

December 24, 2008

Ms. Dee Xenakis, Manager Quality NPP Programs
Westinghouse Electric Company
Nuclear Power Plants
4350 Northern Pike
Monroeville, PA 15146

SUBJECT: NRC INSPECTION REPORT NO. 05200006/2008-201, NOTICE OF
NONCONFORMANCE

Dear Ms. Xenakis:

On October 27–31, 2008, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Westinghouse Electric Company (Westinghouse) facility in Monroeville, PA. The enclosed report presents the results of this 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 Program 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 (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, NRC inspectors found that the implementation of your QA program failed to meet certain NRC requirements imposed on you by your customers. Specifically, the NRC inspectors determined that there were inadequacies in Westinghouse’s policies, procedures, and implementing actions for instructions, procedures, and drawings; design control; control of purchased material, equipment, and services; and instructions, procedures, and drawings. The Notice of Nonconformance enclosed in this letter identifies the specific findings and references to the pertinent requirements.

Please provide a written statement or explanation within 30 days from the date of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390, “Public Inspections, Exemptions, Requests for Withholding,” of the NRC’s “Rules of Practice,” a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC’s Agencywide Documents Access and Management System (ADAMS), 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 it can be made available to the public without redaction. 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 that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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."

Sincerely,
/RA SCrane for/

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

Docket No.: 52-006

Enclosures: 1. Notice of Nonconformance
 2. Inspection Report No. 05200006/2008-201 and Attachment
 3. Appendix, Pilot Engineering Design Verification Inspection at Westinghouse –
 WITHHELD FROM PUBLIC DISCLOSURE UNDER 10 CFR 2.390.

If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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."

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DATE	12/24/2008	12/24/2008	12/ /2008	12/24/2008	12/24/2008

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NOTICE OF NONCONFORMANCE

Westinghouse Electric Company
Nuclear Power Plants
4350 Northern Pike
Monroeville, PA 15146

Docket Number 52-006
Inspection Report Number 05200006/2008-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at Westinghouse Electric Company (WEC) on October 27–31, 2008, the NRC staff found that certain activities were not conducted in accordance with NRC requirements.

- A. Criterion III, “Design Control,” of Appendix B to 10 Part 50, “Domestic Licensing of Production and Utilization Facilities,” of the *Code of Federal Regulations* (10 CFR Part 50) states, in part, that design changes shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

Quality Management System (QMS) Section 4.2, “Design Control,” states, in part, that the engineering organization controls the design process to ensure that the design changes are properly evaluated before implementation. Procedure AP-3.2, “Change Control for the AP1000 Program,” Revision 7.1, dated September 30, 2008, controls the process for approving and implementing changes to the design. AP-3.2 stipulates that proposed Class 1 or 2 changes that will affect the design of the AP1000 be documented through design change proposals (DCPs).

Contrary to the above, as of October 31, 2008, the inspection found the following:

The NRC inspectors noted that Westinghouse had not followed Procedure AP-3.2 as required for control of the AP1000 design control document (DCD) and associated design specifications. Specifically, the NRC inspectors identified (1) multiple instances where changes were made to the design specifications or the DCD without proper documentation (i.e., DCPs), (2) several instances where approved DCP were not incorporated into the DCD, and (3) specific material and inspection requirements for the reactor coolant pump (RCP) flywheel assembly described in Sections 5.4.1.2.1 and 5.4.1.3.6.3 of the AP1000 DCD that were not captured in the applicable sections of the RCP certified design specification, APP-MP01-M2-001, Revision 1. The failure of Westinghouse to follow its design change control procedure has been identified as Nonconformance 05200006/2008-201-01.

- B. Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 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 that 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.”

Westinghouse Procedure/Policy WEC 6.3, establishes requirements for the evaluation and qualification of suppliers and the conduct of a quality program audit. Section 4.3 of the procedure defines "audit" as a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions and drawings, and other applicable documents, and the effectiveness of implementation. Westinghouse Procedure/Policy WEC 6.3, Section 7.12.1, further states that audit records shall include audit plans and reports and identification of objective evidence examined during the audit.

Contrary to the above, as of October 31, 2008, the inspection found the following:

The NRC inspectors identified that, for the audits and surveillances selected as a sample, Westinghouse did not, in all instances, document objective evidence to support the results and conclusions associated with supplier oversight audits performed by Westinghouse to control and maintain the Westinghouse QSL.

The failure of Westinghouse to provide documented objective evidence of its suppliers' ability to provide items or services in accordance with the applicable procurement and regulatory requirements has been identified as Nonconformance 05200006/2008-201-02.

- C. Criterion V, "Instructions, Procedures, and Drawings," of Appendix B, "Quality Assurance Program 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 "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 Policy/Procedure WEC 21, "Identification and Reporting of Conditions Adverse to Safety," Revision 4.1, dated October 21, 2008, states 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. If it is determined that a condition adverse to safety (a deviation or failure to comply) is involved, then an evaluation per 10 CFR Part 21, "Reporting of Defects and Noncompliance," is initiated, and the 60-day clock for completing the evaluation starts.

Contrary to the above, as of October 31, 2008, the inspection found the following:

- WEC 21.0 did not contain adequate procedural guidance for the identification of deviations and failures to comply that must be evaluated to identify a defect or failure to comply that could create a substantial safety hazard. Westinghouse implements an internal process outside of the controls of WEC 21.0 that provides for the assessment and evaluation of conditions adverse to safety to determine whether or not they constitute deviations or failures to comply.

- Westinghouse Procedure/Policy WEC 6.3, "Supplier Qualification and Evaluation Procedure," Revision 10, dated February 29, 2008, contained a procedural step which allowed for alternate methods for maintaining the qualified supplier list (QSL) by individual organizations within Westinghouse without establishing clear criteria for when such alternate methods were acceptable. Also, WEC 6.3 contained an obsolete procedural step, Step 7.12.3, which allowed for the use of a corrective action issues system other than the corrective action process (CAP) database, although all Westinghouse locations have implemented the CAP database and are expected to use the system for collection of issues.

These issues have been identified as examples of Nonconformance 05200006/2008-201-03.

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) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid noncompliances, and (4) the date when your corrective action 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, MD, this 24th Day of December 2008.

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

Docket No.: 52-006

Report No.: 05200006/2008-201

Vendor: Westinghouse Electric Company
Nuclear Power Plants
4350 Northern Pike
Monroeville, PA 15146

Vendor Contact: Ms. Dee Xenakis
Manager Quality NPP Programs
Operational Excellence and Quality
412-374-6593

Nuclear Industry: Westinghouse Electric Company provides fuel, services, technology, plant design, and equipment to utility and industrial customers in the worldwide commercial nuclear electric power industry.

Inspection Dates: October 27–31, 2008

Inspectors: Milton Concepcion, NRO/DCIP/CQVP, Team Leader
Kerri Kavanagh, NRO/DCIP/CQVP
Greg S. Galletti, NRO/DCIP/CQVP
Andy DuBouchet, NRO/DCIP/CQVP
Dori Votolato, NRO/DCIP/CQVP
Jonathan Ortega, NRO/DCIP/CQVP
Samantha Crane, NRO/DCIP/CQVP
Joselito Calle, R-II/DCI/CIB2
Edmund Kleeh, NRO/DCIP/CCIB
Rahsean Jackson, R-II/DCI/CIB2
Molly Keefe, NRO/DCIP/COLP
Paul Pieringer, NRO/DCIP/COLP
Robert Latta, R-IV/DRS/EB2
William Roggenbrodt, NRO/DE/ICE
Jack Zhao, NRO/DE/ICE

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

EXECUTIVE SUMMARY

Westinghouse Electric Company
05200006/2008-201

The purpose of this inspection was to verify that Westinghouse Electric Company (Westinghouse) implemented an adequate quality assurance (QA) program that complies with the requirements 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). The inspection also verified that Westinghouse implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets the regulatory requirements of the U.S. Nuclear Regulatory Commission (NRC). The NRC conducted the inspection at Westinghouse's facility in Monroeville, PA.

The NRC inspection bases were the following:

- 10 CFR Part 21
- Appendix B to 10 CFR Part 50

The NRC inspectors implemented Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," IP 35017, "Quality Assurance Implementation Inspection," IP 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformances," and draft IP 37802, "Engineering Design Verification Inspections."

With the exception of the areas described below, the NRC inspectors concluded that Westinghouse's QA policies and procedures were in compliance with the applicable requirements of 10 CFR Part 21 and Appendix B to 10 CFR Part 50 and that Westinghouse personnel were implementing these policies and procedures effectively.

Design Control

The NRC inspectors issued Nonconformance 05200006/2008-201-01 for the failure on the part of Westinghouse to meet the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50.

Control of Purchased Material, Equipment, and Services

The NRC inspectors issued Nonconformance 05200006/2008-201-02 for the failures on the part of Westinghouse to meet the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Specifically, for the audits and surveillances selected as a sample, Westinghouse failed to provide documented evidence of its supplier's ability to provide items or services in accordance with the applicable procurement and regulatory requirements.

Instructions, Procedures, and Drawings

The NRC inspectors issued Nonconformance 05200006/2008-201-03 with two examples for failure to establish and implement adequate procedures for activities affecting quality. Specifically, Westinghouse's 10 CFR Part 21 implementing procedure does not contain adequate procedural guidance for the identification and evaluation of deviations and failures to comply. In addition, Westinghouse did not implement adequate procedures for maintaining the Qualified Supplier List (QSL), and allowed for the use of a corrective action issues system other than the CAPs database.

REPORT DETAILS

1. 10 CFR PART 21 PROGRAM

a. Inspection Scope

The NRC inspectors reviewed the Westinghouse Quality Management System (QMS) and implementing policies and procedures that govern the 10 CFR Part 21 process, including:

- QMS Section 1.1.1.2, "10 CFR Part 21/10 CFR 50.55," Revision 5, dated October 1, 2002
- Westinghouse Policy/Procedure WEC 21.0, "Identification and Reporting of Conditions Adverse to Safety," Revision 4.1, dated October 21, 2008
- Westinghouse Policy/Procedure WEC 14.4, "Westinghouse Corrective Actions Process," Revision 8 dated February 29, 2008

The NRC inspectors also discussed the 10 CFR Part 21 process with members of Westinghouse's management and technical staff and sampled Westinghouse 10 CFR Part 21 program implementation activities.

b. Observations and Findings

QMS Section 1.1.1.2 stated that Westinghouse maintains procedures that provide for the evaluation of conditions that may require NRC notification in accordance with 10 CFR Part 21. WEC 21.0 establishes the organizational activities and requirements for identifying, evaluating, and processing potential conditions adverse to safety, while WEC 14.4 provides the interface requirements between the corrective action and nonconformance reporting processes with the 10 CFR Part 21 program to identify issues that may be deviations or failures to comply associated with substantial safety hazards. WEC 21.0 states that once a potential condition adverse to safety arises, the condition should be identified, documented, and assessed to determine if an actual condition adverse to safety is involved. In WEC 21.0, Westinghouse defined (in part) a potential condition adverse to safety in WEC 21.0 as "a safety-related deviation, failure to comply, or nonconformance." If Westinghouse determines that a condition adverse to safety is involved, then it begins a Part 21 evaluation with a 60 day time frame.

The NRC inspectors reviewed the corrective action process contained in WEC 14.4 and the process described in WEC 21.0 and interviewed personnel with responsibility for the review of potential 10 CFR Part 21 issues. In these discussions, the NRC inspectors learned that the Issue Review Committee (IRC) is responsible for reviewing corrective action reports (CARs) and finalizing regulatory reporting requirements. The IRC is also responsible for deciding if a potential condition adverse to safety warrants further analysis to determine whether it is a deviation or failure to comply.

In these discussions the NRC inspectors also noted that if the IRC cannot readily identify an issue as a deviation or failure to comply, the IRC continues to assess the issue under two different processes not defined within WEC 21.0. Specifically, Westinghouse uses guideline RLE-4-B, "Potential Deviation or Failure to Comply (PD) Process," to assess if a potential condition adverse to safety is a deviation or failure to comply, and RLE-4-C, "Potential Issue (PI) Procedure," to evaluate deviations and failures to comply in

accordance with 10 CFR Part 21. The NRC inspectors confirmed that RLE-4-B and RLE-4-C are not considered formal procedures but guidance to engineers performing the assessment of issues potentially reportable under 10 CFR Part 21. In addition, RLE-4-B and RLE-4-C are outdated and are not part of the process defined in WEC 21.0. Further, these documents do not reference WEC 21.0 for evaluation of conditions deemed adverse to quality. On this basis, the NRC inspectors determined that Westinghouse has not adopted adequate procedural guidance for the identification of deviations and failures to comply that must be evaluated to identify a potentially reportable defect or failure to comply that could create a substantial safety hazard.

To verify implementation of the 10 CFR Part 21 process outlined in WEC 21.0, the NRC inspectors requested copies of 10 CFR Part 21 records of evaluations and reports that Westinghouse had completed. Specifically, the NRC inspectors reviewed corrective action Issue Report # 08-007-M016, which was entered in the corrective action system on January 7, 2008, and documented a potential deviation associated with the AP1000 design certification document (DCD). The NRC inspectors noted that the issue was assessed in accordance with RLE-4-B to determine if it warranted a 10 CFR Part 21 evaluation. This assessment was completed on March 11, 2008, and it concluded that this issue did constitute a deviation for which a Part 21 evaluation should be performed. The NRC inspectors noted that technical personnel had already performed part of the Part 21 assessment for safety significance of the issue using the process described in RLE-4-B. The Part 21 evaluation was completed on April 21, 2008, using the RLE-4-C process and the assessment done in accordance with RLE-4-B. Westinghouse determined that the issue did not constitute a defect, and therefore did not have to be reported to the NRC or customers pursuant to 10 CFR Part 21. This example demonstrates that timely evaluation of potential deviations or failures to comply may not be achieved since RLE-4-B does not establish timeliness requirements for the initial assessment.

The regulation in 10 CFR Part 21.21(a)(1) states that each entity shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and in all cases with 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard. The regulation in 10 CFR 21.3 also defines "discovery" as 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). The NRC inspectors acknowledged that 10 CFR Part 21, as written, allows for a discovery phase where potential deviations or failures to comply may not be assessed in a timely manner to determine whether additional evaluation (in accordance with Part 21) is warranted. Although this discovery phase provides for further assessment in order to gain more information on a potential deviation or failure to comply, the regulation as written does not impose a deadline on the completion of the documentation first identifying the existence of the deviation or failure to comply. Accordingly, the NRC is assessing the need to initiate rulemaking to resolve this deficiency and ensure that deviations or failures to comply are promptly identified and evaluated in accordance with §21.21(a)(1).

c. Conclusions

The NRC inspectors concluded that the Westinghouse policies and procedures associated with 10 CFR Part 21 do not contain adequate procedural guidance for the identification of deviations and failures to comply that must be evaluated to identify a defect or failure to comply that could create a substantial safety hazard. This issue has been identified as part of Nonconformance 0520006/2008-201-03.

2. Design Control

a. Inspection Scope

The NRC inspectors reviewed the Westinghouse policy and procedures governing design control activities as they relate to the development and translation of the Westinghouse AP1000 design control document into detailed design and procurement documents 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 NRC inspectors reviewed a sample of design packages related to the reactor pressure vessel (RPV), steam generator, reactor coolant pump, and civil structural modules. The NRC inspectors also reviewed a representative sample of design change proposals (DCPs) related to the AP1000 DCD.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following documents:

- Westinghouse QMS Section 4.2, "Design Control," Revision 5, dated October 1, 2002
- Procedure AP-3.2, "Change Control for the AP1000 Program," Revision 7.1 dated September 30, 2008 (AP-3.2)
- AP 1000 Design Control Document (DCD), Revision 17, dated September 22, 2008
- AP1000 Design Specification: AP1000 Reactor Vessel, APP-MV01-Z0-101 Revision 2, dated September 12, 2008
- Steam Generator Certified Design Specification, APP-MB01-Z0-101, Revision 1, dated October 31, 2007
- Reactor Coolant Pump (RCP) Certified Design Specification, APP-MP01-M2-001, Revision 1, dated June 14, 2007
- Civil Structural Design Criteria, APP-GW-C1-001, Revision 1, dated October 5, 2008
- Nuclear Island Structural Modules Specification, APP-GW-Z0-100, Revision 1, dated June 21, 2008

b. Observations and Findings

Westinghouse QMS Section 4.2, states, in part, that the engineering organization controls the design process to ensure that the design changes are properly evaluated before implementation. Westinghouse Procedure AP-3.2 controls the process for approving and implementing changes to the design. The NRC inspectors identified several examples where Procedure AP-3.2 was not followed. The NRC inspectors discussed the change process with the responsible personnel and confirmed that the

responsible manager was knowledgeable in the process for initiating and incorporating changes into design documents. However, the NRC inspectors identified several instances in which the design specifications or the AP1000 DCD were modified without documented evidence that these changes had been properly evaluated before implementation as required by procedure AP-3.2. Examples include the following:

- The NRC inspectors noted that Section 5.3.2.3.3, “Magnetic Particle Examination,” of the AP1000 DCD, Revision 17, limits the examination techniques before the final postweld heat treatment of the RPV to the prod, coil, or direct contact method. Upon reviewing APP-MV01-Z0-101, the NRC inspectors found that Section 8.3.3 allows for the prod coil (direct contact method) or the yoke method to be used before the final post-weld heat treatment. The addition of the yoke method occurred in Revision 2 of the design specification. This change to the design specifications is less conservative than the method specified in the DCD. At the time of the exit meeting, Westinghouse released Issue Report (IR) 08-304-M027 to address this condition.
- The NRC inspectors observed that Table 3.8.4-6 of the AP1000 DCD lists American Society for Testing and Materials (ASTM) A325 bolts, whereas the “Nuclear Island Structural Modules Specification” (APP-GW-Z0-100) specifies A325 or A490 bolts. At the time of the exit meeting, Westinghouse issued IR 08-304-M032 to address this condition.
- The NRC inspectors found that Section 3.8.4.6.1.1, “Concrete,” of the AP1000 DCD specifies that 4,000 or 6,000 pound-per-square-inch (psi) concrete be cured at either 28 (no retardant) or 56 days (with retardant). However, the Civil Structural Design Criteria APP-GW-C1-001 specifies only that 4,000 psi concrete be cured at either 28 or 90 days. At the time of the exit meeting, Westinghouse issued IR 08-304-M033 to address this condition.
- The NRC inspectors noted that Section 5.4.2.4.1, “Selection and Fabrication of Materials,” of the AP1000 DCD, Tier 2, Revision 17 (as well as Revision 16) specifies the cladding material for the steam generator tubesheet to be SFA-5.14 (nickel-chromium-iron alloy). However, Table 7.1-1 of the “Steam Generator Certified Design Specification,” APP-MB01-Z0-101, Revision 1, lists not only SFA-5.14 but also the option to use SFA-5.11. At the time of the exit meeting, Westinghouse issued IR 08-303-M013 to address this condition.
- The NRC inspectors found that Sections 5.4.1.2.1, “Design Description,” and 5.4.1.3.6.3, “Flywheel Integrity,” of the AP1000 DCD, Tier 2, were revised under Revision 17 and incorporated additional information regarding the RCP flywheel assembly material and inspection requirements provided by Westinghouse in response to an NRC request for additional information (RAI-SRP5.4.1-CIB1-01). Contrary to the requirements of Procedure AP-3.2, the AP1000 DCD was revised without issuance of a DCP.

The NRC inspectors identified two instances where approved DCPs (DCPs 94 and 220) were not incorporated into the AP1000 DCD in accordance with procedure AP-3.2. Westinghouse identified four additional instances where approved DCPs were not fully incorporated into the DCD. At the time of the exit meeting, Westinghouse issued IR 08-304-M035 to address this condition.

In addition, the NRC inspectors found that Sections 5.4.1.2.1 and 5.4.1.3.6.3 of the AP1000 DCD, Revision 17, discuss specific material and inspection requirements for the RCP flywheel assembly that are not captured in the applicable sections of the "RCP Certified Design Specification," APP-MP01-M2-001, Revision 1. Specifically, Sections 5.4.1.2.1 and 5.4.1.3.6.3 state the following:

- The RCP flywheel assemblies are fabricated from a tungsten heavy alloy, Type 403 stainless steel, and 18Ni maraging steel.
 - The segments are held into place by an interference fit retainer cylinder of 18Ni maraging steel placed over the outside of the assembly.
 - The assembly is hermetically sealed from primary coolant by endplates and an outer thin shell of Alloy 625.
 - Ni/Fe/Cr Alloy 600 is not used for this application.

Furthermore, Section 5.4.1.3.6.3 specifies the following testing requirements:

- The Type 403 stainless steel inner hub material will be subject to impact testing using three Charpy V-notch tests per ASTM A370, magnetic particle examination per ASTM A788 Supplemental Requirement S18, and ultrasonic examination per ASTM A788 Supplemental Requirement S20, Acceptance Levels BR and S.
- The retainer ring will be subject to fracture toughness testing per ASTM E399, magnetic particle examination per ASTM A788 Supplemental Requirement S18, and ultrasonic examination per ASTM A788 Supplemental Requirement S20, Acceptance Levels BR and S.

The "RCP Certified Design Specification," Sections 3.2.4.2 and 7.5.1.5, discuss the RCP flywheel integrity and inspection requirements, respectively, but does not list the specific requirements discussed in the DCD above.

Westinghouse's failure to follow its design change control process, as documented above, has been identified as Nonconformance 05200006/2008-201-01.

c. Conclusions

The NRC inspectors concluded that Westinghouse's policies and procedures for design control comply with the QA requirements of Criterion III of Appendix B to 10 CFR Part 50 and, except for the issues identified in Nonconformance 05200006/2008-201-01, that Westinghouse personnel are effectively implementing these policies and procedures.

3. Procurement Control

a. Inspection Scope

The NRC inspectors reviewed Section 4.3, "Procurement," of Westinghouse's QMS document and implementing procedures associated with the procurement process. The NRC inspectors also evaluated a selected sample of procurement packages for safety-related items to verify compliance with the established QA program requirements and to confirm adequate implementation of the requirements delineated in Appendix B to 10 CFR Part 50.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following documents:

- Westinghouse Policy/Procedure WEC 6.1, "Control of Purchased Items and Services," Revision 11, dated 08/31/07,
- Squib (Pyrotechnic Actuated) Valves, ASME Boiler and Pressure Vessel Code, Section III Class 1, AP-1000 Design Specification APP-PV70-Z0-001, Revision C, dated 12/11/07
- Purchase Order 4500246636, "Ansaldo Nucleare, AP-1000 Engineering Services," dated November 7, 2007,
- Purchase Order 4500251236, Ansaldo Nucleare, Engineering Services," dated December 20, 2007,
- Purchase Order 4500224550, "SPX Process Equipment, Engineering Services for Valve Design," dated March 1, 2007.

b. Observations and Findings

b.1 Policies and Procedures Governing Procurement

As described in Section 4.3.1 of the QMS, controls of purchased items and services are established to ensure that applicable technical and quality requirements are satisfied. Procurement activities are controlled through documented procedures and instructions that include requirements for bid evaluation, selection of suppliers, communication of requirements to suppliers, evaluation of supplier performance, and resolution of nonconformances. Suppliers of safety-related items and services are evaluated and approved before their designation as a qualified supplier or before placement of a purchase order. Documentation of the acceptability of suppliers is also maintained which identifies the specific items and/or services to be supplied.

Additionally, Section 4.3.4 of the QMS specifies that engineering organizations are responsible for defining the technical and quality requirements for purchased items and services. Quality requirements are incorporated into procurement documents in accordance with the applicable QMS, regulatory, and customer contractual requirements. The engineering organization responsible for the original design is also responsible for controlling design changes, unless another organization has been designated in writing. Changes to approved design documents, including field changes, are subject to the same review and approval process as the original design. Engineering organizations are also responsible for maintaining adequate records of changes, including the reason for the change and effects on existing items.

WEC 6.1 defines the organizational responsibilities for procurement of specified items and services to ensure that procurement documents are adequately prepared, approved, and distributed. This procedure is applicable to all organizations for procurement of items or services affecting quality.

b.2 Review of Purchase Orders

The NRC inspectors reviewed AP1000 Design Specification APP-PV70-Z0-001 associated with squib (pyrotechnic actuated) valves. Based on the results of this review, the NRC inspectors determined that the design specification incorporated appropriate technical and quality requirements including seismic and dynamic loads, environmental qualification, and the reporting of defects and noncompliance. The NRC inspectors confirmed that the purchase orders reviewed contain the necessary provisions for compliance with Appendix B to 10 CFR Part 50 and 10 CFR Part 21 requirements.

c. Conclusions

Based on the above reviews and discussions with cognizant personnel, the NRC inspectors concluded that Westinghouse's procurement control program policies and procedures are consistent with the requirements of Criterion IV of Appendix B to 10 CFR Part 50. The NRC Inspectors also determined that Westinghouse personnel are effectively implementing these policies and procedures.

4. Control of Purchased Material, Equipment, and Services

a. Inspection Scope

The NRC inspectors reviewed the Westinghouse QMS, policies, and implementing procedures that govern the control of purchased material, equipment, and services to verify compliance with the QA requirements of Criterion VII of Appendix B to 10 CFR 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by Westinghouse to select, qualify, and oversee vendors supplying basic components:

- Westinghouse QMS, Section 4.3, "Procurement," Revision 5, dated October 1, 2002.
- Westinghouse Policy/Procedure WEC 6.3, "Supplier Qualification and Evaluation Procedure," Revision 10, dated February 29, 2008,

- Westinghouse Policy/Procedure WP 7.0, "Control of Customer Supplied Items," Revision 0, dated March 31, 2004,
- Westinghouse Policy/Procedure WP 8.1, "Identification and Control of Items," Revision 3, dated May 16, 2003,
- Westinghouse Policy/Procedure WEC 18.2, "Qualification of Audit Personnel," Revision 4, dated February 28, 2007,
- Audit, "Ansaldo Nucleare," WES-2006-160, dated December 15, 2006,
- Audit, "SPX Process Equipment Copes-Vulcan Operation," WES-2008-029, dated May 8 2008,
- Audit, "Shanghai Nuclear Engineering Research and Design Institute (SNERDI)," WES-2008-112, dated June 19, 2008,
- Audit, "Ansaldo Camozzi," WES-2007-071, dated July 12, 2007.

The NRC inspectors also reviewed a sample of external supplier audits to evaluate the adequacy of Westinghouse's measures for verifying the attributes and quality of purchased material.

b. Observations and Findings

b.1 Policies and Procedures for Vendor Qualification

Westinghouse QMS, Section 4.3 describes the programmatic controls on purchased items and services that are established to ensure that suppliers meet applicable technical and quality requirements. The QMS establishes that all procurement activities are controlled through documented procedures and instructions that include requirements for selection of suppliers and evaluation of supplier performance. The QMS further specifies that the Westinghouse quality organization evaluate and approve all suppliers of safety-related items and services before their designation as a qualified supplier and placement of a purchase order. For each qualified supplier, Westinghouse shall identify the scope of supply for which the supplier has been qualified.

Procedure WEC 6.3 further establishes the requirements for the evaluation and qualification of suppliers and for conducting a quality program audit, including, but not limited to (1) requirements for auditor and lead auditor activities, (2) preparation of audit reports, (3) documentation of the results of audit activities, and (4) documentation and implementation of subsequent actions necessary to resolve any audit findings. The procedure applies to audits of material organizations, commercial suppliers, and suppliers of basic components and services

Procedure WEC 18.2 establishes the requirements for training, qualification, and certification of audit personnel, including, but not limited to (1) description of minimal training and experience requirements for audits and lead auditors, (2) requirements for examination of auditors, and (3) documentation and record retention requirements, including certification, for all audit personnel.

The NRC evaluated these procedures to ensure that they are consistent with the regulatory requirements of Appendix B to 10 CFR Part 50. As a result, the NRC inspectors identified several examples of procedural inadequacies in WEC 6.3 associated with the methods used for maintaining the qualified supplier list and the process for capturing audit findings resulting from supplier audits. Specifically, those inadequacies include the following:

- WEC 6.3 contains an obsolete procedural Step 7.12.3 which allows for the use of a corrective action issues system other than the corrective action process (CAPs) electronic database. Currently all Westinghouse locations have implemented the CAP database and are expected to use the system for collection of issues. As currently written, Step 7.12.3, states in part, that audit findings may be documented in other systems provided that these other systems have content equivalent to Appendix B of WEC 6.3.
- WEC 6.3 contains a procedural step which allows for alternate methods for maintaining the qualified supplier list (QSL) by individual organizations within Westinghouse without establishing clear criteria defining what alternate methods were acceptable, or when such alternate methods would be allowed.

The failure of Westinghouse to provide adequate procedural guidance for supplier oversight activities, as documented above, has been identified as Nonconformance 0520006/2008-201-03.

As a result of the NRC inspectors' findings in this area, Westinghouse prepared issue report (IR) #08-303-M016 to document and evaluate these issues.

b.2 Maintenance of the Approved Supplier List

The NRC inspectors reviewed the current Westinghouse QSL and selected a sample of vendors from the QSL to verify that selection and control of suppliers complied with the requirements in WEC 6.3 for supplier oversight and control. The NRC inspectors verified that the QSL adequately identified the scope of supply for each approved supplier, documented the effective period between required re-auditing of each supplier (i.e., either a triennial review for a supplier of basic components or an annual review for all material organizations), and identified any restrictions or limitations associated with the scope of supply for each approved supplier.

The NRC inspectors confirmed that Westinghouse evaluated all pertinent aspects of the suppliers' QA programs for those items and services to be procured and maintained adequate documentation of the scope of the audit for each supplier as required by Appendix B to 10 CFR Part 50. The NRC inspectors also noted that Westinghouse adequately identified any limits on the supply of materials, parts, and service within specific locations, such as within specific countries, when audit activities approving such suppliers were performed.

b.3 Review of Vendor Audit Reports

From a sample of reports from audits that Westinghouse conducted of its suppliers, the NRC inspectors verified that Westinghouse adequately evaluated the vendor compliance with the applicable requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.

The NRC inspectors also verified that audit methods of evaluation or checklists were prepared and completed for the audit and that they contained sufficient objective evidence to support the conclusions made by Westinghouse. The NRC inspectors also verified that the scope of supply identified in the Westinghouse approved QSL was consistent with the items or services supplied to Westinghouse by each vendor in the sample population.

The vendor process for evaluation of potential suppliers includes the use of a detailed supplier audit/evaluation summary (SAES). The SAES specifies the scope of the audit, identifies applicable QA program requirements such as Appendix B to 10 CFR Part 50, 10 CFR Part 21, NQA-1-1994, and applicable ASME codes including NCA-3800 and NCA-4000 for material organizations and nuclear stamp (N-stamp) certificate holders, respectively.

Results of supplier audits were recorded in the SAES and when findings were identified, supplier corrective action reports (SCARs) were prepared to track individual findings and planned corrective actions. These SCARs also provided a means of verifying implementation of corrective actions through supplemental audits at the suppliers. A supplier was either conditionally approved or not approved until SCAR corrective actions had been verified to be complete and implementation had been assessed.

The NRC inspectors verified that the sample of recently completed supplier audits associated with the AP1000 program was adequate to ensure the implementation of the supplier audit process as defined in Westinghouse's program for preparation and maintenance of the QSL and supplier oversight.

The NRC inspectors determined that several of the supplier audits reviewed contained assessments and conclusions for quality-related activities without detailed documented objective evidence for such conclusions. In several instances the only evidence supporting an assessment of a QA criterion was reference to a specific procedure, test report, job number or heat number, or specific item that was tested or inspected. The NRC inspectors did not observe any additional supporting documentation regarding the actual assessment of implementation of the evaluated activity or the completeness or accuracy of the procedures governing such activities.

The failure of Westinghouse to provide adequate objective evidence to support the assessment and conclusions within supplier audit reports, as documented above, has been identified as Nonconformance 0520006/2008-201-02.

As a result of the NRC inspectors' finding in this area, the vendor took timely actions to prepare IR #08-305-M007 to identify and evaluate these issues.

c. Conclusions

The NRC inspectors concluded that Westinghouse's policies and procedures for procurement control comply with the QA requirements of Criterion VII of Appendix B to 10 CFR Part 50 and that, except for the issue identified in Nonconformance 05200006/2008-201-02 and 05200006/2008-201-03, Westinghouse personnel are effectively implementing these policies and procedures.

5. Nonconforming Materials, Parts, or Components

a. Inspection Scope

The NRC inspectors reviewed Westinghouse's QMS and implementing policies and procedures that govern the control of nonconforming materials, parts, and components to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following documents:

- Westinghouse QMS, Section 5.4, "Control of Nonconforming Product, Revision 5, dated October, 1, 2002
- Westinghouse Policy/Procedure WEC 13.1, "Field Deviation Report," Revision 5, dated February 28, 2007
- Westinghouse Policy/Procedure WP 13.2, "Use of Hold Tags," Revision 6, dated December 12, 2005
- Westinghouse Policy/Procedure WP 13.3, "Deviations Notices," Revision 7, February 29, 2008
- Westinghouse Policy/Procedure WEC 21.0, "Identification and Reporting of Conditions Adverse to Safety," Revision 4.1, dated October 21, 2008
- Westinghouse Policy/Procedure WEC 14.4, "Westinghouse Corrective Actions Process," Revision 8, dated February 29, 2008.

The NRC inspectors also discussed the process for control of nonconforming products process with members of Westinghouse's management and technical staff. No samples were reviewed because Westinghouse has not implemented the program.

b. Observations and Findings

QMS Section 5.4 states that Westinghouse maintains procedures for the identification, documentation, evaluation, segregation, review, corrective action, and notification to affected organizations. WEC 13.1 establishes the process for initiating, verifying, processing, controlling, and transmitting instructions for the disposition of field-identified deviations in Westinghouse-supplied systems, equipment, and components. The field deviation report (FDR), as described in WEC 13.1, is intended for applications where the field-identified deviations in Westinghouse-supplied systems, equipment, or components are identified before turnover to a customer. Additionally, the FDR is a permissible alternate to the Westinghouse CAP. WEC 13.2 establishes the responsibilities and requirements for controlling nonconforming items identified during manufacturing, assembly, service, inspection, or testing. WEC 13.3 establishes the methods for the identification, documentation, and disposition of deviations to procurement requirements placed on suppliers. The procedures referred to WEC 14.4 and WEC 21.0 for more guidance on handling and evaluation of nonconformances.

To verify implementation of the control of nonconforming products process, the NRC inspectors requested copies of AP1000 deviation notices records of evaluations and reports that Westinghouse had completed. At the time, Westinghouse had not generated any AP1000-related deviation notices. Westinghouse will implement the control of nonconforming products process once construction of the first AP1000 unit begins.

c. Conclusions

Based on the above reviews and discussions with cognizant personnel, the NRC inspectors concluded that the Westinghouse control of nonconforming products program requirements are consistent with the regulatory requirements of Criterion XV of Appendix B to 10 CFR Part 50. The NRC inspectors also determined that the Westinghouse QMS and associated procedures are being effectively implemented.

6. Corrective Action Program

a. Inspection Scope

The NRC inspectors reviewed Westinghouse's QMS and implementing policies and procedures that govern the control of corrective actions to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50.

Specifically, the NRC inspectors reviewed the following documents:

- Westinghouse QMS, Section 5.5, "Corrective and Preventive Action," Revision 5, October 1, 2002
- Westinghouse Policy/Procedure WEC 14.4, "Westinghouse Corrective Actions Process," Revision 8, dated February 29, 2008
- Westinghouse Policy/Procedure WEC 14.5, "Root Cause Analysis," Revision 6, dated February 29, 2008
- Westinghouse Policy/Procedure WEC 14.9, "Apparent Cause Analysis," Revision 2, February 29, 2008
- Westinghouse Policy/Procedure WEC 14.10, "Corrective Action Review Board," Revision 0, dated February 29, 2008.

The NRC inspectors also discussed the CAP with members of Westinghouse management and sampled Westinghouse CAR program implementation activities.

b. Observations and Findings

QMS Section 5.5 states that Westinghouse maintains procedures that provide for identification; assignment of responsibility for corrective action; documentation of the cause and corrective action taken; implementation, evaluation, and verification of corrective action to prevent recurrence; and reporting to the appropriate levels of management. WEC 14.4 establishes the requirements and responsibilities for identifying, documenting, and resolving issues that require corrective or preventive action to prevent recurrences. Under WEC 14.4, Westinghouse employees or contractors are responsible for generating issue reports under the CAR program whenever they become aware of any situation that satisfies any of the criteria listed in the procedure. The procedures refer to WEC 21.0 for further guidance on evaluating and processing potential conditions adverse to safety.

The NRC inspectors concluded that Westinghouse personnel have a good understanding of how to identify issues that warrant the generation of a CAR. The NRC inspectors reviewed a sample of CARs issued for the AP1000 project for the years 2007 and 2008 and also reviewed the CARs generated as a result of the most recent external

audit that evaluated the adequacy and effectiveness of the Westinghouse QMS. The NRC inspectors noted that each CAR contains a detailed description of the deficiency, includes the appropriate review and signoff, and had been evaluated for applicability of 10 CFR Part 21 requirements. The NRC inspectors evaluated the timeliness of corrective actions and found that, in general, the CARs are processed in a timely fashion.

c. Conclusions

Based on the above reviews and discussions with cognizant personnel, the NRC inspectors concluded that the Westinghouse CAP requirements were consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. The NRC inspectors also determined that the Westinghouse QMS and associated procedures are being effectively implemented.

7. Internal Audits

a. Inspection Scope

The NRC inspectors reviewed Westinghouse's QMS and implementing policies and procedures that govern the internal audit process. The NRC inspectors also evaluated a selected sample of internal audit reports and audit training and qualification records to verify compliance with program requirements and adequate implementation of those requirements.

Specifically, the NRC inspectors reviewed the following documents:

- Westinghouse Policy/Procedure WEC 17.1, "Internal Assessments," Revision 10, dated February 29, 2008
- Internal Audit, WEC-07-48, "AP1000 Organization," dated June 25, 2007
- Internal Audit, WEC-08-38, "New Plants Engineering Systems & Structures," dated September 7, 2008
- Internal Audit, WEC-08-40, "NPP New Plants Engineering & Plant Procedures," dated August 29, 2008.

b. Observations and Findings

b.1 Procedures and Policies Governing the Audit Process

The quality organization is responsible for maintaining and implementing the internal audit program. Specifically, internal audits examined and evaluated objective evidence for compliance with the requirements specified in the QMS in order to determine the effectiveness of QA program implementation. As described in Section 5.6.1 of the QMS, qualified personnel, independent of the activity being assessed, perform audits by using written procedures and/or checklists. Internal audits of activities affecting the quality of items and services are scheduled, planned, and conducted in accordance with established procedural controls. These procedural controls include instructions provided in WEC 17.1. Reports documenting audit results are prepared and distributed to appropriate management.

b.2 Implementation of the Audit Process

The NRC inspectors reviewed a selected sample of recent audit reports performed during the 2007–2008 period to determine if these audits were performed in accordance with program requirements. The NRC inspectors also reviewed the identified conditions and corrective actions associated with these audits, as well as the resolutions of those issues completed at the time of the inspection. The corrective actions adequately addressed the identified findings and were generally completed in a timely manner.

The NRC inspectors also reviewed the training and qualification records for selected auditors and lead auditors. The NRC inspectors confirmed that all auditors and audit team lead requirements had been satisfied and that all audit team leaders had properly maintained their qualification in accordance with program requirements.

c. Conclusions

Based on the reviews described above and discussions with cognizant personnel, the NRC inspectors concluded that Westinghouse's internal audits program policies and procedures are consistent with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The NRC inspectors also determined that Westinghouse personnel are effectively implementing these policies and procedures.

8. Exit Meetings

On October 31, 2008, the NRC inspectors presented the results of the inspections during an exit meeting with Westinghouse personnel.

PERSONS CONTACTED

Daniel Lipman, Senior Vice President, Nuclear Power Plants
Mark Kachmar, Vice President, Operational Excellence and Quality
Dee Xenakis, Manager Quality NPP Programs, Operational Excellence & Quality
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John Papai, Lead Engineer
Gerald Riegel, Senior Engineer, Nuclear Power Plants
Art Trozzi, Principal Quality Engineer
Ronald Wessel, Principal Engineer, Equipment Qualification

2. INSPECTION PROCEDURES USED

IP 35017, "Quality Assurance Implementation Inspection"

IP 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance"

Draft IP 37802, "Engineering Design Verification Inspections"

IP 43002, "Routine Inspections of Nuclear Vendors"

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
05200006/2008-201-01	Opened	Nonconformance	Criterion III
05200006/2008-201-02	Opened	Nonconformance	Criterion VII
05200006/2008-201-03	Opened	Nonconformance	Criterion V

WITHELD FROM PUBLIC DISCLOSURE UNDER 10 CFR 2.390

Appendix

Pilot Engineering Design Verification Inspection at Westinghouse