

January 25, 2012

Hirotoishi Okawa, Quality Assurance Manager
Mitsubishi Electric Corporation
Energy Systems Center
1-1-2, Wadasaki-cho, Hyogo-ku
Kobe, 652-8555, Japan

SUBJECT: NRC INSPECTION REPORT NO. 99901410/2011-202 AND NOTICE OF
NONCONFORMANCE

Dear Mr. Okawa:

On December 5–9, 2011, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at Mitsubishi Electric Corporation (MELCO) Energy Systems Center, hereafter referred to as MELCO, in Kobe, Japan. The purpose of the limited scope inspection was to assess MELCO's compliance with the provisions in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." The inspection focused on quality activities including commercial grade item dedication of hardware, the Mitsubishi Electric Total Advanced Controller (MELTAC) Re-Evaluation Program, and software development activities associated with the MELTAC digital instrumentation and controls (I&C) platform for the Mitsubishi Heavy Industries (MHI) U.S. Advanced Pressurized-Water Reactor. The enclosed report presents the results of this inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

The NRC inspection team sampled the activities listed above and concluded that MELCO is generally effective in implementing its QA and 10 CFR Part 21 programs in support of the MELTAC platform development. However, during this inspection, NRC inspectors found two instances of incomplete documentation of safety related activities that did not meet MELCO procedures or certain NRC requirements, which were contractually imposed on you by your customers or NRC licensees. Although the NRC identified examples did not raise immediate safety concerns, they do warrant your attention and consideration for impact on past and future safety-related work. Specifically, MELCO did not provide objective evidence to demonstrate that the MELTAC cabinet burn-in tests had been performed as verbally described to the team. MELCO also did not provide evidence to demonstrate that MELCO had adequately and completely included the applicable regulatory requirements into the MELTAC Safety System Digital Platform System Specification. The specific findings and references to the pertinent requirements are identified in the enclosure to this letter.

Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you show good cause for us to do so.

The MELTAC platform is comprised of a number of hardware and software components that work together to provide the necessary functionality of the protection and safety monitoring systems. A large majority of such components were not reviewed during this inspection because of the inspection's limited scope and time constraints. Although the NRC inspectors determined that the process implemented by MELCO is consistent with regulatory requirements associated with QA, including software development and commercial grade dedication, the findings documented in this report is not an approval of the MELTAC platform. The MELTAC platform must have a formal licensing review before it is implemented by U.S. applicants.

The implementation of MELCO's commercial grade dedication process for hardware, including performance of commercial grade surveys, may be inspected by NRC staff during a future inspection once a procurement contract has been issued and commercial grade items have been procured and dedicated by MELCO for use in a U. S. nuclear power plant.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide, in detail, the bases for your claim (e.g., explain why the disclosure of the information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

Edward H. Roach, Chief
Construction Mechanical Vendor Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No. 99901410

Enclosures:

1. Notice of Nonconformance
2. Inspection Report No. 99901410/2011-202 and Attachment

The MELTAC platform is comprised of a number of hardware and software components that work together to provide the necessary functionality of the protection and safety monitoring systems. A large majority of such components were not reviewed during this inspection because of the inspection's limited scope and time constraints. Although the NRC inspectors determined that the process implemented by MELCO is consistent with regulatory requirements associated with QA, including software development and commercial grade dedication, the findings documented in this report is not an approval of the MELTAC platform. The MELTAC platform must have a formal licensing review before it is implemented by U.S. applicants.

The implementation of MELCO's commercial grade dedication process for hardware, including performance of commercial grade surveys, may be inspected by NRC staff during a future inspection once a procurement contract has been issued and commercial grade items have been procured and dedicated by MELCO for use in a U. S. nuclear power plant.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide, in detail, the bases for your claim (e.g., explain why the disclosure of the information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

Edward H. Roach, Chief
Construction Mechanical Vendor Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No. 99901410

Enclosures:

1. Notice of Nonconformance
2. Inspection Report No. 99901410/2011-202 and Attachment

DISTRIBUTION:

RidsNroDcip RidsNroDcipCQVA RidsNroDcipCQVB RidsNrrDeEQVB RRasmussen
TSakadales

ADAMS Accession No.: ML12013A353

*concurring via email

NRO-001

OFFICE	NRO/DCIP/CEVB	RES/DE/DICB	NRO/DE/ICE2	NRO/DE/ICE2	NRO/DE/ICE2
NAME	GNewman	MConcepcion	DTaneja	TTruong	RBeacom
DATE	01/19/2012	11/20/2012	01/20/2012	01/23/2012	01/20/2012
OFFICE	NRO/DE/ICE2	NRO/DCIP/CMVB	NRO/DCIP/CAEB	NRO/DCIP/CMVB:BC	
NAME	IJung	RMclntyre	TFrye	ERoach	
DATE	01/20/2012	01/20/2012	01/25/2012	01/25/2012	

OFFICIAL RECORD COPY

NOTICE OF NONCONFORMANCE

MELCO
Kobe, Japan

Docket Number 99901410
Inspection Report Number 2011-202

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Mitsubishi Electric Corporation (MELCO) Energy Systems Center (ESC) facility in Kobe, Japan, on December 5-9, 2011, certain activities were not conducted in accordance with NRC requirements, which were contractually imposed on MELCO by its customers or NRC licensees:

- A. Criterion XI, "Test Control," Procedures, and Drawings," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "a test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed...and that test results shall be documented and evaluated to assure that test requirements have been satisfied."

ESC Procedure N-G000, "Quality Manual for U.S. Nuclear Facility Applications," Revision J, dated April, 2011, Section 11, "Test Control," states, in part, that "Tests shall be performed and the results documented in accordance with appropriate technical requirements, codes, and standards."

Contrary to the above requirements, MELCO could not provide documented objective evidence to demonstrate that the Mitsubishi Electric Total Advanced Controller (MELTAC) burn-in tests were performed. Specifically, JEXU-1022-6301-P, "MELTAC Platform Re-Evaluation Program [MRP] Report," Revision 2, dated December 1, 2011, states that the MELTAC platform satisfied the criteria contained in EPRI-107330, "Generic Requirements Specification for Qualifying Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants," which includes burn-in tests to detect early failures that would corrupt the qualification test results. However, through the review of the MRP report and associated documentation, the NRC inspectors determined that MELCO did not have sufficient objective evidence to demonstrate that the MELTAC burn-in tests were performed.

This issue has been identified as Nonconformance 99901410/2011-202-01.

- B. Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 states, in part, that "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings."

ESC Procedure N-G000, Revision J, states, in part, that "procedures for design control shall be established to ensure that applicable design inputs such as applicable regulations, standards, codes, and customer requirements are correctly translated into design outputs, such as drawings, specifications, calculations, and procedures."

ESC Procedure N-0314, "Requirement Specification Procedure (NQA-1)," Revision D, Section 5.5.1(3) requires that a Requirement Specification describe "requirements including laws/regulation, guidelines, codes, standards, safety analysis report, NRC's safety evaluation report, and supplements thereto," and "Technical Specifications, Regulatory Guides, Code of Federal Regulations, NRC bulletins, circulars, notices and generic letters, and commitments in correspondence with NRC."

Contrary to the above requirements, MELCO did not adequately and completely describe the applicable regulatory requirements contained in JEXU-1024-1010, "Safety System Digital Platform MELTAC-N plus S System Specification," Revision D. Specifically, JEXU-1024-1010 did not describe the applicable NRC regulatory requirements that were included in the MELTAC Update Project Plan, JEXU-1028-1001, "Safety System Platform MELTAC N plus S Update Project Project Plan," Revision A.

This issue has been identified as Nonconformance 99901410/2011-202-02.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Construction Mechanical Vendor Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance (1) the reason for the noncompliance or, if contested, the basis for disputing the noncompliance, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid noncompliance, and (4) the date when the corrective action will be completed. Where good cause is shown, the NRC will consider extending the response time.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC Agencywide Documents Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Dated at Rockville, MD, this 25th day of January 2012.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND
OPERATIONAL PROGRAMS**

Docket No.: 99901410

Report No.: 99901410/2011-202

Vendor: Mitsubishi Electric Corporation
Energy Systems Center
1-1-2, Wadasaki-cho, Hyogo-ku
Kobe, 652-8555, Japan

Vendor Contact: Mr. Hirotooshi Okawa, Quality Assurance Manager

Background: Mitsubishi Electric Corporation (MELCO) Energy Systems Center (ESC) conducts hardware and software development activities associated with the Mitsubishi Electric Total Advanced Controller (MELTAC)-N Plus S platform design and development, and selected digital I&C hardware fabrication activities. MELTAC is the primary digital I&C platform described in the Mitsubishi Heavy Industries (MHI) U.S. Advanced Pressurized-Water Reactor (US-APWR) Design Certification Application.

Inspection Dates: December 5–9, 2011

Inspection Team:	Richard McIntyre	NRO/DCIP/CMVB	Team Leader
	Garrett Newman	NRO/DCIP/CEVB	
	Milton Concepcion	RES/DE/DICB	
	Ian Jung	NRO/DE/ICB	
	Dinesh Taneja	NRO/DE/ICB	
	Royce Beacom	NRO/DE/ICE	
	Tung Truong	NRO/DE/ICE	

Approved by: Edward H. Roach, Chief
Construction Mechanical Vendor Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

EXECUTIVE SUMMARY

Mitsubishi Electric Corporation (MELCO)
99901410/2011-202

The U.S. Nuclear Regulatory Commission (NRC) inspection focused on quality assurance (QA) policies and procedures implemented to support the design and development of the Mitsubishi Electric Total Advanced Controller (MELTAC) digital instrumentation and controls (I&C) platform for the Mitsubishi Heavy Industries (MHI) U.S. Advanced Pressurized-Water Reactor (US-APWR) Design Certification Application (Design Control Document). The purpose of this inspection was to verify that Mitsubishi Electric Corporation (MELCO) Energy Systems Center (ESC), hereafter referred to as MELCO, had implemented an adequate QA program in support of US-APWR digital I&C development activities that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The inspection also verified that MELCO implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets the regulatory requirements of the NRC. The NRC conducted the inspection at the MELCO facility in Kobe, Japan, on December 5–9, 2011.

The following regulations served as the bases for the NRC inspection:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21

During the conduct of this inspection, the NRC inspection team implemented Inspection Procedure (IP) 43002, "Routine Inspection of Vendors," as supplemented by IP 43004, "Inspection of Commercial Grade Dedication Programs," and IP 36100, "Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance."

With the exception of the nonconformances described below, the NRC inspection team concluded that MELCO is effectively implementing its QA and 10 CFR Part 21 programs in support of MELTAC platform development. The results of this inspection are summarized below.

10 CFR Part 21 Program

The NRC inspectors determined that MELCO's Part 21 program and procedures were consistent with the regulatory requirements in 10 CFR Part 21. Based on the sample of documents reviewed and on observation of Part 21 program activities, the inspectors also determined that MELCO is effectively implementing its QA program and the associated Part 21 procedures. No findings of significance were identified.

MELTAC Re-Evaluation Program

The NRC inspection team identified Nonconformance 99901410/2011-202-01 because MELCO did not provide documented objective evidence to demonstrate that the MELTAC cabinet burn-in tests had been performed. With the exception of the nonconformance, the NRC inspectors concluded that MELCO's design control program requirements are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the sample

of MELTAC platform design and testing documentation reviewed, the NRC inspectors determined that MELCO's design control procedures were being effectively implemented.

The NRC inspectors reviewed the documentation associated with the MELTAC Re-Evaluation Program (MRP) to verify whether the process implemented by MELCO is consistent with applicable regulatory requirements and relevant industry standards. For the US-APWR, the MELTAC platform (MELTAC-N Plus S) is applied to the protection and safety monitoring system, which includes the reactor protection system, engineered safety feature actuation system, safety logic system, and safety grade human-system interface (HSI) system. The MELTAC platform is also applied to non-safety systems such as the plant control and monitoring system.

The NRC inspectors reviewed a sample of modules that were dedicated by MELCO as part of the MRP. Based on the selected samples, the NRC inspectors determined that MELCO's commercial grade dedication process adequately identified and verified the critical characteristics of the MELTAC platform that provide assurance that the platform will perform its safety function satisfactorily.

The MELTAC platform is comprised of a number of hardware and software components that work together to provide the necessary functionality of the protection and safety monitoring systems. A large majority of such components were not reviewed during this inspection because of the inspection's limited scope and time constraints. Although the NRC inspectors determined that the process implemented by MELCO is consistent with regulatory requirements associated with QA, including software development and commercial grade dedication, the findings documented in this report is not an approval of the MELTAC platform. The MELTAC platform must have a formal licensing review before it is implemented by U.S. applicants.

MELTAC Software Development

The NRC inspection team identified Nonconformance 99901410/2011-202-02 because MELCO did not provide evidence to demonstrate that MELCO had adequately and completely included the applicable regulatory requirements into the MELTAC Safety System Digital Platform System Specification. With the exception of the nonconformance and based on the review of a sample of MELTAC software development lifecycle and update project documentation, the NRC inspectors determined that MELCO's design control procedures were consistent with the requirements of Criterion III of Appendix B to 10 CFR Part 50.

The MELTAC-N plus S Basic Software Update Project is not scheduled to be finished until the end of March 2012, therefore the NRC inspection team limited its review to completed supporting documents for the requirement, software design, implementation, and maintenance phases. Although the NRC inspectors determined that the process implemented by MELCO is consistent with regulatory requirements associated with software development, the findings documented in this report is not an approval of the MELTAC software development lifecycle.

Commercial Grade Item Dedication of Hardware

The NRC inspection team determined that the implementation of MELCO's commercial grade dedication program is consistent with the regulatory requirements. Based on the sample of documents reviewed, the NRC inspection team also determined that MELCO is implementing its QA program and associated commercial-grade dedication procedures. No findings of significance were identified. The inspection of the implementation of MELCO's commercial

grade dedication process for hardware, including performance of commercial grade surveys, may be inspected during a future inspection when commercial grade items have been procured and dedicated by MELCO.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed Mitsubishi Electric Corporation Energy Systems Center's (MELCO), policies and implementing procedures that govern its program under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance" (Part 21), to verify compliance with the requirements of Part 21. In addition, the NRC inspection team observed Part 21 postings for compliance with the requirements of 10 CFR 21.6, "Posting Requirements," and 10 CFR 21.21, "Notification of Failure To Comply or Existence of a Defect and Its Evaluation," respectively. To verify an adequate link to the Part 21 process, the NRC inspection team also reviewed MELCO's procedures that govern the control and correction of nonconforming items and conditions adverse to quality. The attachment to this inspection report includes the documents reviewed by the inspectors.

b. Observations and Findings

b.1 Postings

The NRC inspection team observed that MELCO had posted notices at conspicuous locations throughout the facility. It included a copy of Section 206 of the Energy Reorganization Act of 1974, a description of the Part 21 procedure and its location, and identifies the individual to whom reports may be made. The Part 21 reporting procedure and posting contained guidance in both English and Japanese. In addition, the inspectors noted that MELCO maintained a list of Part 21 postings that was periodically verified to ensure the posting were in place.

b.2 10 CFR Part 21 Procedure

The NRC inspectors reviewed ESC Procedure N-3000-K, "Procedure for Reporting of Defects and Noncompliance (10 CFR 21) (NQA-1)," Revision K, dated August 29, 2011, and noted that it contained detailed instructions to identify and evaluate potential defects in products or services delivered to the nuclear facilities in the U.S. and to notify the NRC and affected customers of identified defects or failures to comply associated with substantial safety hazards. ESC Procedure N-3000-K identifies the responsibilities of employees and managers and all applicable timelines for reporting and evaluation in accordance with 10 CFR Part 21. The need for Part 21 evaluation is first identified through the nonconformance process outlined in ESC Procedure N-1500-K, "Nonconforming Items Control Procedure (NQA-1)," Revision J, dated November 26, 2011, and ESC Procedure N-1600-J, "Corrective Action Procedure (NQA-1)," Revision J, dated November 4, 2011. Form 1 of ESC Procedure N-1500-K and Form 1 of ESC Procedure N-1600-J, both contain boxes to document the need to perform a Part 21 evaluation. The NRC inspection team discussed the sections of the form pertaining to Part 21 with the Quality Assurance (QA) Manager and MELCO personnel and determined that they provided an adequate link between processes.

b.3 10 CFR Part 21 Program Implementation

At the time of the inspection, MELCO had not performed any Part 21 evaluations. The NRC inspection team reviewed a limited sample of three nonconformances and corresponding documentation to determine if a Part 21 evaluation should have been performed. For the sample reviewed, the NRC inspection team did not identify any instances in which MELCO should have performed an evaluation.

At the time of the inspection, MELCO had not issued any safety-related purchase orders to any suppliers, so the NRC inspection team was unable to verify that the implementation of the procurement document requirements in 10 CFR 21.31.

c. Conclusions

The NRC inspectors determined that MELCO's Part 21 program and procedures were consistent with the regulatory requirements in 10 CFR Part 21. Based on the sample of documents reviewed and on observation of Part 21 program activities, the inspectors also determined that MELCO is effectively implementing its QA program and the associated Part 21 procedures. No findings of significance were identified.

2. MELTAC Re-Evaluation Program (MRP)

a. Inspection Scope

The NRC inspectors reviewed MELCO's policy and procedures governing design control activities as they relate to the development of the Mitsubishi Electric Total Advanced Controller (MELTAC) software and hardware to ensure that those guidelines adequately described the process as required in Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. The NRC inspectors also reviewed a representative sample of design documents, including dedication-related documents, to verify effective implementation of such requirements. The attachment to this inspection report includes the documents reviewed by the inspectors.

b. Observations and Findings

b.1 MELTAC Re-evaluation Plan and Report

The NRC inspectors reviewed the documentation associated with the MRP to verify whether the process implemented by MELCO is consistent with applicable regulatory requirements and relevant industry standards. For the US-APWR, the MELTAC platform (MELTAC-N Plus S) is applied to the protection and safety monitoring system, which includes the reactor protection system, engineered safety feature actuation system, safety logic system, and safety grade human-system interface (HSI) system. The MELTAC platform is also applied to non-safety systems such as the plant control and monitoring system.

MELTAC Technical Report, MHI MUAP-07005-P/JEXU-1012-1002.

The NRC inspectors reviewed MUAP-07005-P, "Safety System Digital Platform – MELTAC," Revision 5, dated April 2010. This document contained a description of the MELTAC platform, including the controller, safety visual display unit

(VDU) panel and processor, communication system, and engineering tool. JEXU-1012-1002-P, "Safety System Digital Platform – MELTAC," Revision 5, dated April 2010 is the MELCO version of the document provided by Mitsubishi Heavy Industries (MHI) for licensing of the digital I&C platform contained in the U.S. Advanced Pressurized-Water Reactor (US-APWR) Design Certification Application. The NRC inspectors noted that the MELTAC Technical Report provided a description of the platform, environmental, seismic, electromagnetic compatibility, qualification activities, lifecycle process, and equipment reliability assessments.

The MELTAC platform was originally designed and developed as the control system for Japanese nuclear power plants in accordance with MELCO's QA policies and procedures. In reviewing the technical report and interviewing MELCO engineering personnel, the NRC inspectors noted that the original QA program used for the MELTAC platform development was based on Japanese Energy Agency Guideline (JEAG) 4101, "Guide for Quality Assurance of Nuclear Power Plants," and International Standard (ISO) 9001, "Quality management systems -- Requirements." To demonstrate the MELTAC platform's suitability for safety applications in the U.S., MELCO conducted various assessments of the design, development, and testing activities of the MELTAC platform, known as the U.S. Conformance Program (UCP) and Expanded UCP. These assessments started in 2006 and consisted of a comparison of the original QA program, implementing procedures, lifecycle requirements and design specifications, and several other technical and quality requirements against the requirements of the MELCO's new QA program (which is based on 10 CFR Part 50 Appendix B) and current industry guidance applicable to U.S. projects such as Institute of Electrical and Electronics Engineers (IEEE) 7-4.3.2, "IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations," and IEEE 1012, "IEEE Standard for Software Verification and Validation."

Although the NRC inspectors confirmed that the original MELTAC platform was designed and developed using a systematic lifecycle approach that covered requirements through implementation (with verification and validation steps and appropriate documentation for each phase of the lifecycle), the NRC inspectors noted that the results of the earlier assessments indicated that the original QA program met most of the new QA program requirements for U.S. projects, with certain exceptions as noted below:

- Lack of compliance with independent verification & validation (IV&V) guidance of IEEE 7-4.3.2.
- No IV&V performed for software with field operation experience greater than one year.
- Field Programmable Gate Array (FPGA) development process was considered part of hardware development and not software development.
- MELCO's new QA program did not satisfy NRC requirements.

In response to the identified deficiencies, MELCO revised the QA program and implementing procedures, redeveloped design documentation, system, software, and hardware specifications, system and software V&V reports, and conducted additional IV&V for specific software. These activities were performed in accordance with new procedures that were established by MELCO.

The NRC inspectors learned that MELCO performed further evaluations of the MELTAC design and design processes (the original MELTAC development process, the original UCP and the Expanded UCP) to confirm that the platform was suitable for safety related applications and demonstrate built-in quality consistent with Appendix B requirements. This evaluation is known as the MRP and is summarized below.

MELTAC Re-evaluation Plan (Dedication Plan), JEXU-1022-0002

The NRC inspectors reviewed JEXU-1022-0002, Revision D, "Safety System Platform MELTAC-N Plus S Re-evaluation Plan (Commercial Grade Dedication Plan)," dated November 25, 2011. This document provided a description of the methodology applied by MELCO for the dedication of the MELTAC platform. Section 3.3, "Technical Evaluation," outlined the process for identifying safety function, relevant technical information, identification of performance requirements, component functional classification, applicable service conditions, identification of critical characteristics, determination of verification method and acceptance criteria, and environmental, seismic, and electromagnetic compatibility considerations. With this information, MELCO determined the critical characteristics of the MELTAC platform, which were outlined in Table 3-2 of the dedication plan. In Table 3-1, the NRC inspectors noted that MELCO identified the items of the MELTAC platform that were subject to commercial grade dedication, including hardware and software modules. In essence, all platform hardware and software modules were targeted for commercial grade dedication. The NRC inspectors noted that Section 3.3 provided a detailed assessment of the platform's safety functions that are implemented in hardware, basic software, and application software, consistent with the technical information provided in EPRI TR-106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications." The safety functions that were identified included the following:

- Functions that acquire analog or digital input signals from connected devices such as analog sensors or binary switches, or other controllers connected via control network and data link.
- Functions that execute application logic (generated and downloaded via the engineering tool) using data retrieved by step 1 above as inputs to perform an operation.
- Functions that provide output analog or digital signals to connected devices such as valves and motors, or other controllers connected via control network and data link.
- Functions related to operator inputs via Class 1E HSI displays.
- Functions that provide for the display of information to operators via Class 1E HSI devices.
- Functions that perform diagnostic monitoring of MELTAC modules and self-protection from erroneous commands from non-safety HSI workstations.

In addition to these critical characteristics, MELCO identified additional critical characteristics related to the qualification of the MELTAC platform. These included the following:

- Environmental tests
- Seismic tests

- Electromagnetic compatibility tests
- Electrical isolation tests

The NRC inspectors also noted that MELCO identified these critical characteristics using the MELTAC Technical Report (MUAP-07005-P/JEXU-1012-1002-P) as its basis. The results of the assessment are documented in JEXU-1022-6301-P, "MELTAC Platform Re-evaluation Program Report," Revision 2, dated December 2011, which is summarized below.

MELTAC Platform Re-evaluation Program Report, JEXU-1022-6301-P

The NRC inspectors reviewed JEXU-1022-6301-P, Revision 2, which provided the final evaluation report of the MELTAC Re-evaluation Program for the MELTAC platform. The NRC inspectors learned that the MRP effort was a one-time activity that further evaluated the MELTAC hardware and software in order to establish configuration control for all future MELTAC lifecycle activities. The scope of the MRP was limited to a review of design, analysis, and testing activities that established the platform's baseline under 10 CFR 50 Appendix B. As stated in the report, future lifecycle activities including design changes, production, and maintenance will be performed under MELCO's Appendix B QA program.

The report structure was based on Sections 4, 5, 7, Appendix A, and B of the MELTAC Technical Report (MUAP-07005-P/JEXU-1012-1002-P). The report presented a description of all evaluation activities and provided results in terms of critical characteristics, built-in quality, and security features of the MELTAC legacy development process. The report also identified the platform's critical characteristics, acceptance criteria, and verification methods used to verify the identified critical characteristics.

In the MRP report, MELCO also expanded the critical characteristics and identified 12 major areas that were considered critical for the MELTAC platform, and developed Table 4-3, "Technical Characteristics Assessment," to present the results of the evaluation of the MELTAC platform and to show how the critical characteristics were verified. The table presented the technical characteristics and acceptance criteria along with the verification documents used. The evaluation consisted of a review of existing MELTAC platform documents to confirm that the identified critical characteristics were adequately controlled.

Section 3.2 of the report outlined all of the critical characteristics that were verified using Method 1, "Special Tests and Inspections." Specifically, the critical characteristics were identified in the following major categories:

- input (from input/output (I/O))
- input (from network)
- operation
- output (to I/O)
- output (to network)
- input (from S-VDU) and operation
- output (to S-VDU)
- self-diagnostics
- environmental tests

- seismic tests
- electromagnetic compatibility tests
- electrical isolation

The NRC inspectors noted that the identified critical characteristics were consistent with the dedication plan. Table 4-3 of the report provided details of the critical characteristics that were identified for the MELTAC platform.

b.2 Selection of Inspection Samples to Verify MELCO's Implementation

The NRC inspectors reviewed a representative sample of design documents, including dedication-related documents, hardware and software components to verify MELCO's evaluation and dedication processes.

The NRC inspectors selected "output (to network)" which is identified as a critical characteristic to verify how MELCO performed dedication of critical hardware components. Specifically, the electrical/optical converter modules for data link communication were selected as an inspection sample to verify the process used by MELCO to identify and verify the critical characteristics of these modules. In reviewing Table 4-3, the NRC inspectors noted that all of the functional aspects of the modules were considered critical characteristics. The NRC inspectors inquired about reports associated with functionality tests to confirm adequate verification of critical characteristics since Table 4-3 provided references to system and hardware specifications but did not provide a reference to test reports. Accordingly, the NRC inspectors reviewed test reports for the MEOJ-01/02 modules, "IPS Electric Optic Conversion Card backboard ZMEJ-01 Evaluation Test Report, Part 2." The inspectors noted that the modules used the same test specification, JEXU-1003-1036. The NRC inspectors also reviewed the specification of the optical conversion modules MEOJ-01, MEOJ-02, and MEOJ-11, JEXU-1003-1036, "Hardware test specification for electrical/optical converter card and including the backboard." The NRC inspectors confirmed that test activities, which included operational checks, signal waveform measurement tests, ground level measurement tests, power consumption tests, and temperature rise measurements were conducted in accordance with established test specifications. No findings of significance were identified.

The NRC inspectors selected the "operation" category of critical characteristics identified by MELCO to verify how they performed dedication of the central processing unit (CPU) module and selected software components. Section 4.1.3.1 of Table 4-3 provides the critical characteristics of basic software, including order of execution, initialization, hardware and watchdog timer reset, diagnostics, and other parameters. As with the electrical/optical converter modules, Table 4-3 provided references to system and software specifications but did not provide a reference to test reports. The NRC inspectors inquired about verification reports to confirm adequate verification of critical characteristics. Accordingly, the NRC inspectors reviewed JEXU-1014-1001-1, "Safety System Platform MELTAC-N Plus S System Specification," JEMV-00A-021, "MELTAC-N Plus CPU Module (PCPJ-11) Development Test," and JEXU-1014-0013, "Safety System Platform MELTAC-N Plus S Basic S/W Configuration Management Sheet (Overall)." The NRC inspectors noted that initialization is called at start-up of the system and the following is executed at initialization: change over CPU from real mode to protect mode; Random Access Memory (RAM) clear; Read-Only Memory (ROM) sum value calculation; initial setting of hardware and software; and self-diagnostic. The NRC

inspectors also reviewed JSX3D634, "Safety System Digital Platform MELTAC-N Plus S Controller Software Specification," and JEXU-1015-1011, "Safety System Platform MELTAC-N Plus S Integration Test Report," which provided details of the MELTAC basic software specifications and integration test results, respectively. Through the review of these reports the NRC inspectors confirmed that initialization activities (including RAM clear, ROM sum value calculation, initial settings of hardware and software, and self-diagnosis) were adequately tested in accordance with specifications. Additionally, the NRC inspectors reviewed test report JSX3A551, "RAM Clear Functional and Structural Test Specification/Report," which provided test results of the RAM memory clear tests and F-ROM clear check, and test report JSX3A569, "Initial Setting Function/Structural Test Specification/Report," which provided the results of the initial setting of hardware and software. The NRC inspectors confirmed that test results were documented and consistent with their associated test specifications. No findings of significance were identified.

The NRC inspectors reviewed digital output modules MDOJ-61/62 which were identified as components that support the "output (to network)" critical characteristics. JEXU-1024-1029, "MDOJ Module Requirement Specification," provided the requirement specifications for the MDOJ modules. These I/O modules receive the signals from various sensors on the field devices and provide control signals to the plant equipment via the distribution module and the terminal unit. Since these modules require qualification, the NRC inspectors reviewed the equipment qualification reports associated with modules MDOJ-61/62. The NRC inspectors noted that one specimen was selected for module types where the structure and position of parts were the same or had differences which had no impact on seismic capability (such as differences in input ranges). The NRC inspectors confirmed that the components performed as designed under stress conditions before, during, and after the excitation. The output of the digital modules was changed periodically and the output signal was recorded on a chart recorder to confirm the contact bounce of the relay. The NRC inspectors noted that the modules demonstrated adequate reliability and availability for the specified environmental conditions. During interviews with MELCO's engineering personnel, the NRC inspectors learned that MELCO utilized seismic parameters that met or exceeded those included in IEEE 344, "IEEE Recommended Practice for Seismic Qualification of Class 1E Equipment for Nuclear Power Generating Stations," and MELCO concluded that the seismic results conformed to IEEE 344. No findings of significance were identified.

The NRC inspectors reviewed a failure modes and effects analysis (FMEA) report, "Safety System Platform MELTAC-N Plus FMEA," which was developed by MELCO to analyze and discover potential failure modes of the MELTAC platform. The NRC inspectors learned that MELCO utilized IEEE 352, "IEEE Guide for General Principles of Reliability Analysis of Nuclear Power Generating Station Safety Systems," as the basis to determine failure modes. The FMEA report provides a list of components that were subject to analysis, reviewed possible failures of the MELTAC components, identified the mechanisms that could cause those failures, and evaluated the consequences of those failures on the operation of the MELTAC platform. In addition, the report identified whether the failure mode is detectable by the self-diagnostic function of the controller and whether proper provisions have been made to eliminate potential failures. No findings of significance were identified.

As part of the review for conformance with U.S. industry standards, the NRC inspectors reviewed MELCO's conformance with EPRI-107330 as MELCO stated its conformance to this guidance in the MRP. This guide describes the hardware qualification tests to demonstrate hardware acceptability for safety-related applications. The NRC inspectors confirmed that MELCO performed qualification testing on a test specimen, as a type test. The test specimen included all the units needed to duplicate a typical MELTAC system. The test equipment was used to generate input signals to, and monitor the output signals from the test specimen during the qualification tests. In reviewing the MRP report, the NRC inspectors noted that Table 4-3, Item 4-4 presented the critical characteristics associated with the platform's response time. The table provided for the verification method, but it only referenced JEXU-1014-1001, "Safety System Platform MELTAC-N Plus S System Specification," and did not provide the test results or a reference to the corresponding test report, consistent with the criteria contained in EPRI-107330. Additionally, the NRC inspectors inquired about the burn-in test reports that are part of the acceptance tests. Such tests are exercised prior to the system being placed in service to detect those particular components that would fail and corrupt the qualification test results. Therefore, MELCO provided a report with evidence of the response time test results; however, there was no evidence to confirm that the burn-in tests were performed in accordance with EPRI-107330. MELCO stated that the test specimen was powered on for 17 days, which is equivalent to 408 hours and more than the 352 hours required by EPRI-107330. Through interviews with MELCO engineering personnel, the NRC inspectors learned that the only available evidence provided by MELCO was a set of informal, undocumented interviews with engineering personnel to confirm that burn-in tests were conducted as part of integration tests. Consistent with Criterion XI, "Test Control," of Appendix B, MELCO was required to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service and test results be documented and evaluated to assure that test requirements have been satisfied. Contrary to this requirement, MELCO did not properly document objective evidence to demonstrate that the MELTAC burn-in tests were performed. This issue is identified as Nonconformance 99901410/2011-202-01.

In summary, the NRC inspectors noted that, although the reports that provided evidence of tests conducted by MELCO to verify critical characteristics were not included in Table 4-3 of the MRP report, the reports that were sampled by the inspectors provided adequate evidence of test activities and satisfactory results.

c. Conclusions

With the exception of the nonconformance identified above, the NRC inspectors concluded that MELCO's design control program requirements are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the review of a sample of MELTAC platform design and testing documentation, the NRC inspectors determined that MELCO's design control procedures were being effectively implemented.

The NRC inspectors reviewed a sample of modules that were dedicated by MELCO as part of the MRP. Based on the selected samples, the NRC inspectors determined that MELCO's commercial grade dedication process adequately identified and verified the critical characteristics of the MELTAC platform that provide assurance that the platform will perform its intended safety function satisfactorily.

The MELTAC platform is comprised of a number of hardware and software components that work together to provide the necessary functionality of the system. A large majority of such components were not reviewed during this inspection because of inspection's limited scope and time constraints. Although the NRC inspectors determined that the process implemented by MELCO is consistent with regulatory requirements associated with QA and commercial grade dedication, the findings documented in this report is not an approval of the MELTAC platform. The MELTAC platform must have a formal licensing review before it is implemented by U.S. applicants

3. MELTAC Software Development

a. Inspection Scope

The NRC inspection team reviewed portions of the MELTAC Basic Software Program Manual and implementing procedures that govern MELCO's software development lifecycle processes to verify compliance with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR 50. The NRC inspection team also reviewed MELCO's implementing procedures and design outputs and discussed the software development activities with MELCO management and staff. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

b.1 Policies and Procedures for Software Development

The NRC inspection team reviewed Section 3 of ESC Procedure N-G000-J, "Quality Manual for U.S. Nuclear Facility Applications," which describes the requirements for design control. This section states that, "Procedures for design control shall be established to ensure that applicable design inputs (e.g., applicable regulations, standards, codes, and customers requirements) are correctly translated into design outputs (e.g. drawings, specifications, calculations, and procedures)." The NRC inspection team also reviewed the implementing procedures that provide guidance for the documentation of regulations and standards as design inputs. Section 5.1(1)(i) of ESC Procedure N-0300, "Design Control Procedure (NQA-1)," provides more detailed guidance on design control activities and states that, "The Project Plan shall include requirements (top-level laws and regulations, codes and customer requirements to be compiled)." Section 5.5.1(3) of ESC Procedure N-0314, "Requirement Specification Procedure (NQA-1)," provides guidance for generating requirement specifications and addresses laws, regulations, guidelines, codes and standards which should be included in these documents.

The NRC inspection team reviewed ESC Procedure N-0352, "Safety System Software V&V Procedure (NQA-1)," which is the V&V procedure for software development activities. This procedure describes the scope, organizational structure and responsibilities, independence, and V&V activities. Through review of documentation and interviews of MELCO's staff, the NRC inspection team was able to confirm that there was technical and organizational independence between the testing and design teams. The V&V staff consists of software developers from MELCO's non-nuclear department.

The NRC inspection team also reviewed ESC Procedure N-0390, "Software Safety Analysis Procedure," which provides guidance for performing software safety analyses in each software development phase to identify critical safety functions and ensure their implementation, to address potential hazards that could adversely affect safety functions, and to identify and mitigate potential security vulnerabilities. MELCO staff walked the NRC inspection team through the software safety analysis workflow and provided supporting documents to demonstrate proper implementation for activities that have been completed. The walkthrough included software safety analysis activities for the regression analysis, system specification V&V, software specification V&V, and source code V&V.

b.2 Implementation of Software Development

MELCO launched the MELTAC-N Plus S update project to update its digital I&C platform due to parts obsolescence and to address NRC comments or requests for additional information. The update project is not scheduled to be finished until 2012 so the NRC inspection team limited its review to completed supporting documents.

The current MELTAC update project was presented by MELCO's staff beginning with JEXU-1028-1007, "Safety System Platform MELTAC N plus S Update Project Software Change Request," Revision B, which is part of the maintenance phase of the project. MELCO also explained the requirement, software design and implementation phases down to the source code implementation. These are as described in Section 2.2, Implementation Stage, of JEXU-1012-1032, "MELTAC Basic Software Program Manual." The unit testing, also part of the implementation phase, and the test phase have not yet been completed for the MELTAC update project.

JEXU-1028-1007 identifies changes to the MELTAC platform. The V&V Team performs a regression analysis in accordance with ESC Procedure N-352, "Safety System Software V&V Procedure (NQA-1)," for the software change requests. JEXU-1035-1001, "Safety System Platform MELTAC N plus S Update Project Regression Analysis Report," identifies the changes and their impacts; identifies the V&V activities; and the test coverage required due to the software change requests.

The NRC inspection team noted that JEXU-1028-1001, "Safety System Platform MELTAC N plus S Update Project Project Plan," Revision A, did include applicable requirements as required by ESC Procedure, N-0300. However, JEXU-1024-1010, "Safety System Digital Platform MELTAC-N plus S System Specification," Revision D, did not include the descriptions of the necessary requirements as specified by ESC Procedure N-0314. This procedure states the system specification shall include "requirements including laws/regulation, guidelines, codes, standards, safety analysis report, NRC's safety evaluation report and supplements thereto," and "Technical Specifications, Regulatory Guides, Code of Federal Regulations, NRC bulletins, circulars, notices and generic letters, and commitments in correspondence with NRC." Specifically, JEXU-1024-1010 did not describe the applicable NRC regulatory requirements that were included in the MELTAC Update Project Plan, JEXU-1028-1001. If all appropriate regulatory requirements of the project plan are not incorporated in the system specification, it could result in design activities failing to meet all applicable requirements. The NRC inspection team identified this issue as Nonconformance 99901410/2011-202-02.

The NRC inspection team reviewed one source code listing and its accompanying V&V report, and noted that the V&V team followed the ESC Procedure N-0390, "Software Safety Analysis Procedure," for verifying source code through a Source Code V&V checklist and Static Analysis Tool Warning Checklist. The NRC inspection team was able to verify that software source code was created from the software design documents using the appropriate procedures.

c. Conclusions

With the exception of the nonconformance identified above and based on the review of a sample of MELTAC software development lifecycle and update project documentation, the NRC inspectors determined that MELCO's design control procedures were consistent with the requirements of Criterion III of Appendix B to 10 CFR Part 50.

The MELTAC-N plus S Basic Software Update Project is not scheduled to be finished until the end of March 2012, therefore the NRC inspection team limited its review to completed supporting documents for the requirement, software design, implementation, and maintenance phases. Although the NRC inspectors determined that the process implemented by MELCO is consistent with regulatory requirements associated with software development, the findings documented in this report is not an approval of the MELTAC software development lifecycle.

4. Commercial Grade Item Dedication

a. Inspection Scope

The NRC inspection team reviewed the MELCO QA manual and implementing procedures that govern MELCO's process for commercial grade dedication to verify compliance with 10 CFR Part 21 and Criterion III, "Design Control," and Criterion VII, "Control of Purchased Material, Equipment and Services," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team discussed the commercial grade dedication program with MELCO management and technical staff. The attachment to this inspection report lists the documents reviewed by the inspectors.

b. Observations and Findings

b.1 Policies and Procedures for Commercial Grade Item Dedication

The NRC inspection team reviewed MELCO's procedures for dedicating hardware to be used for the MELTAC platform. The NRC inspection team reviewed ESC Procedure N-0721-E, "Commercial Grade Item Acceptance Procedure," which contains guidance to accept commercial grade items to be employed in basic components.

The NRC inspection team reviewed ESC Procedure N-0722-G, "Supplier Commercial Grade Survey Procedure," which provided guidance for planning, conducting, and reporting commercial grade surveys. The NRC inspection team also reviewed ESC Procedure N-0203-J, "Auditors Qualification Procedure," which contains requirements for the indoctrination, training, and qualification of personnel performing quality audits and surveys.

b.2 Commercial Grade Dedication Implementation for Hardware

At the time of the inspection, MELCO had not fully developed and manufactured a complete MELTAC platform under its 10 CFR 50, Appendix B, QA program for use in a U.S. nuclear facility. In May 2010, MELCO performed a pilot dedication on an MDOJ-03 digital contact output module to demonstrate their ability to perform commercial grade dedication. Based on the performance of internal and external audits, and other factors, numerous changes and improvements were made to the affected dedication procedures. MELCO staff informed the NRC inspection team that no dedication activities have taken place since the pilot dedication and subsequent procedure changes. Since no official purchase contract has been issued for the MELTAC platform, no procurement or dedication of hardware beyond the pilot run had been conducted using Revision E of ESC Procedure N-0721. Based on the above, the inspection team was unable to review the implementation of this latest version of ESC Procedure N-0721. The NRC inspection team reviewed the pilot dedication documentation in JEXU-1030-1001, "S MDOJ-03/04 Commercial Grade Item Technical Evaluation," to ensure that an appropriate technical evaluation had been performed to identify the applicable critical characteristics and their acceptance methods had been specified. Since this dedication was performed to a previous revision of ESC Procedure N-0721, it was difficult for the inspectors to correlate the dedication activities as to how they would be documented using the revised procedure. The NRC inspection team also reviewed two commercial grade surveys conducted by MELCO in support of the digital contact output module dedication. The NRC inspection team conducted this review to verify that the surveys were conducted by trained personnel and that the surveyed controls adequately controlled the critical characteristics.

The NRC inspectors noted that while the commercial grade surveys contained details of the vendor's procedural controls identified during the survey, they lacked documented objective evidence to explain how implementation was observed, such as the areas and records that were reviewed. The NRC inspectors also noted that, at the time the surveys were conducted, there was no procedural guidance or documented training for audit personnel for conducting the specific commercial grade surveys; this issue had been corrected at the time of the inspection. The NRC inspectors also noted that there was no procedural guidance for including the commercial quality controls that were successfully surveyed in procurement documents. MELCO management informed the NRC inspection team that they would revise the affected procedures to address the inspection observations.

c. Conclusions

The NRC inspection team determined that the implementation of MELCO's commercial grade dedication program appears consistent with NRC regulatory requirements. Based on the review of a sample of documents, the NRC inspection team also determined that MELCO is implementing its QA program and associated commercial grade dedication procedures. No findings of significance were identified. The inspection of the implementation of MELCO's commercial grade dedication process for hardware, including performance of commercial grade surveys, may be inspected during a future inspection when a purchase contract has been issued and commercial grade items have been procured and dedicated by MELCO.

4. Entrance and Exit Meetings

On December 5, 2011, the NRC inspection team discussed the scope of the inspection with Mr. Yamawaki, General Manager, Mr. Okawa, QA Manager, and with the MELCO management and staff. On December 9, 2010, the inspection team presented the inspection results and observations during an exit meeting with Mr. Yamawaki, Mr. Okawa, and other MELCO management and staff members. The attachment to this report lists the entrance and exit meeting attendees, as well as those interviewed by the NRC inspection team.

ATTACHMENT

1. ENTRANCE AND EXIT MEETING ATTENDEES

<u>Name</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>Exit</u>	<u>Interviewed</u>
Richard McIntyre	NRC/NRO	X	X	
Garrett Newman	NRC/NRO	X	X	
Milton Concepcion	NRC/RES	X	X	
Dinesh Taneja	NRC/NRO	X	X	
Royce Beacom	NRC/NRO	X	X	
Tung Truong	NRC/NRO	X	X	
Ian Jung	NRC/NRO	X	X	
Atsuko Fujimoto	Interpreter	X	X	
Tomomi Kojima	Interpreter	X	X	
Masahiko Yamawaki	MELCO	X	X	
Hiroyuki Fukumitsu	MELCO	X	X	X
Hirotohi Okawa	MELCO	X	X	X
Makoto Shibahara	MELCO	X	X	
Takashi Ago	MELCO	X	X	
Satoshi Takano	MELCO	X	X	
Koji Kanematsu	MELCO	X	X	
Shoko Mizutani	MELCO	X	X	
Shiniichiro Yagi	MELCO	X	X	
Tomonori Hayashi	MELCO	X	X	
Futoshi Miyata	MELCO	X	X	
Satomi Endo	MELCO	X	X	
Masaaki Sadahiro	MELCO		X	
Shigeo Yonezawa	MELCO	X	X	
Teruaki Yoshida	MELCO	X	X	X
Toshiyuki Ikeda	MELCO	X	X	
Takahiro Kae	MELCO	X	X	
Masato Chien	MELCO		X	
Keiji Takeda	MELCO	X		
Yuji Morioka	MELCO	X	X	
Teruyuki Hanamura	MELCO	X	X	
Shigeo Katsuta	MELCO	X	X	
Yasuhiro Nomoto	MELCO	X	X	
Keisuke Goto	MELCO	X	X	
Yoshio Omoto	MELCO	X	X	
Atsushi Murakami	MELCO		X	
Yukari Hamaguchi	MELCO	X	X	

<u>Name</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>Exit</u>	<u>Interviewed</u>
Hiroaki Matsui	MELCO		X	
Yasushi Kanazawa	MELCO	X	X	
Yoshifumi Katayama	MELCO	X	X	
Yoshiko Kawamoto	MELCO	X	X	
Yumi Katopri	MELCO	X	X	
Fumiko Kuwamura	MELCO	X	X	
Fumiko Morinaga	MELCO	X	X	
Satoshi Nagao	MELCO		X	
Masahiko Nambu	MELCO	X	X	
Makoto Ito	MELCO	X	X	
Yasunobu Koga	MELCO	X	X	X
Masato Nakamura	MELCO	X	X	
Kentaro Sadayuki	MELCO	X	X	
Tomio Hatakenaka	MELCO	X	X	
Katsumi Akagi	MELCO	X	X	X
Kenichi Furuno	MELCO	X	X	X
Yoshihisa Iwaki	MELCO		X	
Kazuhiro Yamaji	MELCO	X	X	
Toshiaki Matsumura	MELCO	X	X	
Yumi Kawai	MELCO	X	X	
Satoko Yu	MELCO	X	X	
Hozumi Kadohara	MELCO	X	X	
Mitsuo Nakagawa	MELCO	X	X	X
Yasuo Uranaka	MELCO	X	X	
Hitomi Sasaki	MELCO	X	X	
Yikiko Hirano	MELCO	X	X	
Kazufumi Yoshida	MELCO	X	X	
Susumu Okuda	MELCO	X	X	
Yasuhide Nakano	MELCO	X	X	
Masashi Kitamura	MELCO	X	X	
Hiroki Okamoto	MELCO		X	
Tokihiro Fukuhara	MELCO	X	X	
Hajime Nogami	MELCO		X	
Kazuhiko Fujita	MELCO	X	X	
Shoichi Sakamoto	MELCO	X	X	X
Tsuneharu Mitarai	MELCO	X	X	
Koji Hashimoto	MELCO	X	X	
Toshiharu Harada	MELCO	X	X	
Teruo Fukuda	MELCO	X	X	
Toshiaki Iida	MELCO	X	X	

<u>Name</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>Exit</u>	<u>Interviewed</u>
Isami Takahashi	MELCO	X	X	
Kazuhiro Sugizaki	MELCO	X	X	
Hirotoishi Morishita	MELCO	X	X	
Koichi Kuroki	MELCO	X	X	
Sadayuki Kawamoto	MELCO	X	X	
Shinobu Hasegawa	MELCO		X	
Yoshinori Adachi	MELCO	X	X	
Hiroshi Kyuto	MELCO	X	X	
Shinobu Toki	MELCO	X		
Satoshi Itoda	MELCO	X	X	
Akio Akamatsu	MELCO	X	X	
Koichi Okada	MELCO	X	X	
Hiroshi Koike	MELCO	X	X	
Masanori Sugita	MELCO	X	X	X
Akio Toda	MELCO	X	X	
Ikuo Otake	MHI	X	X	
Gil Remley	MNES	X	X	
M. Vann Mitchell	MNES	X	X	

2. INSPECTION PROCEDURES USED

IP 43002, "Routine Inspection of Vendors"

IP 43004, "Inspection of Commercial-Grade Dedication Programs"

IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance"

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

The following items were found during this inspection:

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
99901410/2011-202-01	Open	NON	10 CFR Part 50, App. B, Criterion XI
99901410/2011-202-02	Open	NON	10 CFR Part 50, App. B, Criterion V

4. DOCUMENTS REVIEWED

ARQ-10H002, "NQA-1 Supplier Survey Sheet" for Hokuriku Electric Industry Co., Ltd, dated May 13, 2010

ARQ-10H003, "NQA-1 Vendor Survey Slip" for Matsuo Electric Industry Co., Ltd, dated May 17, 2010

ARQ-10W006-B, "10 CFR 21 Notice Posting Check," dated Jan 26, 2011

CAR ARQ-11D009-A, dated November 16, 2011

ESC Procedure N-0203-J, "Auditors Qualification Procedure," Revision J, dated September 30, 2011

ESC Procedure N-0300, Revision J, "Design Control Procedure (NQA-1)," dated November 16, 2011

ESC Procedure N-0314, Revision D, "Requirement Specification Procedure (NQA-1)," dated November 1, 2011

ESC Procedure N-0331-F, "Design Document Tracking List Procedure," Revision F, dated February 25, 2011

ESC Procedure N-0332-F, "Design Review Procedure," Revision F, dated August 10, 2011

ESC Procedure N-0352, Revision F, "Safety System Software V&V Procedure (NQA-1)," dated July 15, 2011

ESC Procedure N-0353, Revision F, "Safety System Software V&V Implementation Procedure (NQA-1)," dated July 15, 2011

ESC Procedure N-0380, Revision B, "Development Environment Control Procedure", dated November 28, 2011

ESC Procedure N-0390, Revision A, "Software Safety Analysis Procedure", dated August 26, 2011

ESC Procedure N-0700-E, "Purchased Items and Services Control Procedure," Revision E, dated November 29, 2011

ESC Procedure N-0721-E, "Commercial Grade Item Acceptance Procedure," Revision E, dated December 1, 2011

ESC Procedure N-0722-G, "Supplier Commercial Grade Survey Procedure," Revision G, dated November 29, 2011

ESC Procedure N-1500-K, "Nonconforming Items Control Procedure (NQA-1)," Revision J, dated November 26, 2011

ESC Procedure N-1600-J, "Corrective Action Procedure (NQA-1)," Revision J, dated November 4, 2011

ESC Procedure N-3000-K, "Procedure for Reporting of Defects and Noncompliance (10CFR21) (NQA-1)," Revision K, dated August 29, 2011

ESC Procedure N-G000, Revision J, "Quality Manual for U.S. Nuclear Facility Applications," dated April 2011

ESC Procedure N-G000-J, "Quality Manual for U.S. Nuclear Facility Applications," Revision J, dated April 18, 2011

F50-N-10-11-1-0001A, "Safety System Platform MELTAC – N plus S MDOJ 03/04 Commercial Grade Item Receipt Inspection Instruction," Revision A, dated May 19, 2010

Inspection Certificate 4701464266 from Furukawa-Sky Aluminum Corp, dated February 16, 2010

Inspection Report No. F50-N-10-11-1-0001A, "Commercial Grade Item Receipt Inspection Report," for Order ZA5812-HF1, dated May 19, 2010

JEXU-1012-1002-P, "Safety System Digital Platform – MELTAC," Revision 5, dated April 2010

JEXU-1012-1032, Revision 3, "MELTAC Platform Basic Software Program Manual," dated May 2011

JEXU-1022-0002, "Safety System Platform MELTAC-N plus S Re-evaluation Plan (Commercial Grade Dedication Plan)," Revision D, dated November 25, 2011

JEXU-1022-6301-P, "MELTAC Platform Re-evaluation Program Report (MRP)," Revision 2, dated December 2011

JEXU-1024-1010, Revision D, "Safety System Digital Platform MELTAC-N plus S System Specification," dated September 28, 2011

JEXU-1024-1059, "Safety System Platform MELTAC-N plus S Digital Contact Output Module (MDOJ-03/04) H/W Specification," Revision B, dated November 25, 2009

JEXU-1028-1001, Revision A, "Safety System Platform MELTAC N plus S Update Project Project Plan," dated August 31, 2011

JEXU-1028-1007, Revision B, "Safety System Platform MELTAC N plus S Update Project Software Change Request," dated August 8, 2011

JEXU-1030-1001, "S MDOJ-03/04 Commercial Grade Item Technical Evaluation," Revision A, dated May 11, 2010

JEXU-1035-1001, "Safety System Platform MELTAC N plus S Update Project Regression Analysis Report," Revision A, dated August 31, 2011

JEXU-1035-6001, Revision A, "V&V Report of JEXU-1024-1010," dated October 27, 2011

JEXU-1035-6015, Revision A, "V&V Report of JSX4L004," dated November 11, 2011

JEXU-1035-6097, Revision A, "V&V Report of source code director.c (V1.0)," dated November 21, 2011

MUAP-07005-P, "Safety System Digital Platform – MELTAC," Revision 5, dated April 2010

NCR No AU11E5-001-A, dated Nov 15, 2011

Purchase Spec STT-0434, dated April 14, 2010