July 15, 2010

Mr. Jan-Erik Sundstrom, General Manager
Steam Generator Tubing
Sandvik Materials Technology
SE-811 81
Sandviken, Sweden

SUBJECT: NRC INSPECTION REPORT NO. 99901326/2010-201, NOTICE OF VIOLATION, AND NOTICE OF NONCONFORMANCE

Dear Mr. Sundstrom:

On May 31 – June 4, 2010, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Sandvik Materials Technology (SMT) facility in Sandviken, Sweden. The purpose of the inspection was to perform a limited scope inspection to assess SMT'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 staff determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation in the Notice is being cited because SMT did not provide adequate procedural guidance to evaluate deviations and failures to comply associated with substantial safety hazards consistent with the requirements of 10 CFR Part 21.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition, during this inspection, NRC inspectors also 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 SMT was not implementing its corrective action program consistent with regulatory requirements or the SMT Quality Assurance Manual, "Quality System Program." The specific findings and references to the pertinent requirements are identified in the enclosures to this letter.

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 Notice 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 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 (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, (if applicable), 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 is 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.

Sincerely,
/RA/

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

Docket No. 99901326

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report No. 99901326/2010-201 and Attachment

In accordance with 10 CFR 2.390 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 (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, (if applicable), 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 is 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.

Sincerely,
/RA/

Juan Peralta, Chief
Quality and Vendor Branch 1
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& Operational Programs
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Docket No. 99901326
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DATE	7/13/2010	7/14/2010	7/13/2010	7/15/2010	7/14/2010
OFFICE	NRO/DCIP/CQVA/BC				
NAME	JPeralta				
DATE	7/15/2010				

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NOTICE OF VIOLATION

Sandvik Materials Technology
Sandviken, Sweden

Docket Number 99901326
Inspection Report Number 2010-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Sandvik Materials Technology (SMT), facility in Sandviken, Sweden on May 31 – June 4, 2010, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10, Section 21.21, "Notification of Failure to Comply or Existence of a Defect and Its Evaluation," of the *Code of Federal Regulations* (10 CFR 21.21), paragraph 21.21(a), requires, in part, that each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable.

In part, 10 CFR 21.21(a)(1) requires that deviations and failures to comply be evaluated within 60 days of discovery in order to identify a reportable defect or failure to comply that could create a substantial safety hazard were it to remain uncorrected.

Paragraph §21.21(a)(2) requires, in part, that, if an evaluation of an identified deviation or failure to comply cannot be completed within 60 days from discovery, an interim report is prepared and submitted to the Commission through the director or responsible officer in writing within 60 days of discovery of the deviation or failure to comply.

Paragraph §21.21(a)(3) requires, in part, that a director or responsible officer be informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation if the manufacture, construction, or operation of a facility or activity, or a basic component supplied for such a facility or activity (i) fails to comply with the Atomic Energy Act of 1954, as amended, or (ii) contains a defect.

Paragraph §21.21(b) requires, in part, that if a deviation or failure to comply is discovered by a supplier of basic components and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within 5 working days of this determination.

Paragraph §21.21(d)(3)(i) requires, in part, an initial notification by facsimile to NRC Operations Center or by telephone within 2 days following receipt of information by the director or responsible officer on the identification of a defect or a failure to comply.

Paragraph §21.21(d)(3)(ii) requires, in part, a written notification to the NRC within 30 days following receipt of information by the director or responsible corporate officer on the identification of a defect or a failure to comply.

Contrary to the above, as of June 4, 2010, the SMT 10 CFR Part 21 Quality Assurance Instruction Q13-0003, "Control of Non-Conforming Products Reporting of Defects and Deviations According to 10CFR21," Revision 9, dated May 20, 2010, did not provide procedural guidance for: 1) evaluating deviations and failures to comply associated with substantial safety hazards within 60 days of discovery; 2) submitting an interim report to the NRC if an evaluation of an identified deviation or failure to comply cannot be

completed within 60 days of discovery; 3) notifying the SMT's responsible officer within 5 days when it is determined that a defect that could cause a substantial safety hazard exists; 4) notifying the affected purchasers or licensees if SMT does not have the capability to perform the evaluation to determine if a defect exists; and 5) notifying the NRC of defects and failures to comply (i.e., initial and written notification).

This issue has been identified as Violation 99901326/2010-201-01.

This is a Severity Level IV Violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," SMT is hereby required to submit 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 Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. 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, accessible 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 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, "Requirements for the Protection of Safeguards Information."

Dated this the 15th day of July 2010.

NOTICE OF NONCONFORMANCE

Sandvik Materials Technology
Sandviken, Sweden

Docket Number 99901326
Inspection Report Number 2010-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Sandvik Materials Technology (SMT), facility in Sandviken, Sweden on May 31 – June 4, 2010, certain activities were not conducted in accordance with NRC requirements which were contractually imposed on SMT:

> Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states, in part, 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.
>
> SMT procedure QAI Q14-0001, "Corrective and Preventive Actions – Handling of Corrective Action," Revision 13, dated January 4, 2010, states, in part, that the Sandvik electronic corrective action database (C2) shall be used to record and process all corrective action reports generated by SMT.
>
> Contrary to the above, as of June 4, 2010, SMT did not record and process corrective action reports within the C2 electronic system as required by QAI Q14-0001. As a result, SMT's corrective action program lacks measures to ensure that regulatory requirements were adequately met. Specifically, there are no formal methods defined in the SMT corrective action program such as: 1) a screening process for items identified within the corrective action program to identify significant conditions adverse to quality; 2) identifying and verifying timely corrective actions; and 3) ensuring that issues identified within the corrective action program that may create a substantial safety hazard are evaluated for 10 CFR Part 21 applicability.
>
> This issue is identified as Nonconformance 99901326/2010-201-02.

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, 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, 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 15th day of July 2010.

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

Docket No.:	99901326
Report No.:	99901326/2010-201
Vendor:	Sandvik Materials Technology 6814 STQG 81181 Sandviken Sweden
Vendor Contact:	Mr. Per-Olof Lund, Manager Quality Assurance, ST Tube +46 26 26 40 70 E-mail: per-olof.lund@sandvik.com
Nuclear Industry Activities:	Sandvik Materials Technology is an American Society of Mechanical Engineers (ASME) Quality System Certificate Holder currently manufacturing EPR steam generator tubing for the AREVA Chalon/Saint Marcel manufacturing facility.
Inspection Dates:	May 31 – June 4, 2010
Inspectors:	Kerri Kavanagh NRO/DCIP/CQVA, Team Leader Greg Galletti NRO/DCIP/CQVA Samantha Crane NRO/DCIP/CQVB Greg Makar NRO/DE/CIB1
Approved by:	Juan Peralta, Chief Quality and Vendor Branch 1 Division of Construction Inspection and Operational Programs Office of New Reactors

EXECUTIVE SUMMARY

AB Sandvik Materials Technology
99901326/2010-201

The purpose of this inspection was to verify that AB Sandvik Materials Technology (SMT) implemented an adequate quality assurance (QA) program that complied 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 SMT implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that met the regulatory requirements of the U.S. Nuclear Regulatory Commission (NRC). The inspection was conducted at the SMT facility in Sandviken, Sweden, during the period May 31 – June 4, 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 previously performed an inspection at the SMT facility in Sandviken, Sweden, in October 1997, as documented in NRC Inspection Report 99901326/97-01.

The results of the current inspection are summarized below.

10 CFR Part 21

The NRC inspection team concluded that SMT is not implementing the SMT 10 CFR Part 21 program consistent with the requirements of 10 CFR Part 21. The NRC inspection team issued Violation 99901326/2010-201-01 for SMT's failure to adopt appropriate procedures pursuant to 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation." Specifically, the NRC inspection team determined that SMT Quality Assurance Instruction Q13-0003 did not provide procedural guidance for: 1) evaluating deviations and failures to comply associated with substantial safety hazards within 60 days of discovery; 2) submitting an interim report to the NRC if an evaluation of an identified deviation or failure to comply cannot be completed within 60 days of discovery; 3) notifying the SMT's responsible officer within 5 days when it is determined that a defect that could cause a substantial safety hazard exists; 4) notifying the affected purchasers or licensees if SMT does not have the capability to perform the evaluation to determine if a defect exists; and 5) notifying the NRC of defects and failures to comply (i.e., initial and written notification).

Control of Purchased Material, Equipment, and Services and Audits

The NRC inspection team concluded that the implementation of the SMT control of purchased material, equipment, and services, and audit programs is 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 and the provisions of the SMT QAM and associated implementing procedures. Based on the sample reviewed, the NRC inspection team also determined that SMT is effectively implementing its policies and procedures associated with the control of purchased material, equipment, and services, and audits. No findings of significance were identified.

Inspection

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

Control of Special Processes

The NRC inspection team concluded that the implementation of the SMT 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 inspectors concluded that qualified personnel are using qualified equipment and processes to effectively implement SMT’s QAM and the associated fabrication and special process procedures. No findings of significance were identified.

Test Control

The NRC inspection team concluded that the implementation of the SMT program for test control is consistent with the regulatory requirements of Criterion XI, “Test Control,” of Appendix B to 10 CFR Part 50. Based on the sample of test control documents reviewed and activities observed, the NRC inspection team concluded that the SMT is effectively implementing its QAM and the associated test control procedures. No findings of significance were identified.

Control of Measuring and Test Equipment

The NRC inspection team concluded that the implementation of the SMT program for control of measuring and test equipment (M&TE) is consistent with the regulatory requirements of Criterion XII, “Control of Measuring and Test Equipment,” of Appendix B to 10 CFR Part 50. Based on the limited sample of calibration records reviewed, evaluation of controls established within the SMT calibration laboratory, and a walk down of Tube Mill 68, the NRC inspection team determined that SMT is effectively implementing its QAM and the associated M&TE procedures. No findings of significance were identified.

Handling, Storage, and Shipping

The NRC inspection team concluded that the implementation of the SMT program for handling, storage, and shipping is consistent with the regulatory requirements of Criterion XIII, “Handling, Storage, and Shipping,” of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and observation of ongoing production activities at the SMT fabrication

facilities, the NRC inspection team also determined that SMT is effectively implementing its QAM and the associated handling, storage, and shipping procedures. No findings of significance were identified.

Nonconforming Materials, Parts, or Components

The NRC inspection team concluded that the implementation of the SMT 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 SMT fabrication facilities, the NRC inspection team also determined that SMT 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 SMT program for corrective actions was 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 99901326/2010-201-02 for SMT's failure to record and process corrective action reports within the C2 electronic system as required by QAI Q14-0001. As a result, SMT's corrective action program lacks measures to ensure that regulatory requirements were adequately met.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspection team reviewed SMT's policies and implementing procedures that govern their 10 CFR Part 21 (Part 21) process to verify compliance with the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance." Specifically, the NRC inspection team focused on Quality Assurance Instruction (QAI) Q13-0003 Control of Non-Conforming Products Reporting of Defects and Deviations according to 10CFR21, Revision 9, dated May 20, 2010. The NRC inspection team also reviewed procurement documents and the following SMT procedures to verify the implementation of the requirements of Part 21.

- SMT Quality Assurance Manual (QAM), "Quality System Program," Edition 2010, Revision 0, dated January 2010
- QAI Q13-0001, "Control of Non-conforming products – dealing with and reporting of non-conformances," Revision 15, dated January 21, 2010
- QAI Q14-0001, "Corrective and Preventive Actions – Handling of Corrective Action," Revision 13, dated January 4, 2010

b. Observations and Findings

b.1 Postings

The NRC inspection team observed that SMT 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/procedures related to Part 21; and the name of the individual to whom reports may be made.

b.2 10 CFR Part 21 Procedure

SMT QAM Section 8.5, "Control of Examinations, Tests and Nonconforming Material," assigns the QA manager the responsibility and authority to disposition nonconforming items. Section 8.5 also states, in part, that the requirements for reporting safety-related defects and noncompliances per Part 21 and similar standards are established in a QAI. SMT QAI Q13-0003 implements the requirements of the QAM and describes SMT's Part 21 process. QAI Q13-0003 assigns responsibilities to all employees to notify the QA manager if a known defective item has been shipped to a customer, and provides additional instruction to disposition defects and deviations.

The NRC inspection team reviewed QAI Q13-0003 and discussed it with the QA manager, and the SMT senior level personnel responsible for development and maintenance of QAI Q13-0003. The NRC inspection team noted that some of the definitions contained in 10 CFR 21.3, "Definitions," such as basic component, deviation, defect, discovery, and evaluation, were not included in QAI Q13-0003, and the use of these terms within the body of the procedure was inconsistent with the definitions contained in 10 CFR 21.3.

In addition, the NRC inspection team determined that procedure Q13-0003 lacked guidance for the evaluation of deviations or failures to comply consistent with the time requirements of 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and Its Evaluation."

Specifically, QAI Q13-0003 does not provide the following evaluation requirements:

- Guidance is not provided to assure that deviations or failures to comply are evaluated within 60 days of discovery, as required in paragraph 21.21(a)(1).

- Guidance is not provided for the issuance of an interim report to the NRC if an evaluation cannot be completed within 60 days, as required in paragraph 21.21(a)(2).

- Guidance is not provided to inform the SMT's director or responsible officer, within five working days after completion of the evaluation, that a supplied basic component fails to comply with the Atomic Energy Act of 1954, as amended, or contains a defect that could cause a substantial safety hazard, as required in paragraph 21.21(a)(3).

- Guidance is not provided to inform purchasers within five working days when it is determined that SMT is not able to evaluate deviations or failures to comply, as required in paragraph 21.21(b).

- Guidance is not provided to notify the NRC Operations Center by telephone or fax within two days of notifying the director or responsible officer and written notification within thirty days following the identification of a defect or failure to comply, as required in paragraph 21.21(d).

The NRC inspection team identified the lack of procedural guidance to evaluate deviations or failures to comply as Violation 99901326/2010-201-01.

The NRC inspection team noted that SMT had not performed any 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 SMT Part 21 program.

c. Conclusions

The NRC inspection team issued Violation 99901326/2010-201-01 for SMT's failure to adopt appropriate procedures pursuant to 10 CFR 21.21. The NRC inspection team concluded that QAI Q13-0003 did not provide adequate guidance to: 1) evaluate deviations and failures to comply associated with substantial safety hazards within 60 days of discovery; 2) submit an interim report to the NRC if an evaluation of an identified deviation or failure to comply cannot be completed within 60 days of discovery; 3) notify the SMT's responsible officer within 5 days when it is determined that a defect that could cause a substantial safety hazard exists; 4) notify the affected purchasers or licensees if SMT does not have the capability to perform the evaluation to determine if a defect exists; and 5) notify the NRC of defects or failures to comply (i.e., initial and written notification).

2. Control of Purchased Material, Equipment, and Services and Audits

a. Inspection Scope

The NRC inspection team reviewed the implementation of SMT 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 SMT 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, SMT was manufacturing steam generator tubes for an EPR for the U.S. market. The NRC inspection team reviewed a sample of purchase orders (POs), the associated internal and external audit reports, and the supplier evaluations to evaluate compliance with program requirements and adequate implementation of those requirements. In addition, the NRC inspection team reviewed qualifications of auditors and corrective actions that address deficiencies identified by the audit findings for adequacy and timeliness.

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

- SMT Quality Assurance Manual (QAM), "Quality System Program," Edition 2010, Revision 0, Section 5, "Control of Purchased Materials, Source Materials, and Services," January 2010
- SMT QAM, "Quality System Program," Edition 2010, Revision 0, Section 9.1, "Audits," January 2010
- SMT QAM, "Quality System Program," Edition 2010, Revision 0, Section 3.2, "Personnel Records," January 2010
- QP 79, "Quality Plan," Revision 5, dated May 12, 2010
- Areva Chalon/Saint Marcel Plant Purchase Order 08/51892 dated October 12, 2008
- SMT Approved Suppliers List (ASME)
- STQG AU 0902, "Audit Report – Olympus France," dated June 9, 2009
- 09-005, "Supplier Audit Report – Zetec," dated June 25, 2009
- PO Number 5700053959 dated August 31, 2009
- Supplier evaluations for Olympus, Zetec, John Smith, Kanthal AB, SMT SV, and SMT ST, dated April 9, 2010
- Quality Procedure Q06-0061, "Purchasing," Revision 5, dated December 10, 2007
- Quality Procedure Q17-0001, "Internal Quality Audits," Revision 11, dated April 2, 2009
- Internal audit (ISO 9001:2008) of tubes department dated February 8, 2010
- Nonconformance NC-1370/2010 dated February 18, 2010

- SMT ASME audit schedule for 2009 and 2010
- Internal audit (NCA 3800) of tubes department dated on August 31, 2009
- Corrective action Au-393/2009 dated August 31, 2009
- Quality Procedure Q06-0062, "Suppliers List – Products and Services for SMT to ASME Code Section III," Revision 6, dated January 14, 2005
- Quality Procedure Q14-0001, "Handling of Corrective Action," Revision 13, dated April 1, 2009
- Quality Procedure Q17-0002, "Qualification of Leaders for Audit Teams Undertaking Quality System Audits," Revision 11, dated May 20, 2010

b. Observations and Findings

The NRC inspection team reviewed SMT QAM, Sections 5 and 9.1. Section 5 establishes the controls to ensure that purchased materials, source materials, and services conform to procurement documents. These controls include supplier evaluations and selections through quality evaluation and rating, periodic source assessments and inspections, audits, and receipt inspections, as applicable. Section 9.1 establishes an internal audit program to ensure that quality activities comply with the requirements of the SMT QAM, and related procedures, and to determine the effectiveness of the quality system program.

In addition, the NRC inspection team reviewed PO 08/51892 from the Areva Chalon/Saint Marcel facility. PO 08/51892 establishes the manufacture and delivery of steam generator (SG) tubes and associated parts (i.e., set of uneven tubes, set of even tubes, set of tube test coupons, spare tubes, tube for manufacturing test coupon, tube for calibration block, and tube for drain and tests) for four SGs for an U.S. EPR. The NRC inspection team also noted that the following requirements were imposed in PO 08/51892: 10 CFR Part 21, Appendix B to 10 CFR 50, American Society of Mechanical Engineers (ASME) Section II, "Materials," ASME Section III, "Rules for Construction of Nuclear Facility Components," 2004 Edition, ASME Section V, "Nondestructive Examination," 2004 Edition, and ASME Section III, Subsection NCA 3800, "Metallic Material Organization's Quality System Program."

b.1 Maintenance of the Approved Supplier List

Q06-0062 provides guidance on maintaining the ASME supplier list. Specifically, the procedure states that "[s]ubcontractors used for orders to ASME Code Section III or equivalent shall be included in suppliers lists complied and maintained by the person in charge of QA within the respective product area and support function." Q06-0062 also lists the content of the supplier lists. The NRC inspection team verified the that the required information (i.e., name and address, scope of approval, date and revision of QA manual, approval date and period of validity, and any restrictions) was included on the SMT approved supplier list. For the U.S. EPR project, the approved suppliers were Kanthal AB, Zetec, and Olympus, along with other SMT entities.

b.2 SMT Purchase Orders

The NRC inspection team reviewed procurement controls to verify compliance with QAM requirements. The NRC inspection team also reviewed a sample of purchase orders, chemical analysis reports, and receipt inspection reports associated with the sampled purchase orders. After review of the purchase orders, the NRC inspection team confirmed that: 1) purchase orders are reviewed and approved by responsible personnel; 2) technical and quality requirements are imposed in purchase orders; and 3) SMT verifies that their suppliers comply with purchase order requirements.

b.3 External Audits

The NRC inspection team reviewed the external audits and supplier evaluations associated with the U.S. EPR project to verify SMT's approval process. The NRC inspection team noted that the audits reviewed were adequately documented and provided evidence of Kanthal AB, Zetec, and Olympus compliance with ASME and QA requirements. The NRC inspection team also noted that SMT evaluated and closed audit findings based on the respective suppliers' response. In addition, the NRC inspection team reviewed the external audit plan for SG tubes external suppliers for the next three years (i.e., 2010 through 2012) and verified that the audit plan was consistent with the SMT QAM requirements.

b.4 Internal Audits

The NRC inspection team reviewed Q17-0001 which provides guidance on implementing the internal audit process. Q17-0001 states that SMT is required to audit the selected processes every year. In the case of POs requiring ASME compliance, all aspects of the program are audited every year. In addition, Q17-0001 requires that quality system audits of other QMS processes or flows with specific customer quality system requirements according to ASME Section III Subsection NCA 3800 shall be performed according to checklists prepared by the auditor (or lead auditor).

The NRC inspection team reviewed the audit checklist/audit report from the 2009 internal audit of SMT ST Tube department. Three nonconformances were identified in the 2009 internal audit report: 1) missing the ASME edition and addendum on order number 348-95506; 2) new personnel not adequately trained for order function they were assigned; and 3) training of new personnel was not accomplished. The NRC inspection team noted that corrective action, Au-393/2009, was opened to address the three items identified in the internal audit report and that all corrective actions had been complete at the time of the inspection.

The NRC inspection team noted that the 2009 internal audit of the SMT ST Tube department was based on ASME Section III Subsection NCA 3800 and the appropriate NCA 3800 requirements were selected as the basis of the checklist. Based on the audit schedule, the next internal audit of SMT ST Tube department is scheduled to be done in the 3rd quarter of 2010.

c. Conclusions

The NRC inspection team concluded that the implementation of the SMT control of purchased material, equipment, and services, and audit programs is consistent with the regulatory requirements of Criterion VII and Criterion XVIII of Appendix B to 10 CFR Part 50

and the provisions of the SMT QAM and associated implementing procedures. Based on the sample reviewed, the NRC inspection team also determined that SMT is effectively implementing its policies and procedures associated with the control of purchased material, equipment, and services, and audits. No findings of significance were identified.

3. Inspection

a. Inspection Scope

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

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

- Control Procedure (CP) CP-7982, "Inspection of Straight Tubes," Revision 0, dated September 3, 2009
- CP-7988, "Inspection of Bent Tubes," Revision 3, dated May 24, 2010
- CP-7987, "Control of Table Inspections," Revision 1, dated December 18, 2009
- CP-7987, "Internal Inspection Table Calibration," Revision 1, dated December 18, 2009
- CP 7094, "Visual Standards," Revision 0, dated March 9, 2009
- SPPO-06-001, "Visuell Inspektion," dated July 5, 2001
- KSI Q10-0058, "Visual Eye Exam," dated August 21, 2009
- Procedure 126-14, "RV 68 Arbetsinstruktion – QA OCH OFP, Kalificering AV Personal For Inspectionsarbete inom," Revision 2, dated February 10, 2006
- Matkonsult - SMT Rorverk 68, Kontroll av Justerbord 1-4, dated March 2, 2010
- Matkonsult - SMT Rorverk 68, Kontroll av Justerbord 1-4, dated Feb 22, 2008

b. Observations and Findings

The NRC inspection team reviewed the procedures governing in-process and final inspection activities during SG tube production. 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 includes identification of deviations and rejected materials. The NRC inspection team noted that work was controlled through the use of the electronic tracking system (HELGA) which controls the flow of tubes during production, and ensures that the rejected tubes are clearly identified.

The NRC inspection team discussed the inspection program with SMT personnel responsible for inspection program implementation, reviewed documented results of inspections, and observed inspections performed as part of the SG tube production. Specifically, the NRC inspection team observed straight tube visual inspections, discussed bent tube inspections and the preparation of fixtures (e.g., the inspection tables), and verified that these activities were performed in accordance with SMT's documented requirements.

The NRC inspection team verified that the ambient lighting requirements were consistent with SMT inspection procedures and customer technical requirement documentation and that lighting conditions were verified by SMT personnel prior to commencement of inspection activities.

The NRC inspection team reviewed the training and qualification requirements for visual inspection personnel, and 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.

c. Conclusion

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

4. Control of Special Processes

a. Inspection Scope

The NRC inspection team reviewed the implementation of SMT control of special processes, including heat treatment and nondestructive examination (NDE). Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of SMT processes to verify compliance with Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50. Additionally, for heat treatment (i.e., mill annealing and thermal treatment), the NRC inspection team reviewed heat treatment procedures, reviewed calibration labels and documents, observed data displays and records during heat treatment activities, and verified personnel qualifications. For NDE, the NRC inspection team observed ultrasonic testing (UT), reviewed UT procedures, reviewed UT level I, II, and III inspector qualifications, observed eddy current testing (ET), reviewed ET procedures, reviewed ET level I, II, IA, and level III inspector qualifications, and reviewed the calibration certificates for measuring and test equipment.

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

- QAM 7.1, " Manufacturing Process Control," Revision 0, dated January 2010
- QAM 3.4, "Training, examination, and certification of NDE personnel," Revision 0, dated January 2010

- 08-000-020, “Description of Job Card,” Revision 0, dated April 2, 2009
- BUHSFA/NGV0010, “Procurement Specification Alloy 690 Thermally Treated 3/4" OD Tubing For Steam Generators,” Revision B, dated September 25, 2007
- CP 7908, “QA Computer System,” Revision 0, dated September 17, 2009
- CP 7951, “Ultrasonic Test,” Revision 0, September 15, 2009
- CP 7952, “Eddy Current Test,” Revision 1, dated December 11, 2009
- CP 7953, “Dimension Measurement of Straight Tubes,” Revision 0, dated September 15, 2009
- CP 7954, “NDE Reference Standards,” Revision 0, dated September 15, 2009
- CP 7955, “ID Eddy Current Signal to Noise Test,” Revision 1, dated April 29, 2010
- CP 7959, “Multi Frequency EC-examination of U-bent Tubes (Miz-testing),” Revision 3, dated May 20, 2010
- Q10-0058, “Conducting Annual Eye Test within AB SMT Sandviken,” Revision 7, dated February 4, 2009
- Q18-0002, “Procedures and responsibilities at training examination and certification of NDE personnel level I and II,” Revision 10, dated May 11, 2010
- Q18-0003, “Education, training, examination and certification of NDE level I and II personnel according to ASNT-TC-1A and the ASME code,” Revision 1 dated March 14, 1997
- Q18-0003, “Competence Training and Awareness - Education and Certification of NDE Level I and II Personnel according to ASNT-TC-1A The ASME CODE and SS-EN 473,” Revision 17, dated May 17, 2010
- Q18-0004, “Competence Training and Awareness - Education and Certification of NDE Level III Personnel according to ASNT-TC-1A,” Revision 10, dated May 18, 2010
- Q18-0005, “Competence Training and Awareness - Training and examination of Sandvik Level IIA Eddy Current Analysis,” Revision 1, dated May 11. 2010
- QP 79, “Quality Plan,” Revision 5, dated May 12, 2009
- TR 1013706, “EPRI Steam Generator Management Program: Pressurized Water Reactor Steam Generator Examination Guidelines,” Revision 7, dated October 2007
- CP 932, “Bright Annealing,” Revision 1, dated December 3, 2009
- CP 7935, “Belt Grinding,” Revision 1, dated October 22, 2009
- CP 7939, “Long Time Thermal Treatment,” Revision 2, dated October 7, 2009

- TR 7901, “Residual Stress after Belt Grinding,” dated October 20, 2009

- Calibration records

b. Observations and Findings

b.1 Process Control Documents

QAM Section 7.1 describes the overall process at SMT for meeting the provisions in ASME Section III Subsection NCA-3857.2, “Process Control.” In addition, QAM Section 7.1 describes the creation of process control documents such as the control plan, the quality plan, the operations list and job cards and describes the creation of QA records for heat treatment, UT and ET.

Collectively, the control procedures in the U.S. EPR project document QP 79 provide the requisite controls for manufacturing, inspection, and testing activities necessary to meet technical and quality requirements associated with SMT Order No. 381-01084-01088, Areva PO number 08/51892.

QP 79 is implemented through several CPs that govern all critical operations in the manufacturing sequence of SG tubes at SMT. In addition to the CPs and the manufacturing process outlined in Section 7.1 of the QAM, SMT relies on various administrative procedures that control and/or define the role played by the various SMT departments in the production or manufacturing sequence of SG tubes. Specifically, 048-06, “RV 68 Work Instruction – Administration: Production/ Manufacturing Sequence,” describes how the marketing, QA, engineering, and production departments interface to generate project-specific electronic records that ultimately reside in the computer-based QA system that captures all test and inspection data for individual SG tubes in accordance with CP-7908.

CP 7908 describes the computer system used by the QA department to register test and inspection data of individual tubes related to NDE results, straight tube inspection, reworking, destructive tests, bending, final inspection, and packing.

08-000-020 describes the information on the issued job cards. The NRC inspection team noted that the information on the job cards includes the heat number, lot number, operation sequence number, number of tubes, procedures to be used, dimensional tolerances, outgoing dimension, and additional customer requirements. In addition, the job cards track the person performing the activity. The job cards are issued from a computer system that also tracks which station the tubes came from and where they go next.

CP 7954 describes the selection, preparation, manufacturing, verification and documentation of NDE reference standards.

CP 7957 describes the 100% hydrostatic pressure testing of bent tubes. It includes a description of the equipment, testing, evaluation, drying, testing requirements, water grade (i.e., contaminate levels and conductivity and frequency of water testing), surveillances, and documentation of test results in the certified material test report (CMTR).

CP 7959 describes the testing of u-bent tubes after final thermal treatment. It includes a description of the equipment, recording, reference standards, calibration, test speed, data collection, analysis requirements, acceptance criteria, and personnel qualification.

CP 7951 describes the requirements for UT. CP 7952 describes the requirements for ET of straight tubes. CP 7953 describes dimension measurement of straight tubes.

CP 7955 describes the signal to noise test. CP 7959 describes the multi frequency ET of u-bent tubes.

The NRC inspection team verified that the working level procedures for NDE described above contain requirements for personnel qualifications, equipment qualification and calibration, conditions necessary for completing the process, and acceptance criteria. The procedures also include reporting directions. The NRC inspection team noted that ET, UT, and dimensional measurement procedures include the equipment, reference standards (i.e., construction and types of defects), set-up, calibration check, recording, marking and sorting, acceptance criteria for the test, personnel qualification, reporting, and archiving of samples. In addition, UT/ET and dimensional testing is traceable to an individual strip chart which includes the following data:

- Contract name
- Work lot number
- Tube and reference standard number
- Verdict from automatic alarms (good or bad with reject reason)
- Date and time of inspection
- Digital stamp/approval from NDE inspector with employee ID# and certification level
- Tube length

The NRC inspection team verified that SMT had established and implemented procedures for the control of special processes such as NDE and heat treatment. The procedures provided measures for the generation of control documents such as the quality plan, which has QA/QC and customer witness and hold points and identifies specific procedures to be used at each process step; the QA computer system which acts as an electronic shop traveler; job cards; and electronic strip charts. The NRC inspection team verified that process control documents include personnel and equipment requirements, conditions for accomplishing the process, acceptance criteria, results of inspections, and appropriate signatures.

b.2 Heat Treatment

The NRC inspection team reviewed procedures for final mill annealing and thermal treatment for the Alloy 690 tubes for the U.S. EPR project. The NRC inspection team determined that these heat treatment procedures met the requirements of ASME Section III. The procedures also met the additional heat treatment requirements in the procurement specification. These additional requirements are believed to optimize corrosion resistance for Alloy 690 SG tubes in pressurized water reactors but are not required by the ASME Code.

The NRC inspection team also observed final mill annealing and thermal treatment of straight tubes and discussed implementation of the associated procedures with the furnace operators and QA personnel. During these observations in the production area, the NRC inspection team confirmed that the heat treatment practices conformed to the procedures. The NRC inspection team also verified that selected parameters (e.g., temperature,

pressure, hydrogen dewpoint) were consistent with the procedures and were being continuously recorded where required. Calibration stickers or tags were examined on chart recorders, gages and thermocouples, and the NRC inspection team verified calibration for a group of thermocouples about to be used in the furnace. In addition, the NRC inspection team confirmed that the furnace operators were qualified for the work according to SMT's QA program.

b.3 Nondestructive Examination

The NRC inspection team examined procedures for eddy current testing and ultrasonic testing. These NDE methods are used in combination to measure tube wall thickness and to detect surface and subsurface flaws and imperfections. For all of the parameters examined, the procedures met or exceeded the Electric Power Research Institute (EPRI) tube specification guidelines defined in TR 1013706 and the requirements of ASME Section III. The NRC inspection team noted that SMT performs three types of eddy current tests. In the first test, an internal probe on the straight tubing is used to measure the eddy current signal-to-noise (S/N) ratio. In the second test, an encircling probe on the straight tubing is used to detect flaws in accordance with ASME Section III. In the third test, an internal probe on the bent tubing is used to detect flaws following hydrostatic testing.

The NRC inspection team observed the eddy current testing and ultrasonic testing performed in the shop to detect flaws in straight tubes and to measure tube wall thickness. The NRC inspection team confirmed that the specified calibration standards were installed in the test facility and that the through-wall holes were detected. In addition, the NRC inspection team confirmed that the personnel performing the test and data analysis were properly certified.

b.4 Qualification of NDE Personnel

The NRC inspection team reviewed SMT's written practice contained in Q18-002, Q18-0003, Q18-0004, Q18-0005, 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 (ASNT) SNT-TC-1A-2006, "Recommended Practice No. SNT-TC-1A - Nondestructive Testing," and provided the conditions under which SS-EN-473, "Non-destructive Testing - Qualification and Certification of NDT Personnel - General Principles," central certification could fulfill the general examination criterion for SMT NDE personnel certification. In addition, SMT's written practice contained education, training and qualification requirements for ET level IIA personnel. ET level IIA personnel are qualified to analyze ET multi-frequency data of bent SG tubes. The level ET IIA personnel must already be qualified as an SMT level II or III in ET. The testing requirements generally follow EPRI tube specification guidelines, but have been modified to account for the differences between the types of defects present during pre-service examination and in-service examination.

The NRC inspection team also verified training, experience, and qualification of four NDE personnel with certifications as UT level I, UT level II, UT level III, ET level I, ET level II, ET level IIA, ET level III, PT level II, and PT level III.

c. Conclusions

The NRC inspection team concluded that the implementation of the SMT 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 SMT's QAM and the associated fabrication and special process procedures.

5. Test Control

a. Inspection Scope

The NRC inspection team reviewed the implementation of SMT test control process. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of SMT process to verify compliance with Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. The NRC inspection team also observed in-process testing activities and a sample of completed test records associated with SG tube fabrication.

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

- SMT QAM, "Quality Systems Program," Edition 2010, Revision 0, dated January 2010
- QP 79, "Quality Plan, EPR US 1 Project," Revision 5, dated May 12, 2010
- Procurement Specification BUHSFA/NGV0010, "Alloy 690 Thermally Treated ¾" OD Tubing for Steam Generators," Revision B, dated September 5, 2007
- AREVA Drawing 79/19TE, "Steam Generator Tube Bundle," Revision A, dated June 23, 2008
- CP 7965, "Hydrostatic Pressure Test," Revision 1, dated March 23, 2010
- CP 7961, "Sampling Plan," Revision 1, dated October 7, 2009
- CP 7901, "Lot Definition," Revision 0, dated September 3, 2009
- CP 7962, "Chemical Analysis," Revision 1, dated November 19, 2009
- CP 7974, "Surface Roughness Control," Revision 1, dated October 9, 2009
- CP 7963, "Tensile Test at Room Temperature," Revision 1, dated October 9, 2009
- CP 7964, "Tensile Test at 343°C," Revision 3, dated April 12, 2010
- CP 7967, "Flaring Test," Revision 1, dated October 9, 2009
- CP 7968, "Micro Tests," Revision 2, dated May 28, 2010

- CP 7969, “General and Intergranular Attack,” Revision 0, dated September 14, 2009

b. Observations and Findings

Section 8, “Control of Examinations, Tests, and Nonconforming Material,” of the SMT QAM establishes the responsibilities and requirements for the control of testing activities. The program is designed to ensure testing shows that an item will perform according to established criteria. Specific work instructions (CPs) and job cards specify the characteristics to be examined and the methods.

b.1 In-Process Test Control

The NRC inspection team reviewed and evaluated test procedures and observed mechanical, chemical, and metallurgical testing that SMT personnel performed on SG tubes in production. Specifically, the NRC inspection team verified that test procedures identified the objectives, requirements, prerequisites, and acceptance criteria in accordance with the ASME Code and the purchase specification. The NRC inspection team also verified that test results were documented and evaluated by qualified individuals to ensure the requirements were satisfied.

b.1.1 Mechanical Testing

The NRC inspection team reviewed procedures for tensile testing and confirmed that the requirements for yield strength, tensile strength, and elongation meet the requirements for Alloy 690 tubing in ASME Section II and the more restrictive EPRI tube specification guidelines referenced in the purchase specification. The NRC inspection team also reviewed test procedures for hydrostatic testing, flare testing, and the surface roughness testing of the tube internal and external surfaces. The NRC inspection team confirmed that the hydrostatic test pressure and time were consistent with ASME Section II requirements and that the procedure included EPRI water quality requirements and post-test drying.

The NRC inspection team observed room-temperature tensile testing, tube-end flare testing, surface roughness testing, and hydrostatic testing. During the testing the NRC inspection team discussed implementation of the associated procedures with the test personnel and confirmed their certifications. The NRC inspection team also verified that test equipment calibration tags were valid. Based on the observations and interactions with SMT personnel, the NRC inspection team concluded the testing was performed according to the procedures using properly calibrated instruments, and that the test results met the requirements listed in the procedures.

b.1.2 Metallography and Chemical Analysis

The NRC inspection team reviewed procedures for chemical analysis and metallography (i.e., grain size, carbide distribution, inclusions). The NRC inspection team verified that the acceptable chemical composition in the procedures met the EPRI tube specification guidelines referenced in the purchase specification. Hence the chemistry was also more restrictive than the ASME Section II requirements. The NRC inspection team also confirmed that the chemical analysis was performed according to active and appropriate ASTM standards. The metallography procedures included requirements consistent with the EPRI tube specification guidelines, such as grain size and carbide distribution. The NRC

inspection team confirmed that the personnel performing the testing and analysis were properly certified.

The NRC inspection team discussed sample preparation and optical metallography procedures with lab personnel. The NRC inspection team also discussed chemical analysis and scanning electron microscopy with chemistry lab personnel and verified that the correct procedures and reference microphotographs were being used. The NRC inspection team also observed reference samples and accompanying certificates. The NRC inspection team determined that samples were evaluated according to the ASTM procedures, EPRI tube specification guidelines, or reference photographs in the procedures, as appropriate.

b.2 Test Records

The NRC inspection team reviewed several in-process test record files and completed records. The completed records were for an earlier SG replacement project. The files included heat treatment records, chemical analysis, mechanical tests, and metallurgical tests. The NRC inspection team verified that test records included the documentation required by the test procedures, such as the test equipment information and test data. Based on these observations, the NRC inspection team found SMT's test record control was adequate and effectively implemented.

b.3 Training and Qualification

The NRC inspection team observed test personnel performing test activities and discussed issues with them related to the test procedures and tests they were conducting. The NRC inspection team determined the test personnel understood the test responsibilities and test instructions, verified the accuracy of test equipment before performing tests, recorded test data in accordance with instructions, and followed the test procedures. Based on discussions with engineers, lab supervisors, and test performers, and on reviewing a sample of training records, the NRC inspection team confirmed that the SMT staff designated to perform various test functions were qualified accordingly.

c. Conclusions

The NRC inspection team concluded that the implementation of the SMT program for test control is consistent with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50. Based on the sample of test control documents reviewed and activities observed, the NRC inspection team concluded that the SMT is effectively implementing its QAM and the associated test control procedures.

6. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed the implementation of SMT process for control of measuring and test equipment (M&TE). Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of SMT process to verify compliance with Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. The NRC inspection team walked down the Tube Mill 68 shop floor to verify that measuring and testing equipment contained stickers that identified the calibration period. The NRC inspection team interviewed personnel responsible for the control and calibration

of M&TE, reviewed the calibration history for a sample of Tube Mill 68 M&TE and reviewed the qualifications of calibration personnel.

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

- QAM 8.2, "Control of Measuring and Test Equipment"
- Q11-0021, "Control of monitoring and measuring equipment - guidelines for calibration of instruments and measuring equipment," Revision 12, dated January 11, 2010
- Q11-0030, "Control of monitoring and measuring equipment - qualification of personnel to carry out calibration," Revision 6, dated April 2, 2009
- Deficiency Report (DDR) 7601, Revision 1, dated June 6, 2009
- DDR 7602, Revision 1, dated June 6, 2009
- SPPC-10-002, "Arbetsrutiner (Kalibrering) – Kalibrering av Temperaturgivare," Revision 2, dated June 20, 2001

b. Observations and Findings

QAM Sections 8.2 and 8.3 establish program requirements for the control and calibration of M&TE and the process for documenting and evaluating the effect of discrepant M&TE. The QAM provides controls to ensure that calibrations are conducted against known reference standards traceable to national standards or to industrial standards. Calibration labels must be attached to all instruments after calibration. Calibration records must capture all calibration results and are stored in the computer system, SANMETRO, or on record cards.

The NRC inspection team noted that in case of out of calibration, and if repair is necessary, this is documented on the record. If M&TE is found out of calibration at any time, this is reported in writing and the equipment is segregated. For material on which discrepant M&TE was used, the quality management determines whether this may have influenced quality and if it would have, the material is considered nonconforming. If the material has been shipped, the customer is notified. Retesting or re-inspection or other corrective action may be performed if both SMT and the customer agree.

Q11-0021 gives guidelines for calibration of instruments and measuring equipment, including instructions for control of calibration activity. Q11-0021 states that SMT shall meet calibration requirements stated in the QAM, which correspond to the requirements of QA calibration standards such as ASME Section III, Subsection NCA-3800, and International Organization for Standardization (ISO), ISO-9001, "Quality Management Systems - Requirements." Leased or hired equipment shall have the same requirements applied to them.

Q11-0030 gives the general qualification requirements for personnel carrying out calibration of instruments and measuring equipment. General requirements include:

- General knowledge of ISO 9001, SS-EN ISO 10012, "Metrological Confirmation" and applicable calibration instructions

- Knowledge of SMT's calibration system, requirements regarding documentation, traceability, nonconformance reporting

- Having undergone suitable in-house or external training for the calibration equipment concerned

- Practical experience through induction under guidance from an already qualified person

- Being familiar with the activity/processes where the calibration equipment is used

Records of training include: personal data, scope of qualification, background experience, and training.

The NRC inspection team observed activities in the calibration laboratory, selected a representative sample of M&TE identified on test records, travelers, and instrument equipment lists for in-process job orders, and reviewed their calibration records for consistency and compliance to established procedures. The NRC inspection team verified that the laboratory M&TE were calibrated using procedures traceable to known industry standards and traceable to certified equipment that has known valid relationships to nationally recognized standards. The NRC inspection team also verified that the M&TE selected as a sample had appropriate calibration stickers and current calibration dates, including calibration due dates, and that the records were available for review. Calibration records indicated that calibration procedures were followed; these records included information on as-found or as-left conditions, the accuracy required, the date of calibration, and the due date for recalibration. The NRC inspection team also reviewed the process for identifying and segregating equipment that is out of calibration or beyond repair. The NRC inspection team verified that SMT maintained adequate identification and segregation of out-of-tolerance equipment, and verified, through observation of ongoing calibration activities, that M&TE personnel who performed equipment calibration activities properly documented results and adequately labeled, handled, and stored calibration equipment.

c. Conclusions

The NRC inspection team concluded that the implementation of the SMT program for control of M&TE is consistent with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. Based on the limited sample of calibration records reviewed, evaluation of controls established within the SMT calibration laboratory, and a walk down of Tube Mill 68, the NRC inspection team determined that SMT is effectively implementing its QAM and the associated M&TE procedures.

7. Handling, Storage, and Shipping

a. Inspection Scope

The NRC inspection team reviewed the implementation of SMT process for control of handling, storage, and shipping. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of SMT process to verify compliance with Criterion XIII, "Handling, Storage, and Shipping," of Appendix B to 10 CFR Part 50.

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

- QAM 7.3, “Handling, Storage, Shipping Preservation,” Revision 0, dated January 2010
- CP 7901, “Contamination Surveillance Program,” Revision 0, dated September 18, 2009
- CP 7944, “Packing,” Revision 0, dated October 16, 2009
- CP 7945, “Storage Prior to Shipment,” Revision 1, dated October 7, 2009
- DDR 6301 Revision 0, dated April 27, 2004
- Kontrollblad 4-4263, “EPR US 1 Labor,” Revision 0 dated March 23, 2010
- QA Inspection of U-Bent Tubes Checklist
- BUHSFA/NGV0010, “Procurement Specification Alloy 690 Thermally Treated 3/4" OD Tubing For Steam Generators,” Revision B, dated September 25, 2007

The NRC inspection team also reviewed a sample of travelers and observed handling, storage, and shipping activities at the SMT manufacturing facility to verify effective implementation of such requirements.

b. Observations and Findings

Section 7.3 of the SMT QAM states that for tube products, a packing guide describes the various types of packing which are used for tube products to provide transportation protections, moisture barriers, and product protection. Information to be used is given on the mill order which is available at packing station.

CP 7944 describes the packing of U-bent tubes. The tubes for one SG are packed in accordance with the Areva tube bundle drawings as specified in PO 08/51892. The procedure includes instructions for the box design, inspection criteria prior to packing, the packing sequence, labeling and position of tubes, final packaging, control and inspection of final packing, lifting instructions, transportation instructions, and unpacking instructions.

Kontrollblad 4-4263 EPR US 1 Labor includes a list of items on which the supplier of the shipping containers is required to check and sign off. The procedure includes a detailed list of items such as dimensions, materials, cleanliness, requirements for positions of nails and screws.

CP 7945 describes the intermediate storage and box handling prior to packing. CP 7945 includes specifications on location, temperature and humidity control, handling instructions, and an inspection once every two weeks.

QA Inspection of U-bent Tubes Checklist includes QA inspection activities per row of tubes for the U.S. EPR project. The checklist includes checking the packing of each row and the final inspection of the box.

CP 7901 describes the Tube Mill 68 cleanliness requirements including a list of material in physical contact with the final size tubes. This procedure describes the contamination

control program regarding material that may come in contact with tubing during the manufacturing, testing, inspection, cleaning, and packaging process. CP 7901 includes requirements for plant cleanliness, a list of acceptable material coming into physical contact with the final size tubes, documentation requirements, and a list of detrimental materials and their allowable limits.

The NRC inspection team verified that SMT had developed and implemented procedures and process controls to ensure the proper handling, storage, and shipping of materials. The NRC inspection team reviewed a sample of work orders, travelers, and check sheets that SMT prepared to control such activities. These documents specify steps for handling SG tubes throughout the production process and for preparing final shipping packages. These documents also include provisions for the in-process movement of materials, packaging, use of desiccants, preparation of shipment containers, exclusion of foreign materials, labeling, and shipment. Additionally, the NRC inspection team confirmed that prohibited items are identified and restricted from locations where SG tube material is handled and stored. In addition, the NRC inspection team reviewed a sample of chemical test reports to confirm that the material coming into contact with the tubes met the limits prescribed in the Areva PO 08/51892.

The NRC inspection team confirmed that SMT provided special equipment for the proper handling of SG tubes during production and verified that operators of special handling equipment are experienced and trained in the use of the equipment. The NRC inspection team also confirmed that SMT maintained adequate configuration control of the products, including detailed storage and arrangement facilities, and computer-assisted material tracking.

c. Conclusions

The NRC inspection team concluded that the implementation of the SMT program for handling, storage, and shipping is consistent with the regulatory requirements of Criterion XIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and observation of ongoing production activities at the SMT fabrication facilities, the NRC inspection team also determined that SMT is effectively implementing its QAM and the associated handling, storage, and shipping procedures. No findings of significance were identified.

8. Nonconforming Materials, Parts, or Components

a. Inspection Scope

The NRC inspection team reviewed the implementation of SMT process for control of nonconforming materials, parts, or components. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of SMT process 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), deficiency reports (DDRs), and material review board reports (MRBs) associated with the current and previous SG tube campaigns, and discussed the program with SMT personnel responsible for the implementation of the program.

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

- QAI Q13-0001, “Control of Non-Conforming Products – Dealing with and Reporting of Non-Conformances,” Revision 15, dated January 21, 2010

- QAI Q14-0001, “Corrective and Preventive Actions – Handling of Corrective Action,” Revision 13, dated January 4, 2010

- QAM, Section 8.5, “Control of Examinations, Tests and Nonconforming Material,” Revision 0, dated January 2010

- QAI Q11-0021, “Control of Monitoring and Measuring Equipment – Guidelines for Calibration of Instruments and Measuring Equipment,” Revision 12, dated January 11, 2010

- DDR 6301, “Packaging screw damages tubes,” dated September 25, 2006

- DDR 7403, “Bright annealing furnace temp exceeds high limit,” Revision 2, dated September 25, 2007

- DDR 7404, “Restraightening of two lots resulted in higher yield strength,” dated July 12, 2007

- DDR 7601, “Furnace Thermocouple Calibration,” dated June 9, 2009

- DDR 7602, “Calibration – portable reference conductivity gauge not in Sanmetro,” dated June 9, 2009

- DDR 7801, “Test Samples,” dated February 22, 2010

- MRB 7802, “Use of incorrect mass for hardness test,” Revision 1, dated March 30, 2010

- MRB 7803, “Reference photos removed,” Revision 1, dated March 30, 2010

- MRB 7804, “Inadequate procedure regarding notification of inspection authority when new SG production begins,” Revision 0, dated May 7, 2010

- Quality Management System Annual Report and Meeting Minutes of the Quality Management System For Steam Generator Tubes, dated March 15, 2010

- NCR 7302, “Archive sample small bend tubes,” dated July 18, 2007

- NCR 7301, ‘Use of probe pusher during multi-frequency inspection of u-bent tubing,’ dated May 23, 2007

b. Observations and Findings

The NRC inspection team noted that QAM Section 8.5 defined the process for the identification and documentation of nonconforming items. In addition, QAI Q13-0001, and QAI Q11-0021 describe the detailed actions required to implement the program which includes defining the roles and responsibilities of SMT personnel, establishing

documentation requirements, such as NCRs, DDRs, MRBs, identifying internal review processes, and establishing actions to address identified deficiencies.

The NRC inspection team verified that the nonconformance reporting methods adequately identified the equipment, location, calibration information, where applicable, the initiator and QA management reviewer, the affect of the identified deficiency, the justification for product acceptance, the evaluation completion date, and the acceptance of the issue resolution. The NRC inspection team also evaluated the processes SMT had in place to ensure that non-conforming materials were properly identified, marked, and segregated to ensure they were not re-introduced into the production processes. The NRC inspection team verified that SMT had adequate controls and segregation of in-process non-conforming materials. The NRC inspection team did not identify any significant findings in this area.

c. Conclusions

The NRC inspection team concluded that the implementation of the SMT 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 SMT fabrication facilities, the NRC inspection team also determined that SMT is effectively implementing its QAM and the associated nonconformance procedures. No findings of significance were identified.

7. Corrective Actions

a. Inspection Scope

The NRC inspection team reviewed the implementation of SMT process for corrective actions. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of SMT process to verify compliance with Criterion XVI, "Corrective Actions," of Appendix B to 10 CFR Part 50. In addition, The NRC inspection team reviewed a sample of corrective actions associated with DDRs, MRBs, and NCRs, and SMT Annual Reports of the SMT Quality Management System associated with the current and previous SG tube campaigns, and discussed the program with SMT personnel responsible for the implementation of the corrective action program.

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

- QAI Q14-0001, "Corrective and Preventive Actions – Handling of Corrective Action," Revision 13, dated January 4, 2010

- QAI Q13-0003, "Control of Non-Conforming Products Reporting of Defects and Deviations according to 10CFR21," Revision 9, dated May 20, 2010

- QAM, Section 9.2, "Corrective Actions," Revision 0, dated January 2010

- SMT Annual Report, 2009 Report and Meeting Minutes of the Quality Management System For Steam Generator Tubes, dated March 15, 2010

- DDR 6301, "Packaging screw damages tubes," dated September 25, 2006

- DDR 7403, “Bright annealing furnace temp exceeds high limit,” Revision 2, dated September 25, 2007

- DDR 7404, “Restraightening of two lots resulted in higher yield strength,” dated July 12, 2007
- DDR 7601, “Furnace Thermocouple Calibration,” dated June 9, 2009

- DDR 7602, “Calibration – portable reference conductivity gauge not in Sanmetro,” dated June 9, 2009

- DDR 7801, “Test Samples,” dated February 22, 2010

- MRB 7802, “Use of incorrect mass for hardness test,” Revision 1, dated March 30, 2010

- MRB 7803, “Reference photos removed,” Revision 1, dated March 30, 2010

- MRB 7804, “Inadequate Procedure regarding notification of inspection authority when new SG production begins,” Revision 0, dated May 7, 2010

- NCR 7302, “Archive sample small bend tubes,” dated July 18, 2007

- NCR 7301, “Use of probe pusher during multi-frequency inspection of u-bent tubing,” dated May 23, 2007

- SMT QA management tracking system for Projects for SG Tubes

b. Observations and Findings

The NRC inspection team noted that QAM Section 9.2 defines the processes for the identification and documentation of corrective and preventive actions. In addition, QAI Q14-0001 describes the detailed actions required to implement the corrective action program which includes defining the roles and responsibilities of SMT personnel, establishing documentation requirements such as corrective action reports (CARs), identifying internal review processes, and establishing preventive actions to address identified deficiencies and to preclude recurrence of such deficiencies.

QAI Q14-0001 provides additional requirements for SMT staff to use the Sandvik electronic corrective action database (C2) to record and process all CARs. The C2 system was developed by Sandvik to capture site wide corrective actions. However, the NRC inspection team determined that SMT was not implementing the C2 database, as required by QAI Q14-0001. In lieu of using the C2 system, the SMT ST Tubes QA Manager maintains a listing of the corrective actions in a tracking system entitled, “Projects for SG Tubes,” for internal tracking purposes only. This informal system did not, however, provide sufficient measures to ensure that regulatory requirements were adequately met. Specifically there are no formal methods defined in the SMT corrective action program and implementation of the program did not provide for: 1) a screening process for items identified within the corrective action program to identify significant conditions adverse to quality; 2) identifying and verifying timely corrective actions; 3) ensuring that issues identified within the corrective action program that may create a substantial safety hazard are evaluated for 10 CFR Part 21 applicability. The NRC inspection team identified these examples of failures to

implement the regulatory requirements relevant to the corrective action program as Nonconformance 99901326/2010-201-02.

c. Conclusions

The NRC inspection team concluded that the implementation of the SMT 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 99901326/2010-201-02 for SMT's failure to record and process corrective action reports within the C2 electronic system as required by QAI Q14-0001. As a result, SMT's corrective action program lacks measures to ensure that regulatory requirements were adequately met.

10. Entrance and Exit Meetings

On May 31, 2010, the NRC inspection team discussed the scope of the inspection with Mr. Jan-Erik Sundstrom, General Manager – Steam Generator Tubing, Sandvik Materials Technology, and with the Sandvik management, engineering, and production staff. On June 4, 2010, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Sundstrom and other SMT 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

Name	Title	Affiliation	Entrance	Exit	Interviewed
Patric Hogstrom	Production Manager	SMT	X	X	X
Ola Tornstrom	Quality Engineer	SMT	X	X	X
Per-Olof Lund	QA Manager SG Tubing	SMT	X	X	X
Tomas Alexa	Marketing, Project Coordinator	SMT	X		X
Thomas Larsson	Quality Engineer	SMT	X	X	X
Jan-Erik Sundstrom	General Manager SG Tubing	SMT	X	X	X
Magnus Larsson	NDE Manager	SMT	X	X	X
Peter Ekstrom	Senior Analyst	SSM	X	X	
Mark Cederberg	Senior Advisor	STUK	X	X	
Johan Frodigh	Technique & Development SG Tubing	SMT			X
Andreas Rosberg	Technique & Development SG Tubing	SMT			X
Helge Elfstrom	QA Engineer	SMT			X
Anders Sjoden	Lead Auditor	SMT			X
Hakan Coyet	QC Inspector	SMT			X
Roger Wallin	QC Inspector Trainee	SMT			X
Sofia Kadberg	Syning/Visual Control Inspector	SMT			X
Emma Nyberg	Syning/Visual Control Inspector	SMT			X
Maria Forsberg	Syning/Visual Control Inspector	SMT			X
Ove Olsson	Engineer – SG Tubes	SMT			X
Par Soderman	NDE personnel	SMT			X
Ula Nyberg	NDE personnel	SMT			X
Peter Olafsson	Manager, Calibration Center	SMT			X
Lars Bergquist	Supervisor, Mechanical Testing Facility	SMT			X
John He	Supervisor, Mechanical Testing Facility	SMT			X

Andreas Bjornson	Surface Roughness Test Performer	SMT			X
Sven-Erik Larsson	Tube Flaring Test Performer	SMT			X
Alf Flater	Tensile Test Performer	SMT			X
Peter Henningsson	Project Engineer, Chemical Analysis Laboratory	SMT			X
Helena Enstedt	Chemical Analyst	SMT			X
Birgitta Lingborg	Supervisor, Chemical Analysis Laboratory	SMT			X
Anna Carlstrom Wangehn	Chemical Analyst	SMT			X
Lars-Erik Pippola	Heat Treatment Performer	SMT			X
Rolf Wikstrand	Heat Treatment Performer	SMT			X
Sörla Brodin	Electron Microscopist	SMT			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:

Item Number	Status	Type	Description
99901326/2010-201-01	Open	NOV	21.21
99901326/2010-201-02	Open	NON	Criterion XVI