August 12, 2010

Ms. Tara Werner
Manager, Quality Programs
AREVA Quality and Performance
3315 Old Forest Road
Lynchburg, VA 24501

SUBJECT: NRC INSPECTION REPORT NO. 05200020/2010-202 AND NOTICE OF VIOLATION

Dear Ms. Werner:

On June 28–July 1, 2010, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the AREVA NP Inc. (AREVA) office in Lynchburg, Virginia. The purpose of the inspection was to assess AREVA'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 the inspection. This 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 determined that one 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 is being cited in the Notice because the NRC inspection identified one example where AREVA failed to appropriately translate design inputs into design outputs in accordance with Criterion III, "Design Control," of Appendix B to 10 CFR Part Part 50.

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 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 Agencywide Document Access and Management System, (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information, so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide, in detail, the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of

personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,
/RA/

Richard A. Rasmussen, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No.: 05200020

Enclosures: 1. Notice of Violation
2. Inspection Report No. 05200020/2010-202 and Attachments

personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,
/RA/

Richard A. Rasmussen, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No.: 05200020

Enclosures: 1. Notice of Violation
2. Inspection Report No. 05200020/2010-202 and Attachments

DISTRIBUTION:

RidsNroDcipCQVB	RidsNroDcip	RidsNroDnrlNwe1	RidsOgcMailCenter
RidsNro DcipCQVA	NRO/REF	Public	SEdmonds
GNewman	JBartleman	SCrane	JJacobson
KKavanagh	tara.werner@areva.com		

ADAMS Accession No.: ML102170204
INDICATE IN BOX "C"=COPY W/O ATTACHMENT/ENCLOSURE, "E"=COPY W/ATT/ENCL, "N" = NO COPY

OFFICE	RIII/DRS/EB3	E	NRO/DCIP/CQVB	E	RII/DCI/CIB3	E
Name	SEdmonds *		GNewman*		JBartleman*	
Date	08/4/10		08/4/10		08/5/10	
OFFICE	NRO/DCIP/CQVB	E	NRO/DCIP/CQVB	E	NRO/DCIP/CQVB	E
Name	SCrane		JJacobson		RRasmussen	
Date	08/11/10		08/05/10		08/12/10	
OFFICE	NRO/DCIP/CAEB					
Name	TFrye (OTabatabai for)					
Date	08/06/10					

OFFICIAL RECORD COPY

DC AREVA - EPR Mailing List (Revised 06/23/2010)
cc:

Ms. Michele Boyd
Legislative Director
Energy Program
Public Citizens Critical Mass Energy
and Environmental Program
215 Pennsylvania Avenue, SE
Washington, DC 20003

Dr. Charles L. King
Licensing Manager, IRIS Project
Westinghouse Electric Company
Science and Technology Department
20 International Drive
Windsor, CT 06095

Ms. Sherry McFaden
Framatome NP, Inc.
3315 Old Forest Road, OF-16
Lynchburg, VA 24501

Mr. Steve Seitz
AREVA
100 Dean Road
East Lyme, CT 06333

Mr. Tom Sliva
7207 IBM Drive
Charlotte, NC 28262

Mr. Robert E. Sweeney
IBEX ESI
4641 Montgomery Avenue
Suite 350
Bethesda, MD 20814

Mr. Gary Wright, Director
Division of Nuclear Facility Safety
Illinois Emergency Management Agency
1035 Outer Park Drive
Springfield, IL 62704

DC AREVA - EPR Mailing List

Email

alau@washdc.whitecase.com (Albie Lau)
APH@NEI.org (Adrian Heymer)
awc@nei.org (Anne W. Cottingham)
bgattoni@roe.com (William (Bill) Gattoni))
BrinkmCB@westinghouse.com (Charles Brinkman)
carey.fleming@cengllc.com (Carey Fleming)
chris.maslak@ge.com (Chris Maslak)
christian.clement@unistarnuclear.com (Chrisitan Clement)
cwaltman@roe.com (C. Waltman)
david.hinds@ge.com (David Hinds)
david.lewis@pillsburylaw.com (David Lewis)
erg-xl@cox.net (Eddie R. Grant)
gcesare@enercon.com (Guy Cesare)
greg.gibson@unistarnuclear.com (Greg Gibson)
james.beard@gene.ge.com (James Beard)
james.p.mcquighan@constellation.com (Jim McQuighan)
jason.parker@pillsburylaw.com (Jason Parker)
jerald.head@ge.com (Jerald G. Head)
jgutierrez@morganlewis.com (Jay M. Gutierrez)
jim.riccio@wdc.greenpeace.org (James Riccio)
Joseph_Hegner@dom.com (Joseph Hegner)
junichi_uchiyama@mnes-us.com (Junichi Uchiyama)
KSutton@morganlewis.com (Kathryn M. Sutton)
kwaugh@impact-net.org (Kenneth O. Waugh)
lchandler@morganlewis.com (Lawrence J. Chandler)
Len.Gucwa.ext@areva.com (Len Gucwa)
Marc.Brooks@dhs.gov (Marc Brooks)
maria.webb@pillsburylaw.com (Maria Webb)
mark.beaumont@wsms.com (Mark Beaumont)
Martin.Bryan.ext@AREVA.com (Martin Bryan)
matias.travieso-diaz@pillsburylaw.com (Matias Travieso-Diaz)
mbowling@numarkassoc.com (Marty Bowling)
media@nei.org (Scott Peterson)
mike_moran@fpl.com (Mike Moran)
MSF@nei.org (Marvin Fertel)
mwetterhahn@winston.com (M. Wetterhahn)
nirsnet@nirs.org (Michael Mariotte)
Nuclaw@mindspring.com (Robert Temple)
patriciaL.campbell@ge.com (Patricia L. Campbell)
Paul@beyondnuclear.org (Paul Gunter)
pshastings@duke-energy.com (Peter Hastings)
RJB@NEI.org (Russell Bell)
Ronda.pederson@areva.com (Ronda Pederson)
rrsgarro@pplweb.com (Rocco Sgarro)
russell.wells@areva.com (Russell Wells)
sabinski@suddenlink.net (Steve A. Bennett)
sandra.sloan@areva.com (Sandra Sloan)

sfrantz@morganlewis.com (Stephen P. Frantz)
stephan.moen@ge.com (Stephan Moen)
Steve.Graham@hse.gsi.gov.uk (Steve Graham)
steven.hucik@ge.com (Steven Hucik)
strambgb@westinghouse.com (George Stramback)
tkkibler@scana.com (Tria Kibler)
tlharpster@pplweb.com (Terry Harpster)
tom.miller@hq.doe.gov (Tom Miller)
trsmith@winston.com (Tyson Smith)
Vanessa.quinn@dhs.gov (Vanessa Quinn)
vijukrp@westinghouse.com (Ronald P. Vijuk)
Wanda.K.Marshall@dom.com (Wanda K. Marshall)
wayne.marquino@ge.com (Wayne Marquino)
whorin@winston.com (W. Horin)

NOTICE OF VIOLATION

AREVA NP Inc.
P.O. Box 10935
Lynchburg, VA, 24506-0935

Docket Nos.: 05200020
Report No.: 2010-202

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the AREVA NP Inc. office in Lynchburg, VA, on June 28–July 1, 2010, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is described below:

> Criterion III, Design Control, of Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 states, in part, that measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in §10 CFR 50.2 and as specified in the license application, for those structures, systems, and components to which Appendix B to 10 CFR Part 50 applies are correctly translated into specifications, drawings, procedures, and instructions.
>
> EPR-EN-PR-1002, "Design Control Process," Revision 1, dated April 20, 2010, states that the System Description Document shall define the system in sufficient detail to permit verification that the design satisfies the input from the System Design Requirements Document.
>
> Contrary to the above, as of July 1, 2010, AREVA NP Inc. failed to correctly translate the design bases for the emergency feedwater system (EFWS) into specifications. Specifically, Section 5.5 of the EFWS System Description Document incorrectly states that "The EFWS piping within the reactor building, that is *upstream* of the check valve, shall be considered high energy lines." The correct designation should be *downstream* of the check valve as described in Section 2.4.3.1, "Protection from Internal Hazards", of the Emergency Feedwater System (EFWS) System Design Requirements Document. This issue has been identified as Violation 05200020/2010202-01.
>
> This is a Severity Level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," AREVA NP Inc. 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 2, 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 12th day of August 2010.

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

Docket No.:	05200020
Report No.:	05200020/2010-202
Applicant:	AREVA NP Inc. P.O. Box 10935 Lynchburg, VA, 24506-0935
Applicant Contact:	Tara Werner Manager, Quality Programs (434) 832-2836 tara.werner@areva.com
Background:	AREVA NP Inc, submitted an application for Standard Design Certification for the U.S. Evolutionary Power Reactor (U.S. EPR) on December 11, 2007.
Inspection Dates:	June 28 – July 1, 2010

Inspectors:			
	Jeffrey Jacobson	NRO/DCIP/CQVB	Lead Inspector
	Samantha Crane	NRO/DCIP/CQVB	
	Garrett Newman	NRO/DCIP/CQVB	
	Shavon Edmonds	RIII/DRS/EB3	
	John Bartleman	RII/DCI/CIB3	

Approved by:	Richard A. Rasmussen, Chief Quality and Vendor Branch 2 Division of Construction Inspection & Operational Programs Office of New Reactors

ENCLOSURE 2

EXECUTIVE SUMMARY

AREVA NP Inc.
05200020/2009-202

The U.S. Nuclear Regulatory Commission (NRC) inspection focused on quality assurance (QA) policies and procedures implemented to support the design certification (DC) application for the U.S. Evolutionary Power Reactor (U.S. EPR), as described in NRC Inspection Manual Chapter 2508, "Construction Inspection Program: Design Certification." The purpose of this inspection was to verify that AREVA NP Inc. (AREVA) had implemented an adequate QA program that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The inspection also verified that AREVA had implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets NRC regulatory requirements.

During this inspection, the NRC inspection team implemented Inspection Procedure 35017, "Quality Assurance Implementation Inspection," dated July 29, 2008, and Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Noncomplicance," dated October 3, 2007.

With the exception of the violation described below, the NRC inspection team concluded that the AREVA policies and procedures complied with the applicable requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 and that AREVA personnel adequately implemented these policies and procedures.

10 CFR Part 21

The NRC inspection team found that AREVA's process for implementing regulations for reporting defects and noncompliances conformed to the requirements of 10 CFR Part 21 and that AREVA's 10 CFR Part 21 policy and procedures were being effectively implemented. No findings of significance were identified.

Organization

The NRC inspection team found that AREVA's organization conformed to the requirements of Criterion I of Appendix B to 10 CFR Part 50 and that the AREVA QA policy and procedures for organization were being effectively implemented. No findings of significance were identified.

Quality Assurance Program

The NRC inspection team found that AREVA's QA program requirements conformed to the requirements of Criterion II of Appendix B to 10 CFR Part 50 and that the AREVA QA policy and procedures for the QA program were being effectively implemented. No findings of significance were identified.

Design Control

The NRC inspection team identified one example (Violation 05200020/2010202-01) where AREVA had not properly translated design inputs into design outputs. With the exception of the above violation, the NRC Inspection team concluded the AREVA design control process

conforms to the requirements of Criterion III of Appendix B to 10 CFR Part 50 and that the AREVA QA policy and procedures for design control were being effectively implemented.

Procurement Document Control

The NRC inspection team found that AREVA's procurement document control process conformed to the requirements of Criterion IV of Appendix B to 10 CFR Part 50 and that the AREVA QA policy and procedures for procurement document control were being effectively implemented. No findings of significance were identified.

Control of Purchased Material, Equipment, and Services

The NRC inspection team found that AREVA's process for the control of purchased services conformed to the requirements of Criterion VII of Appendix B to 10 CFR Part 50 and that the AREVA QA policy and procedures for the control of purchased services were being effectively implemented. No findings of significance were identified.

Corrective Action

The NRC inspection team found that AREVA's corrective action program conformed to the requirements of Criterion XVI of Appendix B to 10 CFR Part 50 and that the AREVA QA policy and procedures for corrective actions were being effectively implemented. No findings of significance were identified.

Audits

The NRC inspection team found that AREVA's internal audit process conformed to the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50 and that the AREVA QA policy and procedures for internal audits were being effectively implemented. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21

a. Scope

The NRC Inspection Team reviewed the AREVA NP Inc. (AREVA) implementing policies and procedures that govern the Part 21 process to verify compliance with the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance." In addition, the NRC inspection team reviewed the implementing procedures for compliance with the requirements of 10 CFR 21.21, "Notification of Failure to comply or existence of a defect" and evaluated the requirements of 10 CFR 21.31 "Procurement Documents." The NRC inspection team also examined AREVA's implementation of posting requirements in accordance with 10 CFR 21.6, "Posting Requirements," and AREVA's records retention schemes in accordance with 10 CFR 21.51, "Inspection and Maintenance of Records."

Specifically, the NRC Inspection Team reviewed the following AREVA policies, procedures, and supporting documentation:

- Topical Report (TR) ANP-10266, AREVA NP Inc. Quality Assurance Plan (QAP) for Design Certification of the U.S. Evolutionary Power Reactor (EPR), Revision 2, dated December 2008
- CR 2008-3445 , Root Cause Evaluation/Part 21 Deviation Determination and Defect Determination evaluation, Revision 1, dated October 19, 2009
- Administrative Procedure (AP) 1717-01, dated January 2010
- AREVA's Part 21 Policy 0401, dated January 2010

b. Observations and Findings

b.1 Postings

AREVA's Part 21 Procedure 1717-01 provides details of how the regulations in accordance with 10 CFR 21.6, "Posting Requirements" are being achieved at AREVA NP facilities. The NRC Inspection Team verified that AREVA NP implemented and maintained proper posting requirements and that the postings were placed in a conspicuous location. The postings contained the current revision of 10 CFR Part 21, Section 206 of the Energy Reorganization Act of 1974 and provided instructions on where to locate the specific procedures that implement 10 CFR Part 21. The NRC Inspection Team found that AREVA effectively met the requirements of 10 CFR Part 21 regulations and Section 206 of the Energy Reorganization Act of 1974.

b.2 10 CFR Part 21 Procedure

The NRC inspection team reviewed AREVA's Part 21 Procedure 1717-01, which provided definitions and delineates the responsibilities for the evaluation of deviations and failures that comply with 10 CFR 21.21 "Notification of Failure to comply or existence of a defect." Specifically, it contained measures for the analysis of deviations

and failures to comply and stipulated that an interim report shall be submitted to the NRC if an evaluation could not be completed within 60 days of discovery of the deviation or failure to comply. In addition, AREVA's Part 21 Procedure 1717-01 provides a direct connection between control of nonconformance and corrective actions to the Part 21 program. The NRC Inspection Team concluded that the AREVA's Part 21 Procedure 1717-01 and policy 0401 met the regulations and requirements of 10 CFR Part 21(a) (1) for adopting procedures for the notification of a failure to comply or the existence of a defect and its evaluation.

b.3 10 CFR Part 21 Implementation

The NRC Inspection Team verified that AREVA has performed one Part 21 evaluation at the AREVA NP facilities for the U.S. EPR Design Certification application. This Part 21 evaluation contained screening questions, a deviation determination, and a defect determination. The NRC inspection team determined that AREVA performed this part 21 evaluation adequately and the evaluation did not result in a NRC notification requirement. The NRC inspection team also reviewed a select sample of corrective action reports and nonconformance reports to verify that AREVA had adequate guidance in place to evaluate such reports for applicability to 10 CFR Part 21. The NRC inspection team determined that both the nonconformance and corrective actions processes contain the necessary guidance to evaluate applicability to 10 CFR Part 21 requirements. The NRC inspection team verified that a sample of procurement documents specified the applicability of 10 CFR Part 21 as documented in Section 5 of this report.

c. Conclusions

The NRC Inspection Team concluded that the requirements of 10 CFR Part 21 have been appropriately translated into implementing procedures and, for those activities reviewed by the team, implemented as required by AREVA procedures. No findings of significance were identified.

2. Organization

a. Scope

The NRC inspection team reviewed AREVA's policies and procedures that govern the quality assurance (QA) program to verify compliance with the requirements of Criterion I, "Organization," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team interviewed AREVA personnel and reviewed source documentation to verify that organizations performing activities affecting safety-related functions of systems, structures, and components (SSCs) were clearly established.

Specifically, the NRC Inspection team reviewed the following AREVA documents:

- TR ANP-10266, AREVA NP Inc. QAP for Design Certification of the U.S. EPR, Revision 2, dated December 2008

- AREVA NP Inc. Plants Sector Integrated Management Manual, QM DC 55, Revision J, dated June 7, 2009

- AP 1702-22, “Employee Training”, Revision 29, dated March 31, 2010, to define the actions and responsibilities for planning, scheduling, executing, and documenting personnel training

- AP 1719-23, “Qualification of Quality Assurance Audit Personnel”, Revision 19, dated December 16, 2009, to establish the requirements and responsibilities for qualification of personnel who perform supplier and internal QA audits

- AREVA Engineering Guideline, EG-01, “Plants U.S. Training Program”, Revision 2, dated November 24, 2009, to provide guidance to determine, implement and maintain company training requirements

- Lead Auditor Training Qualification Record for G. S. McNeish, last management review conducted on December 15, 2009

- Lead Auditor Training Qualification Record for K. E. Pinkowski, last management review conducted on December 15, 2009

- Lead Auditor Training Qualification Record for M. K. Cox, last management review conducted on December 15, 2009

- Condition Report, CR-2010-2017, Employees working on Design Certification Document (DCD) without required DCD training

b. Observations and Findings

The NRC inspection team reviewed the AREVA policies and procedures that govern the QA organization to verify conformance with Criterion I, Organization, of Appendix B to 10 CFR Part 50. The NRC inspection team verified that a program existed that defined the authority and duties of personnel and organizations performing activities affecting safety-related functions of SSCs. The NRC inspection team also verified that the QA organization had appropriate lines of management and authority for reporting, and functional independence. The AREVA QAP established independence between the organization performing checking functions and the organization responsible for performing the function.

The AREVA QAP covers the activities associated with the Design Certification (DC) of a U.S. EPR. The QA program described in the QAP topical report commits to the applicable guidance of the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Applications"

The AREVA QAP follows the guidance of Draft Standard Review Plan (SRP) Section 17.5, paragraph II.A, for providing an organizational description that includes an organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAP implementation. In addition, the AREVA QAP provides for management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. Responsibility and authority for planning, establishing, and implementing an effective overall QA program are clearly described

and defined. AREVA does not delegate any of these activities and retains responsibility for the QA program.

c. Conclusions

Based on a review of the QAP, implementing procedures, and interviews with AREVA personnel, the NRC inspection team determined that AREVA's organization conformed to the requirements of Criterion I of Appendix B to 10 CFR Part 50. The NRC inspection team verified that the QAP implemented programs for the indoctrination and training of personnel performing activities affecting quality were sufficient. No findings of significance were identified.

3. Quality Assurance Program

a. Scope

The NRC inspection team reviewed AREVA's policies and procedures that govern the QA program and its implementation to verify compliance with the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team interviewed AREVA personnel and reviewed source documentation to verify that the QA program was established that maintained control over activities affecting the quality of identified SSCs consistent with their importance to safety.

Specifically, the NRC Inspection team reviewed the following AREVA documents:

- TR ANP-10266, AREVA NP Inc. QAP for Design Certification of the U.S. EPR, Revision 2, dated December 2008
- 2009 Annual Review of AREVA NP Inc. QAP for Design Certification of the U.S. EPR Topical Report, dated April 12, 2009
- 2010 Annual Review of AREVA NP Inc. QAP for Design Certification of the U.S. EPR Topical Report, dated May 17, 2010
- AREVA NP Plants Sector Integrated Management Manual, QM DC 55, Revision J, dated June 7, 2009

b. Observations and Findings

The NRC inspection team reviewed AREVA's QAP which stated, in part, that the QAP is the top-level policy document that establishes the QA policy and assigns major functional responsibilities for design certification activities conducted by AREVA. The NRC inspection team verified that the scope of the QA program was consistent with the quality-related activities being performed in support of the U.S. EPR DC.

In addition, the NRC inspection team verified that the QAP specified that management of those organizations implementing the QA program, or portions thereof, assess the

adequacy of that part of the program for which they are responsible and ensure its effective implementation is in accordance with established procedures.

c. Conclusions

Based on a review of the AREVA QAP and implementing procedures, the NRC inspection team concluded that AREVA's QA program requirements were consistent with the regulatory requirements of Criterion II of Appendix B to 10 CFR Part 50. No findings of significance were identified.

4. Design Control

a. Scope

The NRC inspection team reviewed AREVA's policies and procedures that govern design control activities, including computer and software control, to verify compliance with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team interviewed AREVA personnel and reviewed source documentation to verify implementation of the design control program. The inspection team also reviewed multiple AREVA Software Release Notification and Software Release Notice documents and the various forms used by AREVA for software and hardware control.

Specifically, the NRC Inspection team reviewed the following AREVA documents:

- AP 0402-01, "Calculations," Revision 39, dated February 18, 2009
- AP 0403-11, "Technical Document Signatures," Revision 27, dated September 29, 2006
- EPR-EN-DI-1001, "Design Responsibilities," Revision 3, dated April 14, 2010
- AP 0412-66, "Release of Product Documentation," Revision 34, dated September 8, 2006
- EPR-EN-PR-1002, "Design Control Process," Revision 1, dated April 20, 2010
- EPR-EN-PR-1003, "Design Change Control Process," Revision 1, dated June 10, 2009
- EPR-EN-PR-1013, "Interdisciplinary Coordination and Review Process," Revision 1, dated May 7, 2010
- AP 0403-05, "Plant Technical Requirements Document," Revision 1, dated September 28, 2007
- EPR-EN-PR-1004, "Development of System Design Requirements Documents," Revision 0, dated October 14, 2008

- EPR-EN-PR-1006, “Development of System Description Documents,” Revision 0, dated October 14, 2008
- EPR-EN-PR-1007, “Design Interface Control,” Revision 1, dated May 14, 2010
- EPR-EN-PR-1009, “Development of Analytical Input Requirements Specifications (AIRS),” Revision 0, dated October 14, 2008
- AP 0418-01, “Preparation, Control, and Revisions to the Final Safety Analysis Report,” Revision 4, dated April 30, 2009
- Form 22310, “Design Verification Checklist,” Revision 6, dated September 2, 200
- AP 0902-13, “Production System Software and Hardware Changes”, Revision 5, dated July 27,2009
- AP 0902-19, “Engineering Software Error Reporting and Evaluation”, Revision 4, dated December 14, 2009
- AP 0902-28, “Development of Engineering Applications Software”, Revision 0, dated December 14, 2009
- AP 0902-29, “Procurement of Engineering Applications Software”, Revision 0, dated December 14, 2009
- AP 0902-30, “Management and Use of Engineering Applications Software”, Revision 0, dated December 14, 2009
- AP 0903-03, “Development and Control of Software Documentation”, Revision 20, dated December 11, 2003

b. Observations and Findings

b.1 Design Control Policy and Procedures

The NRC inspection team reviewed the AREVA policies and procedures that govern design control to verify conformance with Criterion III, Design Control, of Appendix B to 10 CFR Part 50. The NRC inspection team verified that AREVA’s program had provisions to control design inputs, processes, output changes, interfaces, records, organizational interfaces, and storage. The NRC inspection team verified that provisions existed to ensure that design documents specify and include appropriate quality standards and requirements, and the identification, documentation, and control of changes or deviations from specified design requirements and quality standards.

The NRC inspection team also verified that the QA program provided for design verification and that design verification be completed before design outputs are used by other organizations for design work. The NRC inspection team verified that the QA program provided for additional design verification when changes are made to previously

verified and approved designs. This included evaluating the effects of changes on the overall design and on any design analyses or bases.

Procedure EPR-EN-PR-1002 defines the flow and hierarchy of design information to integrate and transform design inputs into design outputs. The process described in EPR-EN-PR-1002 allows for verification that outputs meet inputs and ensures that structures, systems and components (SSCs) are designed, fabricated, erected and tested to quality standards. In addition, it ensures that deviations from quality standards are controlled, and that design documents are approved prior to release to records management.

Procedure EPR-EN-PR-1003 defines the actions and responsibilities necessary to propose, access, review, approve, and document changes to design configuration. It includes provisions that design changes shall be assessed by the same organization and disciplines that reviewed and approved of the original design documents and that the documents are submitted to independent verification.

Procedure 0403-11 defines the meaning and responsibilities related to signatures of technical documents. It states that design review is the preferred method of verification and is implied by signature. It also describes how independent verification and design verification is accomplished and the responsibilities of all parties involved.

Directive EPR-EN-DI-10001 specifies qualified individuals for the design process responsibilities identified in the referenced design procedures for the US EPR Project. The individuals include cognizant engineers, responsible system engineers, responsible discipline engineers, responsible technical managers, engineering discipline leads, the project manager, and the technical integration manager.

Procedure 0403-05 provides instructions for preparing, processing, and revising the plant technical requirements document (PTRD). The PTRD includes the design inputs necessary to perform the design activity and includes reasons for each input. In addition, the PTRD includes a general description of the plant and scope, as well as technical requirements, such as:

- Regulatory requirements
- Design codes, standards, guidelines
- Interpretations and scope of applicability of regulations, codes, industrial standards and guidelines
- Scope of supply
- Plant functional requirements such as plant heat-ups or load following
- Overall plant requirements and restraints such as building layout
- Plant site interface parameters
- Core parameters

- Terminal points (where scope ends and customer scope begins)
- Warranted values (reactor power level, steam flow, pressure, and steam quality at turbine…)
- Design conditions (reactor coolant system or secondary steam design parameters)
- Special engineering requirements such as system international (SI) or US customary units.

Procedure EPR-EN-PR-1004 provides requirements for preparing, processing, and revising system design requirements documents (SDRD). The SDRD documents and conveys system design requirements and includes the reason for each requirement. Higher level design requirements are decomposed into lower level design requirements. For example, requirements from the PRTD are translated into the SDRD.

Procedure EPR-EN-PR-1006 provides instructions for preparing, processing, and revising the system description document (SDD). The SDDs include a description of the system and, to the maximum extent practical, the system components, parts, and structures. The SDDs include how the following requirements are met: each design requirement, functional requirements in SDRD; regulatory requirements, and codes and standards. In addition, the SDDs include system interfaces, system boundaries, component requirements, safety and quality group classification, and how design features satisfy system and component design requirements. The SSD provide the design bases, licensing basis, and design information related to system operation, testing, installation, inspection, and maintenance.

Procedure EPR-PR-1009 specifies the requirements of providing and controlling design inputs for project analyses using the analytical inputs requirement document (AIRS). The AIRS provides configuration control of design inputs. It includes design inputs to analyses in any form such as assumptions/design constraints, internal work-in-progress, third party documents, isometrics, component characteristics, material data, etc. Third party documents are documents derived from AREVA affiliates such as OL3 design data, but must be verified to be acceptable inputs in accordance with applicable procedures first.

Procedure 0418-01 provides instructions for preparing, controlling, verifying, and submitting the final safety analysis report (FSAR) to the NRC; responding to FSAR and other design certification licensing document requests for additional information (RAIs), controlling FSAR configuration, and revising the FSAR.

Form 22310 is the design verification checklist (DCV) and used to confirm that the design meets the applicable design review considerations. One DCV is prepared by each reviewer of a safety related document. It contains a list of questions against which each reviewer must evaluate the document. If the answer is “no” to any of the questions, the reviewer must explain the reason on the comment form. All no answers are routed back to the prepared to resolve. The reviewer reviews the revised document and ensures that there are no “no” answers before signing and indicating acceptance of the document.

Procedure 0402-01 details the process for preparing, reviewing, approving, transmitting to records management, revising, and cancelling calculations.

Procedure 0412-66 defines the actions and responsibilities necessary to release product documentation for use on a specific contract, and to define the purpose, preparation, and processing of the product upgrade list (PUL) Form 20041. The PUL is prepared by individuals releasing a document to indicate needed changes/additions known at the time of the document release or to indicate input requirements or data unavailable at the time of release.

b.2 Implementation of Design Controls

The NRC inspection team reviewed the design change process, the PTRD; the AIRS, SDRD, SSD, several calculations, piping and instrumentation diagrams, design change requests (DCRs), and DCVs for the emergency feedwater system (EFWS) and component cooling water system (CCWS). In addition, the NRC inspection team interviewed AREVA NP personnel to verify that design control was appropriately implemented and that applicable design inputs were correctly translated into design output documents. Specifically, the NRC inspection team reviewed the following technical documents and calculations:

- 114-5061152-008, "Plant Technical Requirements Document for EPR design certification," Revision 8, dated November 16, 2007
- 32-9012164-002, "US EPR CCWS (KA) System Pressure, Temperature, and Overpressure Calculation," Revision 2, dated December 1, 2007
- 113-7001580-000, "DCR: Update to Post Accident Monitoring Instrumentation," Revision 0, dated December 10, 2009
- 113-9107063-000, "DCR for PZR Level Control," Revision 0, dated December 1, 2009
- 113-9057605-000, "US EPR Seismic II Reclassification DCR," Revision 0, dated September 6, 2007
- 113-9086438-000, "DCR for RCS Stainless Steel Material Grade Changes," Revision 0, dated November 25, 2008
- 113-9103010-000, "DCR Supporting WEBCAP 2008-3445 and RAI Sets 103 and 110," Revision 0, dated June 2, 2009
- 115-5067977-004, "US EPR System Design Requirements Document: Emergency Feedwater System," Revision 4, dated October 5, 2007
- 15-9021374-002, "US EPR system Description Document: Emergency Feedwater System," Revision 2, dated June 8, 2009

- 32-9092679-000, “US EPR BTP5-4 Analysis for EFW Sizing,” Revision 0, dated December 16, 2008

- 02-DCD-NPD-LAR-3001-002, “EPR Design Certification Project Emergency Feedwater System Supply, Discharge, and Drain Headers,” Revision 2, dated October 9, 2007

- 02-DCD-NPD-LAR-3010-002, “EPR Design Certification Project Emergency Feedwater System Train 1,” Revision 2, dated October 10, 2007

- 02-DCD-NPD-LAR-3011-002, “EPR Design Certification Project Emergency Pump and Piping Train 1,” Revision 2, dated October 10, 2007

- 51-5065076-00, “Flow Diagram Symbols for the EPR Design Certification Project, Contract 9000034,” Revision 0, dated May 12, 2005

- 15-5070006-003, “US EPR system description, Component Cooling Water System (KA),” Revision 3, dated October 25, 2007

- 115-5067532-005, “US EPR System Design Requirements: Component Cooling Water (KAA/KAB) System,” Revision 5, dated October 9, 2007

- 02-DCD-MPD-KAB-3052, “EPR Design Certification Project USEPR Component Cooling Water System Common 1 Reactor Building RCP 1,” Revision 2, dated December 18, 2007

- 02-DCD-MPD-JEX-3053, “EPR Design Certification Project Reactor Coolant System Primary Coolant Pump Loop 1 Pump Motor,” Revision 3, dated October 28, 2009

- 02-DCD-MPD-KAA-3010, “EPR Design Certification Project USEPR Component Cooling Water System Train 1 water supply,” Revision 2, dated October 18, 2007

- 26-901739-002, “US EPR EFW System Analytical Input Information,” Revision 2, dated September 14, 2007

- WebCAP 2010-4529-CR

- WebCAP 2010-4509-CR

Criterion III, of Appendix B to 10 CFR Part 50 states, in part, that measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in §10 CFR 50.2 and as specified in the license application, for those structures, systems, and components to which Appendix B to 10 CFR Part 50 applies are correctly translated into specifications, drawings, procedures, and instructions.

EPR-EN-PR-1002 states that the SDD shall define the system in sufficient detail to permit verification that the design satisfies the input from the SDRD. In addition, Procedures AP 0403-11 and EPR-EN-PR-1006 state, in part, that the Reviewer(s) shall

review the document to ensure that it is technically correct, complete, and has the appropriate level of detail. As a minimum, the Reviewer shall verify that the technical contents agree with the applicable requirements.

Contrary to the above, while reviewing the source documentation for the EFWS, the NRC inspection team identified one example where AREVA NP failed to appropriately translate the design bases for the emergency feedwater system into specifications. Specifically, section 5.5 of the EFWS SDD incorrectly states that "The EFWS piping within the reactor building, that is *upstream* of the check valve, shall be considered high energy lines." The correct designation should be *downstream* of the check valve as described in section 2.4.3.1, "Protection from Internal Hazards," of the EFWS SDRD. While a DCV was completed, the design described in the SDD did not satisfy the requirements from the SDRD and the technical contents did not agree with the applicable requirements. This issue has been identified as Violation 05200020/2010202-01. AREVA took immediate corrective action and opened WebCAP 2010-4509 to document the discrepancy.

The NRC inspection team reviewed the SDD for the EFWS to verify the control of design interfaces. The NRC inspection team noted that while the SDD contained a section for specifying system interface requirements, the SDD only included the nominal electrical system input parameters and did not provide tolerance ranges for assumed electrical inputs. While this issue does not constitute a violation of NRC requirements, the inspection team discussed with AREAVA the benefits of adding the tolerance ranges to the SDD system interface requirements.

b.3 Computer and Software Control

The NRC inspection team reviewed the AREVA policies and implementing procedures that govern computer and software control to verify conformance with Criterion III, Design Control, of Appendix B to 10 CFR Part 50. The NRC inspection team verified that AREVA's program had provisions to control computer and software usage and that procedures were in place for the quality activities that were performed for the U.S. EPR DC work.

The NRC inspection team reviewed the QAP and verified that it contained the overall AREVA policies that govern computer and software control. The computer and software control program included interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of computer software.

Procedure 0902-13 establishes the requirements for changing system software and hardware, and to define and establish methods for testing system software and hardware. AREVA Procedure 0902-13 contained adequate detail for the initiation to change computer software, and testing needed to ensure that new or updated computer software and hardware will function properly and will handle the types of inputs, as part of AREVA's DC work activities, and that the outputs from such hardware and software is adequate and correct.

Procedure 0902-19 describes the process for reporting, evaluating, correcting, and documenting errors in engineering software. AREVA Procedure 0902-19 contained adequate detail for the initiation, reporting, evaluation, and actions needed to document errors with engineering software.

Procedure 0902-28 defines the requirements for development of engineering software, whether internally developed within AREVA, or obtained from a commercial vendor or another AREVA subsidiary. AREVA Procedure 0902-28 contained adequate detail for the development of engineering applications software to be used for activities to support the U.S. EPR DC.

Procedure 0902-29 defines the requirements to obtain and release engineering applications computer software acquired both from commercial and non-commercial sources. AREVA Procedure 0902-29 contained adequate detail to request new or updated versions of computer software applications and for release of these applications to run on the proper hardware and be used by authorized end users.

Procedure 0902-30 describes the management and use of engineering software that has already been developed, internally or by a third party, or procured. The 0902-30 procedure defines the responsibilities related to the use of and control over software used at AREVA in support of the U.S. EPR DC. This procedure references the forms that are used for the control of software and reporting of software errors, and provides guidance to which form to use and how to complete the form(s).

Procedure 0903-03 provides the guidelines for preparing and issuing documentation for software used in engineering design applications. This procedure, in part, contained adequate detail for the development of documentation (e.g. – design output information) that is the result of or outcome from using engineering software to evaluate a design parameter or condition to verify that the U.S. EPR DC design work meets the applicable requirements.

The NRC inspection team determined that the appropriate level of control had been invoked on the use of computers and engineering software for the U.S. EPR DC work, and that the computer and software control was consistent with AREVA's QAP.

c. Conclusions

With the exception of Violation 05200020/2010202-01 for failure to appropriately translate design inputs into design outputs, the NRC Inspection team concluded the AREVA design control process conforms to the requirements of Criterion III of Appendix B to 10 CFR Part 50.

5. Procurement Document Control

a. Inspection Scope

The NRC inspectors reviewed AREVA policies and procedures governing procurement document control to verify compliance with the QA requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors assessed how those guidelines have been applied to the AREVA U.S. EPR DC application activities. The NRC inspectors focused on AREVA supplier contracts issued in support of US EPR DC application activities. Specifically, the NRC inspectors reviewed purchase orders (POs), associated purchase authorizations (PAs) or requisitions (PRs), and methods used by AREVA to qualify suppliers of items and services to verify that they met the requirements of the licensee's QA program.

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

- TR ANP-10266, AREVA NP Inc. QAP for Design Certification of the U.S. EPR, Revision 2, dated December 2008
- AP 1708-08, Quality Control Surveillance, Revision 24, dated August 8, 2008
- AP 1212-12, Purchasing Documents, Revision 33, dated September 30, 2009
- AP 0412-67, Processing Technical Documents from Suppliers and Customers, Revision 30, dated December 17, 2009
- AREVA NP Inc. Approved Suppliers List for Plants and Services
- PO 100803226, Paul C Rizzo Associates, Inc., dated June 19, 2009, and Change Order (CO) 1
- PR 83-9113251, Paul C Rizzo Associates, Inc., Revisions 000 and 001, dated June 9, 2009
- Rizzo NCR Dated, dated April 22, 2010
- Certificate of Conformance for 32-1909591-000
- PO 179166, Bechtel Power Corporation, dated August 25, 2006
- PA 83-9025336-000, dated August 3, 2006; and Revision 001, dated August 18, 2006
- 38-7006268-000, Bechtel Certificate of Conformance, dated June 17, 2010
- 32-9060766-000, “SSI analysis of the US EPR Essential Service Water Cooling Tower and Pump Structure,” dated November 1, 2007
- PO 1008039080, Mallett Technology, Inc., Revision 0, dated August 26, 2009
- PO 178725 AREVA NP GmbH, Erlangen, dated August 14, 2006; CO 1, dated September 7, 2006; CO 2, dated December 14, 2006
- PA 83-9025595-001, dated September 6, 2006
- PA 83-9025595-002, dated November 28, 2006
- 32-9043829-000, Certificate of Conformance for PO 178725, dated February 21, 2007
- 32-9043830-000, Certificate of Conformance, dated February 21, 2007

- 32-9036742-000, “EPR OL3 Detail Design of Prestressed Containment Reinforcement Calculations: Dome”, dated December 15, 2006
- 38-9027411-000, “Reactor Control, Survaillance and Limitation System I&C Functions,” dated November 8, 2006
- 02-9048137D-000, “OL3 Incore Instrumentation – Interfaces Between Instrumentation Lances and Measurement Probes with RPV-Head”, dated April 11, 2007
- PO 178411 (and CO 2 December 19, 2006), dated August 7, 2006
- PA 83-9026864-000, dated July 27, 2006
- PR 83-9026864-001, dated December 29, 2006
- 38-7004855-00, CoC for US EPR CRDM Design for DC, dated May 3, 2010
- 32-9062529-000, Control Rod Drive Mechanism (CRDM) Stress Analysis for Flange Connection, dated October 1, 2007
- 02-DCD-NCP-JDA-4000A0-001, US EPR Control Rod Drive Mechanism Drive Rod – Acceptance Drawing, dated October 4, 2007
- PA 83-5068279-03, Fuels America, dated May 15, 2006
- PA 83-5068279-04, dated May 26, 2006
- Fuels America PO 4500037686, Revision 1, dated July 6, 2006, Revision 0 dated July 6, 2006, to GmbH Erlangen
- Fuels America PA 83-9022734-000/001, dated June 1, 2006
- QCSR # 9025705, AREVA NP GmbH Technical Center – NTT3-G, June 26 to July 7, 2006
- PNR (Product Nonconformance Report) 4043, July 4, 2006

b. Observations and Findings

b1. Policy and Procedures

The NRC inspection team reviewed the AREVA policies and procedures to verify conformance with Criterion IV, Procurement Document Control, of Appendix B to 10 CFR Part 50. The NRC inspection team verified that AREVA’s program had provisions to ensure that procurement documents include or incorporate applicable regulatory requirements, technical requirements, and QA program requirements. AREVA indicated

that as of the date of the inspection, they do not have a firm contract for constructing an EPR in the U.S., so currently all procurements have been for engineering services.

Section 4.0 of the AREVA QAP defines the procurement document controls for safety-related services. The QAP states that AREVA affiliate companies such as AREVA NP SAS and AREVA NP GmbH, as well as cross-sector affiliates such as AREVA NP Nuclear Fuel, are considered suppliers. As such, products and services procured from these affiliates are subject to the procurement document controls defined in the QAP.

Administrative Procedure (AP) 1212-12, "Purchasing Documents," defines the purchasing method, responsibilities, quality requirements, and actions necessary to prepare and process purchasing documents. The inspectors noted that AP 1212-12 contains appropriate provisions for developing, reviewing and approving documents and changes thereto.

AP 0412-67, "Processing Technical Documents from Suppliers and Customers," defines actions and responsibilities necessary to process technical documents from suppliers and customers. AP 412-67 contains provisions for procuring and approving supplier documents, including safety-related input documents, for use for the U.S. EPR design.

b.2 Implementation of Procurement Document Controls

The NRC inspection team reviewed procurement documents referenced below for the following suppliers, sub-suppliers, and services:

- AREVA NP GmbH for safety-related input documents such as 32-9036742-000, 38-9027411-000, and 02-9048137D-000 referenced above
- AREVA NP GmbH for stress and fatigue analysis for U.S. EPR CRDM Pressure Housing (32-9062529-000)
- AREVA NP Inc. Fuels America for engineering services for fuel and core design and critical heat flux activities and testing
- AREVA NP GmbH for critical heat flux testing (procured by AREVA NP Inc. Fuels America)
- Bechtel Power Corporation for civil and structural engineering design support
- Paul C. Rizzo Associates, Inc., for an independent review of calculations and consulting services
- Mallett Technology for the ANSYS software program

The NRC inspection team confirmed that procurement documents were reviewed and approved in accordance with AP 1212-12. The procurement documents included a detailed scope of work, appropriate technical requirements, identification of acceptance requirements, requirements for use of the audited and approved 10 CFR 50 Appendix B quality assurance program, access to the supplier's facilities and records for inspection

or audit, requirements for documentation submission, and requirements for reporting nonconformances. Additionally, the inspectors verified that procurement documents invoked the provisions of 10 CFR Part 21 as required by 10 CFR 21.31. The inspection team also verified that provisions exist to ensure that changes to procurement documents are subject to the same degree of control, review, and approval as those utilized in the preparation of the original documents.

The inspectors verified that project work plans were submitted by suppliers when required by the procurement document. The inspectors also verified that on-site surveillances were conducted when required using an approved procedure.

The inspectors sampled incoming supplier technical documents with associated certificates of conformance and document comment forms (DCFs) used for acceptance. The inspectors noted that each reviewed supplier document included a DCF and was reviewed and accepted prior to use for safety-related design activities.

c. Conclusions

The NRC inspection team concluded that AREVA's procurement document control process was consistent with the regulatory requirements of Criterion IV of Appendix B to 10 CFR Part 50 and had been appropriately implemented as required by procedures noted above to support U.S. EPR design activities. No findings of significance were identified.

6. Control of Purchased Material, Equipment, and Services

a. Inspection Scope

The NRC inspectors reviewed AREVA policies and procedures governing the control of purchased material, equipment, and services to verify compliance with the QA requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors assessed how those guidelines have been applied to the AREVA U.S. EPR DC application activities.

The NRC inspectors assessed how those guidelines have been applied to the U.S. EPR DC supplier qualification and oversight activities. The NRC inspectors chose a sample of supplier audits covering foreign AREVA affiliates, domestic affiliates, and external suppliers of services.

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

- TR ANP-10266, AREVA NP Inc. QAP for Design Certification of the U.S. EPR, Revision 2, dated December 2008
- AP 1719-22, Quality Assurance Audits of Suppliers, Revision 24, dated May 20, 2009
- OI-1443, Preparing the Annual Supplier Evaluation, Revision 7, dated June 26, 2006

- 2009 Annual Supplier Evaluation, dated March 10, 2010
- AREVA NP Inc. Annual Supplier Evaluation – 2008, dated February 12, 2009
- Audit 563-1, conducted August 29-31, 2006
- Audit 563-2, conducted August 18-20, 2009, dated September 19, 2009
- Audit 549-2, Bechtel Power Corp, conducted February 10-12, 2009
- Audit 549-1, Bechtel Power Corp, conducted January 9-12, 2006, dated February 13, 2006
- Audit 111-30, AREVA NP Inc. Fuels America, conducted February 5-7, 2008, dated March 9, 2009
- Audit 475-3, ANSYS Inc., dated June 29, 2009
- Audit 460-4 , AREVA NP GmbH, conducted June 15-18, 2009, dated July 16, 2009
- Audit 460-1 , AREVA NP GmbH, conducted April 10-12, 2006, dated May 12, 2006

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team reviewed the AREVA policies and procedures that govern control of purchased material, equipment, and services to verify conformance with Criterion VII of Appendix B to 10 CFR Part 50. The NRC inspection team verified that AREVA's program had provisions for auditing, documenting and reviewing audit results, and for designating management levels to review and assess audit results.

Section 7.0 of the AREVA QAP for Design Certification of the U.S. EPR defines the control of purchased safety related materials, items, and services including source evaluation and selection, source inspection, and receiving inspection in accordance with regulatory and contract requirements. The QAP states that AREVA may accept a supplier audit conducted an AREVA NP Inc. affiliate or through the Nuclear Industry Assessment Committee (NIAC) after QA review.

Section 18.0 of the AREVA Quality Assurance Plan (QAP) for Design Certification of the U.S. EPR defines the control of audits. Subsection 18.4 discusses the requirements for supplier audits, restates the audit methods in Section 17.0, and discusses ongoing auditing.

AP 1719-22, "Quality Assurance Audits of Suppliers," defines methods to be used in preparing for and conducting QA Audits of company suppliers of ASME Code items and safety-related products and services. The procedure covers requirements for audit planning, conduct, reporting, and corrective action follow-up. Additionally, AP 1719-22 discusses the methods for conducting the annual supplier evaluation to maintain suppliers on the approved suppliers list. OI-1443, "Preparing the Annual Supplier

Evaluation," provides additional requirements for the annual supplier evaluation including communications and documentation.

b.2 Implementation of Control of Purchased Material, Equipment, and Services

The NRC inspection team reviewed audit reports referenced above for the following suppliers:

- AREVA NP GmbH
- AREVA NP Inc. Fuels America
- Bechtel Power Corporation
- Paul C. Rizzo Associates, Inc.
- ANSYS Inc.

The inspectors determined that the audits for these suppliers had been conducted within the required triennial frequency. The inspectors confirmed that AREVA had conducted audits of its foreign affiliates and domestic affiliates operating under different quality assurance programs as required by the QAP. For the audits reviewed, the NRC inspectors verified that they were conducted by qualified personnel using an approved procedure and detailed checklist. The scope of the audits adequately covered the services procured and the audits included objective evidence to support their conclusions. For the audits conducted by AREVA, the inspectors noted that AREVA followed the suppliers' corrective actions in response to its audit findings through correspondence and objective evidence.

The inspectors reviewed the 2009 audit of ANSYS Inc. which had been performed by NIAC. The inspectors noted that AREVA had appropriately reviewed the audit and corrective actions before accepting the audit and maintaining ANSYS Inc. on the approved suppliers list. Mallett Technology, an ANSYS local sales office, is noted on the approved suppliers list for ordering ANSYS products.

The NRC inspection team reviewed the 2008 and 2009 annual supplier evaluations for suppliers on the approved suppliers list. The inspectors noted that the report was a summary that covered all suppliers collectively; however, detailed information from the review was available upon request. The annual reviews considered audit findings, nonconformance reports, condition reports, and operating experience.

c. Conclusions

The NRC inspection team concluded that AREVA's process for the control of purchased services was consistent with the regulatory requirements of Criterion VII of Appendix B to 10 CFR Part 50 and had been appropriately implemented. No findings of significance were identified.

7. Corrective Action Program

a. Scope

The NRC Inspection Team reviewed the AREVA 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. The NRC Inspection Team also reviewed the following documents to verify adequate implementation of the corrective action procedures:

- TR ANP-10266, AREVA NP Inc. QAP for Design Certification of the U.S. EPR, Revision 2, dated December 2008
- AP 1717-06, dated January 27, 2010
- Trending document/management review report no. T5.33.1-9130554-000, dated 10/23/2009
- Condition Tracking Report and Apparent Cause Report No.2009-1630, dated March 17, 2009
- Condition Tracking Report and Apparent Cause Report No.2009-7772, dated November 17, 2009
- Condition Tracking Report and Apparent Cause Report No.2009-7703, dated November 13, 2009
- Condition Tracking Report and Apparent Cause Report No.2008-3445, dated June 13, 2008
- Condition Tracking Report and Apparent Cause Report No.2010-3022, dated May 03, 2010
- Root Cause Report No.2008-3445, dated October 27, 2009
- Condition Tracking Report and Apparent Cause Report No.2009-2978, dated May 14, 2009
- Condition Tracking Report and Apparent Cause Report No.2009-3468, dated June 03, 2009
- Condition Tracking Report and Apparent Cause Report No.2009-8440, dated 12/17/2009
- Condition Tracking Report and Apparent Cause Report No.2009-5963, dated 09/11/2009
- Condition Tracking Report and Apparent Cause Report No.2008-4742, dated 08/25/2008
- Condition Tracking Report and Apparent Cause Report No.2008-5066, dated May 2010

- Condition Tracking Report and Apparent Cause Report No.2008-5073, dated 08/19/2008

- Condition Tracking Report and Apparent Cause Report No.2010-418, dated 01/21/2010

b. Observations and Findings

AREVA has established a corrective action program under Chapter 16 of the QAP, as implemented by Procedure 1717-06 "Corrective Actions". The QAP defines the elements of the corrective action generation, implementation and verification system for safety related items or services. Procedure 1717-06 provides guidance for all personnel that have the responsibility of reporting and/or recording known or identified conditions adverse to quality. The procedure addresses how nonconformances and failures are evaluated to determine the need for corrective actions, and that such action is taken as necessary. Lastly, the procedure provides instructions for documenting and evaluating significant condition adverse to quality and for taking corrective actions to preclude recurrence.

The NRC inspection team verified condition tracking reports (CRs) were issued for conditions adverse to quality (CAQs) and significant conditions adverse to quality (SCAQs) for failures, deviations, and nonconformances. The NRC inspection team identified that no formal process was in place to screen RAIs for potential CAQs or SCAQs; however, AREVA provided the team with several examples where requests for additional information (RAIs) resulted in the generation of a CR. This issue does not constitute a violation of NRC requirements.

The team reviewed a sample of CRs to ensure that issues were being appropriately entered into the corrective action program, that the CRs were evaluated for significance level, that the root causes for significant conditions adverse to quality were being appropriately identified to prevent recurrence, and that corrective actions had been appropriately identified and implemented.

The team also reviewed the AREVA process outlined in NP 1717-06 for assigning significance levels to identified non-conforming conditions. The team determined that the procedure provided guidance for classifying non-conforming conditions into one of four categories. The guidance and examples provided in the procedure applied to AREVA cooperate wide and focused mainly on non-conforming conditions identified in the support of operations and maintenance activities. There was little specific guidance for evaluating the types of design deficiencies related to development of the U.S. EPR DCD application. Although the NRC inspection team considered the guidance to be weak in this respect, no instances of inappropriately classified CRs were identified.

The NRC Inspection Team verified that AREVA had performed one significant level 1 corrective action report with an associated root cause evaluation between 2008 thru 2010. The corrective action report adequately identified the significance level, the cause of the significant condition adverse to quality, and the actions that were implemented to prevent reoccurrence. The root cause evaluation specifically addressed three examples of how AREVA's Technical specifications did not consider the design basis of the conditions stated in FSAR Chapter 15 "Accident Analysis". The extent of condition indicated that one of AREVA's internal procedures was violated due to the three

examples not being supported by technical analysis and how those examples could have resulted in an unanalyzed condition at the plant, if actually built. The staff noted that AREVA did implement the appropriate corrective actions for each issue identified associated with the root cause evaluation and that several long-term preventive and follow-up actions were issued as a result.

c. Conclusions:

The NRC inspectors concluded that AREVA's corrective action program requirements and implementation for the US EPR project were consistent with the regulatory requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

8. Audits

a. Scope

The NRC inspectors reviewed AREVA policies and procedures governing the internal audit process to verify compliance with the QA requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors assessed how those guidelines have been applied to the AREVA U.S. EPR DC application activities. To accomplish this task, the NRC inspectors chose a sample of internal audits.

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

- TR ANP-10266, AREVA NP Inc. QAP for Design Certification of the U.S. EPR, Revision 2, dated December 2008
- AP 1719-21, Quality Assurance Audits of Internal Activities, Revision 23, dated September 1, 2009
- Q-105, Performance and Evaluation of Cross-Audits, Revision 3, dated February 1, 2010
- Internal Audit Report 10-07, EPR Deign Certification, February 25, 2010, conducted February 1-9, 2010
- Audit Report 09-21 (Fuels America # 09-93), Cross-Audit of AREVA NP Inc., Plants and Services
- QA Internal Audit Report 09-06, EPR & COLA Projects, dated April 14, 2009, conducted March 30-April 3, 2009

b. Observations and Findings

b.1 Policies and Procedures

The NRC inspection team reviewed the AREVA policies and procedures that govern internal audits to verify conformance with Criterion XVIII of Appendix B to 10 CFR Part

50. The NRC inspection team verified that AREVA's program had provisions auditing, documenting and reviewing audit results, and designating management levels to review and assess audit results are established.

Section 18.0 of the AREVA QAP for Design Certification of the U.S. EPR defines the control of audits. Internal audits are conducted to cover all program elements annually.

AREVA covers all program elements annually through audits conducted by the QA organization as well as AREVA NP Inc. Fuels America QA organization for those elements where AREVA QA cannot audit itself. AP 1719-21, "Quality Assurance Audits of Internal Activities," defines the requirements for planning, conducting, and reporting internal audits. Q-105, "Performance and Evaluation of Cross-Audits," covers the performance of cross-audits by one AREVA QA organization of another.

b.2 Implementation of Audits

The NRC inspection team reviewed the most recent internal audit and one cross-audit to verify they had been adequately conducted, documented, and that corrective actions were taken where necessary. AREVA informed the inspectors that all program areas were covered by the one annual internal audit and one cross-audit. The inspectors verified that these audits had been conducted annually. For each of these audits, the inspectors verified that a plan had been developed and approved. The NRC inspectors verified that audit team members were sufficiently qualified and that these auditors were not auditing their own work. The inspectors reviewed the audit reports and attached checklist to ensure that the audits were thorough and contained enough detail to support the report's conclusions. An audit report was issued and sent to the affected organization and appropriate managers within 30 days.

The NRC inspection team verified that observations and findings from internal audits were entered into the corrective action program. The inspectors noted that the internal audit team leader was included in the corrective action program approval process enabling real-time follow-up of audit findings. For the audits reviewed, the inspectors sampled associated CRs included in the reports and concluded that the evaluations and corrective actions were appropriate to the circumstance and were generally completed in a timely manner.

c. Conclusions

The NRC inspection team concluded that AREVA's internal audit process was consistent with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50 and had been appropriately implemented as required by procedures noted above to support U.S. EPR design activities. No findings of significance were identified.

9. Entrance and Exit Meeting Summary

On June 28, 2010, the NRC presented the inspection scope during an entrance meeting with AREVA staff. On April 22, 2010, the NRC presented the inspection results during an exit meeting with Ron Affolter, Vice President, U.S. EPR Deployment, and other AREVA personnel. The entrance and exit meeting attendees are listed in the attachment to this report.

ATTACHMENT 1

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Affiliation	Entrance	Exit
Jeffery Jacobson	NRC/NRO	X	X
Samantha Crane	NRC/NRO	X	X
John Bartleman	NRC/R-II	X	X
Garrett Newman	NRC/NRO	X	X
Shavon Edmonds	NRC/NRO	X	X
Ron Affolter	AREVA	X	X
Michael Morgan	AREVA		X
Sandra Sloan	AREVA	X	X
Russ Wells	AREVA		X
Kevin Connel	AREVA		X
Tim Stack	AREVA		X
Robert Penn	AREVA		X
Ronnie Gardner	AREVA	X	X
Charles Tally	AREVA		X
Dennis Newton	AREVA		X
Fred Maas	AREVA		X
Calvin Coles	AREVA		X
Jeff Patton	AREVA		X
Wandar Fralay	AREVA		X
Thomas Ehrhorn	AREVA		X
Michelle Cobbs	AREVA	X	X
Bernie Copsey	AREVA	X	X
Jeff Tucker	AREVA		X
Ben Kennedy	AREVA		X
Matt Davidsaver	AREVA		X
Tara Werner	AREVA		X
John Walker	AREVA		X
Barbara Minur	AREVA		X
Marty Bryan	AREVA		X
Tehemton Bhapwapan	AREVA		X
Gary Szabatura	AREVA	X	
Ed Bowen	AREVA	X	
Cynthia Wilkerson	AREVA	X	
Steven Graham	HSE UK Regulator	X	X
Fiona Hunter	HSE UK Regulator	X	X

2. PERSONS CONTACTED

Tara Werner – Manager, Quality Programs
Bernie Copsey – Manager, Engineering Support
Michael Saniuk – Manager, Project Quality
Mike Cox – Manager, Audit Programs
Russ Wells – Advisory Engineer, Regulatory Affairs

Tim Stack – Advisory Engineer
John Walker – Advisory Engineer
Jim Newman – IMS Design Tools
Nate Andreu – IMS Design Tools
Katie Accardo – Administrator for Documentum
Matt Davidsaver – Supervisor, EPR Records and Document Management System
Anne Smith – Supervisor, Records Center
Nancy Arena – Corporate Records Manager
Fred Maass – Manager Nuclear Island System Engineering
Ronnie Broughton – Component Cooling Water System Engineer
Tehemton Bhagwagar – Supevisory Engineer
Doug Brownson – Supervisor of Non-LOCA Analysis
Tom Ehrhorn – Quality Engineer
Wanda Fraley – Training Specialist
Brent Still – Engineer 2, Class 1 Piping Analyst Group
Gary Szabatura – Manager ASME Program and Procedures
Jacoben Tone – Engineer 1, Severe Accidents Group
Margarita Villa – Engineer 1, RCS Class 1 Group

3. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection"

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

Item Number	Status	Type	Description
05200020/2010-202-01	Opened	NOV	Criterion III