November 4, 2009

APPLICANT: MITSUBISHI HEAVY INDUSTRIES, LTD

APPLICATION: US-APWR STANDARD DESIGN CERTIFICATION REVIEW

SUBJECT: SUMMARY OF THE OCTOBER 7 - 8, 2009, MEETING WITH MITSUBISHI HEAVY INDUSTRIES LTD. TO DISCUSS THE REVIEW CHANGES AND REQUESTS FOR ADDITIONAL INFORMATION FOR THE UNITED STATES - ADVANCED PRESSURIZED WATER REACTOR DESIGN CONTROL DOCUMENT CHAPTER 7 AND SAFETY SYSTEM DIGITAL PLATFORM - MELTAC TOPICAL REPORTS

On October 7 - 8, 2009, a public meeting was held between the U.S. Nuclear Regulatory Commission (NRC), Mitsubishi Heavy Industries, Ltd. (MHI), Mitsubishi Nuclear Energy Systems, Mitsubishi Electric Power Products, Inc., and Mitsubishi Electric Corporation (MELCO) representatives. Members of the public were also in attendance. This meeting summary includes the discussion of the review changes to the United States – Advanced Pressurized Water Reactor (US-APWR) Design Control Document (DCD), the applicant's Request for Additional Information (RAI) responses to MELTAC, the Safety Instrumentation and Control (I&C) topical report RAI's, and Chapter 7 of the US-APWR DCD.

MEETING DISCUSSION

The NRC staff opened the meeting with discussions and a review of MHI's response (ML092440689) to the MELTAC letter sent on July 10, 2009 (ML091770212), specifically issues pertaining to Quality Assurance, Language Translation, and Technical content. MHI reviewed the content of their response.

MHI outlined MELCO's plan to expand their US Conformance plan to include resolution of quality assurance (QA) issues brought up during an independent audit of the MELCO QA program and the NRC staff concerns. The topical report revision 4 will be clarified to remove any implication that MELTAC was developed in complete accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix B. The topical report revision 4 will also describe the re-evaluation of the MELTAC development process. In accordance with 10 CFR Part 21, the re-evaluation will provide reasonable assurance that MELTAC is equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, QA program.

Previously, MHI and MELCO proposed using operating experience as a surrogate for independent Verification and Validation (V&V), which the NRC staff found unacceptable. MELCO will now conduct the same additional independent V&V activities for Category 2 software, as they conducted previously for Category 1 software. The MELTAC topical report revision 4 will modify the description of the US Conformance Program (UCP) to reflect this change. The technical documentation for these additional UCP activities for Category 2 software will be available for the NRC to audit.

MHI and MELCO discussed their actions 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 those criteria. The following actions were discussed:

1. Resolution of issues from MHI's independent QA audit, including a revision to MELCO's Quality Assurance Program (QAP).

2. The three phase re-evaluation of the MELTAC development process using the revised MELCO QAP.

3. The existing QAP procedures are being replaced as follows:

    a) The document, QUP, will be replaced with six procedures.

    b) Both the Cyber Security and V&V procedures will be replaced with one procedure each.

MHI stated that the Commercial Grade Dedication (CGD) process will be followed, but clarified that MHI will not be the Commercial Dedicator for the MELTAC platform. An independent group within MELCO would perform the CGD activities. The NRC staff indicated that the MELTAC topical report has not been reviewed in accordance with the CGD process and that additional time may be required for these review activities. Also, due to the quality issues still being resolved and the reliance on the CGD process, the NRC staff indicated that the review has changed to an analysis, by the NRC staff, that all claims to meeting the requirements and commitments to guidance are made and that these are all part of the design concepts. This would meet the level of detail required by 10 CFR 52.47 for the US-APWR design certification. The detailed review showing evidence that all technical details are incorporated into the design concepts, which total the process plus hardware and software, will be completed once the quality issues have been adequately addressed.

The docketing of documents, specifically the docketing of QA procedures, was discussed. The NRC staff indicated that if a document was used to make a safety determination, the document should be on the docket. MHI responded that their documents were "living" documents, subject to revision with improved processes. The question was asked that if a docketed document changed, did MHI have to resubmit the document each time a change was made. The NRC staff clarified that information describing how the MELTAC design and design process meets the NRC requirements, including how it addresses the acceptance criteria in the Standard Review Plan (SRP), is needed on the docket for the NRC staff to make a safety conclusion. MHI has the option of providing that information as part of the MELTAC topical report or submitting the QA procedures that would contain that information.

The Software Safety Analysis (SSA) document will show compliance with Interim Staff Guidance (ISG) - 04, Highly Integrated Control Rooms – Digital Communication Systems. Once submitted, the NRC staff will review the document for compliance versus all 20 staff positions of the ISG.

A significant discussion on the engineering tool and the basis for it being permanently connected, versus only being connected to troubleshoot a problem or for software programming manipulation, ensued.

The NRC staff has concerns with the permanent connection both functionally, as in how often the troubleshooting and programming features will dictate the need for a permanent connection, and technically, addressing the permanent two way communication path between safety and non-safety systems. The NRC staff will consider the presentation of how this two way communication path meets the guidance of ISG-04, as it will be presented in the SSA.

SAFETY INSTRUMENTATION AND CONTROLS

During the Safety I&C discussion, the NRC staff inquired as to the detail of the Setpoint Methodology. MHI indicated that they would be submitting a technical report on Setpoint Methodology, which will cover Setpoint details. The NRC staff suggested removing the Setpoint Methodology from the topical report and reference the technical report.

In response to the NRC staff questions regarding self-diagnostics, MHI reported that self diagnostics are verified and validated during system development and confirmed periodically through software memory integrity tests. The coverage of self-diagnostics is documented in the SSA report. The NRC staff stated that the self-testing documentation may be the subject of a future audit.

US-APWR DCD CHAPTER 7

Focus of the Chapter 7 issues concentrated on issues generated during the RAI process.

MHI reported that the failure modes and effects analysis (FMEA) report would be submitted shortly.

The NRC staff indicated that they would consider the application of Branch Technical Position (BTP) 7-13 as it applies to the safe shutdown system. MHI stated that they have fast response resistance temperature detectors in the reactor trip functions, but not in the safe shutdown functions.

With regard to isolation of low pressure systems from high pressure reactor coolant systems, MHI is going to reword DCD Section 7.6 to clearly show how isolation is achieved and interfacing systems Loss of Coolant Accident is prevented in the Residual Heat Removal system.

The NRC staff and MHI discussed normal and safety-related trip setpoints and how Regulatory Guide (RG) 1.105 applies. Both the NRC and MHI will further review the RG and will discuss compliance.

The NRC staff and MHI discussed how the safe state should be addressed for each component. The safe state for each component is determined based on the plant safety analysis. For components that are repositioned at different times during an event scenario, the safe state is the state required initially for event mitigation. It is noted that the state based priority logic within the PIF module is not used for signals from other non-safety equipment, such as the multi-

channel VDU. For the few plant components that have two safe states (depending on plant conditions), such as emergency feedwater isolation valves, a preferred safe state is defined (typically the feed state, not the isolation state). MHI agreed to provide a listing in Section 7.8 of the safe state of all components. The NRC staff will initiate a RAI on this subject.

The NRC staff indicated that several of the RAI responses would be beneficial to include in the DCD to assist readers to track the flow of information. Often the RAI response includes a description of how to find the information which would make the DCD read more clearly.

ADDITIONAL DISCUSSION TOPICS

Defense-In-Depth and Diversity (D3) Application Specific Action Items (ASAI)

No formal progress towards completion of ASAI's. MHI presented a brief conceptual discussion of the ASAI on partial Common Cause Failure and how they may address this issue. MHI is hoping to concur with the Nuclear Energy Institute as all applicants will eventually have to treat this subject.

The next version of the DCD will have a table in Section 7.8 that will have a short description of the ASAI and the compliance method, and will have a pointer to the section(s) of the DCD or technical/topical reports that provide the compliance details.

Software Program Manual (SPM) and BTP 7-14

It was noted by MHI that revision 4 of the MELTAC topical report will have an appendix that addresses BTP 7-14.

Primary discussions focused on testing and testing responsibility, specifically interpretation of BTP 7-14 testing.

The NRC staff's position, is that the V&V team is responsible for all testing, and the actual test team can be made up of the designers. Designers would then be used on a matrix basis to implement the testing but the overall responsibility for testing remains with V&V.

MHI's position, is that the design team, including the designers, can be the team but that the V&V is the final testing and is independently performed from the design team and meets the intent of BTP 7-14.

The NRC staff discussed Criteria 3 in 10 CFR Part 50, Appendix B, which states "that design verification or checking be performed by individuals or groups other than those who performed the original design" and MHI compliance with this criteria.

The NRC staff will write three new RAI's against the SPM as follows:

1. The first RAI will address compliance of 10 CFR 52.47(a)(9), which in part requires all applications to include an evaluation against the SRP. The regulation further states that the application will provide an evaluation where differences exist and, discuss how the alternative proposed provides a acceptable method to meeting the rules and regulations that

underlie the corresponding SRP acceptance criteria (in this case, SRP Section BTP 7-14). This requirement has been discussed in all venues including the RAIs on the DCD, topical reports and the SPM. Therefore a supplemental RAI will be issued on RAI 07-14-1, the first RAI for the SPM.

2. The second RAI will address the testing and responsible group that MHI has identified for testing. This was discussed as Part 3 of the RAI 7-14-14. This will also be a supplemental RAI requesting compliance to BTP 7-14 as well as RG 1.168, or requesting the alternative and with an analysis.

3. The third RAI will discuss MHI not utilizing a Configuration Control Board as described by Institute of Electrical and Electronics Engineers Standard 829 which was endorsed by RG 1.169 without exception on this issue. This was also addressed in the existing RAI 07-14-26. A supplemental to that RAI will be issued on this subject.

MHI suggested submitting a possible SPM for the MELTAC basic software process as well. The NRC staff agreed that this would be the best way to address the guidance in BTP 7-14 for the basic software. At this point in time, the NRC staff believes the management, implementation and resource characteristics described in BTP 7-14, have yet to be addressed for the MELTAC basic software life cycle process.

Cybersecurity

The NRC staff presented their review progress on the cyber security and discussed the design and programmatic issues with cyber security. The I&C staff stated that the Office of Nuclear Security and Incident Response (NSIR) reviews the cyber security plans as part of Chapter 13 reviews for combined license applications. The I&C staff, also, did not think that approval of a generic plan was something that NSIR was planning. From an I&C/Chapter 7 standpoint, MHI has submitted information for a secure software development environment for MELTAC and the US-APWR safety system software. This is sufficient for the I&C staff review (although we have questions on the material that has been submitted). The I&C staff requested that MHI remove the other programmatic cyber security information from Chapter 7 submittals. MHI asked for a future conference call with NSIR to discuss generic approval of a cyber security plan for combined license applicants referencing the US-APWR design.

D3 Coping Analysis Technical Report

MHI is intent on considering the NRC staff's comments on the entire document. The limited reference to this document in Chapter 7 during the Phase 1 review of design certification did not result in a separate and complete review by the NRC staff. The NRC staff will consider a complete and separate review of the document.

PATH FORWARD

Information to be submitted and put on the docket remains a key element in the staffs' ability to come to a reasonable safety determination. The information that the NRC staff relies upon to make the safety determination must be submitted on the docket. As previously discussed, MHI has the option of providing that information as part of, and included in, the MELTAC topical report or submitting the procedures, reports and analysis that would contain that information as separate documents on the docket. The NRC has provided MHI with the issues remaining with our review to date in this discussion and the RAI's. The NRC is anticipating that the ASAI's in the topical reports, when coordinated with the inspection, test, analysis, and acceptance criteria (ITAAC) in the US-APWR Design Certification, will provide an adequate method for review completion and conclusion for a reasonable safety determination.

The NRC staff expects to submit three more RAI's, or supplements, on the SPM.

The NRC staff will send an RAI for the identification of the safe state of components for Section 7.8 of the DCD.

The NRC staff will conduct a separate and comprehensive review of the D3 coping analysis.

MHI may still wish to pursue approval for a generic cyber security plan in the US-APWR DCD application. This could be the subject of a conference call as a Chapter 13 question from MHI with NSIR.

Potential audits after April 2010, once the expanded UCP has been successfully completed and the necessary information is submitted.

US-APWR DCD Revision 2, due at end of October 2010, will have new ITAAC for MELTAC.

Revision 3 of the Safety I&C TR (will be) provided by MHI in October, 2009.

In the immediate future, MHI is also submitting their SSA, Setpoint Methodology, and FMEA.

PUBLIC PARTICIPATION

Using ITAAC to address ASAI's and how they are addressed. Applicant should use tier 2 documents to link the ASAI's to ITAAC.

Control System Setpoints – The NRC staff stated that control system setpoints protect the initial conditions assumed in the DCD Chapter 15 analysis. The public contended that the Initial Conditions were protected by the Technical Specifications Limited Conditions for Operation. Clarification of setpoint uncertainty, is expected in the Setpoint Methodology technical report.

The public asked for clarification of how MHI or MELCO was attempting to submit the MELTAC topical report to the NRC for review. Specifically, was the report being submitted into both the Office of Nuclear Reactor Regulation (NRR) and the Office of New Reactors (NRO) for review. Originally, the MELTAC topical report was submitted for both new and operating reactors.

However, it was determined that NRR would not review the topical report for reasons outlined in the July 2008, MELTAC review letter sent to MHI. NRO review continues, and it is MHI's intent to resubmit the MELTAC topical report for review by NRR in the future.

A comment was made that it should be acceptable to provide a summary in the DCD (or other docketed documents) without the need to submit all of the underlying information on the docket. However, this underlying information must be made available to the NRC staff to audit. Specifically, as it applies to the QA procedures, a programmatic document should be sufficient, with the detailed QA procedures being made available for NRC inspection/audit. Concern for the potentially large amount of information required to be docketed and reviewed would be of limited benefit to safety.

Stating compliance of non-safety components to RG 1.105, may set a poor precedent to the industry. Further clarification of the relationship of "safety-related" and "important-to-safety" is needed. Concern should be given to how the question about compliance with RG 1.105 is phrased.

Please direct any inquiries to Michael S. Magee at 301-415-6988 or via e-mail at Michael.Magee@nrc.gov.

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Docket No. 52-021

Enclosure:
1. Attendance Sheet

cc w/encl: See next page

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MELTAC/Chapter 7 Public Meeting Attendance Sheet

October 7 - 8, 2009

	Name	**Agency**	October 7	October 8
1.	Michael S. Magee	NRO/DRNL/NMIP	X	X
2.	Royce Beacom	NRO/DE/ICE1	X	X
3.	Shunsuke Ishimoto	MHI	X	X
4.	Satoru Kamohara	MHI		X
5.	Gil Remley	MEPPI/MELCO	X	X
6.	Kenichi Furuno	MELCO	X	X
7.	Makoto Ito	MELCO	X	X
8.	Katsumi Akagi	MELCO	X	X
9.	Koichi Takahashi	MELCO	X	X
10.	Makoto Takashima	MHI	X	X
11.	Shinji Kiuchi	MHI	X	X
12.	Alan Levin	Areva	X	
13.	Thomas L. Wilson Jr.	ORNL	X	X
14.	Mike Muhlheim	ORNL	X	X
15.	Terry Jackson	NRC/NRO/DE/ICE1	X	X
16.	Hossein Hamzehee	NRC/NRO/NMIP	X	X
17.	Ken Scarola	MNES/NAE	X	X
18.	Shelby Small	Areva	X	X
19.	Steve Wyman	NRR/EICB	X	
20.	Hiroshi Shirasawa	MNES	X	X
21.	C. Keith Paulson	MNES	X	X
22.	Kenji Mashio	MNES	X	
23.	Skip Butler (Via Teleconference)	GE Nuclear	X	X
24.	John Moore (Via Teleconference)	MNES	X	
25.	Doug Wood	MHI/Advent		X
26.	Bruce Geddes	MHI		X
27.	Rebecca Steinman	MHI/Advent		X
28.	Anthony Wilson	NRC/OGC		X
29.	Bob Tjader	NRO/CTSB		X
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Enclosure

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