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Subject: **Reply to Notice of Violation, and Notice of Nonconformance – NRC Inspection Report for AREVA NP GmbH 99901371/2008-201 from May 7, 2008**

The purpose of this document is to provide a response to the Inspection Report 99901 371/2008-201.

Enclosure 1 addresses the Violation 99901371/2008-201 – 01 identified in section 3.5 of the Inspection Report.

Enclosure 2 addresses the following three identified Nonconformances:

- Nonconformance 99901371/2008-201-01, which is discussed in Section 3.3 of the inspection report.
- Nonconformance 99901371/2008-201-02, which is discussed in Section 3.4 of the inspection report
- Nonconformance 99901371/2008-201-03, which is discussed in Section 3.4 of the inspection report.

Each enclosure provides a description of actions to correct the identified findings, a description of actions to prevent recurrence, and the completion dates of all corrective actions and preventive measures.

We will continue to work toward completion of the required actions and provide you with copies of action taken upon completion. Periodic updates can be provided upon request.

If you have any questions, please do not hesitate to contact me.

Kind regards

Hans-Joachim Nisslein

AREVA NP GmbH
Quality Management and Processes NLQ-G
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IE09
NRO

Enclosures

cc: U.S. Nuclear Regulatory Commission
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Enclosure 1

NRC Inspection Report 99901371/2008-201 and Notice of Violation

1 Reply to Notice of Violation 99901371/2008-201 – 01

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).

1.1 Reason for the Violation

The text of the procedure QM-AW 502, "Processing and Reporting of Defects and Noncompliance of Contracts under 10CFR 21" is not word by word identical with 10 CFR Part 21.

1.2 Corrective Steps that have been taken and the Results achieved

The changes to the procedure text have been identified and interim notification has been made to all persons in AREVA NP GmbH, who are working under 10 CFR Part 21 controls. The interim notification (QEM-Info NEG-G/2008/01) has been posted on the designated employee information boards and will remain posted until the procedure has been revised.

1.3 Corrective Steps that will be taken to avoid further Violations

AREVA NP GmbH will revise procedure QM-AW 502 during the next scheduled annual review of the procedures. All persons in AREVA NP GmbH who are working under 10 CFR Part 21 and 10 CFR Part 50, including the project managers and the project teams, will be provided refresher training after the procedure is revised.

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1.4 Date when full Compliance will be achieved

The procedure will be revised by December 1, 2008.

Refresher training will be provided to affected employees by March 1, 2009.

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Enclosure 2

NRC Inspection Report 99901371/2008-201 and Notice of Nonconformance

2 Reply to Notice of Nonconformance 99901371/2008-201-01

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.

2.1 Reason for the Nonconformance

Nonconformances were not tracked in a formal centralized manner; rather they were tracked by the audit lead as part the overall audit report. The audit reports were kept open until the audit leader reviewed and closed the supplier nonconformances, generally during the next audit.

2.2 Description of Steps that have been taken to correct this Item

AREVA NP GmbH has corrected the database of the "Approved Vendors List" (AVL). The database now includes the nonconformances identified in the supplier audits and the due date to track the follow up.

2.3 Description of Steps that will be taken to prevent Recurrence

AREVA NP GmbH will revise procedure QM-AW 416, "Supplier Audits," during the next scheduled annual review of the procedures. All persons in AREVA NP GmbH who are working as supplier auditors will be trained after the procedure is revised.

2.4 Dates your Corrective Action and Preventive Measures will be completed

The procedure will be revised by December 1, 2008.

Training will be provided to auditors by March 1, 2009.

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Enclosure 3

NRC Inspection Report 99901371/2008-201
and Notice of Nonconformance

3 Reply to Notice of Nonconformance 99901371/2008-201-02

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.

3.1 Reason for the Nonconformance

The nonconformances that were corrected in the same processing phase were considered resolved with no further processing considered necessary.

3.2 Description of Steps that will be taken to correct this Item

AREVA NP GmbH will revise procedure QM-AW 503, "Handling of Nonconformances," during the next scheduled annual review of the procedures. The text part "same processing phase" will be deleted.

3.3 Description of Steps that will be taken to prevent recurrence

All persons in AREVA NP GmbH will be trained after the procedure is revised as part of the annual QEM refresher training.

3.4 Dates your Corrective Action and Preventive Measures will be completed

The procedure will be revised by December 1, 2008.

Refresher training will be provided to affected employees by March 1, 2009.

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Enclosure 4

NRC Inspection Report 99901371/2008-201
and Notice of Nonconformance

4 Reply to Notice of Nonconformance 99901371/2008-201-03

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.

4.1 Reason for the Nonconformance

All nonconformances are processed in the NC Team meetings, without consideration of the significance level or priority for resolution.

4.2 Description of Steps that have been or will be taken to correct this Item

The procedure QM-AW 503, "Handling of Nonconformances," will be revised during the next scheduled annual review of the procedures. Two significance levels will be defined for nonconformances. All open nonconformances will be handled and tracked during the regular NC Team meetings with consideration given to priority based on the assigned significance level. The nonconformance database contains a tool for screening the schedule for resolution of nonconformances.

All nonconformances issued since 2001 have been re-screened. Only one significant condition adverse to quality (safety related) was found. It was not related to U. S. nuclear power plants.
(NCR 2002/052, "Missing pressure release screw in LOCA proof actuators", dated September 4, 2002 closed January 30, 2003)

4.3 Description of Steps that will be taken to prevent Recurrence

All persons in AREVA NP GmbH will be trained after the procedure is revised as part of the annual QEM refresher training.

4.4 Dates your Corrective Action and Preventive Measures will be completed

The procedure will be revised by December 1, 2008.

Refresher training will be provided to affected employees by March 1, 2009.