August 28, 2009

Mr. Patrick Trioen
Quality Assurance Manager
Creusot Forge
56 Rue Clemenceau
BP 112
71203 Le Creusot, France

SUBJECT: NRC INSPECTION REPORT NO. 99901381/2009-201 AND NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE

Dear Mr. Trioen:

From July 20 to July 24, 2009, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Creusot Forge facility in Le Creusot, France. The enclosed report presents the results of this inspection. This was a limited scope inspection, which focused on assessing your 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 Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." This NRC inspection report does not constitute NRC endorsement of your overall quality assurance or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC staff has identified a Severity Level IV violation of NRC requirements. The violation is cited in the enclosed Notice of Violation (NOV) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the NOV because NRC inspectors identified that Creusot Forge failed to meet the requirements set forth in 10 CFR Part 21 for implementing a procedure to evaluate deviations and failures to comply, and for imposing Part 21 in procurement documents.

You are required to respond to this letter with respect to the above violation and should follow the instructions specified in the enclosed NOV 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.

During this inspection, NRC inspectors also found that implementation of your quality assurance program failed to meet certain NRC requirements imposed on you by your customers. Specifically, the NRC inspectors noted that Creusot Forge failed to require the calibration of the temperature measuring thermocouples for the temperature baths for the impact tests to conform to ASME Code, Section III, Subsection NB-2360, and failed to use the current edition of the Creusot Forge Quality Assurance Manual for the conduct of internal audits in accordance with documented procedures. The specific findings and reference to the pertinent requirements are identified in the enclosures to this letter.

Please provide a written statement or explanation with respect to the nonconformances within 30 days from the date of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance. 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 from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or Safeguards Information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material 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.: 99901381

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report 99901381/2009-201

Please provide a written statement or explanation with respect to the nonconformances within 30 days from the date of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance 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 from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or Safeguards Information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material 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.

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DATE	08/24/2009	08/26/2009	08/26/2009	08/27/2009
OFFICE	CAET/DCIP/NRO	BC:CQVP/DCIP/NRO		
NAME	RPascarelli	JPeralta		
DATE	08/27/2009	08/28/2009	/ /2009	

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NOTICE OF VIOLATION

Creusot Forge
Le Creusot, France

Docket Number 99901381
Inspection Report No. 99901381/2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted July 20-24, 2009, of activities performed at the Creusot Forge facility at Le Creusot, France, 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.

Title 10, Section 21.31, Procurement Documents, requires that each entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

Contrary to the above, as of July 24, 2009, the Creusot Forge 10 CFR Part 21 implementing procedure IN 004, "Reporting of Defects in Accordance with 10 CFR Part 21," Revision 3, dated May 29, 2007, 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 Creusot Forge'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 Creusot Forge 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). In addition, Creusot Forge did not impose 10 CFR Part 21 requirements on purchase orders for safety-related ingots.

This issue has been identified as Violation 99901381/2009-201-01.

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

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," Creusot Forge 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 (1) the reason for the violation, or, if contested, the basis for disputing the violation, (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 through the NRC Agencywide Documents Access and Management System (ADAMS), to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/readingrm/adams.html. 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 28th day of August 2009

NOTICE OF NONCONFORMANCE

Creusot Forge
Le Creusot, France

Docket Number 99901381
Inspection Report No. 99901381/2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted July 20 – July 24, 2009, of activities performed at Creusot Forge, certain activities were not conducted in accordance with NRC requirements, which were contractually imposed upon Creusot Forge.

A. Criterion XII, "Control of Measuring and Test Equipment," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that measures shall be established to ensure that tools, gauges, 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.

Section 58.2 of the Creusot Forge Quality Assurance Manual (QAM) , "Control of Measuring and Test Equipment," Edition 5, Revision 0, dated December 18, 2008, states, in part, that, a determination shall be made for each type of device of the required frequency of calibration and/or checking, either on the basis of use, of time, or a combination of use and time.

American Society of Mechanical Engineers (ASME) Code Section III, Subsection NB-2360, "Calibration of Instruments and Equipment," requires that temperature instruments used to control test temperature of specimens shall be calibrated and the results recorded to meet the requirements of NCA-3858.2, applicable to material examination, at least once in each three month interval.

Contrary to the above, as of July 24, 2009, Creusot Forge failed to require the calibration of the thermocouples used to measure the temperature baths for the Charpy V-notch impact tests as required by ASME Code, Section III, Subsection NB-2360. Specifically, thermocouples BFC/VN/09JU1 and BFC/VN/09JU2 were last calibrated on June 23, 2009, and were not scheduled to be recalibrated for one year.

This issue is identified as nonconformance 99901381/2009-201-02.

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 Juan Peralta, 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 non-compliances; and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to 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 document system (ADAMS), 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 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.

Dated this 28th day of August 2009.

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

Docket No.:	99901381
Report No.:	99901381/2009-201
Vendor:	Creusot Forge 56 Rue Clemenceau BP 112 71203 Le Creusot, France
Vendor Contact:	Patrick Trioen Manager, Quality Assurance Phone: +33 (0)3 85 80 07 73 Fax: +33 (0)3 85 80 73 56 patrick.trioen@areva.com
Nuclear Industry:	Creusot Forge is an American Society of Mechanical Engineers (ASME) Quality System Certificate Holder currently manufacturing EPR reactor pressure vessel and steam generator forgings for the AREVA Chalon/Saint Marcel manufacturing facility.
Inspection Dates:	July 20 – July 24, 2009
Inspection Team Leader:	Kerri Kavanagh, CQVP/DCIP/NRO
Inspectors:	Ken Heck, CQVP/DCIP/NRO Milton Concepcion, CQVP/DCIP/NRO John Honcharik, CIB1/DE/NRO
Approved by:	Juan Peralta, Chief, Quality and Vendor Branch 1 Division of Construction Inspection and Operational Programs Office of New Reactors

EXECUTIVE SUMMARY

Creusot Forge
99901381/2009-201

The purpose of this inspection was to review selected portions of Creusot Forge's quality assurance (QA) and 10 CFR Part 21 (Part 21) programs. The inspection was conducted at Creusot Forge's facility in Le Creusot, France.

The NRC inspection bases were:

- 10 CFR Part 21, "Reporting of Defects and Noncompliance" and
- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations*

The French counterpart to the NRC, the Autorite de Surete Nucleaire (ASN), observed the inspection, thus fostering the sharing of international experiences regarding the construction of new reactors, oversight of vendors, and modular construction techniques consistent with the objectives of the Multinational Design Evaluation Program (MDEP).

This is the first NRC inspection performed at the Creusot Forge facility in Le Creusot, France. The results of this inspection are summarized below.

10 CFR Part 21 Program

The NRC inspectors cited Violation 99901381/2009-201-01 based on inadequate procedural guidance to implement the requirements of Part 21. Specifically, Creusot Forge's Part 21 implementing procedure did not include 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 Creusot Forge's responsible officer within 5 days when it is determined that a defect exists that could cause a substantial safety hazard; 4) notifying the affected purchasers or licensees if Creusot Forge 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). In addition, Creusot Forge did not impose Part 21 requirements in purchase orders for safety-related ingots.

Control of Purchased Material, Equipment and Services

The NRC inspectors concluded that Creusot Forge had established appropriate and effective means to control purchased material, equipment, and services consistent with the regulatory requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Control of Special Processes

The NRC inspectors concluded that Creusot Forge control of special processes, such as forging, heat treatment, nondestructive examination, and mechanical testing, was consistent with Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50, and ASME Code requirements. The NRC inspectors concluded that Creusot Forge's implementation of

these processes and practices provided appropriate controls. No findings of significance were identified.

Control of Measuring and Test Equipment

The NRC inspectors issued Nonconformance 99901381/2009-201-02 for Creusot Forge's failure to require the calibration of thermocouples used to measure the temperature of Charpy V-notch impact specimens at intervals consistent with the ASME Code. With the exception of the above noted nonconformance, the NRC inspectors concluded that Creusot Forge had established appropriate and effective means to control measuring and test equipment consistent with the regulatory requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50.

Handling, Shipping and Storage

The NRC inspectors concluded that Creusot Forge control of handling, shipping, and storage was consistent with the regulatory requirements of Criterion XIII, "Handling, Shipping, and Storage," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Nonconforming Material, Parts, or Components

The NRC inspectors concluded that Creusot Forge had established appropriate and effective means to control nonconforming material, parts, or components consistent with the regulatory requirements of Criterion XV, "Nonconforming Material, Parts or Components," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Corrective Action

The NRC inspectors determined that Creusot Forge's corrective action program was consistent with the regulatory requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Audits

The NRC inspectors concluded that Creusot Forge had established appropriate means to conduct internal audits consistent with the regulatory requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part50.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspectors reviewed the Creusot Forge Quality Assurance Manual (QAM) and implementing policies and procedures that govern the 10 CFR Part 21 (Part 21) process to determine compliance with 10 CFR Part 21, "Reporting of Defects and Noncompliance." Specifically, the NRC inspectors focused on Quality Procedure IN 004, "Reporting of Defects in Accordance with 10 CFR Part 21," Revision 3, dated May 29, 2007. The NRC inspectors also reviewed procurement documents and the following Creusot Forge procedures to verify the implementation of the requirements of Part 21.

- Procedure PRM 004, "Control of Nonconformances," Revision 5, dated March 31, 2006
- Procedure PRM 005, "Corrective Action," Revision 3, dated March 31, 2006

b. Observations and Findings

b.1 Postings

The NRC inspectors observed that Creusot Forge had posted notices in different locations within the facility. Each location 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 individuals to whom reports may be made.

b.2 Part 21 Procedure

Section 58.5 of the Creusot Forge QAM assigns the QA manager the responsibility and authority to notify the NRC of nonconformances associated with forgings to ensure compliance with Part 21. Procedure IN 004 implements the requirements of the QAM and describes Creusot Forge's Part 21 process. IN 004 assigns responsibilities to all employees to notify the methods/quality control (QC) manager of any defect on a product. The methods/QC manager performs and documents the evaluation to determine if the identified condition is a substantial safety hazard. IN 004 also describes the information required to be documented in the written report. Additionally, IN 004 states that the QA manager will notify customers of substantial safety hazards and ensure that postings of the Part 21 regulations are posted within the plant. Finally, the sales manager is responsible to submit the written report to customers within 5 days after the defect notification.

The NRC inspectors noted that Creusot Forge had not performed any Part 21 evaluations in the past 2 years. The NRC inspectors reviewed IN 004 and discussed it with the QA director, QA manager, and senior management. During the discussion, the NRC inspectors 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 to IN 004. In addition, the NRC inspectors noted that Section 58.5 of the QAM and IN 004 were not consistent with the regulatory requirements of Part 21. The NRC inspectors observed that IN 004 states that the QA manager will notify customers of substantial safety hazards (instead of the NRC) and assigns the sales manager to provide written reports of "defects" to customers. Furthermore, Section 6.3.4 of IN-004 states that the QA manager will notify the NRC of nonconformances, instead of defects or

failures to comply that could cause a substantial safety hazard. Specifically, the NRC inspectors determined that IN 004 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."

For example, IN 004 does not provide the following evaluation requirements:

a) 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).

b) 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).

c) Guidance is not provided to inform the Creusot Forge'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).

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

e) 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 inspectors also observed, through the review of Creusot Forge procurement documents, that none of the purchase orders issued to the supplier of ingots (i.e., basic components) imposed Part 21 requirements as required in §21.31, "Procurement Documents." As discussed in Section 3 of this report, Creusot Forge imposed supplemental QA requirements for each procured ingot using instruction CF INS034 and CF INS035. The NRC inspectors noted that these supplemental instructions included the imposition of Part 21 requirements. However, the imposition of Part 21 requirements in supplemental QA documents is not consistent with the regulatory requirements of §21.31.

The NRC inspectors identified the lack of procedural guidance to evaluate deviations or failures to comply and the failure to impose Part 21 requirements in safety-related purchase orders as Violation 99901381/2009-201-01.

c. Conclusions

The NRC inspectors issued Violation 99901381/2009-201-01 for Creusot Forge's failure to adopt appropriate procedures pursuant to 10 CFR 21.21 and for its failure to impose 10 CFR Part 21 requirements in procurement documents for basic components. The NRC inspectors determined that procedure IN 004 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 Creusot Forge'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 Creusot Forge 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 Manufacturing Process (Order Entry)

a. Inspection Scope

The NRC inspectors reviewed the Creusot Forge QAM, policies, and implementing procedures that govern the control of order entry to verify compliance with the requirements of Criterion III, "Design Control" of Appendix B to 10 CFR Part 50. Order entry is the initial phase of the manufacturing process. At the time of the inspection, Creusot Forge had orders for 20 EPR forgings for the U.S. market. Specifically, the NRC inspectors reviewed the following policies and procedures established by Creusot Forge and the quality plans and technical appendixes related to heavy forgings under contract for US EPRs:

- Creusot Forge, CF MQ003, "Creusot Forge Quality Assurance Manual," Edition 5, Revision 0, December 18, 2008
- SFARSteel PRO016, "Inquiries and Orders Documents" Revision 3, July 13, 2006
- PRO017, "Order Review and Release," Revision 5, July 13, 2006
- PRO020, "Quality Plan and Customer Notification," Revision 3, November 4, 2005
- Reactor Vessel Closure Head heat number Z5653/Z5654 quality plan PQ 1020, Revision C, March 17, 2009
- Reactor Vessel Transition Ring heat number Z5650/Z5651 quality plan PQ 1029, Revision C, April 10, 2009
- Steam Generator Lower Shell heat number Z5638/Z5639 quality plan PQ 1018, Revision C, March 13, 2009
- Steam Generator Intermediate Shell heat number Z5687/Z5688 quality plan PQ 1020, Revision C, April 10, 2009
- Steam Generator Upper (High) Shell heat number Z5657/Z5658 quality plan PQ 1019, Revision D, May 5, 2009
- Technical Appendix AT 001 dated October 2008
- Technical Appendix AT 003 dated May 4, 2009

b. Observations and Findings

Section 54 of the Creusot Forge QAM describes the order review and release for manufacture of heavy forgings. SFARSteel procedure PRO017 describes the process for the review of inquiries, contracts or orders and order amendments. In particular, the sales manager is responsible for the issuance of the technical appendix and distribution of the customer specifications and drawings with their revisions.

The sales manager is also responsible for reviewing the order which consists of 1) performing a complete and systematic review of the requirements; 2) identifying any deviations between the inquiry and the order as well as any comments following the review; 3) submitting to the customer any deviations, comments or requests for information; 4) performing wherever necessary a further complete review of the subsequent customer decisions; and 5) accepting the order when deviations and comments are closed out and accepted between Creusot Forge and its customers. The QA manager is responsible for the review and acceptance of the order

for application of codes, including ASME Code Section II and applicable paragraphs of the ASME Code Section III.

The NRC inspectors noted that the technical appendix is a form used by Creusot Forge for technical review of an inquiry and/or order and that the release review and the technical appendix are quality records. The release review documents the release of an item for forging.

Procedure PRO020 describes the measures implemented for preparation, review, approval and use of the quality plan. The NRC inspectors observed that the quality plan is the transcription of the list of manufacturing and examination operations. The quality plan may be provided by the customer or prepared upon the customer's request. The inspection and test status is documented in the quality plan to include 1) records of the required inspection and the test report numbers; and 2) notification of conformance or the identification of the relevant nonconformance reports (NCR) in case of nonconformance. The QC coordinator is in charge of checking the status of the inspections and test, which consists in the satisfactory review of the following elements: 1) compliance of final marking; 2) satisfactory completion of all operations, as required by the quality plan; 3) compliance of inspection, examination and test results; 4) full treatment of nonconformances, if any; and 5) issue of the Certificate of Compliance (CofC) or Certified Material Test Report (CMTR) for Creusot Forge ASME orders.

The NRC inspectors reviewed the quality plans and technical appendixes for the following US EPR components:

- Reactor Vessel Closure Head (RVCH) heat number Z5653/Z5654
- Reactor Pressure Vessel (RPV) Transition Ring heat number Z5650/Z5651
- Steam Generator (SG) Lower Shell heat number Z5638/Z5639
- SG Intermediate Shell heat number Z5687/Z5688
- SG Upper (High) Shell heat number Z5657/Z5658

The NRC inspectors determined that the quality plans and technical appendixes were complete and contained the required information specified in the Creusot Forge procedures.

c. Conclusions

The NRC inspectors concluded that the Creusot Forge policies and procedures for order entry were consistent with the requirements of Criterion III of Appendix B to 10 CFR Part 50. The NRC inspectors also concluded based on the records reviewed, that Creusot Forge personnel were implementing these policies and procedures effectively.

3. Control of Purchased Material, Equipment, and Services

a. Inspection Scope

The NRC inspectors reviewed the Creusot Forge QAM, policies, and implementing procedures that govern the control of purchased material, equipment, and services to verify compliance with the quality assurance requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by Creusot Forge to select, qualify, and oversee suppliers of material and services:

- Creusot Forge QAM, Section 55, "Control of Purchased Materials, Source Materials, and Subcontracted Services," Edition 5, Revision 0, dated December 18, 2008
- Procedure PRS 031, "Control of Purchased Materials, Source Materials, and Subcontracted Services," Revision 5, dated April 4, 2008
- Instruction for the supply of ingots, No. CF INS034, "Prescription Approvisionnement Lingots," Revision 2, dated September 22, 2008
- Applicability Matrix of the Quality Prescription CF INS 034—CF INS 035, "Grille D'Applicabilite de la Prescription Qualite—Relation Forge/Aciére," Revision 0, dated September 22, 2008

The NRC inspectors also reviewed a sample of source reviews, receipt inspection reports, material procurement documents, and external audits to evaluate the adequacy of Creusot Forge's measures for verifying the attributes and quality of purchased material.

- Purchase Order (P.O.) No. 8837 for an ingot weighing 171.6 tons; to be forged into a RCS hot leg; Commande C.F. No. 87711008; dated January 30, 2008
- P.O. No.: 8838 for an ingot weighing 170.3 tons; to be forged into a replacement nozzle shell; Commande C.F. No. 85621023; dated February 26, 2008
- P.O. No. 8839 for an ingot weighing: 84.0 tons; to be forged into RCS piping pressurizer and steam generator (coolant pump piping); Commande C.F. No.: 85091012; dated February 12, 2008
- P.O. No. 8840 for an ingot weighing 76.4 tons; to be forged into RCS piping pressurizer and steam generator (coolant pump piping); Commande C.F. No's.: 85091019 and 85091022; dated January 30, 2008
- P.O. No. 9098 for an ingot weighing 156.9 tons; to be forged into a lower head; Commande C.F. No.: 88781003, dated February 20, 2009
- Audit Report No. 20080519, Revision 0, conducted on June 18-19, 2008
- Audit Report No. 20070604, Revision 0, conducted on June 4-5, 2007

b. Observations and Findings

b.1 Policies and Procedures for Supplier Selection and Control

The NRC inspectors noted that QAM Section 55 defines the control system used to assure that purchased material, source material, and subcontracted services conform to the applicable requirements of the ASME Code and customer purchase orders. QAM Section 55 provides details describing the general requirements, responsibilities, and controls associated with the control of suppliers of source materials and services. Section 55.3 of the QAM provides measures for the approval and control of suppliers and describes the assessment process used by Creusot Forge to conduct technical and/or QA audits as required. The assessment process allows Creusot Forge to verify, based on a documentary evaluation and audit, that: 1) suppliers are capable to meet the procurement quality requirements; 2) provisions delineated in QA program are implemented by suppliers; and 3) periodic evaluations assess the quality system effectiveness and improvements in supplier's quality-related activities. Section 55.4 of the QAM describes the controls for the purchase of ingots and source materials, including the controls to ensure that procurement documents are prepared, approved, and reviewed by designated individuals. Controls also provide for purchase order revisions and modifications to ensure that procured documents are prepared, reviewed, and approved in the same way as original documents. The QAM further states that operations and/or services are required to be subcontracted by using a subcontracting specification or a work request which contains all

requirements for performing operations and/or services. Section 55.5 of the QAM contains measures for the utilization of unqualified ingots or source material. The NRC inspectors noted that although Creusot Forge is allowed per Section III of the ASME Code to utilize or furnish unqualified source material, Creusot Forge had not utilized or provided unqualified source material.

Procedure PRS 031 describes the steps for evaluation, assessment, and approval of suppliers. PRS 031 explains the process for evaluating suppliers, taking into account the quality aspect and the technical capability of suppliers to provide the products or services. PRS 031 also provides controls for source selection, evaluation of objective evidence, audit requirements, and receipt inspections activities upon delivery of items and services.

b.2 Maintenance of the Approved Supplier List

According to Section 55.3 of the QAM, the approved supplier list (ASL) is maintained, distributed, and periodically updated by the QA manager. The QA manager is also responsible for reviewing the results of audits and approving the addition and deletion of suppliers to/from the list. The NRC inspectors reviewed Creusot Forge's ASL and noted that only one approved metal supplier (Industeel Creusot, an ASME NCA-3800 Certificate Holder) and 10 approved suppliers of services (calibration, metallurgical analyses, machining operations) are on the ASL. In addition, the NRC inspectors observed that the ASL documented: 1) the name and address of the supplier; 2) name and address of facilities or premises where the work is performed; 3) scope of the assessment (products or services provided by the supplier); 4) applicable quality system requirements and/or applicable QA program; 5) assessment classification; 6) remarks on the assessment; 7) conditions on the assessment (if any); 8) third party certificate expiration date (e.g., ASME, ISO, etc.) of registered supplier and facilities; 9) last audit or evaluation date; and 10) assessment validity (next audit or evaluation date), which prevents placing an order if the supplier approval has expired. The NRC inspectors verified the listings from the ASL database and cross-referenced the information with applicable audit reports (or documentation) furnished by Creusot Forge. The NRC inspectors also verified that suppliers listed on the ASL remained in good standing.

b.3 Creusot Forge Purchase Orders

The NRC inspectors reviewed procurement controls to verify compliance with QAM requirements. The NRC inspectors 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 inspectors confirmed that: 1) purchase orders are reviewed and approved by responsible personnel; 2) technical and quality requirements are imposed in purchase orders; and 3) Creusot Forge verifies that Industeel Creusot complies with purchase order requirements.

The NRC inspectors noted that Creusot Forge has a contract in place with Industeel Creusot for the exclusive supply of ingots. As part of this contractual relationship, Creusot Forge imposed supplemental QA requirements for each procured ingot using instructions CF INS034 and CF INS035. These instructions provide the general requirements applicable to Creusot Forge and Industeel Creusot for forgings, castings, and projects to be forged; and describe the responsibilities for the implementation of QA requirements and industry codes and standards during the preparation of ingots. In addition, the NRC inspectors reviewed documentation that showed that Industeel Creusot accepted the requirements imposed by Creusot Forge.

b.4 Supplier Audit Reports

The NRC inspectors reviewed a sample of external audits to verify Creusot Forge's approval process of metal supplier, Industeel Creusot. The NRC inspectors noted that the audits reviewed were adequately documented and provided evidence of Industeel Creusot's compliance with ASME and QA requirements. The NRC inspectors also noted that Creusot Forge evaluated and closed audit findings based on the response by Industeel Creusot.

c. Conclusion

The NRC inspectors concluded that Creusot Forge adequately approved and controlled activities performed by the supplier of source materials and subcontracted services, consistent with the regulatory requirements of Criterion VII of Appendix B to 10 CFR Part 50. Based on the documentation reviewed, the NRC inspectors determined that the Creusot Forge QAM and associated procedures were being effectively implemented.

4. Control of Manufacturing Process (Control of Special Processes)

a. Inspection Scope

The NRC inspection team reviewed the Creusot Forge QAM and implementing procedures that govern the control of production and special processes (including heat treatment, forging, non-destructive examination (NDE), and mechanical testing). Specifically, the NRC inspectors reviewed the sections of the QAM related to personnel indoctrination, training, and qualification (Section 52), process control (Section 57) and control of examinations, tests and nonconforming material (Section 58). The NRC inspectors reviewed implementing procedures associated with these QA requirements for forging, heat treatment, NDE, and mechanical testing to verify compliance with Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50.

For heat treatment, the NRC inspectors reviewed shop travelers, heat treatment procedures, records and charts, and the calibration certificates for thermocouples. For forging, the NRC inspectors reviewed shop travelers and forging procedures. For NDE, the NRC inspectors reviewed magnetic particle testing (MT) procedures and reports and MT Level III examiner qualifications, ultrasonic testing (UT) procedures, UT Level II inspector qualifications, UT Level III examiner qualifications, and calibration of equipment. For mechanical testing, the NRC inspectors reviewed work authorizations for cutting test rings and test samples, machining procedures, metallographic grain size determination procedures and calibration of associated mechanical test equipment and temperature measuring instruments. Within the scope of this area of inspection, the NRC inspectors reviewed the following documentation:

- Creusot Forge IN040, Revision 3, "Program for the Calibration and Verification of Thermal Units"
- PRM015, Revision 3, "Indoctrination, Training and Qualification of Personnel"
- RPO017, " Order Review and Release"
- Procedure PRM002, "Shop Travelers," Revision 4, dated July 27, 2008
- Manufacturing Program PTS-243 Revision D, "Bi-Code Project Heat treatment"
- Document No. DQ 294, Revision C, "Qualification Program" dated June 3, 2009 for US EPR lower dome
- Manufacturing Program PTF 242, Revision E, for RPV lower head (ASME code)
- Manufacturing Program PTF 134, Revision E for RPV lower head (RCC-M code)

- Manufacturing Program PTF 243, Revision D, for RPV lower shell (RCC-M code)
- CF CT F003, Revision 1 Forging Elongation (US EPR)
- CF CT-F004, Revision 1 Forging Intermediate (US EPR)
- CF CT F006, Revision 1 Forging Final Upset (US EPR)
- CF CT C0001, Revision 1 In- process ultrasonic examination
- UT ND-US 474, Revision A (ASME) Ultrasonic Examination
- MT ND M 144, Revision A Magnetic Particle Examination
- ND M-137, Revision B, Basic Inspection for Intermediate steam Generator intermediate shell (EPR-China)
- ND US 476, Revision B, Ultrasonic Examination of Forging (lower, intermediate, upper and nozzle shells for Steam Generator (US EPR)
- CF-CT-EM006, Revision 1, Grain Size
- PTF 228, Revision E, Cutting and Machine Test Coupons

b. Observations and Findings

Since both the RCC-M Code (French Design and Construction Rules for Mechanical Components of PWR Nuclear Islands) and the ASME Code are used in the manufacturing of forgings at Creusot Forge, the NRC inspectors evaluated the Creusot Forge ASME Code program, including Procedure DQ 294, "Qualification Program - US EPR Lower Head." In addition, the NRC inspectors reviewed a Creusot Forge white paper, "A Practical Example of Code Comparison Evaluation of Conformance to the ASME III Code of Large Nuclear Replacement Parts Manufactured According to RCC-M." On the basis of this evaluation, the NRC inspectors concluded that Creusot Forge has implemented a program to ensure that ASME Code requirements are reconciled with the RCC-M Code.

Section 57.2 of the Creusot Forge QAM establishes program requirements for controlling the Creusot Forge manufacturing process. These processes are implemented by qualified personnel in accordance with specific and qualified technical instructions and/or procedures. The principal operations steps in the Creusot Forge manufacturing process include receiving inspection, forging, heat treatment, machining, nondestructive examination, dimensional examination, mechanical tests, and inspection after manufacturing operations have been completed. Documents used to follow-up and control manufacturing and QC operations include procedures, customer drawings, manufacturing drawings, test instructions, and shop travelers. The shop traveler is the primary document used for controlling operations and their status, especially for essential operations that are systematically included. Specifically, a QC coordinator is assigned responsibility for the shop travelers throughout all operations. The shop traveler identifies the customer drawings, specifications, and applicable procedures for the activity being performed. The shop traveler identifies applicable procedural and technical information for all operations, including, machining, forging, furnace operation, inspection and examination.

After reviewing the applicable Creusot Forge QAM sections and specific technical instructions and procedures, the NRC inspectors verified manufacturing activities for a US EPR RPV lower head, US EPR SG lower shell, US EPR RPV upper head, and US EPR SG upper shell. At the time of the inspection, the NRC inspectors observed one US EPR SG lower shell (heat number Z5630/Z5631) and one US EPR SG upper shell (heat number Z5657/Z5658) undergoing machining operations. In addition, a US EPR RPV transition ring (heat number Z5650/Z5651) was waiting on machining operations prior to UT and the US EPR RPV upper head (heat

number Z5590) was waiting on machining operations prior to forming. The following observations of special process operations refer to these specific components.

b.1 Heat Treatment

For heat treatment, QAM Section 57.2 assigns operational responsibilities and technical instructions through the shop traveler and associated documentation. The NRC inspectors verified that heat treatment procedures conformed to ASME Code, Section III and the material specification (ASME Code, Section II, SA-508) for quenched and tempered alloy steel. Creusot Forge procedure PTS-243 includes time and temperature values for austenization and tempering consistent with the grade of material being heat treated and thermocouple locations. The NRC inspectors verified that Creusot Forge had properly calibrated the chart recorder and had identified the appropriate material traceability controls and heat treatment start time.

b.2 Forging

For the forging process, QAM Section 57.2 assigns operational responsibilities and technical instructions through shop traveler and associated technical instructions. The NRC inspectors reviewed documentation for the EPR RPV lower head (Job No. 88781003), including certification of the ingot. The NRC inspectors verified that the mill chemical analysis report for this heat (Z5579/Z5580) conforms to the applicable ASME Code, Section II material specification A508, Grade 3, Class 1. The NRC inspectors confirmed that the Creusot Forge chief metallurgist verifies that the ingot material conforms to the design documents incorporated in the Creusot Forge purchase order or metal order, which is specific to the ingot. The metallurgist also verifies that that the ingot received meets the specifications in the receiving inspection report. For traceability, the Creusot Forge receipt inspector verifies that the heats and control number on the ingot conform to the material specification. The NRC inspectors reviewed the shop traveler for the US EPR RPV lower head and confirmed that it specified the dimensions from the customer drawings and referenced the technical instructions for forging: CT F003, CT F004, and CT F006. The NRC inspectors determined that these instructions were consistent with the requirements of the ASME Code and would result in a finished, rough forging conformable to design requirements. The NRC inspectors noted that the shop traveler identified the heats for the material, and that marking on the forging was correct.

b.3 Welding

For welding, QAM Section 57.3 documents that no repair welding is performed on forgings produced for ASME Code components. The NRC inspectors observed that no welding operations were being performed on ASME Code forgings and no weld repairs were documented on shop travelers. Although temporary attachments are welded as thermal barriers to forged test rings to simulate heat treatment representative of the main forging, this practice is consistent with ASME Code, Section III, Subsection NB-2200. These welds are not integral to the ASME Code finished forgings and are removed prior to mechanical testing. The NRC inspectors concluded that welding is not performed on ASME Code forgings.

b.4 Non-destructive Examination

For NDE, QAM Section 58.1 assigns responsibilities of the Level III expert and QAM Section 57.2 specifies the use of NDE procedures as identified by the shop traveler for the component. The NRC inspectors examined the qualification records for inspectors and examiners for MT, PT, and UT to verify that they were qualified in accordance with the ASME Code and SNT-TC-

1A, as specified by PRN-015. The NRC inspectors verified that vision tests are performed yearly and that inspectors and Level III examiners are recertified as required by the ASME Code, Section V. Creusot Forge procedures UT ND-US 474, MT ND M 144, and ND US 476 were determined to conform to ASME Code requirements. The NRC inspectors witnessed calibration of UT equipment in accordance with CT C0001 for the SG lower shell calibration of UT equipment in accordance with US 287. For each calibration, the UT inspector was able to detect the required flat bottom hole for the required appropriate thickness being examined, using the applicable calibration block.

b.5 Mechanical Testing

For mechanical testing, QAM Section 58.1 (4), "Mechanical Tests; Micrographic Examination," assigns responsibilities for ensuring that test instructions comply with applicable Code requirements; Section 57.2 (7), "Mechanical Tests; Micrographic examination; product analysis," requires that applicable test instructions and procedures be identified by the shop traveler. In the machine shop, the NRC inspectors witnessed test specimen removal from a forging test ring for a lower shell (Job No. 88371003- heat number Z5446/Z5447) in accordance with PTF 228. PTF 228 is written by the QC coordinator responsible for the contract and incorporates the requirements for each material specification. The NRC inspectors verified that the test specimens were removed in accordance with PTF 228, including the removal depth of ¼ of the forging thickness from the surface.

Mechanical testing of the test specimens, including tensile tests, Charpy V-notch impact tests and grain size determination, are performed in the Creusot Forge test lab. The NRC inspectors verified that procedure CF-CT-EM006, applicable to determining the grain size of alloy steels, was consistent with ASTM E112 requirements.

c. Conclusion

The NRC inspectors concluded that Creusot Forge control of special processes, such as forging, heat treatment, NDE, and mechanical testing, was consistent with Criterion IX of Appendix B to 10 CFR Part 50, and ASME Code requirements. The NRC inspectors concluded that Creusot Forge's implementation of these processes and practices provided appropriate controls and that Creusot Forge personnel were effectively implementing these requirements in the manufacture of US nuclear components.

5. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspectors reviewed Creusot Forge policies and procedures to verify compliance with Criterion XII, "Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the implementation of Creusot Forge procedures governing the control of measuring and test equipment (M&TE) to assure that gauges, tools, instruments, and other measuring devices were properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

Within the scope of this area of inspection, the NRC inspectors reviewed the following procedures and records:

- Section 58.2, “Control of Measuring and Test Equipment,” of the Creusot Forge QAM, Revision 5, dated December 18, 2008
- Section 58.3, “Discrepancies in Measuring or Test Equipment,: of the Creusot Forge QAM, Revision 5, dated December 18, 2008
- Creusot Forge Procedure IN040, “Program for the Calibration and Verification of Thermal Units,” Revision 3, dated March 23, 2009
- Creusot Forge Procedure CT E005, “Calibration of Thermocouples,” Revision 2, dated August 7, 2008
- Creusot Forge Procedure CT E006, “Calibration of Devices for Dimensional Verification,” Revision 2, dated October 29, 2008

b. Observations and Findings

b.1 Policies and Procedures

Section 58.2 of the Creusot Forge QAM establishes program requirements for control and calibration of M&TE used to verify compliance of material with the material specifications and ASME Code. Calibration responsibilities are assigned in the areas of heat treatment, manufacturing, and NDE. Technical instructions are issued for each type of M&TE. Masters used for calibration have valid relationships to nationally recognized standards. If no national standard exists, standards are supported by documented justification. Calibrations are performed at predetermined intervals and are documented by calibration reports. Section 58.3 establishes requirements for M&TE found to be noncompliant, which includes withdrawal of the device from service, issuance of a nonconformance report, and evaluation of products that may have been affected by the noncompliant M&TE.

b.2 Temperature Measurements

The NRC inspectors observed the operation of a strip recorder monitoring temperatures at an annealing furnace while annealing of a RPV upper head was in process. The NRC inspectors reviewed the recorder history, calibration documentation, and controlling procedure. The NRC inspectors verified that the heat treatment process met the requirements of ASME Code Section III, Section NB-2180. The NRC inspectors observed that the thermocouples were supplied by BFC Dexis, which is the sole supplier of thermocouples used at Creusot Forge. Creusot Forge thermocouples are calibrated against a BFC reference standard, which was calibrated against a French COFRAC national standard. BFC was verified to be on the Creusot Forge ASL and was last audited by Creusot Forge on December 18, 2008.

Calibration of the thermocouples was verified by the NRC inspectors to conform to CF IN040, Revision 3. The NRC inspectors noted that there was no established calibration interval in CF IN040 for the thermocouples and that the failure to establish a maximum calibration interval had been identified in a previous internal Creusot Forge audit. The NRC inspectors also noted that the ASME Code does not specifically state a calibration maximum time limit. The NRC inspectors reviewed the history of thermocouple calibration and found that the thermocouples had been calibrated approximately every three months due to their high usage and that Creusot Forge had a practice of calibrating the thermocouples after each furnace operation. During the inspection, CF IN040 was revised to specify a maximum interval of one year for thermocouple calibration.

During their review of mechanical testing (Section 4 of this report), the NRC inspectors verified that the Zwick/Roell tensile test machine was calibrated annually and the Tinius Olsen Charpy V-notch impact machine was calibrated annually, in accordance with ASTM E23. The calibration records for the impact machine included a National Institute of Standards and Testing (NIST) certification letter, dated September 3, 2008. However, the NRC inspectors identified that the calibration of the thermocouple for the temperature baths for the impact tests did not conform to ASME Code, Section III, Subsection NB-2360. Specifically, thermocouples BFC/VN/09JU1 and BFC/VN/09JU2 were last calibrated on June 23, 2009, and were not scheduled to be recalibrated for one year. This calibration interval does not conform to the ASME Code Section III, Subsection NB-2360 requirement to calibrate these thermocouples within a three month interval. Creusot Forge initiated a Corrective Action Document No. AC 09.047, Revision 01, date July 23, 2009, to resolve this nonconformance with the ASME Code. This corrective action also included an immediate change to the calibration labels to specify a recalibration date of September 23, 2009. The NRC inspectors noted that no ASME Code forgings had been tested to date. The failure to calibrate thermocouples consistent with the ASME Code, Section III, Subsection NB-2360, is identified as Nonconformance 99901381/2009-201-02.

b.3 Dimensional Verifications

The NRC inspection team observed machining operations on the inside diameter of a US EPR SG lower shell (Job No. 88791001). The NRC inspectors noted that the only calibrated instrument used for the operation was a measuring tape used for verification of the inside diameter of the shell. The NRC inspectors were accompanied by Creusot Forge technical personnel to the calibration room, where records for the tape documented that its accuracy had been certified by the French national testing laboratory, and that such devices were no longer used after the calibration period of one year expired. The NRC inspectors selected a 300 mm spindle vernier stored in the calibration room and observed the proficiency of the technician to calibrate the instrument in accordance with the calibration procedure.

While in the calibration area, the NRC inspectors observed the instrument supply room and discussed the issuance and receipt of instrumentation for specific contracts with Creusot Forge personnel. The NRC inspectors found the transactions, conducted across a window limiting access to the room, to provide adequate control for M&TE. The NRC inspectors also discussed the process for withdrawing noncompliant M&TE from service, follow-up by a NCR, and evaluation of products that could be affected by the noncompliant M&TE and determined that they conformed to the governing Creusot Forge procedures.

c. Conclusion

With exception of Nonconformance 99901381/2009-201-02 related to the calibration of thermocouples, the NRC inspectors concluded that the control of measuring and test equipment met the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50 and that Creusot Forge personnel were effectively implementing these requirements in the manufacture of nuclear components.

6. Handling, Shipping, and Storage

a. Inspection Scope

The NRC inspection team reviewed Creusot Forge policies and procedures to verify compliance with Criterion XIII, "Handling, Shipping, and Storage," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed Creusot Forge procedures and activities controlling handling, storage, and shipping of manufactured components.

Within the scope of this inspection area, the NRC inspectors reviewed the following procedures and records:

- CF QAM, Section 57.4, "Handling, Storage, Shipping and Preservation," and Section 56, "Identification, Marking and Material Control," Revision 5, dated December 18, 2008
- Procedure PRM002, "Shop Travelers," Revision 4, dated July 27, 2008
- Maintenance Records, 236 metric ton forge crane, January through July 2009
- Packaging Procedure IN EX 1235, "High, Lower and Intermediated Shells," Revision C, dated June 27, 2009
- Packaging Procedure IN EX 150, "Hot and Cold Leg Piping," Revision A, dated December 18, 2008

b. Observations and Findings

b.1 Policies and Procedures

Section 57.4 of the CF QAM addresses provisions for handling, storage, shipping, and preservation of components manufactured by Creusot Forge. Operations are performed by the manufacturing departments in accordance with Creusot Forge instructions or customer requirements that accompany the shop traveler. A QC coordinator is responsible for overseeing all operations to ensure that they are conducted in accordance with Creusot Forge and customer requirements. For items shipped directly from a Qualified Material Supplier, Creusot Forge specifies all controls for release inspection and material marking in the purchase order and, when possible, performs the release inspection at the supplier's facilities. The NRC inspectors determined that protection, packing, and shipping methods are in accordance with Creusot Forge procedures, as approved and/or revised per customer specifications.

b.2 Receipt Inspection

The NRC inspectors observed inspection activities related to verification of an ingot that had been delivered to the forging shop on June 20, 2009. Each ingot is ordered for a specific contract and is ordered from the supplier Industeel Creusot through a formal procurement document, which specifies material and chemistry requirements. The ingot inspected was ordered for forging of a hot leg component for a Chinese nuclear reactor system. The NRC inspectors and the Creusot Forge receipt inspector discussed the traceable markings on the ingot, which included heat numbers Z095703 and Z095704, purchase order number (9135), and Creusot Forge job number. The purchase order specified the Creusot Forge technical requirements for the ingot, which were verified by the Creusot Forge metallurgical/chemistry staff upon delivery of the ingot. The job number is a unique identifier used to track the order through the manufacturing process from ingot delivery through release for shipping of the finished component. Other documented information delivered with the ingot included order number, weight and ingot type. This information and signed verifications by the receipt inspector and technical staff were included with the shop traveler. The NRC inspectors noted that the manufacturing schedule was adjusted for the actual date of delivery.

b.3 Forging Operations

The NRC inspectors observed handling operations associated with unloading of the ingot transported by rail, receipt inspection, and the forging operation with one of the two hydraulic presses. Ingots are delivered from the Industeel Creusot melting shop, approximately two miles away. Loading and unloading of the ingot is accomplished using a lifting device that is mounted on a second railcar.

Three overhead cranes, which traverse the length of the forging mill, are used to move the ingot through the forging process. The NRC inspectors observed the hydraulic press in operation in forming two pressure vessel shells. Forging operations were performed by three operators working in a control room adjacent to the press, taking orders from a supervisor on the shop floor. The NRC inspectors reviewed maintenance records for the 235-ton forging crane and discussed the operation of the crane with maintenance personnel. Maintenance records were available for weekly, monthly, and biannual inspections, with an annual inspection to be completed at the end of 2009. Each record documented more than 50 crane functions that were inspected for the maintenance period, including tracking of associated maintenance and/or diagnostic actions and signoffs by technical specialists. The NRC inspectors determined that the records were complete and adequately documented.

Other observations included discussions with shop personnel of the various lifting devices including devices for moving and positioning ingots and forgings through the shop and annealing furnaces. After forging, components were moved to the adjacent machine shop on railcars. The crane maintenance records and all handling operations observed by the NRC inspectors were found to be controlled, orderly, and in accordance with Creusot Forge procedures.

b.4 Shipping

The NRC inspectors examined the packaging of a SG lower shell that had been released for shipping (Job No. 87191001). The packaging conformed to Creusot Forge packaging procedure IN EX 125, as revised by the customer, AREVA. The NRC inspectors found that the part was properly marked with information that included heat treatment, alloy, part number, and purchase order number. Surfaces were free of foreign material and covered by a protective film. Weld bevels on the circumferences were protected by plywood. Handling emplacements were banded with metal reinforcements. The component was supported by blocks with a clearance of six inches from the shop floor. The NRC inspectors reviewed packaging information for cold leg piping (Job. No. 871910.01) and found it to conform to the requirements of packaging procedure IN EX 150. The NRC inspectors also reviewed the completed shipping and freight documentation for another SG lower shell which had been shipped in June and discussed with Creusot Forge shipping personnel. The NRC inspectors verified that the shipping and freight documentation was consistent with the End of Manufacturing Report, maintained by Quality Assurance Department as a permanent record for the component.

c. Conclusions

The NRC inspectors concluded that Creusot Forge adequately controlled handling, shipping, and storage consistent with the regulatory requirements of Criterion XIII of Appendix B to 10 CFR Part 50. The NRC inspectors determined that Creusot Forge personnel were effectively implementing these requirements in the manufacture of nuclear components.

7. Nonconforming Material, Parts, or Components

a. Inspection Scope

The NRC inspectors reviewed the Creusot Forge QAM and implementing policies and procedures that govern the control of nonconformances to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by Creusot Forge and six NCRs initiated during the past six months.

- Creusot Forge QAM, Section 58.5, "Control of Nonconformances," Revision 5, dated December 18, 2008
- Procedure PRM 004, "Control of Nonconformances," Revision 5, dated March 31, 2006
- NCR No. FNC 09 002, Revision 1, dated January 14, 2009
- NCR No. FNC 09 005, Revision 1, dated February 2, 2009
- NCR No. FNC 09 016, Revision 1, dated March 18, 2009
- NCR No. FNC 09 019, Revision 1, dated April 14, 2009
- NCR No. FNC 09 025, Revision 1, dated June 9, 2009
- NCR No. FNC 09 029, Revision 1, dated June 25, 2009

b. Observations and Findings

Section 58.5 of the Creusot Forge QAM defines the measures for the identification, documentation, evaluation, segregation, and disposition of material or source material that does not conform to the requirements of the material specification. As stated in Section 58.5, all Creusot Forge employees are responsible for identifying quality incidents affecting forgings or the quality system. The QAM also defines the responsibilities and authorities for the disposition of nonconformances in these materials. Specifically, the QA manager is responsible for issuing NCRs in response to an identified deficiency on material or source material, segregate when practical, and review for acceptance, rejection, or repairs, and provide for the notification of affected suppliers or customers. The NRC inspectors noted that, in accordance with this policy, Creusot Forge documented all nonconforming conditions on a NCR.

Procedure PRM 004 describes the measures implemented for the treatment of nonconformances. PRM 004 establishes that nonconformances associated with forgings are documented; nonconforming parts are segregated to prevent and control the use of potentially defective products; and measures are provided to disposition nonconformances consistent with ASME Code requirements for Material Organizations.

To verify implementation of the nonconformance process, the NRC inspectors reviewed a sample of six open and closed NCRs generated by Creusot Forge. The NRC inspectors confirmed that the nonconforming material and/or source material was adequately identified, segregated, reviewed for acceptance; rejected or repaired as required in documented procedures; and dispositioned by responsible personnel. All of the sampled NCRs documented the description of the nonconformance, proposed resolution, resolution approval by the QA manager, customer notification and acceptance (when required), verification of the implementation of the resolution, and closure of the NCR.

c. Conclusions

The NRC inspectors concluded that the Creusot Forge program requirements for the control of nonconformances are consistent with the regulatory requirements of Criterion XV of Appendix B to 10 CFR Part 50. Based on the NCRs reviewed, the NRC inspectors determined that the Creusot Forge QAM and associated nonconformance procedures were being effectively implemented.

8. Corrective Action

a. Inspection Scope

The NRC inspectors reviewed the Creusot Forge QAM and implementing policies and procedures that govern the control of corrective action to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following documents:

- Creusot Forge QAM, Section 59.2, "Corrective Action," Revision 5, dated December 18, 2008
- Procedure PRM 005, "Corrective Action," Revision 3, dated March 31, 2006

The NRC inspectors also reviewed five corrective action reports (CARs) initiated during the past six months. These CARs were primarily the result of deficiencies identified by Creusot Forge's customers and by internal audits/inspections performed by Creusot Forge personnel.

- CAR No. AC 08.076, Revision 2, dated September 8, 2008.
- CAR No. AC 08.083, Revision 1, dated October15, 2009.
- CAR No. AC 09.005, Revision 1, dated February 17, 2009
- CAR No. AC 08.078, Revision 1, dated September 16, 2008.
- CAR No. AC 08.081, Revision 1, dated October 15, 2008

b. Observations and Findings

Section 59.2 of the Creusot Forge QAM outlines the process for identifying and analyzing conditions that require corrective action, determining the root cause, implementing corrective action, and verifying the effectiveness of the corrective action. Section 59.2 states that the QA manager has the responsibility and the authority to document conditions adverse to quality, malfunctions, faulty equipment or products, and to designate an action leader responsible to handle the corrective action.

Procedure PRM 005 describes the measures implemented for treatment of corrective actions at Creusot Forge. PRM 005 specifies controls to: 1) identify and document nonconformances using procedure PRM 004; 2) provide a description of solutions to preclude recurrence; 3) verify implementation of solutions; and 4) conduct effectiveness analysis through periodic review of NCRs, CARs, audit and inspection reports, and deficiencies reported by customers.

The NRC inspectors reviewed a sample of CARs to verify the implementation of the corrective action process. The NRC inspectors confirmed that the cause of significant or recurring conditions adverse to quality are determined, corrected, reported, and evaluations of the effectiveness of implemented corrective actions are documented.

c. Conclusions

The NRC inspectors concluded that the Creusot Forge corrective action program requirements are consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Based on the CARs reviewed, the NRC inspectors determined that the Creusot Forge QAM and associated corrective action procedures were being effectively implemented.

9. Audits

a. Inspection Scope

The NRC inspectors reviewed the Creusot Forge QAM and implementing policies and procedures that govern the control of audits action to verify compliance with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following documents:

- SFARSteel PRM007, "Internal and Supplier Audit," Revision 3, dated April 4, 2008
- QM procedure Q-102 (procedure PO NP SDI BQ4), "Corporate Quality Management Procedures Internal and Supplier Audits," Revision 4, dated December 1, 2006
- PAI 2009, "Planning D'Audit Interne," Revision 1, dated February 13, 2009
- Audit Report 20080414 (wrong number) RAI SC, dated April 29, 2009
- Audit Report 200905018-19-20, RAI SC, dated June 26, 2009
- SFARSteel, PRM012, "Qualification of Auditors and Lead Auditors," Revision 2, dated April 4, 2008
- Corrective Action, AC 09.046, Revision 1, dated July 22, 2009

b. Observations and Findings

Section 59.1 of the Creusot Forge QAM establishes the measures implemented to ensure the qualification of auditors and the performance of internal audits. SFARSteel, PRM012 defines the requirements for qualification of individuals performing internal and supplier quality management system (QMS) audits. The NRC inspectors noted that Creusot Forge had two lead auditors that perform as auditors and lead auditors. The NRC inspectors reviewed qualifications and requalifications for the two lead auditors and confirmed that the qualifications met requirements of PRM012. In addition, seven AREVA NP auditors perform audits for Creusot Forge.

SFARSteel procedure PRM007 defines the requirements, methods and responsibilities for scheduling, preparation, performance, documentation of internal and supplier audits and the related follow-up of actions. Specifically, the QA manager is responsible for revising audit schedule as necessary when: 1) significant modifications are introduced in the organization of the QMS; 2) quality of products is jeopardized due to a deficiency in the QMS; 3) verification of implementation of corrective actions is required; and 4) consideration of an acceptable external request.

Since AREVA NP is the parent company of Creusot Forge, PRM007 references AREVA NP Quality Management (QM) procedure Q-102. Q-102 is the AREVA NP cross audit process, which is defined as an internal audit performed annually by an independent AREVA NP audit team on an AREVA NP QM organization to assess compliance with AREVA NP Corporate QM directives, Corporate QA procedures and concerned Sector's QM system. The purpose of

Q-102 is the description of methods and responsibilities for the scheduling, preparation, performance, documentation of internal and supplier QM system audits as well as for the related follow-up actions.

The NRC inspectors reviewed the internal audit schedule, PAI 2009. At the time of the inspection, Creusot Forge had performed three of ten internal audits planned for 2009. The ten planned audits did not include the two audits being performed under the cross audit process, e.g., Creusot Forge management audit and audit of the quality assurance section, by an external auditor. The three completed audits included human resources (July 2009), purchasing (April 2009), and manufacturing (May 2009).

The NRC inspectors reviewed two of the three 2009 internal audit reports and associated audit plans. The audit report for human resources was not complete at the time of the inspection. In addition, the NRC inspectors verified that the audit report for the Purchasing audit was sent to the responsible individuals via email dated May 6, 2009, requesting a response within 30 days. At the time of the inspection, the responses had been received and the observations/findings were entered into the Creusot Forge corrective action process.

c. Conclusions

The NRC inspectors concluded that the Creusot Forge QA policies and implementing procedures that govern audits are consistent with the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50.

10. Exit Meeting

On July 24, 2009, the inspectors presented the inspection scope and findings during an exit meeting with SFAR Steel Chief Executive Officer, Jean-Bernard Ville and other Creusot Forge personnel. SFAR Steel is the parent holding company of Creusot Forge. AREVA is the parent company of SFAR Steel.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Title	Affiliation	Entrance	Exit	Interviewed
Jean-Bernard Ville	CEO	Creusot Forge	X	X	
Bruno Blonski	Plant Manager	Creusot Forge	X	X	
Phillippe Tollini	Commercial VP	Creusot Forge	X		
Dominique Maire	Deputy CEO	Creusot Forge	X	X	
Anne-Sophie Pomykala	Sustainable Development Quality Manager	SFARSteel/Areva NP	X	X	X
Patrick Trioen	Quality Manager	Creusot Forge	X	X	X
Thierry Berger	Supplier Surveillance Manager	Areva NP	X	X	X
Etienne Touzain	Equipment Business Unit Manger	Areva NP	X		
Bernard Chapelle	Management Systems and Audit Manager	Areva NP	X		X
Xavier Lesage	Manager of Dept Relations w/ ASN	Areva NP	X	X	X
Daniel Jobard	Technical Director	Creusot Forge	X		X
Claude Herda	Human Resources Manager	SFARSteel	X	X	
Miguel Gomez	Manufacturing Manager	Creusot Forge	X	X	X
Nalika Cebel	Human Resources	Creusot Forge	X	X	
Noel Brugniaux	Thermal Manager	Creusot Forge	X	X	
Gary Hack	Quality Engineer	Areva NP INC	X	X	
Al Pitts	Procurement Quality Assurance Manager	UniStar Nuclear Energy	X	X	
David Pignard	Quality Control	Creusot Forge			X
Robbe	Forging Manager	Creusot Forge		X	
Jean Paul Menager	CFO	SFARSteel		X	
Elizabeth Perrin	Accounting Manager	SFARSteel		X	
Milaud Lancen	Machining Shop Manger	Creusot Forge		X	
Fredero Bordrjot	Deputy Technical Director	Creusot Forge		X	
Pascal Perrel	Maintenance Manager	Creusot Forge		X	

The following individuals observed the inspection from July 20 – July 24, 2009:

S. Gitkoff, Project Manager, ASN
R.K. Wild, Audit Manager, USNRC Office of Inspector General (OIG)
S. Miotla, Team Leader, USNRC OIG

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”

4. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

No previous NRC inspections had been performed at Creusot Forge’s facility in Le Creusot, France, prior to this inspection.

The following items were found during this inspection:

Item Number	Status	Type	Description
99901381/2009-201-01	Open	NOV	21.21 and 21.31
99901381/2009-201-02	Open	NON	Criterion XII
99901381/2009-201-03	Open	NON	Criterion XVIII