May 7, 2008

Mr. Hans-Joachim Nisslein
QEM Liaison Officer
AREVA-NP GmbH
Paul-Gossen-Strasse 100
91001 Erlangen, Germany

SUBJECT: NRC INSPECTION REPORT FOR AREVA-NP GmbH 99901371/2008-201, NOTICE OF VIOLATION, AND NOTICE OF NONCONFORMANCE

Dear Mr. Nisslein:

From March 10–14, 2008, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the AREVA-NP GmbH (AREVA) facility in Erlangen, Germany. The enclosed report presents the results of that inspection.

This was a limited scope inspection that focused on assessing your compliance with the provisions of Title 10, Part 21, "Reporting of Defects and Noncompliance," of the *Code of Federal Regulations* (10 CFR Part 21) 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.

During this inspection, the NRC found that the implementation of your quality assurance program failed to meet certain NRC requirements as discussed in the enclosed Notice of Violation (NOV), Notice of Nonconformance (NON), and NRC Inspection Report. Specifically, a review of the AREVA 10 CFR Part 21 implementation revealed that AREVA did not adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards. The enclosed NOV cites the violation of 10 CFR Part 21, and the enclosed report discusses the circumstances surrounding the NOV. Please note that you are required to respond to this letter and should follow the instructions 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.

In addition, the inspectors found that the implementation of your quality assurance program failed to meet certain NRC requirements imposed on you by your customers. Specifically, the inspectors determined that the AREVA procedures contained inadequate instructions related to the oversight of suppliers and the nonconformance and corrective action process as required by Appendix B to 10 CFR Part 50. The enclosed NON cites these nonconformances, and the enclosed report describes the circumstances surrounding them. Please respond to the nonconformances and follow the instructions specified in the enclosed NON when preparing your response.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," the NRC will place a copy of this letter, its enclosures, and any associated

correspondence in the NRC's Public Document Room or in the NRC's Agencywide Documents Access and Management System, which is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that the agency can make the response available to the public without redaction.

Sincerely,
/RA/

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

Docket No.: 99901371

Enclosure:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report No. 99901371/2008-201

correspondence in the NRC's Public Document Room or in the NRC's Agencywide Documents Access and Management System, which is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that the agency can make the response available to the public without redaction.

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NAME	MConcepcion: tsm6	MGareri	GGalletti	RPascarelli	JPeralta
DATE	04/29/2008	05/1/2008	04/292008	05/7/2008	05/7/2008

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NOTICE OF VIOLATION

AREVA-NP GmbH
Paul-Gossen-Strasse 100
91001 Erlangen, Germany

Docket Number 99901371
Inspection Report Number 2008-201

A U.S. Nuclear Regulatory Commission (NRC) inspection, conducted March 10–14, 2008, of activities performed at AREVA-NP GmbH (AREVA), identified a violation of NRC requirements. 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, "Reporting of Defects and Noncompliance," 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(d)(1) requires that a director or responsible officer subject to the regulations of this part or a person designated under 10 CFR 21.21(d)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect.

Contrary to the above, as of March 14, 2008, the AREVA 10 CFR Part 21 implementing procedure QM-AW-502, "Process and Reporting of Defects and Noncompliance of Contracts under 10CFR21," dated November 14, 2006, does not provide procedural guidance for (1) evaluating deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards and (2) notifying the Commission when a director or responsible officer subject to the regulations of this part obtains information reasonably indicating a failure to comply or a defect in accordance with 10 CFR 21.21(a) and 10 CFR 21.21(d)(5), respectively.

This issue has been identified as Violation 99901371/2008-201-01.

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

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," AREVA 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.

ENCLOSURE 1

Because your response will be made available electronically for public inspection in the NRC Public Document Room or 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/reading-rm/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 at Rockville, Maryland, this 7th day of May 2008.

NOTICE OF NONCONFORMANCE

AREVA-NP GmbH
Paul-Gossen-Strasse 100
91001 Erlangen, Germany

Docket Number 99901371
Inspection Report Number 2008-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted March 10–14, 2008, of activities performed at AREVA-NP GmbH (AREVA), it appears that AREVA did not conduct certain activities in accordance with NRC requirements that NRC licensees contractually imposed on AREVA.

A. Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10, Part 50, "Domestic Licensing of Production and Utilization Facilities," of the *Code of Federal Regulations* (10 CFR Part 50) states, in part that, measures shall be established to assure the purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

Procedure QM-AW-402, "Supplier Assessment (QM/EM/technical/commercial)," Revision E, dated August 28, 2006, defines the methods to approve and assess performance of suppliers to maintain their approved vendor status. The procedure is applicable to all suppliers of products and services including hardware, software, design, maintenance, and installation.

Contrary to the above, the AREVA vendor survey report (SEQ-G/2007/en/0059) dated August 8, 2007, did not contain sufficient evidence to support the closure of nonconforming conditions identified as a result of this survey. The vendor's supplier survey process does not provide a systematic method or adequate guidance for the review of supplier survey-related nonconformances or associated corrective actions to determine if they are being completed in a timely fashion or if measures are effective in precluding recurrence of the deficiencies.

This issue has been identified as Nonconformance 99901371/2008-201-1.

B. Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50 states, in part, "measures shall be established to control materials, parts, or components which do not conform to requirements These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations."

Procedure QM-AW-503, Revision E, dated October 17, 2007, defines responsibilities and procedures for handling nonconformances in supplies and services for nuclear

facilities. The procedure describes the process for identifying, evaluating, reporting, and correcting all nonconformances.

Contrary to the above, QM-AW-503, Section 1.3, "Definitions," contains a definition of nonconformance that permits identified nonconformances to remain outside the scope of the nonconformance process if the nonconformance can be corrected within the "same processing phase."

This issue has been identified as Nonconformance 99901371/2008-201-02.

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

Procedure QM-AW-503, Revision E, dated October 17, 2007, defines responsibilities and procedures for handling nonconformances in supplies and services for nuclear facilities. The procedure describes the process for identifying, evaluating, reporting, and correcting all nonconformances.

Contrary to the above:

1. The vendor's corrective action program does not provide a systematic method or contain adequate guidance for the review of corrective actions to determine if they are being completed in a timely fashion and are effective in precluding recurrence of the deficiencies.

2. The vendor's corrective action program does not provide a systematic method or contain adequate guidance for establishing the significance level or priority for nonconformances and their associated corrective actions.

These issues have been identified as examples of Nonconformance 99901371/2008-201-03.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality and Vendor Branch 1, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include (1) a description of steps that have been or will be taken to correct this item, (2) a description of steps that have been or will be taken to prevent recurrence, and (3) the dates your corrective action and preventive measures were or will be completed. Where good cause is shown, the NRC will consider extending the response time.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or the NRC Agencywide Documents Access and Management System

(ADAMS), 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. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/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 at Rockville, Maryland, this _7th_ day of May 2008.

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

VENDOR INSPECTION REPORT

Report No:	99901371/2008-201
Organization:	AREVA-NP GmbH Paul-Gossen-Strasse 100 91001 Erlangen, Germany
Vendor Contact:	Mr. Hans-Joachim Nisslein, QEM Liaison Officer AREVA-NP GmbH Paul-Gossen-Strasse 100 91001 Erlangen, Germany email: Hans-joachim.Nisslein@areva.com
Nuclear Industry:	AREVA-NP GmbH (AREVA) is a world-wide supplier of digital I&C systems for use in safety-related and nonsafety-related applications for commercial nuclear power plants.
Inspection Dates:	March 10-14, 2008
Inspection Team Leader:	Greg S. Galletti, DCIP/NRO
Inspector:	Juan Peralta, DCIP/NRO
Inspector:	Milton Concepcion, DCIP/NRO
Inspector:	Mario Gareri, DE/NRO
Observer:	Mr. Stefan Schielke, from the German Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety (BMU)

Approved by:

Juan Peralta
Quality and Vendor Branch 1
Division of Construction Inspection
and Operational Programs (DCIP)
Office of New Reactors (NRO)

Date

1.0 INSPECTION SUMMARY

The purpose of this inspection was to review selected portions of the quality assurance (QA) controls and controls under Title 10, Part 21, "Reporting of Defects and Noncompliance," of the *Code of Federal Regulations* (10 CFR Part 21) established and implemented by AREVA. The U.S. Nuclear Regulatory Commission (NRC) conducted the inspection at the AREVA facility in Erlangen, Germany. The NRC inspection bases were the following:

- 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."

- 10 CFR Part 21

1.1 VIOLATIONS

The inspection identified Violation 99901371/2008-201-01, which is discussed in Section 3.5 of this report.

1.2 NONCONFORMANCES

- The inspection identified Nonconformance 99901371/2008-201-01, which is discussed in Section 3.3 of this report.

- The inspection identified Nonconformance 99901371/2008-201-02, which is discussed in Section 3.4 of this report.

- The inspection identified Nonconformance 99901371/2008-201-03, which is discussed in Section 3.4 of this report.

2.0 STATUS OF PREVIOUS INSPECTION FINDINGS

The NRC had not previously performed an inspection at the AREVA facility in Erlangen, Germany.

3.0 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 DESIGN CONTROL

a. Inspection Scope

The inspectors reviewed the AREVA policy and procedures governing design control activities as they relate to the development of the TELEPERM XS (TXS) software and

hardware to ensure that those guidelines adequately described the process as required in Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. The inspectors also reviewed a representative sample of design packages and observed testing activities at the AREVA TXS Integration Center to verify implementation of such requirements.

b. Observations and Findings

b.1 Generic System Qualification of TXS System Platform

The inspectors reviewed the software documentation associated with the TXS system platform to verify whether the process implemented by AREVA is consistent with applicable regulatory requirements and relevant industry standards, including the Institute of Electrical and Electronics Engineers (IEEE) Standard 7-4.3.2-2003, "Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations," which gives specific requirements concerning software development activities. In addition to reviewing the documents governing the process, the inspectors also interviewed AREVA personnel to ensure that activities were commensurate with their responsibilities.

TXS Platform Software Development and Configuration Management

FAW TXS-1.1en, Revision A, "Phase Model for the Development of Software Components for TELEPERM XS," dated August 1, 2006 provides controls for developing, qualifying and maintaining software components of the digital safety I&C system TXS. The procedure defines the software life cycle processes to be implemented in the development of a safety-related digital system. The procedure was developed using the following the industry guidance:

- International Electrotechnical Commission (IEC) 60880: "Nuclear Power Plants—Instrumentation and Control Systems Important to Safety—Software Aspects for Computer-Based Systems Performing Category A Functions"

- DIN International Organization for Standardization (ISO) 9000-3, 1997: "Guidelines for the application of ISO 9001, 1994, to development, supply, installation, and maintenance of computer software"

- IEEE 1074-1997: "Standard for Developing Life Cycle Processes"

- American National Standards Institute (ANSI)/IEEE 7-4.3.2: Also covered by IEC 60880

The Teleperm XS system platform architecture consists of a layered software structure that includes system hardware, system software, and application software. This architecture is qualified once and maintained in accordance with the configuration management plan for the Teleperm XS system platform. The inspectors noted that changes in the Teleperm XS system platform can be related to hardware/software components due to reported complaints from customers or plant personnel involved with

the creation and modification of application software, changes or additions to task descriptions, and changes in limit values or other parameters.

FAW TXS 6.3en, "Software Requirements Specifications," Revision A, dated May 8, 2006, defines the general structure and content of TXS software requirements specification documents. The inspectors noted that the structure of the design process for the Teleperm XS includes the development of software requirements specifications, software design, implementation of the software in both general purpose and application oriented language, and system integration and validation. The inspectors also noted that the procedure considers the requirements of IEC 60880 and IEEE 830, "Recommended Practice for Software Requirements Specifications."

FAW TXS-6.4en, "Software Design Descriptions," Revision A, dated May 8, 2006, defines the general structure and content of TXS software design description documents. A TXS software design description document is a representation of a software system and is a part of the developer documentation of a TXS Configuration management (CM) plan. The inspectors noted, through the review of design documents related to the Teleperm XS platform, that a TXS design description is used as a method for communicating software design information. The inspectors were able to witness how the software system will be structured to satisfy the requirements identified in a TXS software requirements specification document. The procedure considers the requirements of IEC 60880 and IEEE 1016, "Recommended Practice for Software Design Descriptions."

FAW TXS-6.6en, Revision A, "Software Implementation Descriptions," dated May 8, 2006, defines the general structure and content of TXS software implementation descriptions. An implementation description precisely states the implementation and refinement of a TXS software design description. The inspectors verified that the TXS software implementation description is a part of the developer documentation of a TXS software component, which is developed according to the TXS phase model (FAW 1.1) and the TXS CM plan (FAW 1.5). The inspectors also noted that the procedure considers the requirements of IEC 60880.

FAW TXS 1.5en, "Configuration Management Plan for the TELEPERM XS System Platform," Revision C, dated October 4, 2005, provides controls for the configuration requirements and specifies the processes for generating configuration identifiers, controlling changes, and maintaining version control during the development process. Configuration management (CM), as described in this engineering procedure, is based on the system platform of TXS and represents a generic basis for developing and implementing safety-related digital I&C systems. The CM as specified comprises the technical support and management of the product life cycle of the TXS system platform, which includes all the hardware and software components recorded in the product structure plan as well as the associated development documentation. This engineering procedure also addresses the requirements of the type tests for the TXS system platform which covers the recommendations of relevant parts of DIN EN ISO 10007, "Quality Management, Guidelines for Configuration Management," issued December 1996, and IEEE 828, "Software Configuration Management Plans," dated May 1998.

NFLE-F DM 100008, “Method and Rules for Configuration Identification and Change Management of TELEPERM XS Plant-Specific Software,” Revision A, dated May 25, 2007, provides the rules and methods to manage the configuration and changes of all software items within a TXS project. The procedure includes controls for documenting changes to a plant-specific project, routine review activities, controls for management review and approval of such changes, and documentation requirements. The inspectors reviewed documentation related to changes to software items in the Teleperm XS system platform, including documents dealing with the management of the specification and coding environment (SPACE) databases and the qualified display system (QDS) files. Report NLTD-G/2007/en/0140, “Configuration of the Software Package ‘TXS CORE Software’ for LINUX, Release 3.3.2,” Revision B, dated December 21, 2007, identifies the configuration items, describes the structure of the software package, and assigns the test certificates to the respective configuration items. The inspectors noted that the report adequately identified the configuration items and their respective test certificates. Also, the report was reviewed and approved by the responsible organization. The inspectors also reviewed TXS Change Request (CR) 1284, dated October 6, 2005. This CR was generated because of a simulation-based validation tool (SIVAT) feature request. The situation or problem leading to the request was that SIVAT could not plot monitoring signals. The inspectors reviewed the resolution of this CR and noted that it contained all of the necessary information as required by the change management process. The inspectors found no issues associated with the software development or configuration management aspects of the TXS platform. Additional information regarding configuration management control for plant-specific applications can be found on pages 12 and 13 of this inspection report.

TXS Platform Verification and Validation

FAW TXS 1.6en, “Software Verification and Validation Plan (V&V Plan),” Revision A, dated March 29, 2006, provides controls for the development and maintenance of software components of the TXS system platform. The procedure specifies the areas of application, the organizational responsibilities, requirements for independent V&V activities, and documentation requirements. The inspectors noted that the structure established by AREVA is based on IEC 880-1986, “Software for Safety Systems in Nuclear Power Stations,” which is compatible with IEEE 7-4.3.2. The inspectors also noted that the V&V process is adequately documented, and included the system specification phase, the functional specification phase, the detailed design description phase, the implementation phase, the test specification phase, and the test phase. Additional review of V&V activities is documented on page 12 of this inspection report.

TXS Platform Testing

FAW TXS 4.1en, “Software Tests,” Revision B, dated February 12, 2008, provides rules for the specification, performance, and evaluation of tests including documentation and presentation of the results to ensure that the software testing process in the digital safety I&C system TXS is uniform, structured, and traceable. The procedure specifies the testing phase of the TXS development process as prescribed in engineering procedure

FAW 1.1. Testing requirements include specifying the test requirements, performing the tests, and producing the test report. Testing includes module testing, component testing, and system testing in a simulated and real environment. The inspectors reviewed Test Report No. 66-5065211-00, "Surveillance and Functional Test Report for Additional Equipment," dated December 13, 2005. This test report included a description of the test configuration, configuration control (hardware/software), test summary, and resolution of anomalies or acceptance criteria deviations. The test report provided the results for the component qualification tests performed in Procedure 51-5055032-00, "Teleperm XS Functional Test Procedure for TXS and Support Equipment IAW EPRI 107330 and TR102323." As the test report describes, Procedure 51-5055032-00 provides the details for each test to be performed, as well as the data sheets used to record the data collected during each test. The inspectors found no issues or discrepancies with engineering procedure FAW TXS 4.1en or the associated Summary Test Report.

FAW NL-G-008, "Preparation and Handling of Certificates of Conformance and Quality Control Inspection Reports in NL-G," Revision A, dated December 11, 2007, provides controls for the preparation of Certificates of Conformances (CoCs) and/or Quality Control Inspection Reports (QCIRs). The procedure defines the preparation and handling of CoC and quality control inspection, manufacturing surveillance, acceptance, and documentation review of electrical and I&C components/services for power plants. The inspectors confirmed that AREVA shall issue a CoC for hardware/software in the scope of 10 CFR Part 50, Appendix B/NQA-1 orders if a CoC is contractually agreed on with the customer. The inspectors noted that preparation of a QCIR is necessary if AREVA personnel performs independent inspections at suppliers. The inspectors reviewed the CoC for Oconee "TXS Software" (CoC/NLQ-G/07/NI/003B, Revision B, and dated July 20, 2007) to verify that it was prepared in accordance with the vendor's program guidance and that it contained the required information. The inspectors confirmed that the document contained the required information including: the customer name, plant site, customer order number, and safety relevance, as well as a summary of data and certification statement. The inspectors found no issues associated with the platform test activities.

Development Infrastructure Security

The inspectors requested engineering procedure FAW-TXS 1.7, "Information Security," dated August 23, 2004, to review the security aspects during the development of the TXS operating system software and function block library software to determine whether AREVA has a secure software development infrastructure. The vendor indicated that a corporate-wide procedure for information technology security incorporating all of the FAW 1.7 requirements had superseded this procedure. The inspectors reviewed the new procedure, AREVA NP GmbH "Informationssicherheit," dated November 25, 2005, with support from the vendor's technical staff. The inspectors also conducted detailed interviews with AREVA personnel to ensure that this new replacement procedure covered the necessary security aspects and requirements of a secure software development infrastructure. The inspectors requested information regarding, but not limited to, isolation of the development computers/network from the corporate network, access control and access rights to particular development computers, process for using

purchased software, and physical access restrictions to the development lab. Additionally, the inspectors verified implementation of security measures during the tour of the TXS platform development lab. The inspectors found no issues associated with the security controls used for the development of TXS software.

b.2 Project-Specific Qualification of TXS System Application

The inspectors reviewed the design process used by AREVA for the qualification of TXS for project-specific applications. For each plant system controlled by the TXS system, AREVA develops a system quality plan and software quality plan. These quality plans complement the project's QA plan with measures that are specific to I&C. Design procedures describe the engineering process for I&C activities that need to be performed for a specific project. The process developed by AREVA ensures that the TXS platform is qualified for each project.

The inspectors focused the design review on the Olkiluoto 3 (OL3) project documentation. For this review, the inspectors selected the protection system of the OL3 design. Specifically, the inspectors selected a function within the protection system that is used to trip the reactor on low pressurizer pressure (REACTOR TRIP ON PZR PRESSURE <MIN2p). The inspectors verified the process used to design, manufacture, qualify, and test the TXS software and hardware, starting from general and functional requirements contained in the OL3 preliminary safety analysis report (PSAR), the translation of these requirements into system processing requirements and function specifications, and the incorporation of these requirements into functional diagrams, generation of software code, software validation, factory acceptance testing, and system configuration control. To this end, the inspectors reviewed a sample of project-specific procedures and reports that documented different activities associated with the qualification of the TXS platform to verify compliance with administrative requirements contained in the AREVA design control process. Additionally, the inspectors interviewed AREVA personnel to ensure that activities were commensurate with their responsibilities.

System and Software Quality Plans for Olkiluoto 3

NFLE DC 1005, "Protection System (PS) System Quality Plan," Revision F, dated January 14, 2008, provides the system quality plan for the protection system in the OL3 project. It specifies how the general, functional, and safety requirements contained in the contract, PSAR, and regulatory guidelines are applied during the development of the OL3 protection system design. The inspectors reviewed the system quality plan and noted that it describes organizational responsibilities and provides detailed descriptions of the steps necessary for the realization of the protection system design. This description includes input/output data requirements, software and hardware design specification requirements, qualification requirements, installation and testing requirements, documentation requirements, review requirements that need to be accomplished throughout the life cycle, problem reporting and corrective action, V&V activities, and configuration and change management activities. The system quality plan also includes a requirements traceability matrix that documents project-specific requirements for the OL3 project, including YVL Guides issued by the Radiation and

Nuclear Safety Authority and generic requirements established in the contract. The inspectors identified no issues.

NFLE DC 1015, "Protection System, Severe Accident, Rod Position and Boron Concentration I&C Software Quality Plan," Revision G, dated February 18, 2008, describes the software quality plan for the protection system, the severe accident I&C, the rod position measurement, and the boron concentration measurement system in the OL3 project. The inspectors reviewed the software quality plan and noted that it describes the life cycle for the SVE2 application software, the life cycle for the software installed in the service unit used for monitoring, testing, maintaining, and diagnosing the TXS system, and the life cycle for the software installed in the QDS. The software quality plan also provides details of specific software development activities that are unique to each system. In addition to software life cycle controls, the software quality plan describes organizational responsibilities, documentation requirements, review and audit requirements throughout the life cycle, problem reporting and corrective action, training for personnel involved in development and testing activities, risk management, and interfaces with the development of the TXS platform. The inspectors reviewed the process implemented by AREVA which is consistent with IEEE 730-1998, "Software Quality Assurance Plans"; IEEE 1012-1998, "Software Verification and Validation"; and IEEE 1028-1997, "Software Reviews," and no issues were identified.

Functional Requirements and Function Diagram Generation

NFPSR DC 1014, "Functional Requirements of P/S Protection and Functions," Revision J, dated July 18, 2007, provides guidance for the development of functional requirements for primary and secondary protection I&C functions used in the OL3 protection system. The procedure controls the translation of functional requirements into inputs that are used for the definition of the protection system, I&C instrumentation, and further elaboration of functional diagrams. The inspectors reviewed Appendix A2 of NFPSR DC 1014 which was completed for the OL3 project. The inspectors noted that process engineers extracted this description from the OL3 PSAR and translated it into functional requirements. The inspectors verified that Appendix A2 contains the functional description, tasks, relevant events, safety functions, general requirements, inputs, and outputs for, among other functions within the protection system, the REACTOR TRIP ON PZR PRESSURE <MIN2p function, which the inspectors selected as a sample.

NFLE DC 1018, "Protection System—Functional Diagrams," Revision I, dated November 27, 2007, controls the development of functional diagrams used in the protection system. This procedure provides instructions for the generation of functional diagrams that are implemented in the protection system for the OL3 project. These functional diagrams describe the digital signal processing performed by the protection system from the acquisition of the sensors to the orders sent to the actuators. The inspectors reviewed functional diagrams and functional descriptions contained in Appendix A of NFLE-DC 1018 associated with the REACTOR TRIP ON PZR PRESSURE <MIN2p function, which are based on the general requirements in NFPSR DC 1014. The inspectors verified that functional diagrams include delimitations, inputs, analog and binary processing, transfer of information, and order outputs for each

division of the protection system. The inspectors noted that the functional description of the REACTOR TRIP ON PZR PRESSURE <MIN2p function includes safety classification, relevant events associated with the actuation of the function, and signal processing requirements.

NFLE DC 1114, "Protection System, Rod Position, Boron Concentration I&C Function Specification, Level 3," Revision F, dated January 17, 2008, introduces I&C function specifications for the protection system, rod position, and boron concentration I&C for the OL3 project. These function specifications provide the structure of the application software in terms of TXS inputs, outputs, algorithms, coding of internal and external signals, and delimitation and coding of the I&C function diagrams. The procedure provides guidance for the generation of I&C functions to be implemented, allocates them to the different processing units, and combines functional diagrams with processes related to the architecture of the protection system and the TXS platform. These function specifications are further used for the detailed design of software requirements and for the preparation of software validation tests. The inspectors reviewed the function specification associated with the REACTOR TRIP ON PZR PRESSURE <MIN2p function selected as a review sample. Appendix A to NFLE DC 1114 provides a matrix with all the functions and submodules that constitute the I&C function specifications of the protection system used in the OL3 design. The inspectors observed that the sampled function is represented as a detailed functional chain from sensor measurement through information processing and actuator control. Other I&C functions are categorized based on the type of action required. The inspectors noted that functions are grouped for reactor trip functions, engineered safety features actuation system functions, emergency diesel generator functions, permissive functions, and monitoring functions. Submodules describe processes that are common to several I&C functions, including sensor measurements and actuations. The inspectors identified no issues.

NFLE DC 1129, "Protection System, Rod Position, and Boron Concentration I&C Function Specification," Revision E, dated January 16, 2008, supplements NFLE DC 1114 by providing complete, detailed function specifications for software and hardware of I&C systems used in the protection system, rod position, and boron concentration systems of the OL3 project. These function specifications are structured hierarchically, starting with I&C functions and followed by modules and submodules, including input, actuation, processing, and TXS service submodules. This procedure also provides input to software validation test analyses and the software detailed design employing the SPACE software tool, used for software code generation and code verification activities. The inspectors reviewed the I&C functions specification of the REACTOR TRIP ON PZR PRESSURE <MIN2p, contained in Appendix 1.1 of NFLE DC 1129. This functions specification is created using the Functional Requirements Specification Database (FunBase) tool. The inspectors noted that the functions specification lists all signals that are exchanged to/from other I&C functions or modules and specific thresholds and parameters associated with this function. Additionally, the inspectors observed the models created for the sampled function in SPACE, and AREVA personnel showed the inspectors the process for generating code using procedure NLE-F DM 10008, "Method and Rules for Configuration Identification and Change Management of Teleperm XS Plant-Specific Software," Revision A, dated

May 25, 2007, which controls code generation activities and configuration and changes of all software items of TXS projects. The inspectors identified no issues.

Software Design Review Activities

NFLE 05-5049, "Guidelines for Detailed Design Reviews," Revision C, dated August 1, 2006, provides controls for software reviews defined in software quality plans. This procedure documents the steps needed to conduct a software review, including input data utilized, anomaly management, and adherence to applicable quality plans, software V&V plans, and software CM plans. The inspectors reviewed the following reports of review meetings associated with the OL3 project:

- Report of Review Meeting No. NLE-F 07.5283, technical review meeting to review correctness and completeness of system requirements and system specifications for the protection system and priority and actuator control system, dated August 14, 2007

- Report of Review Meeting No. NLE-F 07.5172, Revision B, assessment of adequacy and completeness of input data required to perform system, hardware, and software design of the protection system and submodule actuation I&C systems, dated August 22, 2007

- Report of Review Meeting No. NLE-F 07.5390, system requirements specification review for the protection system, dated October 25, 2007

The inspectors verified that documentation of the review activities was in accordance with NFLE 05-5049 and followed the review report template in Appendix A of NFLE 05-5049. The inspectors noted that these reviews were very comprehensive and included action items based on the analysis of technical comments collected during these reviews. The inspectors identified no issues.

Hardware Design and Configuration

Engineering procedure FAW No. NGLL-127, "Basics and Provisions for the Engineering Process Execution Planning for Teleperm XS Projects," Revision A, dated October 5, 2005, controls the design, manufacturing, and testing of hardware equipment used in the TXS system. AREVA uses this procedure to develop project-specific hardware requirements. For the OL3 project, the inspectors reviewed hardware configuration descriptions, design output documents, and cabinet drawings to verify compliance with program requirements. To this end, the inspectors requested a review report of a cabinet design conducted by AREVA. As required in procedure NGLL-127, cabinet documentation needs to be reviewed and approved before being released to manufacturing. The inspectors verified that the review was adequately documented and conducted by personnel not involved in the preparation of such documents. The inspectors noted that, for changes in hardware design, AREVA used project-specific procedure IPI-6-233, "Teleperm XS I&C Change Management after Official Start Hardware Detail Engineering," Revision A, dated June 20, 2006. The inspectors reviewed a modification sheet prepared for two cabinets, 30CLE24 and 30CLF24. The

inspectors verified that the responsible organizations had appropriately signed and verified the documentation. The inspectors identified no issues.

Software Verification and Validation

NFLE DC 1142, "Protection System Software Validation Tests (Stage 1)—Test Analysis APU 1," Revision D, dated March 5, 2008, specifies the tests that were designed to validate the TXS application for the Acquisition and Processing Unit 1 (APU 1) of the protection system for the OL3 design. With the SIVAT, this test analysis is used to validate the implementation of the SVE2 processor software in the TXS system. The test analysis provides the test case to be used for the validation of, among other functions within the protection system, the processing channels that use the pressurizer pressure signal, which include the function within the protection system that is used to trip the reactor on low pressurizer pressure (REACTOR TRIP ON PZR PRESSURE <MIN2p) selected as a review sample by the inspectors. The inspectors verified that the structure of each test case includes the objectives and a detailed description of validation requirements, including the definition of the test case, input/output signals, service parameters to be used during the test, and graphics of the expected results, as required in NFLE DC 1142.

NFLE DC 1151, "Protection System Software Validation Tests (Stage 1)—Test Report APU 1," Revision B, dated February 14, 2007, documents the results of the software validation tests and the analysis of these results for the APU 1 of the protection system for the OL3 design. The report provides an analysis of the expected results given in NFLE DC 1142. The inspectors reviewed the results for the REACTOR TRIP ON PZR PRESSURE <MIN2p selected as a review sample. The inspectors noted that, for the sample selected, the test results showed a discrepancy. The inspectors asked AREVA personnel if this discrepancy had been tracked and documented. AREVA personnel showed the inspectors the discrepancy report, which indicated that the cause of the discrepancy was erroneous parameters in the test analysis. The analysis conducted by AREVA personnel and documented in the discrepancy report concluded that this discrepancy had no functional impact on the system. The inspectors found this acceptable and consistent with the procedural guidance.

Configuration Management Control

Engineering procedure FAW No. NLL-G-101, "Project-Related Configuration Management for Design Modification of I&C Systems with Teleperm XS," Revision A, dated December 7, 2007, specifies the requirements for the CM of projects with TXS systems. This procedure provides technical and organizational requirements, configuration identification, and testing documentation requirements for hardware and software, including TXS code software and application software. The procedure also provides controls for the implementation of modifications performed on hardware and software. The inspectors reviewed project-specific procedure NLLP-G/2006/en/1007, "Reactor Control, Surveillance and Limitation System (RCSL) Change Management and Configuration Identification Document," Revision A, dated April 24, 2007. This procedure provides the configuration identification document for the software, hardware, and test environment configuration of the TXS I&C system implemented in the OL3

RCSL system. The inspectors noted that changes are controlled via the tool LOPster, which is a database used by AREVA to document all hardware and software modifications on I&C systems. Changes are related to hardware/software components because of detection of errors, reported complaints from existing customers, changes or additions to task descriptions, or changes in system parameters. The inspectors identified no issues.

Tour of TXS Integration Center

During the inspection, the inspectors toured the TXS Integration Center. Highlights of the tour included the observation of several cabinets for the OL3 project that are undergoing integration testing at the test bay, demonstration of the TXS platform implemented on a mockup control rod drive mechanism, detailed description of the TXS cabinet hardware components, demonstration of the QDS, and observation of software/hardware integration tests using a computer-aided testing system (ERBUS).

c. Conclusions

The inspectors concluded that AREVA design control program requirements are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of TXS platform and application design, CM, and testing documentation reviewed, the inspectors determined that the AREVA design control procedures were being effectively implemented.

3.2 PROCUREMENT CONTROL

a. Inspection Scope

The inspectors reviewed the AREVA implementing policies and procedures that govern the procurement process. The inspectors also evaluated a limited sample of procurement packages for safety-related components to verify compliance with the program requirements and adequate implementation of those requirements.

b. Observations and Findings

b.1 Policies and Procedures Governing Procurement

The inspectors reviewed the procedures governing the procurement of parts and services associated with the TXS program.

Subsection 4.4, “Purchasing,” of Section 4, “Product Realization,” of the AREVA “Plants Quality and Environment Management Manual” (QEM), Revision H, dated May 10, 2007, describes the process for development of purchase orders (POs) including a description of the procedure for purchasing materials and equipment, organizational roles and responsibilities, scope of purchase documentation, verification of purchased product, supplier surveillance, and control of production and service processes.

QM-AW-405, "Quality Management for Purchase Orders," Revision E, dated April 4, 2007, describes the AREVA purchasing process requirements, which ensure that all procurement requirements for materials and parts used in the manufacturing of AREVA products, are adequately prepared, approved, and distributed. The requirements also ensure that materials, parts, and services conform to the technical and quality requirements specified for each of the respective AREVA products. This procedure applies to all AREVA external POs for safety-related products.

NLL-G-131, "Hardware Purchasing in the TELEPERM XS Product Business," Revision A, dated October 23, 2007, describes the procedures for the purchase of hardware, as well as the quality requirements for the TXS product line including the selection process for suppliers, identification of formal qualification requirements for suppliers, and receipt inspection of hardware delivered to AREVA. The procedure contains detailed formal checklists for each subprocess, which must be completed as part of the purchasing package.

Based on the inspectors' review, these policies and procedures provide sufficient guidance for the development and deployment of procurement documentation consistent with Appendix B to 10 CFR Part 50.

b.2 Implementation of the Procurement Process

The inspectors reviewed a limited sample of PO packages to verify that the packages were developed in accordance with the vendor's administrative requirements and to ensure that vendor personnel responsible for their preparation were knowledgeable about the procurement process requirements and adequately implemented those requirements.

Purchase Orders Reviewed

The inspectors reviewed the following POs:

- PO217823, dated March 8, 2007—multiple module purchase contract to Siemens
- PO194835, dated January 25, 2006—manufacture of standard cable by FEAG
- PO194836, dated January 25, 2006—manufacture of TXS cabinet enclosures by FEAG

The inspectors reviewed the purchase orders writeup to verify technical and quality information, including identification of the engineering requirements for the purchased parts and components; the definition of scope of supply; and appropriate references to the technical and quality instructions, requirements, test requirements, and plans. The inspectors also confirmed that the POs properly identified the project managers' responsible for the procurement and their respective review and approval responsibilities; clearly defined the quality standards for the PO, consistent with industry standards including ISO-9001, "Quality Management System," dated December 2000,

Kerntechnischer Ausschuss, KTA-1401, "General Requirements Regarding Quality Assurance," dated June 1996, and Appendix B to 10 CFR Part 50; provided the chain of authority for the PO; and contained all required signatures. The inspectors verified that the POs contained adequate information identifying the required parts as safety-related and that the suppliers were currently approved vendors identified on the approved vendors list.

The inspectors did not identify any issues with the implementation of associated procurement procedures described in Section 3.2.b.1 of this report, nor with the quality, content, or detail provided in the PO packages requesting fabrication of these safety-related parts and components.

c. Conclusions

The inspectors concluded that the AREVA procurement control program requirements are consistent with the regulatory requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. Based on the limited sample reviewed, the inspectors also determined that the AREVA QEM and associated procurement control procedures were being effectively implemented.

3.3 CONTROL OF PURCHASED MATERIAL EQUIPMENT AND SERVICES

a. Inspection Scope

The inspectors evaluated a limited sample of vendor survey reports and auditor training and qualification information to verify compliance with the program requirements and adequate implementation of those requirements.

b. Observations and Findings

b.1 Policies and Procedures Governing Purchased Material Equipment and Services

The inspectors reviewed Subsection 5.2.2, "Audit," of Section 5, "Measurement Analysis and Improvement," of the AREVA QEM, Revision H, dated May 10, 2007, which describes the processes for collecting, analyzing, and identifying ways of improving product development and delivery. Section 5.2.2 describes the methods and responsibilities for planning and conducting both internal audits and vendor surveys, the frequency of audits and surveys, the responsibilities for corrective actions and verification of the actions taken, and the filing of audit reports.

QM-AW-301, "Qualification of Audit Personnel," Revision D, dated July 17, 2006, defines the process for qualifying auditors and leads auditors for AREVA, including the process for qualification and maintenance of the auditor qualification and requisite education, training, and experience necessary to perform the audit function.

QM-AW-402, "Supplier Assessment (QM/EM/Technical/Commercial)," Revision E, dated August 28, 2006, defines the methods to approve and assess performance of suppliers to maintain their approved vendor status. The procedure is applicable to all suppliers of

products and services including hardware, software, design, maintenance, and installation.

b.2 Implementation of the Vendor Survey Process

The inspectors selected a sample of vendors from the AREVA approved vendors list for the review of vendor survey reports. The inspectors reviewed the most recent audit report for all suppliers for the TXS system. The inspectors reviewed the following vendor survey reports:

- Siemens AG I&S EDM (SEQ-G/2007/en/0059), dated August 8, 2007—manufacturer of TXS modules
- Phoenix Contact GmbH & Co. (NGLTH/2005/de/0120), dated December 14, 2005—Manufacturer of interfacing components with the TXS modules
- FEAG GmbH (NGLTH/2005/de/0119), dated December 9, 2005—manufacturer of TXS cabinets
- Industrianlagen-Betriebsgesellschaft mbH (SEQ-G/2007/en/0098), dated December 7, 2007—supplier of testing services

The inspectors confirmed that the audit reports contained a review for each of the relevant QA criteria contained in Appendix B to 10 CFR Part 50 for the activities performed by the individual suppliers and documentation of pertinent supplier guidance associated with each criterion. Additionally, for each criterion, the AREVA survey team reviewed and documented at least one implementation example to confirm proper program implementation by the supplier. The inspectors confirmed that the audit report described recommendations and nonconformances identified during the supplier audits. The vendor noted that if those items were not adopted or adequately resolved, then nonconformance reports (NCRs) would be written for the issue and evaluated by AREVA. However, the inspectors identified that these NCRs are not tracked in a formal centralized manner; rather they are tracked only within the audit report and their disposition is the responsibility of the audit lead. The audit reports are kept open until the audit leader reviews and closes all NCRs. Although the audit leader is responsible for confirming that NCR issues from audits are resolved, the process does not provide a systematic method for the review of corrective actions to determine if they are being completed in a timely fashion. Additionally, the process does not provide for a systematic evaluation of all NCRs from supplier audits to determine if common issues are being identified or if measures are effective in precluding recurrence of the deficiencies.

For example, in the audit report Siemens AG I&S EDM (SEQ-G/2007/en/0059), dated August 8, 2007, a nonconformance was written to develop a specific QA plan for nuclear power plant orders which cover all relevant quality management requirements. The audit report noted that the closure of this NCR was scheduled for August 24, 2007; however, as of March 11, 2008, the issue remained open. When questioned about this

apparent discrepancy, the vendor was unable to verify the status of the NCR until the audit team leader reviewed the audit file and found that Revision B of the audit report, issued in February 2008, provided closure of the NCR.

The inspectors determined that neither the QEM nor the associated procurement supplier assessment procedures described in Section 3.3.b.1 of this report contain adequate provisions for addressing nonconformances or corrective actions for issues identified through supplier audits. The inspectors identified this issue as Nonconformance 99901371/2008-201-01.

b.3 Auditor Training and Qualification

The inspectors reviewed the qualification records for a sample of lead auditors and auditors. The inspection team verified that all auditors and audit team leads had met the requirements and that all audit team leads had performed at least one audit in the last 12 months to maintain their qualification in accordance with program requirements. Documentation supporting the qualification of each auditor and lead auditor was well detailed and provided strong evidence to support the finding that qualification requirements for each auditor had been successfully completed and maintained current.

c. Conclusions

Except for the issue identified as Nonconformance 99901371/2008-201-01, the inspectors concluded that the AREVA program requirements are consistent with the regulatory requirements of Criterion VII, “Control of Purchased Equipment, Material, and Services,” of Appendix B to 10 CFR Part 50. Based on the limited sample reviewed, the inspectors also determined that the AREVA QEM and associated procurement control procedures were being effectively implemented.

3.4 NONCONFORMANCE AND CORRECTIVE ACTIONS

a. Inspection Scope

The inspectors reviewed the AREVA QEM and implementing policies and procedures that govern the corrective action process. The inspectors also evaluated a limited sample of NCR datasheets and corrective action reports (CARs) associated with the TXS program to verify compliance with the program requirements and adequate implementation of those requirements.

b. Observations and Findings

b.1 Policies and Procedures for the Control of Nonconformances and Corrective Action

The inspectors reviewed Subsections 5.3, “Control of Nonconforming Product,” and 5.5, “Improvement,” of Section 5, “Measurement Analysis and Improvement,” of the AREVA QEM, Revision H, dated May 10, 2007, which describe the nonconformance and corrective action processes for AREVA. The document describes the process for

identifying, documenting, segregating, evaluating, and handling nonconformances, as well as describing the notification of affected organizations and customers.

QM-AW-503, Revision E, dated October 17, 2007, defines responsibilities and procedures for handling nonconformances in supplies and services for nuclear facilities. The procedure describes the process for identifying, evaluating, reporting, and correcting nonconformances. The procedure contains multiple process flow diagrams and sample reporting forms that further describe and govern the nonconformance and corrective action processes.

The inspectors determined that Section 1.3, "Definitions," of QM-AW-503, contained a definition of nonconformance that permitted identified nonconformances to go unreported if the nonconformance could be corrected within the "same processing phase." The inspectors discussed the rationale of this remark with the vendor, and although it was not the intent of the vendor to exclude identified nonconformances from being processed within the NCR program, the procedure explicitly allowed for such actions. The inspectors identified this issue as Nonconformance 99901371/2008-201-02.

b.2 Review of Deviation Reports

The AREVA process for identifying and documenting nonconformances is implemented via NCRs in accordance with Appendix 3, "Nonconformance Notification," to QM-AW-503. The inspectors reviewed the database log of NCRs for all issues associated with the TXS platform and applications and sampled several NCRs concerning suppliers who furnished materials for the manufacture of the TXS applications. In addition, the inspectors discussed the nonconformance process with the vendor including the establishment and roles of the nonconformance team (NCT) responsible for reviewing all potential nonconformances generated against the program. The NCT, which convenes every 6 weeks to review NCRs, comprises quality and project managers and technical subject matter experts with TXS experience. The inspectors noted that each NCR contains a detailed description of the concern and at least one proposed corrective action associated with the identified deficiency. The inspectors verified that the NCRs include the appropriate review and signoff and, when applicable, verified that each corrective action is assigned to an organization lead responsible for its completion.

b.3 Implementation of Corrective Action Program

The inspectors reviewed a sample of corrective actions associated with the database log of NCRs for the TXS platform and applications and additional corrective actions identified as a result of the AREVA audits of selected suppliers.

The inspectors noted that although most of the corrective actions had been completed in a timely manner, several remained open beyond the initial assigned due date. The inspectors discussed this with the vendor and determined that QM-AW-503 did not explicitly define the process for ensuring timely closure of corrective actions. As described by the vendor, if the due date for a corrective action is not met, the NCT will contact the responsible person with a reminder to complete the work. At that time, a

new due date is established for closure of the corrective action. Although the NCT maintains a list of all corrective actions, the vendor's program does not provide a systematic method or adequate guidance for the review of corrective actions to determine if they are being completed in a timely fashion and are effective in precluding recurrence of the deficiencies. The inspectors identified this issue as an example of Nonconformance 99901371/2008-201-03.

In addition, the inspectors determined that the vendor did not have any formal method or adequate guidance for establishing the significance level or priority for nonconformances and their associated corrective actions. During the inspection, the vendor initiated an NCR to address these deficiencies (NCR 2008 015). At the conclusion of the inspection, this NCR remained open. The inspectors identified this issue as an example of Nonconformance 99901371/2008-201-03.

c. Conclusions

Except for the examples identified in Nonconformances 99901371/2008-201-02 and 99901371/2008-201-03, the inspectors concluded that the AREVA control of nonconformances and corrective action program requirements are consistent with the regulatory requirements of Criterion XV, "Nonconforming Materials, Part, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Based on the limited sample reviewed, the inspectors determined that the AREVA QEM and associated nonconformance and corrective action procedures were being effectively implemented.

3.5 10 CFR PART 21 PROGRAM

a. Inspection Scope

The inspectors reviewed the AREVA QEM and implementing policies and procedures that govern the 10 CFR Part 21 process. The inspectors also sampled the vendor's 10 CFR Part 21 program implementation activities.

b. Observations and Findings

b.1 10 CFR Part 21 Procedure

QM-AW-502, "Process and Reporting of Defects and Noncompliance of Contracts under 10CFR21," dated November 14, 2006, outlines the process used at AREVA for the reporting of defects and nonconformance discovered by the vendor or reported to the vendor by its suppliers or customers.

The procedure provides for the review of such deviations by a group consisting of the organization manager of the affected area and the head of the quality management system. The group decides whether the deviation is a defect or noncompliance and uses the standard NCR form provided in QM-AW-503 to document its decision, along with the supporting documentation to substantiate the decision. The group then

compiles the results of the review into a report and submits the report to the customer within 48 hours of determining that a defect exists.

The inspectors reviewed QM-AW-502 and QM-AW-503 and discussed the 10 CFR Part 21 process with members of the vendor's management and technical staff. Additionally, the inspectors reviewed the vendor's electronic NCR database and confirmed that procedural guidance was adequate to initiate the 10 CFR Part 21 process when an NCR was written that could have an impact on a U.S. facility or a customer of AREVA providing equipment or services to a U.S. facility.

b.2 10 CFR Part 21 Implementation

The inspectors sampled the vendor's 10 CFR Part 21 program implementation activities to ensure that the NCR process was effective in identifying and evaluating conditions adverse to quality that may require entry into the 10 CFR Part 21 process. The inspectors discussed the AREVA 10 CFR Part 21 program with the head of the quality management system and various QA and technical staff and inquired as to how a nonconformance identified as a condition adverse to quality in an NCR would be evaluated under this program. The inspectors determined that QM-AW-502 and QM-AW-503 contain adequate procedural guidance to initiate the 10 CFR Part 21 process when an NCR is written, and the vendor's staff was knowledgeable about the conditions that would warrant a 10 CFR Part 21 evaluation. However, the inspectors determined that neither QM-AW-502 or QM-AW-503 contain adequate provisions for the evaluation, as defined in 10 CFR Part 21, of deviations and failures to comply associated with substantial safety hazards for issues identified in the AREVA NCR process. In addition, the inspectors determined that QM-AW-502 does not specify adequate requirements for notifying the Commission when information reasonably indicates a failure to comply or a defect in accordance with 10 CFR Part 21.21(d)(5). The inspectors identified this issue as Violation 99901371/2008-201-01.

During the inspection, AREVA issued NCR 2008 014, dated March 13, 2008, which describes the deficiencies in the QM-AW-502 procedure and requires the performance of a formal review and revision of the procedure to address the identified deficiencies. At the conclusion of the inspection, this NCR remained open.

c. Conclusions

Except for the issue identified in Violation 99901371/2008-201-01, the inspectors concluded that the AREVA 10 CFR Part 21 program requirements are consistent with the regulatory requirements.

4.0 MANAGEMENT MEETINGS AND PERSONNEL CONTACTED

4.1 ENTRANCE AND EXIT MEETINGS

In the entrance meeting on March 10, 2008, the inspectors discussed the scope of the inspection, outlined the areas to be inspected, and established interfaces with the AREVA Senior Vice-President I&C and Electrical Systems and several staff personnel.

During the exit meeting on March 14, 2008, the inspectors discussed the inspection findings and observations with AREVA management and staff.

4.2 PARTIAL LIST OF PERSONNEL CONTACTED

Dr. Patrick Weber	Senior Vice-President I&C and Electrical Systems, AREVA
Dr. Steffen Richter	Director I&C Development, AREVA
Dr. Wolfgang Michel	Director Quality Management and Processes, AREVA
Hans-Joachim Nisslein	QEM Liaison Officer, AREVA
Tom Nickel	QEM Engineer, AREVA
Arthur Gottschick	Quality Engineer, AREVA
Stefan Frauenknecht,	Quality Engineer, AREVA
Pete Heisenstein	Test Bay Leader, AREVA
Mark Milo	Manager I&C Quality, AREVA
Vic Fregonese	U.S. EPR Technical Manager, AREVA

4.3 OBSERVER

Mr. Stefan Schielke, from the German Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety, participated as an observer of the AREVA inspection.