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Subject: Re: Staff Comments Regarding DSER Open Item 17.3.2-2
Creation Date: 10/15/03 4:04PM
From: John Segala

Created By: JPS1@nrc.gov

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From: John Segala
To: Vijukrp@westinghouse.com
Date: 10/15/03 4:04PM
Subject: Re: Staff Comments Regarding DSER Open Item 17.3.2-2

Ron,

Attached is the staff's comments regarding DSER Open Item 17.3.2-2 as a result of the QA Inspection conducted September 15-18, 2003.

John

CC: Colaccino, Joseph; Corletti, Mike; Dudes, Laura; Pettis, Robert; Starefos, Joelle

Staff Comments Regarding DSER Open Item 17.3.2-2

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted September 15-18, 2003, of activities supporting Westinghouse's design certification for AP1000, it appears that certain activities were not conducted in accordance with NRC requirements.

1. Criterion VII, "Control of Purchased Material, Equipment, and Services," of 10 CFR 50, Appendix B, states, in part, that measures shall be established to assure that purchased material, equipment, and services, 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, source inspection, and examination of products upon delivery.

Westinghouse Quality Management System (QMS), Revision 5, dated October 1, 2002, states in Section 4.3.1 that suppliers of safety-related items are evaluated and approved prior to designation as an approved supplier, or placement of a purchase order, and that active suppliers are evaluated annually and audited at least every three years. Further, Section 4.3.2 states that suppliers of safety-related items and services are evaluated and selected prior to their designation as a qualified supplier.

Westinghouse Policy/Procedure Westinghouse 6.3, "Supplier Qualification and Evaluation," Revision 4, dated May 16, 2003, is a documented procedure which provides requirements for the selection of suppliers for the AP1000 Project. Westinghouse 6.3 states, in part, in Section 2.0, "Policy," that suppliers of safety-related items and services be evaluated and approved prior to their designation as a qualified supplier, or placement of a purchase order, while Section 7.2 states, in part, that an audit must be performed prior to the acceptance of any product or service. Further, Section 7.11 requires an annual evaluation of each qualified supplier to assess the supplier's capability to supply acceptable items and services. Additionally, Section 4.3.1 of QMS Revision 5 states, in part, that procurement activities are controlled through documented procedures and instructions that include requirements for bid selection and selection of suppliers. The results of each evaluation shall be approved by Westinghouse Quality Management and documented on a Supplier Audit/Evaluation Summary, Form F-6.3-2.

Contrary to the above, Westinghouse could not produce objective evidence demonstrating compliance with their quality program and procedures to support the basis for qualification and evaluation of suppliers used in support of safety-related design certification activities for the AP1000 Project. Specifically, as of the August 19, 2003, AP1000 Suppliers List, a total of 27 suppliers are listed however, 21 suppliers are active in providing services used for safety-related activities in support of AP1000 Design Certification. This issue is considered to be a potential nonconformance with the QMS and 10 CFR 50, Appendix B. The inspection report will be provided to Westinghouse by October 31, 2003, and the staff intends to request a written response to address the issue.

To address the above, the NRC requests Westinghouse to:

- a. Evaluate the impact of this finding on the AP1000 Project and establish the adequacy of the quality assurance review process, including the integrity of the design.
 - b. Demonstrate that the requirements of 10 CFR 50, Appendix B, and the applicable design certification provisions of 10 CFR Part 52 are being satisfied.
2. Internal Westinghouse Quality Assurance (QA) audit Westinghouse-01-50, dated November 16, 2001, identified that the AP1000 project utilized outside design analysis from sources not on the Westinghouse qualified suppliers list. This issue was also identified in Westinghouse corrective action Issue Report (IR) 01-003480. The corrective action for IR 01-003480 included: (1) issuance of AP1000 project procedures to establish methods and processes for AP1000 supplier qualification, and (2) an update to the approved AP1000 suppliers list in accordance with these project procedures. A subsequent internal audit, dated November 22, 2002 (Westinghouse-02-20), reviewed the effectiveness of the IR 01-003480 corrective actions and determined that the implementation of these actions was effective. However, during the QA implementation inspection, the inspectors determined that Westinghouse lacked objective evidence demonstrating that AP1000 suppliers had been approved in accordance with AP1000 project procedures. Consequently, the inspectors concluded that the corrective actions of IR 01-003480 had not been effectively implemented. Further, the team concluded that internal audit Westinghouse-02-20 should have reasonably identified the lack of objective evidence supporting the qualification of AP1000 project suppliers. To assist the staff in determining if the internal audit and corrective action processes are capable of reliably identifying and correcting performance issues, please provide the following information:
 - a. Explain why the corrective actions of IR 01-003480 failed to ensure that AP1000 project suppliers were qualified in accordance with applicable project procedures. Additionally, provide an explanation for the failure of internal audit Westinghouse 02-20 to identify the lack of objective evidence supporting AP1000 project suppliers.
 - b. Describe corrective actions taken to address any identified performance issues associated with the implementation of corrective actions for IR 01-003480 and conduct of internal audit Westinghouse-02-20.
3. In reviewing internal audits and self-assessments associated with the AP1000 project, the NRC inspection team determined that the scope of these oversight reviews focused primarily on procedural adherence rather than the technical validity of design analyses and calculations. Although this issue was noted in internal audit Westinghouse-02-20 and IR 02-326-M004, the inspectors determined that actions intended to assess the technical validity of calculations were not fully implemented. For example, although audit Westinghouse-02-20 and IR 02-326-M004 recommended a technical review of approximately 20 calculation notes, the inspectors determined that the technical validity of only one calculation appeared to have been independently evaluated.

- a. In light of the limited scope of internal audit and self-assessment calculation technical validity reviews, please describe any methods and oversight activities utilized by Westinghouse to assess the effectiveness of the AP1000 design control measures, particularly those related to the technical validity of design products.
- b. In your response to Item a. above, describe any additional assessments or reviews that have been performed, including the scope of the these reviews.

As a result of the issues identified by the NRC inspection team noted in Items 1-3 above, the effectiveness of Westinghouse's implementation of the AP1000 QA program remains indeterminate pending an acceptable response to this request.