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U.S. Nuclear Regulatory Commission
Document Control Desk
11555 Rockville Pike
Rockville, MD 20852

Reply to Notice of Violation

Ref. 1: Letter, Kerri Kavanagh (NRC) to Pedro Salas (AREVA NP Inc.), "Nuclear Regulatory Commission Inspection Report No. 05200020/2013-201 and Notice of Violation," June 13, 2013.

This letter and its enclosures provide AREVA NP Inc.'s (AREVA NP's) reply to the Notice of Violation (NOV) in Reference 1. The NOV identifies a failure to establish measures for the selection and review for suitability of its soil-structure interaction analysis computer program. Specifically, the NOV states that AREVA NP did not perform an adequate commercial-grade dedication technical evaluation to sufficiently identify the performance requirements and critical characteristics for the MTR/SASSI program and did not include or reference the limits of the dedicated capabilities within the related dedication plans.

Attachment A to this letter addresses the reason for the violation, corrective steps that have been taken and the results achieved, corrective steps that will be taken to avoid future violations, and the date when full compliance will be completed. Attachment B identifies the commitments being made to the NRC.

If you have any questions related to this submittal, please contact Ms. Gayle F. Elliott, Product Licensing Manager at 434-832-3347 or by e-mail at gayle.elliott@areva.com.

Sincerely,

A large, stylized handwritten signature in black ink, appearing to read 'Pedro Salas', is written over the word 'Sincerely,' and extends across the signature line.

Pedro Salas, Director
Regulatory Affairs
AREVA NP Inc.

cc: K.A. Kavanagh, Chief
Quality Assurance Branch
Division of Construction Inspection and Operational Programs
Office of New Reactors

J.G. Rowley
Project 728

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Enclosures:

1. Attachment A, "Inspection Report Number 05200020/2013-201 Reply to Notice of Violation"
2. Attachment B, "Table of Commitments"

Attachment A

Inspection Report Number 05200020/2013-201
Reply to Notice of Violation

I. Restatement of Notice of Violation 05200020/2013-201

- A. Criterion III, "Design Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states in part that measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components.

Section 7.3.1, "Dedication of Commercial Grade Items and/or Services," of AREVA NP Inc.'s topical report ANP-10266, Revision 4, "AREVA NP Inc., Quality Assurance Plan (QAP) Design Certification of the U.S. EPR™," dated December 13, 2012, states in part that commercial-grade items and/or services for safety-related applications may be procured from suppliers where specific quality controls for nuclear applications cannot be imposed in a practical manner. In these instances, an evaluation of the suitability of the item or service for nuclear applications is performed by the responsible technical manager and quality organization. The critical characteristics of the item or service are also determined and documented as part of this evaluation. Section 7.2, "General," states in part that the control of purchased safety-related materials, items, and services are in accordance with written procedures and instructions.

Section 4.4.1, "Technical Evaluation," of AREVA NP Inc.'s Administrative Procedure AP 0902-29, "Procurement of Engineering Application Software," Revision 005, dated July 27, 2012, states in part that the technical evaluation shall be performed by the responsible engineering organization to identify performance requirements and to identify the critical characteristics including acceptance criteria.

Section 4.4.10 of AREVA NP Inc.'s Administrative Procedure AP 0902-29, states in part that the dedication plan shall include instructions for use of the software within the limits of the dedicated capabilities or identification of a related document containing these instructions.

Contrary to the above, as of May 3, 2013, AREVA NP failed to establish measures for the selection and review for suitability of its soil-structure interaction analysis computer program. Specifically, AREVA NP did not perform an adequate commercial-grade dedication technical evaluation to sufficiently identify the performance requirements and critical characteristics for the MTR – System for Analysis of Soil-Structure Interaction (MTR/SASSI) program and did not include or reference the limits of the dedicated capabilities within the related dedication plans. Furthermore, the tested limits of impedance frequency calculations for soil-structure interaction analyses and half-space boundary conditions for uniform site profiles during dedication of MTR/SASSI Version 9.5 HPC (high performance computing) and Version 9.4.2 were not sufficient to cover the full range of the use of MTR/SASSI in support of AREVA NP's U.S. EPR™ Design Certification application.

This issue has been identified as Violation 05200020/2013-201-01.

II. AREVA NP's Reply to the Notice of Violation

AREVA NP performed an apparent cause evaluation under its Corrective Action Program to investigate the contributing causes of the findings listed in this violation, understand the extent of condition and put in place corrective actions to prevent recurrence.

(1) Reason for the Violation

The apparent cause evaluation highlighted the lack of thorough understanding of the commercial-grade dedication process by those involved in the MTR/SASSI software dedication work. Although the procedure requirements were reviewed by the dedication personnel prior to performing work, full implementation was still not achieved. The First of a Kind (FOAK) nature of the dedication process by the personnel involved along with the lack of in-depth understanding of the commercial-grade dedication process were the main contributors to the violation.

Specifically, the MTR/SASSI vendor had a standard set of validation problems that has been used in past verifications and validations of the software. This same set of test problems was used with new test problems added, as appropriate, to test new features. Due to the FOAK nature of the dedication process for the personnel involved, and the error likely situation of relying on previous sets of test problems, the dedication range was not consistent with the intended use of the software (i.e., the range of parameters to be used needs to be bounded by the dedication test problems).

In addition, the performance requirements including software limitations and critical characteristics were neither clearly and fully identified in the dedication report nor separately identified in another document due to the lack of in-depth understanding of the dedication process.

(2) Corrective Steps that Have Been Taken and the Results Achieved

Additional analyses were performed during the week of the NRC inspection to expand the range of the analysis parameters to cover the use of the software. A new test problem was created to increase the shear wave velocity and extend the computed frequencies up to 50 Hz.

A readiness review was performed in this area prior to the NRC inspection. As a result of this review, an additional interim corrective action in the form of a Lessons Learned entry into AREVA NP's Corrective Action Program was made to provide an interim barrier.

(3) Corrective Steps that Will Be Taken to Avoid Further Violations

1. (a) Update MTR/SASSI dedication documents to include additional test problems to cover the higher shear wave velocities and computed frequencies up to 50 Hz, and (b) revise MTR/SASSI dedication plans and reports to meet the requirements of 0902-29, Rev. 006, Section 4.4.11 regarding:
 - Identification of the capabilities of the software and limitations applicable to its intended use.
 - A description of the test plans and test cases to be used to determine the capability of the software within the limitations and accept the software for use in engineering applications.
 - Instructions for use of the software within the limits of the dedicated capabilities or identification of a related document containing these instructions.
2. Update the dedication documentation for all impacted MTR/SASSI versions used by AREVA NP in accordance with item II.(3).1.
3. Conduct a review of approximately 20% sample (six) of other software dedication packages to ensure the dedication documentation appropriately addresses Procedure 0902-29, Section 4.4.11, regarding limitations of use of the software and instructions for using the software within the dedicated limits.
4. Recurrence Prevention: (a) In-depth training will be provided to those directly engaged in performing commercial-grade dedication work for procured software to ensure full understanding of the critical

characteristics and performance requirement concepts and the need to properly follow documentation requirements of Procedure 0902-29. (b) A Lessons Learned Condition Report has been initiated that includes a software dedication checklist which can be used by engineering to ensure Procedure 0902-29 requirements are specifically addressed in the dedication documentation.

(4) Date When Full Compliance Will be Achieved

All corrective actions will be completed by December 20, 2013.

Attachment B

Table of Commitments

Action Number	Action	Completion Date
2013-201-1(a)	Update MTR/SASSI dedication documents to include additional test problems to cover the higher shear wave velocities and computed frequencies up to 50 Hz.	8-30-2013
2013-201-1(b)	<p>Revise MTR/SASSI dedication plans and reports to meet the requirements of 0902-29 Section 4.4.11 regarding:</p> <ul style="list-style-type: none">• Identification of the capabilities of the software and limitations applicable to its intended use.• A description of the test plans and test cases to be used to determine the capability of the software within the limitations and accept the software for use in engineering applications.• Instructions for use of the software within the limits of the dedicated capabilities or identification of a related document containing these instructions.	8-30-2013
2013-201-2	Update the dedication documentation for all impacted MTR/SASSI versions used by AREVA NP in accordance with item II.(3).1.	8-30-2013
2013-201-3	Conduct a review of approximately 20% sample (six) of other software dedication packages to ensure the dedication documentation appropriately addresses Procedure 0902-29, Section 4.4.11, regarding limitations of use of the software and instructions for using the software within the dedicated limits. Additional violations to 0902-29, Section 4.4.11 will be documented in our Corrective Action Program and will be addressed accordingly.	12-20-2013
2013-201-4(a)	In-depth training will be provided to those directly engaged in performing commercial-grade dedication work for procured software to ensure full understanding of the critical characteristics and performance requirement concepts and the need to properly follow documentation requirements of Procedure 0902-29.	12-20-2013
2013-201-4(b)	A Lessons Learned Condition Report has been initiated that includes a software dedication checklist which can be used by engineering to ensure Procedure 0902-29 requirements are specifically addressed in the dedication documentation.	12-20-2013