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LTR-NRC-11-66

December 2, 2011

Subject: Reply to a Notice of Nonconformance for 99901408/2011-201-(01, 02, 03)

Enclosed is the Reply to the Notice of Nonconformance for Nonconformances 99901408/2011-201-01, 99901408/2011-201-02, and 99901408/2011-03 that were transmitted to Westinghouse Electric Sweden AB on November 4, 2011 with subject entitled "NRC Inspection Report No. 99901408/2011 and Notice of Nonconformance." These Nonconformances have been entered as issues in Westinghouse's Corrective Actions Process (CAPs).

Correspondence with respect to the information provided in this transmittal should be addressed to J. A. Gresham, Manager, Regulatory Compliance, Westinghouse Electric Company LLC, Suite 428, 1000 Westinghouse Drive, Cranberry Township, Pennsylvania 16066.

Very truly yours,

A handwritten signature in black ink, appearing to read 'J. A. Gresham', written over a printed name.

J. A. Gresham, Manager
Regulatory Compliance

Attachment

cc: M. C. Murphy (NRC OWFN 12 D3)

JE09
NR0

bcc: J. A. Gresham
C. B. Brinkman
C. L. Olesky
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J. G. Belechak
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G. Hede (Sweden)
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Nonconformance 99901408/2011-201-01

A. Criterion V, "Instructions, Procedures, and Drawings," 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 "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings."

10 CFR 21.3, "Definitions," to 10 CFR Part 21, "Reporting of Defects and Failures to Comply," states, in part, that "*Discovery* means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21(a)."

10 CFR 21.21(a)(1) states, in part, to "evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected."

Westinghouse Engineering Services Procedure (ES) 21.1, "WEC 21.0 Level 3 Implementation Procedure," Revision 1, dated December 6, 2010, states, in part, that "this Level 3 procedure implements the requirements of Westinghouse Policy/Procedure WEC 21, Revision 6, 'Identification and Reporting of Conditions Adverse to Safety,' and that once a potential condition adverse to safety arises, the condition is identified, documented, and assessed to determine if an actual condition adverse to safety exists."

Contrary to the above, as of September 16, 2011, Westinghouse failed to prescribe an appropriate procedure to ensure the timely identification and evaluation of deviations and failures to comply that could create a substantial safety hazard. Specifically, ES 21.1 includes a 30-day discovery phase evaluation timeframe that may be extended for 2 weeks at a time, thus inappropriately delaying discovery and initiation of the evaluation required by 21.21(a)(1).

This issue has been identified as Nonconformance 99901408/2011-201-01.

Response:

1) *The reason for the noncompliance or, if contested, the basis for disputing the noncompliance:*

As 10CFR21 does not prescribe a period of time for Discovery, the provision allowing a two week extension to the time limit for discovery is not in conflict with the regulation. However, Westinghouse agrees that the two week extension could theoretically result in an extended discovery period because there was no limit to the number of times the extension could be granted.

2) *The corrective steps that have been taken and the results achieved:*

None

3) *The corrective steps that will be taken to avoid noncompliance:*

ES 21.1 will be revised to eliminate the provision for an extension of the 30 day limit. If Discovery cannot be completed with 30 days, it will be conservatively assumed that a deviation or failure to comply exists and proceed with the evaluation.

4) *The date when the corrective action will be completed:*

This change will be implemented immediately on an administrative basis with the formal change to the procedure being completed by February 29, 2012.

Nonconformance 99901408/2011-201-02

B. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 states, in part, that "applicable regulatory requirements and the design basis...are correctly translated into specifications, drawings, procedures, and instructions." It also states that "measures shall 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."

10 CFR 21.3 defines "Dedication," in part, as "an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analysis performed by the purchaser or third-party dedicating entity."

Criterion V of Appendix B to 10 CFR Part 50 states, in part, that "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings."

"Westinghouse Quality Management System (QMS)," Section 4.3.9, "Commercial-Grade Items," Revision 6, dated April 8, 2011, states that "commercial-grade items, items not originally intended for safety-related applications, are subjected to a dedication process that is defined and authorized by the engineering organization in accordance with procedures that meet the requirements of the governing regulatory agency, before the items are supplied for safety-related applications."

Westinghouse Policy / Procedure (WEC) 7.2, "Dedication of Commercial Grade Items," Section 6.1, Revision 1, dated August 3, 2009, states that "Engineering is responsible for determining the safety-related function of the item, identifying both the critical characteristics of design and acceptance of the item, and identifying the dedication method(s) to be used to verify the critical characteristics of acceptance."

Contrary to the above, as of September 16, 2011, Westinghouse failed to appropriately dedicate commercially procured software in accordance with WEC 7.2. Specifically, Westinghouse did not conduct a technical evaluation to identify safety function, critical characteristics, and acceptance methods for a commercially procured version of the ANSYS finite-element analysis software.

This issue has been identified as Nonconformance 99901408/2011-201-02.

Response:

- 1) *The reason for the noncompliance or, if contested, the basis for disputing the noncompliance:*

Westinghouse has investigated this issue and concluded that Westinghouse Electric Sweden had not purchased the ANSYS Quality Assurance Package available for ANSYS code releases or validated the commercially available ANSYS product using

Westinghouse developed methods due to inadequate procedure requirements in EP-313, Third Party Software, and an incomplete understanding of the existing requirements in EP-313.

2) *The corrective steps that have been taken and the results achieved:*

Based on dialogue with the vendor, ANSYS Inc., Westinghouse understands there are no known physical, mathematical or other differences in the commercially procured version of ANSYS and the version purchased with the Quality Assurance Package. Thus, there is no immediate concern of delivered deficiencies. However, the corrective actions noted below will be taken.

3) *The corrective steps that will be taken to avoid noncompliance:*

- a) Westinghouse Electric Sweden will work with the local ANSYS provider to purchase the appropriate ANSYS Quality Assurance Package. It is intended to verify previously used code versions through the ANSYS Quality Assurance Package and confirm calculations are correct for U.S. customer deliveries. (Completion date: April 30, 2012)
- b) As an intermediate step, until implementation of the corrective action planned in item (a), upcoming deliveries to US customers based on ANSYS calculations will be final-calculated for delivery using the Westinghouse Electric Company's ANSYS versions purchased with the Quality Assurance Package that are available on servers in the United States. (Completion date: April 30, 2012)
- c) EP-313, Third Party Software, will be updated to reference WEC 7.2, Dedication of Commercial Grade Items, and to provide other procedural clarifications and improvements. (Completion date: March 30, 2012)

4) *The date when the corrective action will be completed:*

The completion dates associated with the corrective steps are included in item (3).

Nonconformance 99901408/2011-201-03

C. Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50 states, in part, that "a test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents."

Criterion V of Appendix B to 10 CFR Part 50 states, in part, that "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings."

EP-310, "Computer Software Development and Maintenance," Section 9.1.5, Revision 25, dated March 14, 2011, states that "a Test Plan shall be developed, documented and reviewed. The plan shall specify [a] description of the Test Cases which are to be used in the testing, including items to be tested, the Test Cases to be performed, test sequences, and acceptance criteria."

Contrary to the above, as of September 16, 2011, Westinghouse failed to specify and document acceptance criteria. Specifically, Westinghouse failed to identify acceptance criteria in test plans for computer software verification and validation tests supporting changes to the BISON and POLCA-T evaluation models in documents SET 10-165, "WCAP-17202-P, Supplement 4 to BISON Topical Report RPA 90-90-P-A, June 2010," and SET 09-248, "POLCA-T Qualification Against Peach Bottom 2 EOC 2 Turbine Trip Tests 1 and 2."

This issue has been identified as Nonconformance 99901408/2011-201-03.

Response:

- 1) *The reason for the noncompliance or, if contested, the basis for disputing the noncompliance:*

The requirements in EP-310, Computer Software Development and Maintenance, Section 9.1.5 associated with specification and documentation of acceptance criteria for test cases were not addressed for computer programs BISON and POLCA-T due to inadequate training of personnel responsible for preparation of the test plans and performance of the test cases and associated difficulties in understanding how to apply the acceptance criteria requirements.

- 2) *The corrective steps that have been taken and the results achieved:*

None

- 3) *The corrective steps that will be taken to avoid noncompliance:*

- a) Establish a plan to update the BISON and POLCA-T test plan and testing documentation to include acceptance criteria. (Completion date: December 20, 2011)
- b) Implement the plan prepared in item (3a). (Completion date: April 30, 2012)

- c) Provide refresher training in EP-310 test plan and testing requirements to software test planning and testing personnel along with management responsible for software test planning and testing. (Completion date: April 30, 2012)
- d) Update EP-310 to provide requirements that shall be met whenever acceptance criteria cannot be defined in the test plan until after testing is performed. (Completion date: March 30, 2012)
- e) To address the extent of condition as requested by the NRC the following actions will be taken:
 - a. Identify codes and versions that should be investigated for other cases of missing acceptance criteria in software test documentation. (Completion date: January 31, 2012)
 - b. For identified code versions, an evaluation of the software testing documentation will be conducted to evaluate possible non-compliance situations. (Completion date: May 31, 2012)
 - c. Update any software test documents with missing acceptance criteria that were identified in the previous action. (Completion date: June 29, 2012)

4) *The date when the corrective action will be completed:*

The completion dates associated with the corrective steps are included in item (3).