

September 27, 2017

Mr. Gilbert W. Remley
Nuclear Systems Department Manager
Mitsubishi Electric Power Products, Inc.
547 Keystone Drive
Warrendale, PA 15086

SUBJECT: REGULATORY AUDIT PLAN FOR NOVEMBER 28-30, 2017, "SAFETY SYSTEM DIGITAL PLATFORM – MELTAC [MITSUBISHI ELECTRIC TOTAL ADVANCED CONTROLLER] –TOPICAL REPORT REVISION 0" (TAC NO. MF4228)

Dear Mr. Remley:

By letter dated April 30, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14121A415), Mitsubishi Electric Corporation (MELCO) submitted for U.S. Nuclear Regulatory Commission (NRC) staff review the topical report (TR); "Safety System Digital Platform – MELTAC –Topical Report Revision 0." The TR is supported by documentation that includes plans, requirements, design specifications, programming and hardware testing, independent verification and validation, and equipment qualification testing.

The U. S. Nuclear Regulatory Commission (NRC) staff is currently reviewing the TR for use in safety system equipment at nuclear power plants. As part of its review, the NRC staff will be performing a regulatory audit of MELCO. The dates for this audit will be November 28-30, 2017.

The audit will determine the degree that the processes and outputs used have resulted in satisfying regulatory requirements for safety system applications at nuclear power plants. This audit will provide information necessary to complete the NRC staff's evaluation of the TR. Enclosed is a copy of the plan the NRC staff will follow on the audit.

If you any questions or require any additional information, please feel free to contact me at 301-415-7297 or Joseph.Holonich@nrc.gov.

Sincerely,

/RA/

Joseph J. Holonich, Senior Project Manager
Licensing Processes Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Enclosure:
Audit Plan

Project No. 751

SUBJECT: REGULATORY AUDIT PLAN FOR NOVEMBER 28-30, 2017, "SAFETY SYSTEM DIGITAL PLATFORM – MELTAC [MITSUBISHI ELECTRIC TOTAL ADVANCED CONTROLLER] –TOPICAL REPORT REVISION 0" DATED: SEPTEMBER 27, 2017

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**U.S. Nuclear Regulatory Commission Staff
Regulatory Audit Plan for
“Safety System Digital Platform – MELTAC [Mitsubishi Electric Total Advanced
Controller] –Topical Report Revision 0”**

Warrendale, PA

Background

The U. S. Nuclear Regulatory Commission (NRC) staff is currently performing a review of the Mitsubishi Electric Corporation (MELCO) Topical Report (TR), “Safety System Digital Platform - MELTAC - Topical Report Revision 0” (Agencywide Document Access and Management System (ADAMS) Accession No. ML14121A413).

MELCO is seeking generic approval of the MELTAC platform for use in safety systems in nuclear power plants. This regulatory audit is intended to assist the NRC staff in confirming information submitted as part of the licensing TR.

Regulatory Audit Bases

As part of its safety evaluation (SE), the NRC staff is reviewing MELCO design and development processes used for the MELTAC Platform. To support this review, the NRC staff will visit the MELCO facility in Warrendale, PA. The primary purpose of this audit is to gain a better understanding of the MELTAC development life-cycle processes to support the SE of the MELTAC Platform.

The NRC staff will use the results of this audit to support its safety conclusions. A secondary purpose of the audit will be to assess the capabilities of the MELTAC Platform to determine if a MELTAC based system will be capable of meeting regulatory criteria described in Chapter 7 of the NUREG-0800, “NRC Standard Review Plan” (ADAMS Accession No. ML070460342).

Regulatory Audit Scope

This audit will be conducted in accordance with Office of Nuclear Reactor Regulation Office Instruction LIC-111, “Regulatory Audits” (ADAMS Accession No. ML082900195). The NRC staff will review non-docketed procedures and records related to the MELTAC Platform development processes. Also, the NRC staff will evaluate the effectiveness of software development activities and confirm that processes described in the TR are being implemented correctly to achieve a high quality system that can be used to perform safety-related functions in a nuclear power plant.

Audit Requirements

- Software Verification and Validation (V&V) - Verify the MELTAC Platform software V&V program meets the criteria of Institute of Electrical and Electronics Engineers (IEEE) Standard 1012, “IEEE Standard for Software Verification and Validation,” and the V&V program is implemented in a manner which reliably verifies and validates the design outputs at each stage of the MELTAC software development process.

- Configuration Management - Verify the MELTAC configuration management processes include appropriate hardware and software under configuration management, and the configuration management system is effectively controlling the items being managed by these processes.

Enclosure

- Software Quality Assurance (SQA) - Verify the SQA program is effective in controlling the MELTAC software development process to assure quality of MELTAC platform software.
- Software Safety - Verify that software safety plans and procedures used for safety analysis activities are adequate to determine that MELTAC software is safe to be used for safety-related nuclear power plant operations.
- Secure Development Environment - Evaluate the MELTAC platform development environment. The results of this audit activity will be used to determine conformance to the secure development environment requirements of Regulatory Guide 1.152, Revision 3, "Criteria for Use of Computers in Safety Systems of Nuclear Power Plants" (ADAMS Accession No. ML11101A013).

Information Necessary for the Regulatory Audit

MELCO should be prepared to have the following documentation and information available.

- Requirements Threads - To gain an overview of the MELTAC Platform hardware and software development processes, the NRC staff would like to have access to documentation from requirements phase through testing (i.e., records related to requirements, design, coding, testing and verification).
- Commercial Grade Dedication - To confirm the MELTAC commercial grade dedication activities, the NRC staff will perform the following activities:
 - Dedication report for a dedicated component of the MELTAC Platform. The NRC staff would like to review the records from the internal audit. If practical, the NRC staff would also like to interview MELCO personnel involved in the handling and acceptance of components that have undergone commercial grade dedication.
 - Procedures followed for processing of non-conformance reports. Those procedures, as well as recent examples of records related to non-conformance reports, should be valuable for review during the audit.
- Digital Safety System Software Quality
 - Confirm the V&V processes are implemented, with a focus on record keeping, documentation, and management activities (including identification of documents associated with safety-related components).
 - Confirm configuration management processes are implemented, with a focus on record keeping, documentation, and management activities (including identification of documents associated with safety related components).
- Secure Development Environment
 - This section of the audit will include interviews with MELCO personnel and a review of the MELTAC development environment documentation.

- MELTAC Re-Programming Chassis Design Review
 - The NRC staff requests access to design documentation for the MELTAC Re-Programming Chassis used to reconfigure a MELTAC central processing unit (CPU) using the MELTAC Engineering Tool.
 - The NRC staff is evaluating the processes used to re-configure MELTAC components. Observations made during this activity will be documented in the audit report and referenced by the safety evaluation to provide a basis for the safety conclusions.

Team Assignments

The NRC staff performing the audit will be:

- Richard Stattel – audit team lead; software processes (focus: Requirements Thread Reviews, and Quality Assurance Program)
- Rosnyev Alvarado – Software Processes (focus: Independent V&V and Software Safety activities)
- Samir Darbali – software processes (focus: Configuration Management, and Secure Development Environment).

Logistics

The audit will take place at the MELCO facility in Warrendale, PA. The audit will start on the morning of November 28, 2017 (Tuesday) and conclude at the close of business November 30, 2017 (Thursday). The tentative schedule for the audit is as follows:

- Tuesday, November 28, 2017 (8:30 am – 5:00 pm)
 - Entrance meeting (NRC staff – purpose of audit; MELCO staff – brief overview of platform and facility)
 - 10 am – Facility tour
 - 1 pm – audit team to jointly work on a requirements thread to see an overview of the entire software development process
- Wednesday – November 29, 2017 (8:30 am – 5:00 pm)
 - 9 am – Morning meeting between NRC staff and MELCO to discuss activities and logistics for the day
 - 9:30 am – Review of MELCO documentation/Interviews with MELCO personnel – NRC staff may work together or individually, as circumstances dictate
 - 1:00 pm – MELTAC CPU Programming Chassis Demonstration/Discussion
 - 4:30 pm – NRC staff internal meeting
 - 5 pm (as needed) - NRC staff and MELCO discuss any observations from the day
- Thursday, November 30, 2017 (8:30 am – 5:00 pm)
 - 9 am – NRC staff internal meeting - identification/resolution of any open items
 - 2 pm – Exit meeting (NRC staff – general overview of observations and identification of any open items)

Special Requests

MELCO has been contacted about making reasonable efforts to translate requested documents. MELCO should provide Japanese-English translators to facilitate interviews with MELCO employees, as well as help translate documents. The NRC staff does not want to place an unreasonable burden on translation services and thus would appreciate feedback on any translation requests.

Because MELTAC development activities are performed in Kobe Japan, the NRC staff will not be able to directly audit the secure development environment during the audit at the Warrendale facility. To compensate for this limitation, the NRC staff requests that a MELCO representative who is familiar with the physical attributes and network configuration of the Kobe development facilities be present to discuss security measures in place to establish the secure MELTAC development environment. The NRC staff also requests that documentation of the Kobe facility development environment such as the network architecture be available for NRC staff review during the audit.

Deliverables

The NRC regulatory audit report should be issued by January 31, 2018.