines of this BTP may be used as appropriate in assessing the software engineering processes used to develop commercial software. MHI should also review the discussion of the commercial dedication of pre-developed software described in NUREG-0800, SRP Appendix 7.0-A, "Review Process for Digital Instrumentation and Control Systems."

Review Procedures

As stated in BTP 7-14, reviews of the life cycle processes are carried out by a combination of inspection and analysis of documents. New software, or an unproven development team, will require greater emphasis on the adequacy of the planning phase. A sample of Verification and Validation, safety analysis, and configuration management documentation for various life cycle activity groups should be audited to confirm that the developer's life cycle activities have been properly implemented.

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