

September 29, 2010

Mr. Davide Vanin, Managing Director  
Mangiarotti S.p.A.  
ZI Pannellia di Sedegliano  
33039 Sedegliano (UD), Italy

SUBJECT: NRC INSPECTION REPORT NO. 99901393/2010-201 AND NOTICES OF  
NONCONFORMANCE

Dear Mr. Vanin:

From July 19–23, 2010, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Mangiarotti S.p.A. (Mangiarotti) facility in Sedegliano (UD), Italy. The purpose of the inspection was to perform a limited scope inspection to assess Mangiarotti's compliance with the provisions of 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 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.

Based on the results of this inspection, the NRC inspection team found that the implementation of your QA program failed to meet certain NRC requirements imposed on you by your customers. Specifically, the NRC inspection team determined that Mangiarotti was not implementing aspects of its corrective action program, measurement and test equipment program, and external audit program consistent with regulatory requirements or the Mangiarotti QA manual, "Quality System Program." The enclosures to this letter identify the specific findings and references to the pertinent requirements.

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

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 document system (Agencywide Documents Access and Management System (ADAMS)), accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible (and if applicable), your response should not include any personal privacy, proprietary, or Safeguards Information so that the response 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 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/*

Juan Peralta, Chief  
Quality and Vendor Branch 1  
Division of Construction Inspection  
& Operational Programs  
Office of New Reactors

Docket No. 99901393

Enclosures:

1. Notice of Nonconformance
2. Inspection Report No. 99901393/2010-201 and Attachment

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 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."

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<b>NAME</b>	JPeralta (KKavanagh for)				
<b>DATE</b>	09/29/2010				

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## NOTICE OF NONCONFORMANCE

Mangiarotti S.p.A.  
Sedegliano (UD), Italy

Docket Number 99901393  
Inspection Report Number 2010-201

A U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Mangiarotti S.p.A. (Mangiarotti) facility in Sedegliano (UD), Italy, on July 19–23, 2010, found that certain activities were not conducted in accordance with NRC requirements that were contractually imposed on Mangiarotti:

- A. Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B, “Quality Assurance Program 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 measures shall be established to ensure that purchased material, equipment, and services conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

Criterion XVIII, “Audits,” of Appendix B to 10 CFR Part 50 states, in part, that “a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.”

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.”

Mangiarotti Nuclear S.p.A. (Mangiarotti Nuclear), “Nuclear Quality Assurance Manual” (NQAM), Edition 1, Revision 1, dated February 19, 2010, Section 6.2, “Supplier Qualification,” states, in part, that Project Quality Assurance (QUA) shall provide for evaluating prospective suppliers through either review of their American Society of Mechanical Engineers (ASME) certificates or survey of their quality program by review of the quality manual for adequacy, and audit at their facilities to verify implementation of ASME Code and quality program requirements.

Mangiarotti Nuclear NQAM, Section 14.2.4, “Audit Performance,” states, in part, that the lead auditor shall conduct the audit on the basis of the audit plan and checklist.

Contrary to the above, the review of the Mangiarotti Nuclear external supplier audits performed at three Italian forging suppliers identified that the audit report did not include or reference the audit checklist that was to be used during the review of the program implementation. Instead of using the audit checklist required by the NQAM, the lead auditor used a copy of the supplier’s quality assurance manual as the checklist and recorded audit annotations and findings directly on the supplier’s quality assurance manual in lieu of using the formal audit checklist. As a result, a formal quality record of the supplier audit was not developed in accordance with the written requirements of the Mangiarotti Nuclear NQAM.

This issue is identified as Nonconformance 99901393/2010-201-01.

- B. Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50 states that, "Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

The Mangiarotti Nuclear NQAM, Section 4.12.3.1, "Calibration," states, in part, that equipment is calibrated to its type and/or accuracy using standards having a valid relationship to nationally recognized standards.

Mangiarotti Nuclear Management Procedure PGE.06, "Calibration Manual," Revision 1, dated January 20, 2010, states, in part, that each thermometer shall be calibrated by comparison with a master gauge thermometer, taking at least two significant readings in the field of use.

Contrary to the above, Mangiarotti's measuring and test equipment calibration practices necessary to ensure that instruments are properly calibrated to maintain accuracy within necessary limits did not meet regulatory requirements. Specifically, Mangiarotti failed to adequately calibrate a contact pyrometer over the entire working range of the instrument or the actual operational temperature range used during the welding fabrication.

This issue is identified as Nonconformance 99901393/2010-201-02.

- C. Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states that, "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

Mangiarotti QAM, Section 4.16, "Corrective Action," states, in part, that Mangiarotti has to promptly identify conditions adverse to quality in order to correct them and determine causes for any significant conditions in order to preclude their recurrence, with appropriate and documented corrective actions.

Mangiarotti Nuclear Management Procedure PGE.18, "Corrective and Preventive Actions," Revision 0, dated July 9, 2009, states, in part, that conditions adverse to quality should be promptly documented on a corrective action request form.

Contrary to the above, in two instances, Mangiarotti failed to promptly enter conditions adverse to quality into its corrective action program. Specifically:(1) Mangiarotti failed to initiate a corrective action request resulting from a self-identified instance of the use of improper material for temporary welding supports and; (2)Mangiarotti failed to promptly initiate a corrective action request related to the identification of an inadequate quality plan

which did not contained all desired surveillance inspection and hold points, developed by one of it's subsuppliers.

This issue is identified as Nonconformance 99901393/2010-201-03.

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, Quality and Vendor Branch 1, 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 your 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 from the NRC'S Agencywide Documents Access and Management System (ADAMS), which is 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 of your response that deletes such information. If you request that such material be withheld, 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 this the 29th day of September 2010.

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

Docket No.: 99901393

Report No.: 99901393/2010-201

Vendor: Mangiarotti S.p.A.  
ZI Pannellia di Sedegliano  
33039 Sedegliano (UD), Italy

Vendor Contact: Mr. Eddy D'Anna  
Mangiarotti S.p.A.  
ZI Pannellia di Sedegliano  
33039 Sedegliano (UD), Italy  
E-mail: [Danna.Eddy@mangiarotti.it](mailto:Danna.Eddy@mangiarotti.it)

Nuclear Industry Activities: Mangiarotti is an American Society of Mechanical Engineers (ASME) Nuclear Stamp Holder currently manufacturing ASME Class 1 components under contract to Westinghouse for use in future AP1000 commercial nuclear power plants in the United States. Previously, Mangiarotti provided replacement steam generators and other components for U.S. utilities.

Inspection Dates: July 19 - 23, 2010

Inspectors: Greg Galletti NRO/DCIP/CQVA, Team Leader  
Richard McIntyre NRO/DCIP/CQVB  
Jeffrey Jacobson NRO/DCIP/CQVB  
Eric Reichelt NRO/DE/CIB1

Approved by: Juan Peralta, Chief  
Quality and Vendor Branch 1  
Division of Construction Inspection  
& Operational Programs  
Office of New Reactors

## **EXECUTIVE SUMMARY**

Mangiarotti S.p.A.  
99901393/2010-201

The purpose of this inspection was to verify that Mangiarotti S.p.A. (Mangiarotti) implemented an adequate quality assurance (QA) program 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 Mangiarotti implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets the regulatory requirements of the U.S. Nuclear Regulatory Commission (NRC). The inspection was conducted at the Mangiarotti facility in Sedegliano (UD), Italy, during the period July 19–23, 2010.

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

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

The NRC inspection team implemented Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," and IP 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance," during the conduct of this inspection.

The NRC had not previously performed an inspection at the Mangiarotti facility in Sedegliano (UD), Italy.

The results of the current inspection are summarized below.

### **10 CFR Part 21**

The NRC inspection team concluded that the implementation of the Mangiarotti program for reporting of defects and noncompliance is consistent with the regulatory requirements of 10 CFR Part 21. Based on the sample reviewed, the NRC inspection team also determined that Mangiarotti is effectively implementing its policy and procedures. No findings of significance were identified.

### **Design Control**

The NRC inspection team concluded that the implementation of the Mangiarotti program for design control is consistent with the regulatory requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the NRC inspection team also determined that Mangiarotti is effectively implementing its quality assurance manual (QAM) and the associated design control procedures. No findings of significance were identified.

### **Control of Purchased Material, Equipment, and Services and Audits**

The NRC inspection team concluded that the implementation of the Mangiarotti program for the control of purchased material, equipment, and services, and the Mangiarotti audit program are not consistent with the regulatory requirements of Criterion VII, "Control of Purchased Material,

Equipment, and Services,” and Criterion XVIII, “Audits,” of Appendix B to 10 CFR Part 50. The NRC inspection team issued Nonconformance 99901393/2010-201-01 for Mangiarotti’s failure to properly implement the auditing program associated with the oversight and qualification of its subsuppliers.

#### Inspection

The NRC inspection team concluded that the implementation of the Mangiarotti program for inspection activities is consistent with the regulatory requirements of Criterion X, “Inspection,” of Appendix B to 10 CFR Part 50. Based on the sample of records reviewed and observation of inspection activities performed by Mangiarotti staff, the NRC inspection team concluded that qualified personnel are effectively implementing Mangiarotti’s QAM and the associated inspection procedures. No findings of significance were identified.

#### Control of Special Processes

The NRC inspection team concluded that the implementation of the Mangiarotti program for control of special processes is consistent with the regulatory requirements of Criterion IX, “Control of Special Processes,” of Appendix B to 10 CFR Part 50. Based on the sample of records reviewed, the NRC inspection team concluded that qualified personnel are using qualified equipment and processes to effectively implement Mangiarotti’s QAM and the associated fabrication and special process procedures. No findings of significance were identified.

#### Control of Measuring and Test Equipment

The NRC inspection team concluded that the implementation of the Mangiarotti program for control of measuring and test equipment is not consistent with the regulatory requirements of Criterion XII, “Control of Measuring and Test Equipment,” of Appendix B to 10 CFR Part 50. The NRC inspection team issued Nonconformance 99901393/2010-201-02 for Mangiarotti’s failure to properly control and maintain accuracy within necessary limits for a contact pyrometer used during welding fabrication.

#### Nonconforming Materials, Parts, or Components

The NRC inspection team concluded that the implementation of the Mangiarotti program for control of nonconforming material, parts, or components is consistent with the regulatory requirements of Criterion XV, “Nonconforming Materials, Parts, or Components,” of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and observation of ongoing production activities at the Mangiarotti fabrication facilities, the NRC inspection team also determined that Mangiarotti is effectively implementing its QAM and the associated nonconformance procedures. No findings of significance were identified.

#### Corrective Actions

The NRC inspection team concluded that the implementation of the Mangiarotti program for corrective actions is not consistent with the regulatory requirements of Criterion XVI, “Corrective Actions,” of Appendix B to 10 CFR Part 50. The NRC inspection team issued Nonconformance 99901393/2010-201-03 for Mangiarotti’s failure to enter conditions adverse to quality into its corrective action program in a timely manner.

## REPORT DETAILS

### 1. 10 CFR Part 21 Program

#### a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed Mangiarotti's policies and implementing procedures that govern its process for verifying compliance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance." Specifically, the NRC inspection team focused on Mangiarotti procedure PGE.30, "Reporting of Defects and Noncompliance as Required by the 10 CFR Part 21," Revision 1, dated July 10, 2010. The NRC inspection team also reviewed procurement documents and the following Mangiarotti procedures to verify the implementation of the requirements of 10 CFR Part 21:

- Mangiarotti Quality Assurance Manual (QAM), Sections 4.15, "Control of Nonconforming Items," and 4.16, "Corrective Action"
- Mangiarotti Nuclear S.p.A., Milan (Mangiarotti Nuclear) Quality Management Procedure (QMP) PQA-19, "Control of Non Conformities," Revision 4, dated July 30, 2009
- Mangiarotti Nuclear QMP PGE.18, "Corrective and Preventive Actions," Revision 0, dated July 9, 2009
- Mangiarotti Nuclear QMP PGE.07, "Control of Non Conformities," Revision 0, dated July 9, 2009
- Westinghouse Electric Corporation (WEC) Purchase Order (PO) 4500274213 dated August 1, 2008, to Mangiarotti Nuclear for the purchase of two passive residual heat removal heat exchangers
- Mangiarotti Nuclear PO QA-201000158 to Mangiarotti for the fabrication of two passive residual heat removal heat exchangers

#### b. Observations and Findings

##### b.1 Postings

The NRC inspection team observed that Mangiarotti had posted a notice on the fabrication floor in a conspicuous location within the facility. The notice included a copy of Section 206 of the Energy Reorganization Act of 1974, a notice describing the regulations and procedures related to 10 CFR Part 21, and the name of the individual to whom reports may be made.

##### b.2 10 CFR Part 21 Procedure

The team determined that the Mangiarotti procedures contain appropriate measures for the evaluation of deviations and failures to comply. The procedures stipulate that an interim report shall be submitted to the NRC if an evaluation cannot be completed within 60 days of discovery of the deviation or failure to comply. In addition, the procedures provide a direct

connection between control of nonconformance and corrective actions to the 10 CFR Part 21 program.

The NRC inspection team noted that Mangiarotti had not performed any 10 CFR Part 21 evaluations in the past several years. The NRC inspection team reviewed a sample of recent Nonconformance Reports and Corrective Action Reports and did not identify any specific issues that would have warranted further evaluation under the Mangiarotti 10 CFR Part 21 program.

### b.3 10 CFR Part 21 Implementation

The team reviewed WEC PO 4500274213 to Mangiarotti Nuclear for the purchase of two passive residual heat removal heat exchanges. Section 3.0 of the PO contained the quality requirements 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"; American Society of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities"; and 10 CFR Part 21. Appendix 3 to the PO contained the "Technical Requirements for the AP1000 Purchase Order for the Southern Project," which also invoked NRC Regulatory Guide 1.28, Revision 3, "Quality Assurance Program Requirements (Design and Construction)," issued August 1985, and APP-GW-GAH-030, "Quality Assurance Requirements for Safety Related Components/Services of Standard AP1000 Plants." APP-GW-GAH-030 is a generic WEC quality assurance (QA) specification that summarizes requirements to be imposed on all subvendors providing components and services for the AP1000. Section 8.0 of the document provides specific guidance on how nonconformances and deviations are to be reported to WEC by its subvendors, including Mangiarotti.

### c. Conclusions

The NRC inspectors concluded that Mangiarotti effectively implements a program for reporting defects and noncompliance consistent with the regulatory requirements of 10 CFR Part 21. Based on the documentation reviewed, the NRC inspectors determined that Mangiarotti was effectively implementing its 10 CFR Part 21 procedure.

## 2. Design Control

### a. Inspection Scope

The NRC inspection team reviewed the implementation of Mangiarotti's process for design control. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of Mangiarotti's process to verify compliance with Criterion III "Design Control," of Appendix B to 10 CFR Part 50. In addition, the team reviewed specific design documentation governing the design and fabrication of the structural assembly of the AP1000 passive residual heat removal heat exchanger (PRHR HX), including the process used by Mangiarotti to qualify the PRHR HX tube bundle support plate material, and design control and order entry associated with the Vogtle Unit 3 and 4 pressurizer, to verify that the implementation of the program was consistent with Mangiarotti's documented controls.

The NRC inspection team reviewed the following documents for this inspection area:

- Mangiarotti QAM, Section 4.3, “Contract Entry and Design Control,” Revision 02, dated October 19, 2009
- WW-QAP-00-00-01, “Quality Assurance Plan,” for Westinghouse Clients, Revision 3, dated June 9, 2010
- WEC PO 4500274162, dated August 1, 2008, to Mangiarotti Nuclear, Milan
- APP-MV20-V2-002, “Westinghouse AP1000 Pressurizer Complete Assembly Drawing,” Revision 1, dated February 6, 2010
- APP-MV20-V6-002, “Westinghouse AP1000 Pressurizer Lower Head Machining Drawing,” Revision 1, dated January 9, 2010
- Mangiarotti Nuclear W2-DWF-10-001, “AP1000 Pressurizer Lower Head Machining Drawing,” dated March 3, 2010
- WEC AP1000 Procurement Advisory Release Document for Pressurizer Lower Head Machining for Vogtle, dated May 10, 2010
- Mangiarotti PGE.09, “Contract Review,” Edition 3, Revision 0
- APP-MV20-VFX-001, “Westinghouse AP1000 Pressurizer Document List”
- SV0-MV20-Z5-003, “Westinghouse Appendix 3, Technical Requirements for the AP1000 Pressurizer Purchase Order,” Revision 1
- APP-MV20-Z0-200, “Westinghouse AP1000 Pressurizer Fabrication Specification,” Revision 1
- AP1000-RMP-N016-19-20-013, “Westinghouse Engineering & Design Coordination Report, for AP1000 Pressurizer Heat Exchanger,” Revision 0
- Mangiarotti W2-SPF-00-00-002, “Pressurizer Fabrication Specification for US Jobs Levy County, Southern Vogtle, and Scana VC Summer,” Revision 0
- Mangiarotti W2-PCF-00-05-000, “Master Fabrication Control Plan (PCF) VC Summer AP1000 Pressurizer,” Revision 0
- Mangiarotti W2-PCF-10-09-001, “Vogtle Unit 3—AP1000 Pressurizer Lower Head Machining PCF,” Revision 0
- Mangiarotti W2-SPV-00-00-0, “SA-508 Grade 3 Class 2 Material Specification, Forgings for Use in Pressurizer for US Jobs Levy County, Southern Vogtle, and Scana VC Summer,” Revision 0
- Mangiarotti Design Specification APP-ME02-Z0-101, “Design Specification for AP1000 Passive Residual Heat Removal Heat Exchanger (PRHR HX),” Revision 4
- Mangiarotti Specification No. HX-SPV-00-011, “SA-240 Type 304 Plates, ANS Safety Class 1,” Revision 1

- Mangiarotti Drawing No. HX-DWF-00-001, “AP1000—Passive Heat Removal Heat Exchanger,” Revision 2
- Mangiarotti Fabrication Control Plan (FCP) HX-PCF-21-R01, Revision 0
- Mangiarotti Fabrication Control Plan HX-PCF-17-R02, Revision 0
- Mangiarotti Fabrication Control Plan HX-PCF-17-R01, Revision 0
- Mangiarotti Final Acceptance Report RAF 15973 (Plates THK 40), dated July 28, 2009
- Mangiarotti Final Acceptance Report RAF 15975 (Plates THK 15, 20, 25, 30, 40, 80), dated July 28, 2009
- Mangiarotti Final Acceptance Report RAF 15973 (Plates THK 15), dated July 28, 2009

b. Observations and Findings

b.1 Passive Residual Heat Removal Heat Exchanger

WEC WW-QAP-00-00-001, Revision 3, dated June 9, 2010, “Quality Assurance Plan,” dated June 9, 2010, identifies the quality management methods being applied by Mangiarotti to the contracts between Mangiarotti and WEC, for supply of subcontracted manufacturing of the nuclear safety-related components, including Job No. N024, Southern Vogtle Units 3 and 4 PRHR HX.

Section 8.0, “Fabrication Requirement,” of APP-ME02-Z0-101 stipulates that the PRHR HX supplier must prepare a fabrication specification meeting specific technical and quality requirements. To meet this requirement, Mangiarotti developed several fabrication control plans (PCFs).

Mangiarotti procured the material for the AP1000 PRHR HX structural assembly from an unqualified supplier (Outokumpu). To qualify the material in accordance with Mangiarotti specification HX-SPV-00-011, Mangiarotti conducted visual examinations, dimensional checks, chemical analyses, metallographic analyses, and tensile and hardness tests on each individual plate consistent with several PCFs. The NRC inspection team reviewed a sample of the final acceptance reports (RAFTs) generated by Mangiarotti to certify that the unqualified material supplied by Outokumpu meets the chemical and material properties specified in HX-SPV-00-011. The team also verified that all tests, measurements, and analyses documented in the RAFTs were documented and conducted in accordance with Mangiarotti’s QAM. No issues of significance were identified.

The NRC inspection team reviewed documents governing the design and fabrication of the structural assembly of the AP1000 PRHR HX, including the process used by Mangiarotti to qualify the PRHR HX tube bundle support plate material.

The NRC inspection team reviewed a sample of the RAFTs generated by Mangiarotti to certify that the unqualified material used in the fabrication of the structural supports for the PRHR HX meets the chemical and material properties specified in material specification HX-SPV-00-011. The team also verified that all tests, measurements, and analyses described

in the RAFs were documented and conducted in accordance with Mangiarotti's QAM. No issues of significance were identified.

#### b.2 Vogtle Unit 3 and 4 Pressurizer

Mangiarotti has also implemented WEC WW-QAP-00-00-001 Revision 3, "Quality Assurance Plan," dated June 9, 2010, to identify the quality management methods being applied to WEC, for supply of subcontracted manufacturing of the nuclear safety-related components, including the Vogtle Unit 3 and 4 pressurizers.

WEC PO 4500274162, to Mangiarotti Nuclear, is the nuclear safety-related purchase agreement with Mangiarotti Nuclear for the procurement of materials. The PO covers areas including documentation, fabrication, inspection, testing, packaging, quality assurance/quality control services, installation support, spare parts, tooling transportation and delivery, associated with the pressurizers for Vogtle Units 3 and 4. The PO also includes appendices containing other information for specific technical and QA requirements associated with those components. The NRC inspection team reviewed the PO and the associated technical requirements documents identified above and confirmed that the documents contain technical requirements including, but not limited to, fabrication control, examination and tests, QA requirements, reference to specific ASME Code editions, customer drawings, and fabrication specifications. The NRC inspection team reviewed the QA requirements imposed on Mangiarotti by WEC and confirmed that the technical documentation incorporates the QA requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21. No findings of significance were identified.

#### c. Conclusions

The NRC inspection team concluded that the implementation of the Mangiarotti design control program is consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the NRC inspection team also determined that Mangiarotti is effectively implementing its policy and procedures. No findings of significance were identified.

### 3. Control of Purchased Material, Equipment, and Services and Audits

#### a. Inspection Scope

The NRC inspection team reviewed the implementation of Mangiarotti's process for control of purchased material, equipment, and services and audits. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of Mangiarotti processes to verify compliance with Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. At the time of the inspection, Mangiarotti had purchased the core makeup tank (CMT) shell forgings and pressurizer upper and lower head forgings for the AP1000 U.S. market. This purchasing activity was conducted by Mangiarotti Nuclear (Milan). The team reviewed a sample of POs, the associated internal and external audit reports, and the supplier evaluations to evaluate compliance with program requirements and adequate implementation of those requirements.

The NRC inspection team reviewed the following documents for this inspection area:

- Mangiarotti Nuclear, "Nuclear Quality Assurance Manual (NQAM)," Edition 1, Revision 1, dated February 19, 2010, Section 6.2, "Procurement Control and Supplier Qualification"
- NQAM, Section 14, "Audits"
- WW-QAP-00-00-01, "Quality Assurance Plan, for Westinghouse Clients," Revision 3, dated June 9, 2010
- WW-SPQ-00-00-01, "Quality Assurance Requirements Specification for ASME Code Class 1 Materials," Revision 1, dated May 11, 2009
- Mangiarotti Quality Procedure PQA-13, "Suppliers Selection and Qualification," Revision 6, dated February 17, 2010
- Mangiarotti Quality Procedure PGE.03, "Suppliers Selection and Assessment," Edition 4, Revision 0
- Mangiarotti Qualified Vendor List, Revision 12, dated July 19, 2010
- Mangiarotti External Audit Report EAR 536 of Forge Monchieri S.p.A., dated November 12, 2008
- Mangiarotti External Audit Report EAR 549 of Forgiatura Morandini S.p.A., dated February 15, 2010
- Mangiarotti External Audit Report EAR 550 of Forgiatura A. Vienna, dated February 25, 2010
- Mangiarotti PO OA-200900120, Revision 3, dated February 25, 2009, to Forgiatura A. Vienna for CMT shell forgings
- Mangiarotti PO OA-200900123, Revision 4, dated February 25, 2009, to Forge Monchieri for CMT upper and lower pressurizer head forgings
- Mangiarotti PO OA-200900110, Revision 4, dated February 25, 2009, to Forgiatura Morandini for CMT upper pressurizer head forgings

b. Observations and Findings

b.1 External Audits

The NRC inspection team reviewed the Mangiarotti Nuclear NQAM and implementing procedures to identify the requirements for the conduct of supplier audits. Section 6, "Procurement Control," states in Section 6.2, "Supplier Qualification," that Project Quality Assurance (QUA) shall provide for evaluating prospective suppliers through review of either their ASME certificates or survey of their quality program by review of the quality manual for adequacy. This also includes an audit at their facilities to verify implementation of ASME Code and quality program requirements. Further, NQAM, Section 14, "Audits," states in

Section 14.2.4, "Audit Performance," that the audit shall be conducted by the lead auditor on the basis of the audit plan and checklist.

The NRC inspection team reviewed a sample of suppliers providing safety-related products and materials to Mangiarotti. Mangiarotti currently performs all activities related to supplier selection and qualification for components related to U.S. supply for new reactor plants such as Vogtle Units 3 and 4. The NRC inspection team concentrated on forging suppliers who were procuring ingots from steel mills that do not hold ASME quality system certification (QSC) as a material organization and thus would be required to be reviewed and qualified by Mangiarotti in order to perform activities required by ASME Section III, Subsection NCA-3855.5, related to the utilization of unqualified source (upgrading) material. These forging suppliers had all applied to ASME to receive QSCs as material organizations and were in the process of upgrading their QA programs to meet the requirements of ASME NCA-3800, "Metallic Material Organization's Quality System Program."

The NRC inspection team chose three forging suppliers who had supplied various forgings such as core makeup tank (CMT) shell forgings and pressurizer upper and lower head forgings. Mangiarotti has qualified all three of these suppliers to provide safety-related basic components per 10 CFR Part 50, Appendix B, quality assurance requirements and reporting requirements of 10 CFR Part 21. The NRC inspection team reviewed the Mangiarotti POs, audit reports, and external supplier checklists for the following suppliers:

- Forgiatura A. Vienna, Milano, Italy
- Forge Monchieri, Civate Camuno, Italy
- Forgiatura Morandini, Civate Camuno, Italy

The NRC inspection team verified that the Mangiarotti audit and the audit report included a review of the applicable quality and technical requirements that were included in the PO to the suppliers such as 10 CFR Part 50, Appendix B; ASME NQA-1-1994; 10 CFR Part 21; ASME Section III NCA-3800, "Material Organizations;" appropriate ASME material specifications; the appropriate design drawings; appropriate edition of ASME Section III Code requirements; and the WEC QA Requirements Specification, WW-SPQ-00-00-001, Revision 1, applicable to WEC customers. Also, the NRC inspection team verified that an evaluation of the supplier's ability to use unqualified source material as required by NCA-3855.5 was performed. During the review of the Mangiarotti external supplier audit reports, the NRC inspection team requested the audit checklist for review. The auditor stated that he did not use the Mangiarotti checklist but instead used the supplier's QAM as the checklist. Instead of using the audit checklist required by the NQAM, the lead auditor used a copy of the supplier's QAM as the checklist and recorded his audit annotations and findings directly on the supplier's QAM and considered this as his audit checklist.

When questioned as to why the auditor was not following NQAM program requirements, the vendor stated that during its ASME nuclear survey in October 2009, the ASME survey team leader suggested that the auditor use the supplier's QA manual and not the Mangiarotti checklist when performing and documenting information during external supplier audits. The NRC inspection team told the vendor that it was not only not implementing its NQAM program requirements, but it also was not performing as detailed an audit as would be achieved by reviewing and auditing the areas outlined in the checklist. The vendor committed to reestablishing the use of the external supplier audit checklist according to the NQAM requirements. The NRC inspection team identified the audit checklist issue as Nonconformance 99901393/2010-201-01.

### c. Conclusion

The NRC inspection team concluded that the implementation of the Mangiarotti program for control of purchased material, equipment, and services, and audits was not consistent with the regulatory requirements of Criterion VII and Criterion XVIII of Appendix B to 10 CFR Part 50. The NRC inspection team issued Nonconformance 99901393/2010-201-01 for Mangiarotti's failure to properly implement the auditing program associated with the oversight and qualification of its subsuppliers.

## 4. Control of Special Processes

### a. Inspection Scope

The NRC inspection team reviewed the implementation of Mangiarotti's process for control of special processes. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of Mangiarotti's process for verifying compliance with Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team observed various in-process activities, including welding, heat treatment, and nondestructive evaluations (NDEs) to verify that the implementation of the program was consistent with Mangiarotti's documented controls.

The NRC inspection team reviewed the following documents for this inspection area:

- Mangiarotti QAM, Section 4.9, "Control of Special Processes"
- Mangiarotti QAM, Section 4.8.3.2, "Identification and Traceability of Welding Materials"
- QMP PGE.29, "Storage, Maintenance and Distribution of Welding Materials," Revision 1, dated May 20, 2010
- WPS-00-001, "Submerged Arc Welding (SAW) Procedure for the Build-up of the Shell Forging," Revision 1, dated July 1, 2010
- Procedure Qualification Record (PQR) PQR-WQ-1277 for WPS-00-001, dated June 1, 2010
- Welding Book WB-2496, Revision 2, dated March 6, 2010
- N040-SPG-00-002, "Liquid Penetrant Procedure," Revision 3, dated February 23, 2010

### b. Observations and Findings

Mangiarotti QAM Section 4.9 describes the details of the control of special processes. The QAM states that special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Special processes instructions shall include or reference procedure, personnel, and equipment qualification requirements. Conditions necessary for accomplishment of the process shall be included. These conditions shall include proper equipment, controlled parameters of the process specified environment, and equipment and calibration requirements. Mangiarotti identified special

processes as those processes that control or verify quality such as welding, heat treatment, and NDE.

#### b.1 Welding

Mangiarotti QAM Section 4.9.2.2 provides the details describing the control of welding and identifies that all welding procedures and welder/welding operators will be qualified in accordance with ASME Section IX and Section III, Divisions 1 and 3. Mangiarotti identified that the Welding and Technology Department (INS) is responsible for the generation, qualification, and approval of all welding procedure specifications (WPSs). INS is also responsible for the qualification and certification of welders and for welding operator qualification tests. INS will supervise the welding of the test coupons and monitor and record the actual variables during welding. The welding of the coupons and the preparation and testing of the specimens will be in accordance with Section IX and Section III, Divisions 1 and 3, of the ASME Code. INS is also responsible for revising or rewriting a new WPS whenever there is a change in nonessential variables. Changes to essential or supplementary essential variables will require a new qualification. INS and the Welding School (SSA) are responsible for maintaining a welder list to ensure that qualifications are kept current and for distributing this list at least every 6 months to the Production Department (PRO).

The Production Shop (OFF) foreman is responsible for assigning qualified welders and welding operators on Code items based on the qualified welder list. In addition, OFF ensures that WPSs, as listed in the Welding Book, are available to the assigned welders at their workplace.

The NRC inspection team observed production welding during fabrication activities. Specifically, the NRC inspection team observed the circular buildup of a low-alloy steel (LAS) shell forging using the SAW process and SFA 5.23 (LAS) filler material, and the longitudinal welding of the top half of a hemispherical head to be assembled to a shell to fabricate a high-pressure absorber. The NRC inspection team reviewed the supporting documentation for this activity including the quality control plan (i.e., shop traveler), WPSs, supporting procedure qualification records, preheat data, welder qualifications, certificate material test report, and the calibration certificates of the measuring equipment and welding equipment. The NRC inspection team determined that the welding procedure was in compliance with the requirements of Section IX of the ASME Code.

Specifically, the NRC inspection team reviewed WPS-00-001 and WPS-02 and confirmed that the welding procedures were in compliance with the requirements of Section IX of the ASME Code. In addition, the NRC inspection team reviewed the production weld records for measuring preheat and interpass temperature requirements and confirmed that the temperatures recorded met the ranges identified on the WPSs. The NRC inspection team reviewed the Certified Material Test Reports for the welding material being used and determined that they were in compliance with the requirements of ASME Section II, Part C, and included the correct ASME material specifications and diameters as identified on the WPSs. The NRC inspection team also reviewed PQR-WQ-1277 (which supports WPS-00-001) and PQRs WQ225m, WQ1308, and WQ1310 (which supports WPS-2) and determined that they were met the requirements of ASME Section IX. In addition, the team reviewed the welder qualifications for the assigned welders and determined them to be in accordance with the requirements of Section IX. The NRC inspection team also verified that

the assigned welders had performed welding within the last 6 months and that their qualifications were maintained as required by Section IX of the ASME Code.

The NRC inspection team also verified Mangiarotti's process for welding material control through direct interview of personnel and review of welding material control activities. The NRC inspection team verified the implementation of the process for withdrawal and release of covered electrodes and flux from the welding crib in accordance with QAM Section 4.8.3.2 and PGE.29.

## b.2 Nondestructive Evaluations

Mangiarotti QAM Section 4.9.2.4 provides the details describing the control of NDE. Section 4.9.2.4 states that all NDE shall be performed using detailed written method specifications in accordance with Section V of the ASME Code. These specifications have been developed by the technical department (UTE), approved by Quality (RDQ), and proven by actual demonstration to the satisfaction of the Authorized Nuclear Inspector (ANI). The method specifications and training class programs shall be approved by a Level III individual, as indicated by signature and date on a cover sheet of the method specification. A Level III employee shall review and approve method specifications of vendors before they perform any examinations in accordance with these method specifications. Qualification and certification for NDE personnel will be in accordance with the requirements in QAM Section 4.9.2.4.1 and Mangiarotti's Written Practice PGE.28.

The NRC inspection team observed the visual and penetrant testing of the bottom-to-body weld of a semifinished cask. The NRC inspection team reviewed the supporting documentation for this activity, which included quality control plans, liquid penetrant examination procedure N040-SPG-00-002, and certification of the NDE operator.

The NRC inspection team witnessed the complete liquid penetrant examination of the cask and verified, through direct examination and discussions with the NDE operator, that the liquid penetrant examination was performed satisfactorily in accordance with N040-SPG-00-002 and the Mangiarotti QAM.

The NRC inspection team reviewed PGE.28 and verified that it contained education, training, and qualification requirements for NDE Level I, II, and III personnel in accordance with the American Society of Nondestructive Testing, "Recommended Practice SNT-TC-1A Nondestructive Testing." The NRC inspection team reviewed the operator's qualifications and confirmed that he was a certified Level II NDE operator, qualified according to Italian National Standardization Body UNI EN 473, "Non-destructive Testing—Qualification and Certification of NDT Personnel—General Principles," and International Standardization Organization (ISO) 9712, "Non-destructive Testing—Qualification and Certification of Personnel," standards, and as a Level II operator according to SNT-TC-1A, 2001 Edition, and PGE.28.

## b.3 Heat Treatment

The NRC inspection team reviewed the Mangiarotti QAM and implementing policies and procedures that govern the control of heat treatment. Specifically, the NRC inspection team reviewed Mangiarotti QAM Section 4.9.2.3, "Heat Treatment," and confirmed that all heat treatment procedures will (1) be reviewed by Design Project Coordinator (PCO) and approved by RDQ, (2) describe the control measures used to verify that the accumulated

time of a specific weld within a fabricated item does not exceed the qualified post weld heat treatment requirements, and (3) detail the temperature, heating and cooling rates, placement and method of attachment of thermocouples, holding time at temperature and the record requirements.

The NRC inspection team confirmed that OFF is responsible for assigning qualified operators to execute the heat treatment activities and ensuring that only calibrated equipment shall be used for heat treatment control. In addition, personnel performing heat treatments shall be qualified and certified either by experience or after adequate practical training, as applicable. Personnel qualifications will be reviewed triennially and updated on the basis of continuing satisfactory performance. Personnel not having performed heat treatment during the last 3 years shall be requalified.

The NRC inspection team reviewed the heat treatment data for a shell and channel side to be used for the construction of a hot feed/reactor effluent exchanger. Specifically, the NRC inspection team reviewed the applicable work instruction, heat treatment record, and production heat treatment chart against the heat treatment procedure. In addition, the team reviewed the calibration records of the thermocouples used for the heat treatment and the qualification and training records of the heat treatment operator. The NRC inspection team determined that these activities were performed in accordance with Mangiarotti QAM Section 4.9.2.3 and the applicable procedures.

#### c. Conclusion

The NRC inspection team concluded that the implementation of the Mangiarotti program for control of special processes is consistent with the regulatory requirements of Criterion IX of Appendix B to 10 CFR Part 50. Based on the sample of records reviewed, the NRC inspection team concluded that qualified personnel are using qualified equipment and processes to effectively implement Mangiarotti's QAM and the associated fabrication and special process procedures.

### 5. Inspection

#### a. Inspection Scope

The NRC inspection team reviewed the implementation of Mangiarotti's process for inspection. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of Mangiarotti's process to verify compliance with Criterion X, "Inspection," of Appendix B to 10 CFR Part 50. In addition, the team observed various in-process inspection activities to verify that the implementation of the program was consistent with Mangiarotti's documented controls.

The NRC inspection team reviewed the following documents for this inspection area:

- Mangiarotti QAM, Section 4.10, "Inspection," Revision 2, dated October 19, 2009
- QMP PGE.04, "Receiving Inspection and Qualification of Base Material," Revision 00, dated July 9, 2009
- QMP PGE.23, "Inspection and Test Personnel Qualification," Revision 00, dated July 9, 2009

- QMP PGE.05, “Fabrication and Installation Control,” Revision 01, dated July 9, 2010
- Final Acceptance Report (RAF)—“Vogtle Unit 3 PRHR Upper Extended Flange,” RAF 15992, Job No. NO24/01
- RAF—“Upper and Lower Tube Sheet (Vogtle Unit 3),” RAF 15995, Job No. 4N0024

b. Observations and Findings

The NRC inspection team reviewed the procedures governing in-process and final inspection activities during component fabrication. The NRC inspection team confirmed that the procedures include pertinent information that clearly identify and control the production activities at the inspection workstations, including the item inspected, inspection date, type of observation, and the results of examinations, which include identification of deviations and rejected materials.

The NRC inspection team discussed the inspection program with Mangiarotti personnel responsible for inspection program implementation, reviewed documented results of inspections, and observed inspections performed as part of the ongoing nuclear-related fabrication activities. Specifically, the NRC inspection team reviewed a sample of RAFs related to the items associated with the Vogtle Unit 3 PRHR upper extended flange, RAF 15992, Job No. NO24/01, and upper and lower tube sheet (Vogtle Unit 3), RAF 15995, Job No. 4N0024. The NRC inspection team confirmed that the RAFs adequately identify material composition, technical specifications, associated drawing, the specific quality control plan (PCF) in effect, and that Mangiarotti personnel performed all required activities necessary to confirm that the PO requirements were met.

The NRC inspection team reviewed the training and qualification requirements for quality control inspection personnel as defined in QMP PGE.23. The team verified that the procedure (1) describes methods to qualify and certify personnel who perform inspections and testing activities, (2) provides minimum education and experience qualifications, (3) includes a description of training programs and a qualification matrix that identifies activities for on-the-job training, and (4) defines the requirements for visual exams.

The NRC inspection team verified, through the evaluation of records and training documentation, that inspection personnel were trained on visual inspection techniques, adequately passed visual acuity testing, and were formally qualified to perform such activities. The NRC inspection team also reviewed a sample of work capability evaluations (SPV), the Mangiarotti qualified personnel list, and selected qualification journals for inspectors currently involved in nuclear safety-related shop inspection, and verified that those records were developed and maintained in accordance with the Mangiarotti QAM and QMP PGE.23.

c. Conclusion

The NRC inspection team concluded that the implementation of the Mangiarotti inspection program is consistent with the regulatory requirements of Criterion X of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the NRC inspection team also determined that Mangiarotti is effectively implementing its policy and procedures. No findings of significance were identified.

## 6. Control of Measuring and Test Equipment

### a. Inspection Scope

The NRC inspection team reviewed the implementation of Mangiarotti's process for control of measurement and test equipment (M&TE). Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of Mangiarotti's process for verifying compliance with Criterion XII, "Control of Measurement and Test Equipment," of Appendix B to 10 CFR Part 50. In addition, the team observed various in-process activities, including welding, heat treatment, and NDE, to verify that the implementation of the program is consistent with Mangiarotti's documented controls.

The NRC inspection team reviewed the following documents for this inspection area:

- Mangiarotti QAM, Section 4.12, "Control of Measuring and Test Equipment"
- QMP PGE.06, "Calibration Manual," Revision 1, dated January 20, 2010

The NRC inspection team verified the implementation of the control of M&TE through direct interviews with Mangiarotti personnel and the review of certificates of calibration for thermocouple probes, digital thermometers, direct current arc welding machines, gauge blocks, dryer ovens, and heat treatment chart recorders.

### b. Observations and Findings

While performing a surveillance of the production weld shop, the NRC inspection team reviewed the calibration stickers for a contact pyrometer (S/N 33TR), which was being used for temperature verification at the welding station. The NRC inspection team determined that although the contact pyrometer (S/N 33TR) had a working range of 50 degrees Celsius (C) to 1,200 degrees C, the calibration record for the instrument indicated that the calibration range checked was limited to 120–240 degrees C. The NRC inspection team discussed this observation with Mangiarotti personnel and verified that the calibration was performed over the limited range from 120–240 degrees C and not the full working range of 50–1,200 degrees C, and that this was considered a standard calibration practice for pyrometers and other temperature instrumentation. Importantly, the limited range did not encompass the actual operational temperature range of the welding activity. As a result, the NRC inspection team determined that the current calibration practice did not meet regulatory requirements necessary to ensure that instruments are properly calibrated to maintain accuracy within necessary limits. The NRC inspection team identified this example of a failure to implement the regulatory requirements relevant to the M&TE program as Nonconformance 99901393/2010-201-02.

While performing a surveillance of the production weld shop, the NRC inspection team found a calibration sticker on two welding machines (7PM and 3PM) that indicated that the machines were calibrated through 2012. QAM Section 4.9.2.2 states, "Welding machines are periodically, yearly as minimum, verified in order to assure correctness of the parameters showed at the control panel." In addition, PGE.06, paragraph 4.3, states, "Equipments, except for master gauges, are identified by a label directly attached to the instrument or otherwise to its case, where is indicated, by indelible writing, internal code. In the label is also indicated the expiry period of calibration (i.e.: marking of 1<sup>st</sup> quarter of 2010 means that device is validated up to 31-03-2010 included)." When the Welding Engineer was questioned about the sticker, he stated that the sticker was placed over an old sticker

and the ink ran through the new sticker. Mangiarotti took immediate action by issuing Corrective/Preventive Action Report RAC 055. In addition, at the request of the NRC inspection team, the Mangiarotti QA Manager agreed to review all equipment requiring calibration and remove any stickers placed over the old stickers and replace them with new stickers. As a result of RAC 055, the practice of placing new calibration stickers over old calibration stickers will no longer be acceptable.

c. Conclusions

The NRC inspection team concluded that the implementation of the Mangiarotti program for control of M&TE was not consistent with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. The NRC inspection team issued Nonconformance 99901393/2010-201-02 for Mangiarotti's failure to properly control and maintain accuracy within necessary limits for temperature measurement instrumentation used during welding fabrication.

7. Nonconforming Materials, Parts, or Components

a. Inspection Scope

The NRC inspection team reviewed the implementation of the Mangiarotti processes for the control of nonconforming materials, parts, and components. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of the Mangiarotti processes to verify compliance with Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team reviewed a sample of nonconformance reports (NCRs) associated with components being supplied to the U.S. market. The team also discussed the program with Mangiarotti personnel responsible for its implementation.

The NRC inspection team reviewed the following documents for this inspection area:

- Mangiarotti QAM, Section 4.15, "Control of Nonconforming Items"
- Mangiarotti QMP PQA-19, "Control of Non Conformities," Revision 4, dated July 30, 2009
- Mangiarotti QMP PGE.18, "Corrective and Preventive Actions," Revision 0, dated July 9, 2009
- Mangiarotti QMP PGE.07, "Control of Non Conformities," Revision 0, dated July 9, 2009

b. Observations and Findings

Section 4.15 of the QAM describes Mangiarotti's process for documenting and evaluating conditions adverse to quality. These requirements are implemented at Mangiarotti through QMP PGE.07 and at Mangiarotti Nuclear through procedure PQA-19.

At Mangiarotti, each item entered into the nonconformance process is assigned one of four levels defined by Mangiarotti as Level 1—important nonconformances that require application of 10 CFR Part 21 requirements; Level 2—important repairs that involve

changes in design that require client approval; Level 3—important repairs that do not involve changes to the design; and Level 4—nonconformances that can be resolved through substitution or reworking during fabrication. The NRC inspection team reviewed a sample of nonconformances issued in 2009 and 2010 and concluded that their significance had been appropriately classified and that they had been appropriately evaluated. At Mangiarotti Nuclear, such a significance classification system does not exist; however, all NCRs are screened for the applicability of 10 CFR Part 21. The NRC inspection team verified that the nonconformance reporting methods adequately identify the nature of the nonconformance, the disposition, and the justification for product acceptance, as applicable.

Working from WEC-supplied design drawings and specifications, Mangiarotti Nuclear performed the design work and fabrication specifications for the PRHR HXs. Mangiarotti Nuclear then issued PO QA-201000158 to Mangiarotti to fabricate the actual components. All WEC quality requirements are passed down through this PO, the related fabrication specifications, and the QA plan.

#### c. Conclusions

The NRC inspection team concluded that the implementation of the Mangiarotti program for control of nonconforming material, parts, and components is consistent with the regulatory requirements of Criterion XV of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and observation of ongoing production activities at the Mangiarotti fabrication facility, the NRC inspection team also determined that Mangiarotti is effectively implementing its QAM and the associated nonconformance procedures. No findings of significance were identified.

### 8. Corrective Actions

#### a. Inspection Scope

The NRC inspection team reviewed the implementation of the Mangiarotti process for corrective actions. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of Mangiarotti process to verify compliance with Criterion XVI, “Corrective Actions,” of Appendix B to 10 CFR Part 50. In addition, the team reviewed a sample of corrective action requests associated with material being supplied to the U.S. market and discussed the program with the Mangiarotti personnel responsible for the implementation of the corrective action program.

The NRC inspection team reviewed the following documents for this inspection area:

- Mangiarotti QAM, Section 4.16, “Corrective Action”
- Mangiarotti QMP PGE.18, “Corrective and Preventive Actions,” Revision 0, dated July 9, 2009

#### b. Observations and Findings

Section 4.16 of the QAM describes Mangiarotti’s process for documenting and evaluating conditions adverse to quality. These requirements are implemented at Mangiarotti through QMP PGE.18. This procedure provides guidance for documenting, classifying, and

evaluating conditions and significant conditions adverse to quality. The team reviewed a sample of corrective action requests issued in 2009 and 2010 to ensure that conditions adverse to quality were being appropriately entered into the corrective action program and were being evaluated for significance level. In addition, the team verified that appropriate corrective actions had been specified and implemented for conditions adverse to quality and that the root causes for significant conditions adverse to quality had been appropriately identified to prevent recurrence.

For the sample of corrective action requests reviewed, the team found that Mangiarotti had classified the majority of issues as significant conditions, even though very few of the issues described on the corrective action requests appeared to meet the threshold for a significant condition adverse to quality as defined in the Mangiarotti management procedure. Although appropriate corrective actions were specified for the items reviewed, the team was concerned that this overclassification of the significance of issues could hinder the effective evaluation of actual significant issues should they occur in the future.

The team observed that the Mangiarotti quality procedures also state that nonconformances that point to possible weaknesses in the quality system are also supposed to be entered into the corrective action system; however, as the NRC inspection team noted in the following example, this has not always occurred.

Nonconformance report RNC-792 concerned the use of incorrect material as a temporary support during the welding of several PRHR support beams. According to the welding specification for this job, the support material was supposed to be SA240-304 (dual-grade) material; however, the actual material used was SA240-304H, which does not meet SA240-304 (dual-grade) requirements. According to Mangiarotti QA personnel, a corrective action request was not generated for this issue as the understanding at the time was that the welder had just picked up the wrong material.

During the inspection, the team interviewed the welder and weld foreman associated with this work and determined that some misunderstanding remained with regard to the meaning of the dual-grade material designation. The welder and foreman stated that they believed that dual-grade meant that either SA240-304L or SA240-304H material could be used. This is incorrect as the dual-grade designation requires the material to meet both SA240-304L and SA240-304H requirements. Before the inspection, Mangiarotti had not identified this lack of understanding concerning the meaning of dual-grade material. While the safety significance of this particular example was relatively minor since the mistake involved only temporary support material that is ultimately removed, the team was concerned that this lack of understanding regarding the meaning of dual-grade material could result in errors that affect other, more safety-significant components. The NRC inspection team identified this example of a failure to implement the regulatory requirements relevant to the corrective action program as Nonconformance 99901393/2010-201-03.

The team also identified one example where a corrective action request was not written promptly after identification of a condition adverse to quality. In this instance, Corrective Action Request 748 was written to document concerns associated with the establishment of hold points for PRHR tubes being manufactured for Mangiarotti by Valinox. The intended use of these tubes was for the AP1000 being supplied to the Vogtle Station. The corrective action request indicated that Mangiarotti had failed to ensure that the quality plan developed by Valinox and supplied to Mangiarotti for its approval contained the desired surveillance inspection and hold points. As detailed in the corrective action request, Mangiarotti had

asked Valinox to provide a quality plan that contained the same requirements as those implemented for a previous set of PRHR tubes that Valinox had supplied for another AP1000 order. For the Vogtle order, however, Valinox did not include the hold points as requested, and Mangiarotti failed to recognize this as part of its review of the Valinox documents. Mangiarotti ultimately identified the issue on May 12, 2010, after Valinox had already begun manufacture of the tubes. During the team's review of this issue, it determined that Mangiarotti did not enter this issue into its corrective action program until June 16, 2010, some 5 weeks after learning about the issue. In addition, a similar issue regarding the lack of effective subvendor control was also identified on April 26, 2010, during an audit of Mangiarotti by Southern Company and documented on Corrective Action Request 740, dated April 26, 2010. The NRC inspection team identified this example of a failure to implement the regulatory requirements relevant to the corrective action program as Nonconformance 99901393/2010-201-03.

c. Conclusions

The NRC inspection team concluded that the implementation of the Mangiarotti program for corrective actions was not consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. The NRC inspection team issued Nonconformance 99901393/2010-201-03 for Mangiarotti's failure to enter conditions adverse to quality into its corrective action program in a timely manner.

9. Entrance and Exit Meetings

On July 19, 2010, the NRC inspection team discussed the scope of the inspection with Mr. Davide Vanin, Managing Director, Mangiarotti, and with the Mangiarotti management, engineering, and production staff. On June 23, 2010, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Paolo Di Salvio, President and Chief Executive Officer, Mangiarotti, and other Mangiarotti management and engineering staff. 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/EXIT MEETING ATTENDEES

<u>Name</u>	<u>Title</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>Exit</u>	<u>Interviewed</u>
Paolo Di Salvio	President & CEO	Mangiarotti		X	
Davide Vanin	Managing Director	Mangiarotti	X	X	
Eddy D'Anna	QA/QC Manager	Mangiarotti	X	X	X
Gianpaolo Cecchini	Safety & Maintenance Manager	Mangiarotti	X		
Guido Villa	Project Manager	Mangiarotti	X		
Francesco Feruglio	Project Manager	Mangiarotti	X		
Luca Venudo	Quality Department	Mangiarotti	X		
Federico Maggioni	Engineer Manager	Mangiarotti	X		
Federico Dissegna	WDA	Mangiarotti			X
Luca Dell'asino	Quality Control Inspector	Mangiarotti			X
Daniel Tilatti	MAG—Storage Manager	Mangiarotti		X	X

### 2. INSPECTION PROCEDURES USED

IP 43002, "Routine Inspections of Nuclear Vendors"

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>
99901393/2010-201-01	Open	NON	Criterion V Criterion VII Criterion XVIII
99901393/2010-201-02	Open	NON	Criterion XII
99901393/2010-201-03	Open	NON	Criterion XVI