

July 21, 2010

Scott M. Head
Regulatory Affairs Manager
South Texas Project Nuclear Operating Company
P.O. Box 289
Wadsworth, Texas 77483

SUBJECT: NRC INSPECTION REPORT NOS. 05200012/2010-201 AND 05200013/2010-201 AND NOTICE OF VIOLATION

Dear Mr. Head:

On April 19–22, 2010, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the South Texas Project Nuclear Operating Company (STPNOC) facility in Bay City, Texas. The purpose of the inspection was to perform a limited scope inspection to assess STPNOC's compliance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," 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," for activities performed in support of the amendment application to the design certification rule (DCR) for the U.S. Advanced Boiling Water Reactor (ABWR). An additional purpose of this QA implementation inspection was to determine if STPNOC was technically qualified to engage in the proposed activities related to the amendment of the ABWR design certification rule in accordance with the regulations in 10 CFR 52.47. The enclosed report presents the results of these inspections. This 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, the NRC staff determined that one violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation in the Notice is being cited because STPNOC did not establish measures to ensure that a condition adverse to quality was corrected in accordance with Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part Part 50.

In addition, the staff observed that STPNOC, by itself, does not appear to be technically qualified to supply the amended portion of the ABWR design certification without the support of its prime contractor, TANE; however, the staff observed that STPNOC and TANE acting together could be found to be qualified to supply the amended portion of the ABWR design certification.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 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 Document Access and Management System, (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, (if applicable), 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, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

Richard A. Rasmussen, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket Nos.: 05200012 and 05200013

Enclosures: 1. Notice of Violation
2. Inspection Report Nos. 05200012/2010-201 and 05200013/2010-201 and Attachments

In accordance with 10 CFR 2.390 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 Document Access and Management System, (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, (if applicable), 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, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

/RA/

Richard A. Rasmussen, Chief
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(Revised 04/19/2010)

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NOTICE OF VIOLATION

South Texas Project Nuclear Operating Company
P.O. Box 289
Wadsworth, TX 77483

Docket Nos.: 05200012 and 05200013
Report No.: 2010-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the South Texas Project Nuclear Operating Company (STPNOC) facility in Bay City, TX, on April 19–22, 2010, one violation of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violation is described below.

- A. Criterion XVI, "Corrective Action," of Appendix B, "Quality Assurance Program 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 be established to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected.

Contrary to the above, as of April 22, 2010, STPNOC did not establish measures to ensure that a condition adverse to quality was corrected. Specifically, STPNOC did not ensure that sufficient documentation was included in the records management system to furnish evidence of training and qualifications of personnel. As identified in a January 2009 NRC inspection (Inspection Report Nos. 05200012/2009-201 and 05200013/2009-201), the NRC issued a noncited violation for inadequate documentation of training. During this inspection, the NRC inspectors identified three more incidents of inadequate documentation of training records in the records management system.

These issues have been identified as Violations 05200012/2010-201-01 and 05200013/2010-201-01.

This is a Severity Level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," South Texas Project Nuclear Operating Company is hereby required to submit 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 Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. 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 from the NRC's Agencywide Documents Access and Management System, accessible at <http://www.nrc.gov/reading-rm/adams.html>, 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. 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 this 21st day of July 2010.

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

Docket Nos.: 05200012 and 05200013

Report Nos.: 05200012/2010-201 and 05200013/2010-201

Applicant: South Texas Project Nuclear Operating Company (STPNOC)
P.O. Box 289
Wadsworth, TX 77489

Applicant Contact: Scott M. Head
Regulatory Affairs Manager
979-479-3890
dmhead@stpegs.com

Background: By letter dated June 30, 2009, South Texas Project Nuclear Operating Company (STPNOC) submitted an application to amend the advanced boiling water reactor (ABWR) design certification rule (DCR). The purpose of this amendment is to demonstrate compliance to the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.150, "Aircraft Impact Assessment," the Commission's new aircraft impact rule.

Inspection Dates: April 19–22, 2010

Inspectors: Michael Morgan NRO/DCIP/CQVB Lead Inspector
Samantha Crane NRO/DCIP/CQVB
Robert Prato NRO/DCIP/CQVP
Shavon Edmonds NRO/DCIP/CQVB
John Bartleman RII/DCI/CIB3
Roger Lanksbury RII/DCP/CPB2

Approved by: Richard A. Rasmussen, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

EXECUTIVE SUMMARY

South Texas Project Nuclear Operating Company
05200012/2009-201 and 05200013/2009-201

This U.S. Nuclear Regulatory Commission (NRC) inspection focused on quality activities that South Texas Project Nuclear Operating Company (STPNOC) implemented to support the development of the amendment to the U.S. Advanced Boiling Water Reactor (ABWR) design certification rule (DCR) to comply with the Commission's aircraft impact rule, Title 10 of the *Code of Federal Regulations* (10 CFR) 50.150, "Aircraft Impact Assessment," in accordance with 10 CFR 52.47, "Contents of Applications; Technical Information."

Regulations in 10 CFR 50.150 state, in part, that the requirements of 10 CFR 50.150(a)(i) and 10 CFR 50.150(a)(ii) are applicable to combined licenses (COLs) issued under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," that reference a standard design certification issued before July 13, 2009, which has not been amended to address the requirements of 10 CFR 50.150. The requirements in 10 CFR 50.150 can be addressed by a COL applicant by either amending the ABWR DCR or by addressing the requirements in the COL application (COLA). STPNOC elected to address the requirements of 10 CFR 50.150 by applying for an amendment to the ABWR DCR. As such, STPNOC became the design certification applicant for the portion of the design described in the ABWR DCR amendment submitted to demonstrate compliance with the requirements in 10 CFR 50.150. The Code of Federal Regulations, specifically 10 CFR 52.47(a)(7), requires that the applicant for a design certification include in their final safety analysis report (FSAR) the technical qualifications of the applicant to engage in the proposed activities in accordance with NRC regulations.

Part of the purpose of this QA implementation inspection was to provide information to support the NRC's determination of STPNOC's technical qualification to engage in the proposed activities related to the amendment in accordance with the regulations in 10 CFR 52.47. Based on the results of this limited scope QA implementation inspection, the staff observed that STPNOC, by itself, does not appear to be technically qualified to supply the amended portion of the ABWR design certification. However, based on STPNOC's oversight of its contractors and the technical qualification of its prime contractor, TANE, the staff observed that STPNOC and TANE acting together could be found to be qualified to supply the amended portion of the ABWR design certification.

In addition, the inspection sought to verify that STPNOC implemented an adequate quality assurance (QA) program for the ABWR DCR amendment activities that complied with the requirements 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."

The inspection also verified that STPNOC implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," (hereafter referred to as 10 CFR Part 21), that met the regulatory requirements of the NRC.

The following regulations served as the bases for the NRC inspection:

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

The NRC inspection team implemented Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection," and IP 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance."

The NRC previously performed a QA inspection at STP Units 3 and 4 in Bay City, TX, on January 13–15, 2009. The NRC performed this inspection to (1) determine if STPNOC was adequately translating the appropriate technical and quality requirements for Toshiba, the alternate vendor for the ABWR, to enable Toshiba and its subcontractors to implement them for COL activities at STP Units 3 and 4, and (2) verify that STPNOC implemented an adequate QA program for COL activities that complied with the requirements of Appendix B to 10 CFR Part 50.

With the exception of violation described below, the NRC inspection team concluded that the STPNOC QA policies and procedures complied with the applicable requirements of 10 CFR Part 21 and Appendix B to 10 CFR Part 50. The NRC inspection team further concluded that STPNOC personnel adequately implemented these policies and procedures.

10 CFR Part 21

The NRC inspection team concluded that STPNOC appropriately translated the requirements of 10 CFR Part 21 into implementing procedures and, for those activities reviewed by the team, implemented them as required by STPNOC procedures to support quality-related activities and components for the ABWR DCR Amendment. No findings of significance were identified.

Organization

Based on a review of the QA program description (QAPD), implementing procedures, and interviews with STPNOC personnel, the NRC inspection team determined that STPNOC's organization conformed with the requirements of Criterion I, "Organization," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Quality Assurance Program

Based on a review of STPNOC's QAPD and implementing procedures, the NRC inspection team concluded that STPNOC's QA program requirements are consistent with the regulatory requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Training and Qualification of Personnel

The NRC inspection team concluded that STPNOC's program requirements for training and qualification of personnel were consistent with the requirements of Criterion II of Appendix B to 10 CFR Part 50. The NRC inspection team also concluded that STPNOC's QA program and associated training and qualification procedures provided indoctrination and training of personnel performing activities affecting quality and ensured that proficiency was achieved and maintained. No findings of significance were identified.

Design Control

The NRC inspection team concluded that the STPNOC design control process conformed to the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. STPNOC has contracted for design control activities with Toshiba America Nuclear Energy (TANE) through the master engineering, procurement, and construction (EPC) agreement and was not performing design control activities. Therefore, the NRC inspection team could not verify the adequacy of STPNOC's implementation of the design control process.

The team also concluded that STPNOC does not appear to be the design authority for the amended portion of the ABWR design and may not have the technical capability to provide the amended portion of the ABWR design without the support of its prime contractor, TANE.

Procurement Document Control

The NRC inspection team concluded that the procurement document control process requirements for the aircraft impact assessment (AIA) analysis and ABWR DCR amendment development work were consistent with the regulatory requirements in place for these types of activities and had been appropriately implemented, as required by the STPNOC procedures described above, to support the STPNOC ABWR DCR amendment procurement activities. No findings of significance were identified.

Control of Purchased Material, Equipment, and Services

The NRC inspection team concluded that the requirements for the oversight of suppliers for the STPNOC AIA and ABWR DCR amendment activities were consistent with applicable requirements and had been appropriately implemented, as required by the STPNOC procedures related to the control of purchased material, equipment, and services. No findings of significance were identified.

Nonconforming Materials, Parts, or Components

The NRC inspection team concluded that the STPNOC process for the control of nonconforming materials, parts, or components conformed to the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Corrective Action

With the exception of the Notice of Violation (NOV) 05200012/2010-201-01 and NOV 05200013/2010-201-01 issued for ineffective corrective action related to the inadequate documentation of personnel training and qualification, the NRC inspection team found that STPNOC's corrective action program (CAP) conformed to the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50.

Quality Assurance Records

The NRC inspection team concluded that the STPNOC QA records program conformed to the regulatory requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. Based on the QA records reviewed, the NRC inspection team also determined

that STPNOC adequately implemented its QAPD and implementing procedures. No findings of significance were identified.

Audits

The NRC inspection team concluded that the internal audits performed by STPNOC were consistent with the regulatory requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. Based on the internal audit reports reviewed, the NRC inspection team also determined that STPNOC adequately implemented its QAPD and implementing procedures. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21

a. Scope

The NRC inspection team reviewed the STPNOC implementing policies and procedures that govern the 10 CFR Part 21 (Part 21) process to verify compliance with the requirements of 10 CFR Part 21. In addition, the NRC inspection team reviewed the following: the master engineering, procurement, and construction (EPC) agreement between STPNOC and Toshiba America Nuclear Energy (TANE) for compliance with the requirements of 10 CFR 21.31, "Procurement Documents"; , " reviewed STPNOC's implementation of posting requirements, in accordance with 10 CFR 21.6, "Posting Requirements"; and STPNOC's records retention schemes, in accordance with 10 CFR 21.51, "Inspection and Maintenance of Records."

Specifically, the NRC inspection team reviewed the following STPNOC policies, procedures, and supporting documentation:

- U7-P-L102-0006, "NRC Reporting," Revision 1, dated October 19, 2009
- U7-P-AD01-0004, "Units 3 & 4 Procedure Use and Adherence Policy," Revision 2, dated September 30, 2009
- U7-P-QP01-QAPD, "STP 3 & 4 Quality Assurance Program Description," Revision 3, dated April 12, 2010
- U7-P-AD02-0009, "Units 3 & 4 Required Postings Bulletin Boards," Revision 0, dated September 30, 2009
- "Master Engineering, Procurement, and Construction Agreement" (between STPNOC and TANE), dated February 24, 2009
- Sargent & Lundy, 10 CFR Part 21 Report, "ACS SASSI Computer Program," dated September 11, 2009
- Sargent & Lundy Report No. SL-009993, "Extent of Condition & Evaluation for PIP No. 2009-1281," dated September 11, 2009

b. Observations and Findings

b.1 Postings

Procedure U7-P-AD02-0009 describes, in part, the requirements for postings to comply with 10 CFR 21.6., "Posting Requirements." The NRC inspection team verified that STPNOC had implemented and maintained proper posting requirements and had placed the postings in a conspicuous location. The applicant met the requirements of 10 CFR Part 21 and Section 206 of the Energy Reorganization Act of 1974. STPNOC had posted the current revision of 10 CFR Part 21, Section 206 of the Energy Reorganization Act of 1974, and the cover page to STPNOC Procedure

U7-P-L102-0006, NRC Reporting. The NRC inspection team observed that STPNOC had posted all these items on a bulletin board at the employee entrance of the STPNOC Units 3 & 4, Bay City, TX, facility.

b.2 10 CFR Part 21 Procedure

The NRC inspection team reviewed Procedure U7-P-L102-0006, which provided definitions and outlined the responsibilities to identify, control, document, and resolve conditions used for reporting of deviations and failures to comply discovered at STPNOC. Specifically, Procedure U7-P-L102-0006 contained measures for the analysis of deviations and failures to comply and stipulated that an interim report shall be submitted to the NRC if an evaluation cannot be completed within 60 days of discovery of the deviation or failure to comply. In addition, U7-P-L102-0006 stated that the responsible manager shall be notified within 5 days of the completion of an evaluation identifying a defect or failure to comply. The procedure also contained directions on how to submit a Part 21 report to the NRC. The NRC inspection team concluded that Procedure U7-P-L102-0006 conformed to the regulations and requirements of 10 CFR 21.21(a)(1) for adopting procedures for the notification of a failure to comply or the existence of a defect and its evaluation.

b.3 10 CFR Part 21 Implementation

The NRC inspection team verified that STPNOC had not performed any 10 CFR Part 21 evaluations for the ABWR DCR amendment. The NRC inspection team also reviewed a select sample of corrective action reports (CARs) and nonconformance reports to verify that adequate guidance was in place to evaluate such reports for applicability to 10 CFR Part 21. The NRC inspection team determined that both the nonconformance and corrective actions processes contained the necessary guidance to evaluate applicability to 10 CFR Part 21 requirements.

b.4 Purchase Orders

The NRC inspection team noted that the STPNOC procurement process imposed the requirements of 10 CFR Part 21 on its qualified safety-related suppliers by incorporating supplier quality requirements into all purchase orders (POs) for nuclear safety-related materials, items, and services.

The NRC inspection team reviewed the master EPC agreement between STPNOC and TANE that governs the ABWR DCR amendment work and verified that STPNOC had implemented its 10 CFR Part 21 program in a manner consistent with the requirements described in 10 CFR 21.31, "Procurement Documents," for basic components.

c. Conclusions

The NRC inspection team concluded that STPNOC appropriately translated the requirements of 10 CFR Part 21 into implementing procedures and, for those activities reviewed by the team, implemented them as required by its procedures to support quality-related activities and component procurement for the ABWR DCR Amendment. No findings of significance were identified.

2. Organization

a. Scope

The NRC inspection team reviewed the STPNOC policies governing its organization to ensure that the policies provided an adequate description of the implementation requirements of Criterion I, "Organization," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspection team reviewed the organization program requirements that STPNOC had in place for ABWR DCR amendment activities. The NRC inspection team also reviewed STPNOC's associated implementing procedures.

Within the scope of this area of the inspection, the NRC inspection team reviewed the following procedures:

- U7-P-QP01-QAPD, "STP 3 & 4 Quality Assurance Program Description," Part II, QAPD Details, Section 1, "Organization", Revision 3, dated April 12, 2010
- U7-P-EN01-0001, "Units 3 & 4 Engineering Organization and Responsibilities, Revision 3, dated March 31, 2010
- STPNOC letter to the NRC, "Quality Assurance Program Description Revision 3 for STP Units 3 & 4", dated April 8, 2010
- STPNOC's, "Master Engineering, Procurement, and Construction Agreement", dated February 2009

b. Observations and Findings

By letter dated April 8, 2010, STPNOC submitted changes to Chapter 17 of the ABWR Design Control Document (DCD) to include Revision 3 of the STP Units 3 and 4 QAPD. This revision updated the scope and applicability sections to include design certification activities associated with the ABWR DCR amendment application. The NRC inspection team reviewed the STPNOC QAPD and verified that the scope and description of STPNOC's organization was consistent with other quality-related activities being performed in support of the ABWR DCR amendment application.

The NRC inspection team reviewed the organizational description in the QAPD and the associated implementing procedure and met with STPNOC's QA supervisor and senior licensing lead to discuss overall organizational activities and assigned responsibilities. The NRC inspection team verified that STPNOC had identified the individuals and organization responsible for defining the overall effectiveness of the QA program. In addition, the NRC inspection team verified that the organizational description addressed the organizational structure, functional responsibilities, levels of authority, and interfaces.

Through its master EPC agreement with TANE, STPNOC contracted for design related quality activities. The NRC inspection team verified that STPNOC described the portions of its organization responsible for overseeing the design work, the management controls and lines of communication between STPNOC and TANE, the extent of management oversight and the formal evaluation of the contracted design work.

Through discussions with the STPNOC's QA supervisor and senior licensing lead, the NRC inspection team verified that personnel or organizations performing QA program implementation and verification activities had the authority, independence, and organizational freedom to identify quality problems, recommend solutions, and verify their implementation. Lastly, the inspectors verified that the QAPD specifies that quality personnel had the authority and responsibility to stop work in progress that was not being done in accordance with approved procedures or where safety or structures, systems, and components (SSC) integrity may have been jeopardized. This extended to offsite work performed by suppliers that furnish materials and services to STPNOC.

The NRC inspectors noted that STPNOC implemented the same QAPD and organizational structure for the ABWR amendment work as for the STP 3 and 4 COL work. The inspectors discussed with STPNOC's QA supervisor and senior licensing lead the organizational structure for the construction and preoperational phase and the transition to the operations phase. The NRC inspection team noted that the described structures and responsibilities aligned with the organizational structures presented in the QAPD, Section 1, and STPNOC Procedure U7-P-EN01-0001.

c. Conclusions

Based on a review of the QAPD, implementing procedures, and interviews with STPNOC personnel, the NRC inspection team determined that STPNOC's organization conformed to the requirements of Criterion I of Appendix B to 10 CFR Part 50. No findings of significance were identified.

3. Quality Assurance Program

a. Scope

The NRC inspection team reviewed the STPNOC policies that govern the QA program to ensure that those policies provided an adequate description of the implementation requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspection team reviewed the QA program requirements that STPNOC had implemented for the ABWR DCR amendment activities, along with the implementing procedures.

Within the scope of this area of the inspection, the NRC inspection team reviewed the following procedures and records:

- U7-P-QP01-QAPD, "STP 3 & 4 Quality Assurance Program Description," Revision 3, dated April 12, 2010
- U7-P-AD01-0004, "STP 3 & 4 Procedure Use and Adherence Policy," Revision 2, dated September 30, 2009

b. Observations and Findings:

The NRC inspection team reviewed QAPD Part I, Section 1, "General," which stated, in part, that the QAPD is the top-level policy document that establishes the QA policy and assigns major functional responsibilities for design certification amendment activities

(associated with the aircraft impact amendment) conducted by or for STPNOC. In addition, Section 1 stated that changes to the facility design as a result of the AIAs are subject to the full design controls described in this QAPD.

The NRC inspection team reviewed the STPNOC QAPD and verified that the scope of the QA program was consistent with the quality-related activities being performed in support of the ABWR DCR amendment application. At the time of the inspection, some of the STPNOC quality-related activities being implemented included training, procurement, quality oversight of suppliers, internal and external audits, corrective actions, and quality records management.

In addition, the NRC inspection team reviewed QAPD Part II, Section 2, "Quality Assurance Program," and verified that the QAPD specified that management of those organizations implementing the QA program, or portions thereof, assess the adequacy of that part of the program for which they are responsible and ensure its effective implementation in accordance with established procedures. The NRC inspection team reviewed the implementation of the internal audit process. Section 11 of this report describes the observations and findings associated with that inspection activity.

Lastly, the NRC inspection team reviewed QAPD Part II, Section 2, "Quality Assurance Program," and verified that the QAPD specified that programs are implemented for the indoctrination and training of personnel performing activities affecting quality. The NRC inspection team reviewed the implementation of the training program. Section 4 of this report describes the observations and findings associated with that inspection activity.

Before September 30, 2009, STPNOC implemented its QA program through the use of the Operations Quality Assurance Plan (OQAP) and the QAPD, in parallel. At the time of the inspection, STPNOC had made a complete transition to the STP Units 3 and 4 QAPD.

The NRC inspectors reviewed Procedure U7-P-AD01-0004, which provides expectations for the use of Unit 3 and 4 procedures and adherence to them. Procedure U7-P-AD01-0004 includes two addenda. Addendum 1 provides a list of Unit 1 and 2 procedures authorized for Unit 3 and 4 quality-related activities and a list of procedures that contain scopes that encompass STPNOC Units 1 through 4. Addendum 2 provides a list of Unit 1 and 2 procedures that were once but are no longer authorized for Unit 3 and 4 quality-related activities.

The NRC inspection team evaluated the STPNOC implementing procedures developed for Units 3 and 4 and the implementing procedures developed for Units 1 and 2 that were identified as being applicable to the ABWR DCR amendment work. The NRC inspection team verified that procedures were in place for the quality activities being performed and that the Unit 1 and 2 procedures, which were authorized for use for Units 3 and 4, contained an applicability statement in their scope.

c. Conclusions

Based on a review of the STPNOC QAPD and implementing procedures, the NRC inspection team concluded that STPNOC's QA program requirements were consistent with the regulatory requirements of Criterion II of Appendix B to 10 CFR Part 50. No findings of significance were identified.

4. Training and Qualification of Personnel

a. Scope

The NRC inspection team reviewed STPNOC's policies and procedures for the indoctrination and training of personnel performing activities affecting quality, to assess compliance with the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspection team reviewed procedures and records to verify that STPNOC adequately implemented and maintained personnel training and qualification processes to ensure that it was achieved and maintained personnel proficiency.

Within the scope of this area of the inspection, the NRC inspection team reviewed the following procedures and records:

- U7-P-QP01-QAPD, "STP 3 & 4 Quality Assurance Program Description," Revision 3, dated April 12, 2010
- U7-P-TR02-0039, "Units 3 and 4 Training Program Development," Revision 1, dated September 30, 2009
- U7-P-TR02-0004, "Units 3 and 4 Implementation of Training Programs," Revision 3, dated September 30, 2009
- U7-P-QP02-0002, "Units 3 and 4 Training, Qualification, and Certification of Oversight Personnel," Revision 4, dated February 2, 2010
- 0PQP02-ZA-0004, " Training, Qualification, and Certification of Oversight Personnel," Revision 6, dated November 16, 2006
- U7-P-TR02-0006, "Units 3 and 4 Training and Indoctrination of Nuclear Training Personnel," Revision 2, dated September 30, 2009
- U7-P-AD01-0002, "Units 3 and 4 Personnel Training and Qualification," Revision 1, dated February 3, 2010
- Training, qualification, and certification records for Units 3 and 4 auditing personnel
- Condition Tracking Report (CTR) No. 08-19051, dated April 21, 2010

b. Observations and Findings

The QAPD provides the overall requirements for qualification, training, and certification of personnel whose activities may affect SSCs and activities at STPNOC. The QAPD also provides general indoctrination and training programs for personnel to ensure that they achieve and maintain adequate knowledge of quality programs and requirements.

Procedure U7-P-AD01-0002 described the criteria for initial training, which provide basic knowledge and skills necessary for the job performance of all STPNOC staff.

Addendum 1 contained a list of initial training that includes the following courses: Nuclear Quality Assurance Fundamentals for Units 3 and 4 (QA-101), Units 3 and 4 Project Manual Training, Units 3 and 4 User Orientation for Records Databases and Project Documents, and Units 3 and 4 Corrective Action Program. Procedure U7-P-AD01-0002 stated that training records, including department-developed forms containing training qualification, certification, and attendance, shall be forwarded to the record management system (RMS) for retention. Procedure U7-P-QP02-0002 described the requirements for training, qualification, and certification of independent oversight personnel.

The NRC inspection team verified that qualification records and certifications existed for specialized personnel performing activities affecting quality. The team also verified that qualification records of personnel are certified and in accordance with program requirements. In addition, the NRC inspectors verified that STPNOC had procedures in place for training and indoctrination programs for personnel performing quality activities.

The NRC inspection team also reviewed and verified departmental training in the areas of engineering, procurement, and quality. The NRC inspection team noted that STPNOC schedules training of its personnel on applicable quality policies, manuals, and procedures, as determined by the responsible organization.

c. Conclusions

The NRC inspection team concluded that STPNOC's program requirements for the training and qualification of personnel are consistent with the requirements of Criterion II of Appendix B to 10 CFR Part 50. The NRC inspection team also concluded that STPNOC's QA program and associated training and qualification procedures provide the indoctrination and training of personnel performing activities affecting quality and ensures that they achieve and maintain proficiency. No findings of significance were identified.

5. Design Control

a. Scope

The NRC inspection team reviewed the STPNOC policies that govern the design control activities to verify compliance with the requirements of Criterion III of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed the implementation of these policies and engineering-related overview procedures.

Specifically, the NRC inspection team reviewed the following documents:

- U7-P-QP01-QAPD, "STP 3 & 4 Quality Assurance Program Description," Part II, Section 3, "Design Control," Revision 3, dated April 12, 2010,
- STPNOC Doc./Dwg. No. U7-P-AD02-0007, "Units 3 & 4 Document Submittal Oversight Reviews," Revision 2, dated March 11, 2010
- U7-P-LI02-0005, "Preparation of Correspondence to the NRC," Revision 2, dated March 11, 2010

- STPNOC Doc./Dwg. No. U7-PROJ-D-PRD-0009, "Project Specific Pre-Baseline Design Change Control Procedure," Revision F, dated April 16, 2010

In addition, the NRC inspection team reviewed a number of STPNOC's design packages and interviewed members of the STPNOC QA, licensing, and engineering organizations. Specifically, the NRC inspection team requested that STPNOC describe its design control activities, its review of the ABWR DCR amendment application submitted to the NRC, and its engineering oversight process. In addition, the NRC inspection team reviewed the following engineering and supporting documents:

- "Circulating Water System," System Design Descriptions, STPNOC Doc./Dwg. No. U7-CW-M-SDD-0001, Revision E, dated February 22, 2010
- Piping and Instrument Diagrams, Circulating Water System, STPNOC Doc./Dwg. No. U3-CW-M-DWG-P&ID-0001-01, 02, 03, and 04, Revision F, dated November 17, 2009
- "Equipment Requirement Specification for Alternate Feedwater Injection Pump (AFI Pump)," equipment requirements specification, STPNOC Doc./Dwg. No. U7-AFI-M-SPEC-PUMP-0001, Revision 0, dated February 23, 2010
- "Soil Structure Interaction Analyses of Reactor Building STP 3&4 Site Specific (COLA Revision 3)," STPNOC Doc./Dwg. No. U7-RB-C-CALC-DESN-6004, Revision A, dated July 16, 2009
- "Soil Structure Interaction Analyses of the UHS-Pump House Building," STPNOC Doc./Dwg. No. U7-UHS-C-CALC-DESN-6001, Revision A, dated December 22, 2009
- "Soil Structure Interaction Analyses of Control Building STP 3&4 Site Specific (COLA Revision 3)," STPNOC Doc./Dwg. No. U7-CB-C-CALC-DESN-6004, Revision A, dated July 17, 2009
- "Alternate Feedwater Injection System, System Design Description," STPNOC Doc./Dwg. No. U7-AFI-M-SDD-0001, Revision B, dated November 13, 2009
- Document Comment Resolution Form, DCRF 7P15-2101-0001-00001-R0, STP-34-001530/1622, 7P15-2101-0001/Revision 0, U7-AFI-M-DWG-P&ID-0001, Revision A, NT-5103546, Sheet 1, Revision 0, review date December 3, 2009
- Document Comment Resolution Form, DCRF 7P15-1001-0001-R0, STP-34-001519/2020, 7P15-1001-0001/Revision 0, U7-AFI-M-DDD-0001, Revision A, RS-5136851, Revision 0, review date December 1, 2009
- Document Comment Resolution Form (no DCRF number indicated), "ERS, Feed Water Injection Pump," STP-34 001956/2115, 7P15-3001-0001/Revision 0, U7-AFI-M-SPEC_PUMP-0001, Revision A, RS-5139615, Revision 0, review date March 6, 2010

b. Observations and Findings

The NRC inspection team reviewed the QAPD and verified that it contained the overall STPNOC policies that govern design control. Specifically, the QAPD included provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within STPNOC and with suppliers. The design control program included interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. The QAPD stated that the STPNOC design process provides for design verification to ensure that items and activities subject to the provisions of the QAPD are suitable for their intended application, consistent with their effects on safety.

On the basis of an interview with the design engineer lead and QA manager, the NRC inspection team determined that STPNOC is not currently performing design activities and, therefore, has not yet implemented design control procedures. STPNOC personnel stated that they have contracted for design control activities with TANE through the master EPC agreement. The design engineer lead and QA manager informed the NRC that STPNOC will begin to perform design control activities after system turnover from the EPC contractor.

Based on information provided by STPNOC and observations during this inspection, the NRC inspection team observed that STPNOC does not appear to be the design authority for the amended ABWR design and does not appear to have the in-house expertise to provide the amended portion of the ABWR design without the support of its prime contractor, TANE.

c. Conclusions

The NRC inspection team concluded that the STPNOC design control process conforms to the requirements of Criterion III of Appendix B to 10 CFR Part 50. STPNOC had contracted for design control activities with TANE through the master EPC agreement and was not performing design control activities at the time of this inspection. Therefore, the NRC inspection team could not verify the adequacy of STPNOC's implementation of the design control process.

The team also concluded that STPNOC does not appear to be the design authority for the amended portion of the ABWR design and may not have the technical capability to provide the amended portion of the ABWR design without the support of its prime contractor, TANE.

6. Procurement Document Control

a. Scope

The NRC inspection team reviewed STPNOC's policies and implementing procedures that govern the controls for the procurement of material, equipment, and services by STPNOC through its primary contractor, TANE, and its contractors and subcontractors (such as Westinghouse) for the ABWR DCR amendment application to verify compliance with Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed the STPNOC process governing the control of design engineering services for the various suppliers related to the

STPNOC ABWR DCR amendment application development. Specifically, the NRC inspection team reviewed POs, work scope EPC technical requirements, contract services requirements, and methods used by STPNOC to qualify suppliers of items and services to verify that they met the requirements of the licensee's QA program.

Within the scope of this area of the inspection, the NRC inspection team reviewed the following policies and procedures:

- U7-P-QP01-QAPD, Part II, Section 4, "Procurement Document Control" , " Revision 3, dated April 12, 2010
- U7-P-SC02-0007, "Units 3 & 4 Procurement of Material, Equipment and Services," Revision 3, dated September 30, 2009
- U7-P-SC02-0008, "Units 3 & 4 Procurement Document Preparation, Review, Control and Administration" Revision 2, dated September 30, 2009
- STPNOC Units 3 & 4 EPC Technical Specification 07-001 Document, dated July 30, 2007
- "Master Engineering, Procurement, and Construction Agreement" (between STPNOC and TANE), dated February 24, 2009
- U7-P-QP02-0007, "Units 3 & 4 Vendor Audits," Revision 0, dated February 23, 2010
- U7-P-QP02-0010, "Units 3 & 4 Quality Evaluation of Vendors," Revision 0, dated February 23, 2010
- U7-P-QP02-0011, "Units 3 & 4 Approved Vendors List," Revision 0, dated February 23, 2010

b. Observations and Findings

Part II, Section 4, of the STPNOC QAPD established the requirements for the procurement of items and services. These activities included procurement document control, bid evaluation, vendor evaluation, verification of vendor activities, and receiving inspection. Procedure U7-P-SC02-0007 identified the responsibilities and requirements for reviewing, approving, and submitting requisitions for the procurement of material, equipment, and services for STPNOC ABWR DCR amendment application activities. Procedure U7-P-SC02-0008 established controls for the preparation, review, control, and administration of all purchasing activities for the ABWR DCR amendment application. These included processing requisitions; evaluating proposals; selecting vendors; preparing and issuing POs, contracts and revisions; and the final security and control of procurement activities.

To verify program implementation, the NRC inspection team reviewed procurement documents and contracts that STPNOC had placed with TANE for the ABWR DCR amendment application development activities. The NRC inspection team also reviewed the STPNOC Units 3 & 4 TANE Work Task Request and Authorization Form, dated July 28, 2008, and Revision 1, dated March 29, 2010. TANE is a wholly owned

subsidiary of Toshiba Corporation that it established in 2008 to act as its agent for POs to the Toshiba Japan offices.

The EPC document that STPNOC used to control work accomplished by TANE invoked the overall technical and quality requirements for the project. Among the requirements contained in the EPC were Exhibit BB-1, "Quality Assurance Program," and the STPNOC Units 3 & 4 EPC Technical Specification 07-001, dated July 30, 2007. Exhibit BB-1, in general, included references to the specific QA program requirements, such as American Society of Mechanical Engineers (ASME) NQA-1-1994, Appendix B to 10 CFR Part 50, and 10 CFR Part 21.

TANE contracted with Westinghouse for the beyond-design-basis AIA and the resulting ABWR DCR amendment application. Westinghouse issued POs to ANATECH Corporation and ERIN Engineering and Research Inc. to perform the AIA. In addition, TANE contracted with Sargent & Lundy through Fluor to develop any changes to the detailed design resulting from the ABWR DCR amendment application developed by Westinghouse.

The NRC inspection team reviewed the following contractual arrangements and POs regarding STPNOC Unit 3 and 4 EPC contractors and subcontractors:

- STPNOC Units 3 & 4 TANE Work Task Request and Authorization Form, Revision 1, dated March 29, 2010, defined the TANE EPC team scope, schedule, and cost for the STPNOC Units 3 and 4 design, licensing, procurement, construction planning, and project management and control activities.
- Contract B03582 Task Order (TO) 53, dated July 28, 2008, provided the initial authorization for the ABWR DCR amendment application work.
- Toshiba International Corporation (TIC) (subsequently replaced by TANE) PO SFP-2066, Revision 0, dated July 9, 2008, and Toshiba Project Document Control Number 7A90-3601-0008, "Procurement Specification for Preparation of ABWR DCD Amendment for Aircraft Impact Assessment for Related Conceptual System Design," Revision 0, dated February 20, 2009, were issued to Westinghouse. The latter referenced Project Document Number 7A70-3602-0004, "Quality Assurance Specification of Engineering and Design Activities Other than those for Electrical, Control and Monitoring System Components (WEC)," Revision 0, dated March 10, 2008.
- PO 4500278022, dated September 11, 2008, from Westinghouse Electric Co. to ANATECH Corporation requesting AIA-related activities.
- PO 4500272562, dated July 15, 2008, from Westinghouse Electric Co. to ERIN Engineering and Research Inc. requesting AIA-related training.

The development of the ABWR DCR amendment application was included in the EPC contract through TO 53. On July 28, 2008, STPNOC issued TO 53 to the master EPC agreement that included a list of items to be worked. It described one of the items (Task 7.10) only as "airplane crash analysis."

STPNOC explained that the TO was solely a method for releasing a scope of work to the contractor that had already been described in the EPC agreement. STPNOC stated that the technical and quality requirements of the EPC covered all of the proposed design changes and the development of the amendment application. In November 2008, STPNOC held an AIA concept meeting with Toshiba, Westinghouse, Sargent & Lundy, and Fluor to communicate additional technical requirements and establish the assessment methodology for the AIA. The NRC inspection team determined that the appropriate level of quality requirements had been invoked through the EPC for the ABWR DCR amendment application work and that they were consistent with Part II, Section 4, of the QAPD.

c. Conclusions

The NRC inspection team concluded that the procurement document control process requirements for the AIA and the resulting ABWR DCR amendment application development work were consistent with the regulatory requirements in place for these types of activities and had been appropriately implemented, as required by the STPNOC procedures described above, to support STPNOC ABWR DCR amendment application procurement activities. No findings of significance were identified.

7. Control of Purchased Material, Equipment, and Services

a. Scope

The NRC inspection team reviewed the implementation of the STPNOC QA program for the control of purchased material, equipment, and services for the ABWR DCR amendment application. Specifically, the NRC inspection team reviewed the STPNOC policies and procedures governing the process to verify the quality of suppliers providing engineering design services for STPNOC ABWR DCR amendment application activities. The NRC audit team also reviewed the policies and procedures to verify that they provided an adequate description of the process and implemented requirements, consistent with Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50.

Within the scope of this area of the inspection, the NRC inspection team reviewed the following policies and procedures:

- U7-P-QP01-QAPD, Part II, Section 7, "Control of Purchased Material, Equipment, and Services," Revision 3, dated April 12, 2010
- U7-P-AD02-0007, "Units 3 & 4 Document Submittal Oversight Reviews," Revision 2, dated March 11, 2010
- U7-P-EN02-0004, "Changes to Units 3 & 4 Requirements Documents," Revision 5, dated December 12, 2009
- U7-P-LI02-0005, "Preparation of Correspondence to the NRC," Revision 2, dated March 11, 2010

- U7-P-SC02-0007, “Units 3 & 4 Procurement of Material, Equipment and Services,” Revision 3, dated September 30, 2009
- U7-P-QP02-0010, “Units 3 & 4 Quality Evaluation of Vendors,” Revision 0, dated February 23, 2010
- U7-P-QP02-0011, “Units 3 & 4 Approved Vendors List,” Revision 0, dated February 23, 2010

b. Observations and Findings

The NRC inspection team reviewed the STPNOC policies and procedures governing the control of design engineering services and activities for the ABWR DCR amendment application, including audits and evaluations of TANE and a review of surveillances and vendor evaluations of other vendors on the approved vendor list (Sargent & Lundy and Bechtel). These policies and procedures governed the implementation of quality activities performed for the COL and ABWR DCR amendment design by STPNOC and Toshiba and its subcontractors.

The NRC inspection team reviewed the above-referenced procedures used to implement the quality activities related to vendor oversight and qualification. Section 7 of the STPNOC QAPD also included the specific requirements for vendor selection and the quality process for vendor oversight activities.

At the time of this inspection, TANE was the prime contractor with retained responsibility for design and quality activities. It had responsibility for the qualification and oversight of its subcontractors and suppliers (such as Toshiba Keihen and Toshiba Fuchu, Fluor, and Westinghouse). TANE planned to complete the STP Units 3 and 4 project with an EPC team comprised of the various Toshiba facilities, Fluor, Sargent & Lundy, and Westinghouse. In addition, Westinghouse provided the ABWR DCR amendment application.

As part of the implementation review for the above EPC contractors, the NRC inspection team reviewed quality records, such as POs and contractual requirements; approved vendors list information; audit plans, reports, and checklists; supplier responses to audit findings; and STPNOC tracking of the audit findings and deficiencies to closure.

The NRC inspection team reviewed the following STPNOC oversight reports:

- Audit U7-08-003 of TANE, dated November 10–4, 2008
- Audit U7-09-006 of TANE, dated December 3–9, 2009
- Vendor quality evaluation of TANE, dated January 28, 2010
- Quality surveillance U7-S-09-005 of Sargent & Lundy, dated May 14, 2009
- Vendor quality evaluations of Sargent & Lundy, dated January 21, 2009
- Vendor quality evaluations of Sargent & Lundy, dated March 24, 2009
- Vendor quality evaluations of Sargent & Lundy, dated April 28, 2009
- Vendor quality evaluations of Sargent & Lundy, dated January 27, 2010
- Vendor quality evaluations of Sargent & Lundy, dated March 29, 2010
- Vendor quality evaluation of Bechtel, dated March 24, 2009
- Vendor quality evaluation of Bechtel, dated March 29, 2010

The NRC inspection team verified that STPNOC had performed an appropriate level of supplier oversight for the above EPC contractors. The NRC inspection team noted that STPNOC conducted annual audits of TANE.

Procedure U7-P-EN02-0004 described the STPNOC process for submitting and processing changes to STPNOC Units 3 and 4 requirements documents: changes to engineering technical specifications (ETS); departures from Tier 1, Tier 2*, technical specifications, and significant Tier 2 information; and amendments to the NRC-approved ABWR DCR.

The NRC inspection team discussed the development of the ABWR DCR amendment application with STPNOC staff, reviewed the requirements change request (RCR) package, and confirmed that the development of the amendment application followed Procedure U7-P-EN02-0004. After receiving the AIA analysis from Anatech Engineering, Westinghouse identified the necessary changes to the DCR and initiated an RCR. The RCR contained the information needed to disposition the proposed changes to the ABWR DCR, including a summary of the conclusions from the Anatech AIA analysis.

The RCR package was dispositioned through the project design review board (PDRB), which consisted of 5 members and their delegates: the STPNOC engineer manager, the STPNOC regulatory affairs manager, the Toshiba project manager, the Fluor project manager, and the Sargent & Lundy project manager. Additional participants at the PDRB for the ABWR DCR changes associated with the AIA included Westinghouse and CPS Energy. The PDRB dispositioned the RCR based on technical, regulatory, and financial criteria. Once the RCR was approved, the configuration manager issued a change authorization notification to the EPC contract manager.

Westinghouse incorporated the proposed changes and issued a draft revision of the ABWR DCR amendment application to STPNOC Engineering for review and acceptance. STPNOC Engineering used Procedure U7-P-AD02-0007 to review the draft DCR amendment application and provided comments. The draft DCR amendment application was also sent to the EPC team for comment.

Westinghouse submitted the DCR amendment application to STPNOC Regulatory Affairs, which reviewed it in accordance with Procedure U7-P-LI02-0005, the procedure for preparing correspondence to the NRC.

c. Conclusions

The NRC inspection team concluded that the requirements for oversight of suppliers for the STPNOC AIA activities were consistent with Criterion VII of Appendix B to 10 CFR Part 50 and had been appropriately implemented, as required by the STPNOC procedures related to the control of purchased material, equipment, and services. No findings of significance were identified.

8. Nonconforming Materials, Parts, or Components

a. Scope

The NRC inspection team reviewed STPNOC policies and procedures for control of nonconforming materials, parts, or components to verify compliance with Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of vendor deficiency reports to verify that STPNOC implementation and control over nonconforming quality materials, parts, or components was adequate.

The NRC inspection team reviewed the following documents:

- U7-P-QP01-QAPD, "STP 3&4 Quality Assurance Program Description," Revision 3, dated April 12, 2010
- U7-P-QP02-0005, Units 3 & 4 Supplier Evaluation, Oversight and Inspection, Revision 2
- U7-P-QP02-0009, Units 3 & 4 Vendor Deficiency Reports (VDRs), Revision 0, dated February 23, 2010
- VDR 08-17985-07
- VDR 10-201-02
- VDR 10-201-04
- VDR-10-201-05
- VDR-10-201-08
- VDR 10-201-09
- VDR 10-201-10
- VDR 10-201-11
- CR 10-201, Tracking CR for 2010 VDRs, dated January 5, 2010
- Corrective Action Request (CAR) 09-146, Toshiba Evaluation/Review of STPNOC's VDR No. CR08-17985-07, Interim Report to VDR-08-17985-07 (7A70-7501-1001), dated September 8, 2009
- CAR-09-147, Toshiba Evaluation/Review of STP NOC's VDR No. CR08-17985-07, Interim Report to VDR-08-17985-07 (7A70-7501-1001), dated September 7, 2009
- CAR-09-148, Toshiba Evaluation/Review of STP NOC's VDR No. CR08-17985-07, Interim Report to VDR-08-17985-07 (7A70-7501-1001), dated September 8, 2009
- CAR-09-149, Toshiba Evaluation/Review of STP NOC's VDR No. CR08-17985-07, Interim Report to VDR-08-17985-07 (7A70-7501-1001), dated September 7, 2009

- CAR-09-150, Toshiba Evaluation/Review of STP NOC's VDR No. CR08-17985-07, Interim Report to VDR-08-17985-07 (7A70-7501-1001), dated September 8, 2009
- CAR-09-151, Toshiba Evaluation/Review of STP NOC's VDR No. CR08-17985-07, Interim Report to VDR-08-17985-07 (7A70-7501-1001), dated September 8, 2009
- CAR-09-152, Toshiba Evaluation/Review of STP NOC's VDR No. CR08-17985-07, Interim Report to VDR-08-17985-07 (7A70-7501-1001), dated September 7, 2009
- STPNOC (Units 3 & 4) Quality Audit Report U7-A-09-006 (VA), Toshiba Corporation Power Systems Company NED at Isogo Nuclear Engineering Center, dated January 7, 2010
- AS-400A001, Toshiba Corporation NED, Purchasing Procedure, Revision 11

b. Observations and Findings

The NRC inspection team reviewed the STPNOC process and policies governing the control of nonconforming materials, parts, or components for the ABWR DCR amendment application activities. The inspectors reviewed the QAPD and STPNOC procedures U7-P-QP02-0005 and U7-P-QP02-0009. QAPD Part II, Section 15, "Nonconforming Materials, Parts, or Components," provided the high-level STPNOC policy establishing measures and governing procedures to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use.

STPNOC Procedure U7-P-QP02-0005 described the requirements and responsibilities for ensuring that materials, equipment, and services from suppliers meet the quality requirements defined in purchasing documents, specifications, and other requirements, such as those described in applicable codes and standards. STPNOC Procedure U7-P-QP02-0005 contained adequate detail for the initiation, evaluation, and actions needed to handle nonconformances of materials, parts, or components.

STPNOC Procedure U7-P-QP02-0009 defined the requirements and responsibilities for documenting and resolving deficiencies identified during vendor audits, surveillances, surveys, or other vendor activities. The NRC inspection team concluded that STPNOC Procedure U7-P-QP02-0009 contained adequate information and detail to evaluate the deficiency to determine if 10 CFR Part 21 applied.

The NRC inspection team review included several examples of VDRs associated with items or services provided to STPNOC and CAR reviews and evaluations performed by contractors working for STPNOC. The inspectors verified that the VDRs were generated and reviewed in accordance with documented procedures.

c. Conclusions

The NRC inspection team concluded that STPNOC adequately implemented the process for control of nonconforming materials, parts, or components, consistent with the requirements of Criterion XV of Appendix B to 10 CFR Part 50. No findings of significance were identified.

9. Corrective Action Program

a. Scope

The NRC inspection team reviewed the OQAP and QAPD, as well as 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. The NRC inspection team reviewed a sample of CRs associated with ABWR DCR Amendment application and QA program development activities, to verify compliance with program requirements and the adequate implementation of those requirements.

Specifically, the NRC inspection team reviewed the following documents:

- U7-P-QP01-QAPD-P-QP01-QAPD, "STP 3 & 4 Quality Assurance Program Description," Revision 3, dated April 12, 2010
- "South Texas Project Electrical Generating Station Operations Quality Assurance Plan," Chapter 13, "Control of Conditions Adverse to Quality," Revision 13, dated February 10, 2010
- U7-P-AD02-0003, ABWR Corrective Action Program, Revisions 2 and 3
- U7-P-L102-0006, NRC Reporting, Revision 1, dated October 19, 2009
- STP Units 3 & 4 Manual U7-COM-T-TRNG-LP-0004, "Apparent Cause Evaluator's Manual," Revision 0
- STPNOC Manual RCA-0001, STPNOC Root Cause Investigator's Manual, Revision 11
- CR 08-12460, ABWR DCD Tier 1, Subsection 2.15.5, which notes that the EDG HVAC system may be inaccurate, dated August 15, 2008
- CR 08-12461, discussing nonconservative assumptions made in the DCD regarding feedwater flow and drywell connecting vent loss coefficients following a feed or steamline break accident, dated August 15, 2008
- CR 08-18145, Regulatory Affairs Audits, which notes that sufficient documentation is not being maintained as a quality record to document that personnel are trained and qualified with the scope of work being performed, dated November 20, 2008
- CR 08-18157, Engineering Audits, which notes that sufficient documentation is not being maintained as a quality record to document that personnel are trained and qualified on the scope of work being performed, dated December 15, 2008
- CR 08-19051, Documentation of Training, dated December 15, 2008

- CR 09-4012, regarding a QA audit of the supply chain during which it was noted that some training requirements were not met, dated March 18, 2009
- CR 09-5734, responding to NRC requests for additional information (RAIs) for the COLA are not being followed at all times, dated April 14, 2009
- CR 09-6172, describing instances where some CRs were closed without an action being created, dated April 21, 2009
- CR 09-6174, describing instances where some CRs that closed actions did not provide adequate documentation or description of the basis for the closure, dated April 21, 2009
- CR 09-6177, describing instances where corrective actions were completed after the due date without contacting the condition owner as the procedure requires, dated April 21, 2009
- CR 09-6840, training department procedures that do not meet the needs of the training department, dated April 30, 2009
- CR 09-7321, which notes that no review against Appendix 19I of DCD was performed for specific design changes associated with the service water system redesign, dated May 7, 2009
- CR 09-7890, which notes that Quality Procedure U7-P-EN02-0002 was inadvertently deleted (is still deleted), dated May 18, 2009
- CR 09-8960, which notes that, during the QA internal audit of RMS and document control, there was no documented control system that identifies the assignment of responsibility to STPNOC for preparing, approving, and issuing PRDS, dated June 9, 2009
- CR 09-10194, which notes that, during a QA audit, it was determined that sufficient programmatic controls do not exist to implement the CAP properly, dated July 2, 2009
- CR 09-10198, which notes that, during a QA audit, it was determined that two conditions adverse to quality (CAQs) existed with overdue corrective actions with no evidence of a revised due date, dated July 2, 2009
- CR 09-11914, which notes that, during an internal surveillance of RMS and document control, two CAQs were found with overdue corrective actions, dated August 5, 2009
- CR 09-12615, which notes that a review of training records found that some personnel had not received the required QA-101 training, dated August 18, 2009
- CR 09-13815, which notes that a QA audit found that supply chain contracts were not transmitted to RMS, dated September 10, 2009

- CR 09-14726, which notes that STPNOC Units 3 and 4 received a letter from Sargent & Lundy to the NRC regarding a 10 CFR Part 21 reportable condition associated with a soil structure interaction/seismic analysis, dated September 23, 2009
- CR 09-16650, which notes that a QA audit of engineering and construction found that training and qualification records were submitted to RMS through a nonquality CR, dated October 15, 2009
- CR 09-16964, which notes that a QA audit of engineering and construction found that personnel had not filed training and qualification documents in RMS, dated October 19, 2009
- CR 09-17040, which notes that a QA audit of engineering and construction found that training and qualification records for one employee were not filed in RMS, dated October 20, 2009
- CR 09-17113, which notes that, during a QA audit of engineering and construction, it was discovered that the training and qualification guideline was not consistent with job functions and the process for training less experienced employees, dated October 21, 2009
- CR 09-17198, which notes that some figures in the STP 3 and 4 COLA, Revision 3, Chapter 21, were discovered with revision identification errors, dated October 20, 2009
- CR 09-17816, which notes that safety-related contracts were not transmitted to RMS as required, dated October 29, 2009
- CR 09-17817, which notes that quality surveillance found additional quality and safety-related contracts not being transmitted to RMS as required, dated October 29, 2009
- CR 09-17820, which notes that an NRC 10 CFR Part 52 audit discovered issues with drawings submitted in Revision 3 of the COLA, dated October 29, 2009
- CR 09-18056, which notes that review forms for two procedures mandated training as required reading but it was not completed, dated November 2, 2009
- CR 09-18800, which notes that the completed checklist for external vendor audit U7-A-08-003 of the Toshiba Corp. could not be located in RMS, dated November 12, 2009
- CR 10-2079, which notes that the RAI response in the letter U7-C-STP-NRC-100015 was different from the approved response on CERTREC, dated February 4, 2010
- CR 10-2550, which notes that STPNOC does not have a systematic, controlled process for identifying, tracking, and resolving EPC issues, nonconformances, and deficiencies identified by STPNOC, dated February 10, 2010

- CR 10-3579, which notes that user orientation training in the licensing management system does not meet the stated training objective, dated February 24, 2010
- CR 10-4812, which notes that the NRC believes that STPNOC's responses to RAIs on the emergency diesel generator room temperature are incomplete or incorrect, dated March 10, 2010

b. Observations and Findings

b.1 Policies and Procedures for the Corrective Action Program

STPNOC created some of the CRs reviewed by the NRC inspection team under the OQAP before the full transition to the QAPD for the ABWR DCR amendment application work in September 2009. The OQAP and QAPD established the high-level requirements and responsibilities for the control of CAQs and required personnel to report CAQs to appropriate management for resolution in accordance with procedures. The OQAP and QAPD also set forth requirements for procedures to have adequate measures in place to identify CAQs and the requirements that these conditions violate; to notify responsible management; and to resolve, disposition, and document these conditions.

Procedure U7-P-AD02-0003 provided both a corrective action and an action tracking mechanism used for the identification, control, documentation, classification, and correction of CAQs, as well as conditions not adverse to quality. The procedure applied to licensing, engineering, training, document control, procurement, and construction activities conducted before the operational phase. The procedure asserted that any employee may identify a condition that requires documented review, evaluation, action for resolution, or action tracking. These conditions could be categorized as CAQs or significant CAQs (SCAQs) that are documented on CRs, or conditions not adverse to quality that are documented on CTRs.

Procedure U7-P-AD02-0003 required that every SCAQ have a documented root cause investigation and that the investigation report be reviewed by the Action Tracking Review Group. It also required that at least one corrective action be implemented to address the root cause. The OQAP and QAPD required that procedures be developed for the control of items, services, or activities that do not conform to established requirements and that these procedures provide for the notification of responsible management.

The NRC inspection team verified that the STPNOC corrective action procedure provided a link to the STPNOC 10 CFR Part 21 program. Corrective Action Tracking Procedure U7-P-AD02-0003 required the originator of a CR to notify STPNOC Regulatory Affairs if the condition could be reportable under 10 CFR Part 21. If so, STPNOC Regulatory Affairs would implement STPNOC Units 3 and 4 Procedure U7-P-LI02-0006 to conduct the evaluation for 10 CFR Part 21 applicability and complete any requisite reporting and notifications.

b.2 Implementation of the Corrective Action Program

The NRC inspection team reviewed the STPNOC process and policies governing implementation of its CAP. The inspectors reviewed 33 CRs and training records for individuals qualified to perform a cause analysis for quality conditions. The NRC

inspection team noted that, for the records that it reviewed, the descriptions of the conditions were adequate and that each CR included a sufficient description of the condition's cause, the corrective actions taken, the action owner, and the type and level of the condition.

During an NRC team inspection conducted on January 13–15, 2009, documented in Inspection Report Nos. 05200012/2009-201 and 05200013/2009-201, the NRC issued a non-cited violation (NCV) to STPNOC. This NCV dealt with CRs identified by STPNOC, which noted that there was a programmatic issue with the personnel training and qualification process in which STPNOC did not include adequate training documentation. Since STPNOC self-identified the problem, the NRC issued an NCV.

Criterion XVI of Appendix B to 10 CFR Part 50 states, in part, that measures shall be established to ensure that CAQs, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

Contrary to the above, STPNOC did not establish measures to ensure that a CAQ was corrected. Specifically, STPNOC did not ensure that it had included sufficient documentation in the RMS to furnish evidence of training and qualifications of personnel. As discussed in Inspection Report Nos. 05200012/2009-201 and 05200013/2009-201, STPNOC initiated CR 08-19051 in December 2008 that identified three internal audits with similar deficiencies related to training documentation. STPNOC issued corrective actions and closed the CR.

In 2009, STPNOC self-identified nine examples of personnel training and qualification records that did not include adequate training documentation and opened CRs to address the conditions. In October 2009, STPNOC initiated CR 09-16964, which stated that corrective actions associated with CR 08-19051 may not have been adequate to resolve the condition. The inspectors noted that, for CR 08-19051, implementation of corrective actions did not adequately address the CAQ.

In addition, the NRC inspection team reviewed the training records for Quality, Engineering, and Regulatory Affairs personnel that had been performing Units 3 and 4 DCR quality-related activities and found that STPNOC failed to maintain quality records that sufficiently documented evidence of personnel qualifications. Specifically, STPNOC did not maintain portions of training and qualifications in the quality RMS.

Procedure U7-P-RM02-0001 stated that the Information Management System is an electronic database that lists and tracks stored records, including controlled document revisions and amendments, retrieval locations, and required record retention times, and that Filenet is the record copy storage system for the Information Management System.

Three out of four training records reviewed in the areas of engineering, quality, supply chain, and licensing lacked documentation of the minimal initial training, because those documents were not located in Filenet, the official RMS for retention. This is a repetitive issue as a result of inadequate corrective action and has been identified as Violations 05200012/2010-201-01 and 05200013/2010-201-01.

b.3 Corrective Action Associated with Violations 05200012/2009-201-01 and 0520002009-201-01

During an inspection in January 2009, the NRC found that the STPNOC QA program did not include a list of the Unit 1 and 2 procedures that were applicable to Unit 3 and 4 activities. The NRC identified this issue in Violations 05200012/2009-201-01 and 05200013/2009-201-01.

During this current inspection, the NRC inspection team reviewed the licensee's response to these violations and the corrective actions taken. In response to these violations, STPNOC wrote CR 09-721. As part of the corrective actions, STPNOC created a new procedure, U7-P-AD01-0004, to provide expectations for the use of, and adherence to, Unit 3 and 4 procedures. The NRC inspection team reviewed U7-P-AD01-0004 and found that it included a list of authorized Unit 1 and 2 procedures to be used for Unit 3 and 4 quality-related activities. Based on the review by the NRC inspection team, these violations are closed.

b.4 Corrective Action Associated with Violations 05200012/2009-201-02 and 05200013/2009-201-02

During an inspection in January 2009, the NRC found that STPNOC guidance on numbering was not maintained as a controlled document. The NRC identified this issue as Violations 5200012/2009-201-2 and 05200013/2009-201-02.

During this current inspection, the NRC reviewed the licensee's response to these violations and the corrective actions taken. In its response to the violations, STPNOC stated that it revised Procedure U7-P-AD02-0002, "Units 3 & 4 Procedure Development, Review and Approval," to include the STPNOC Units 3 and 4 procedure numbering scheme and added a requirement stipulating that, if a controlled procedure makes a transition statement to another procedure, the second procedure must also be a controlled procedure. The NRC inspection team reviewed U7-P-AD02-0002 and found that Addendum 3 describes the procedure number format for Unit 3 and 4 procedures. U7-P-AD02-0002 is a controlled procedure. Based on the review by the NRC inspection team, these violations are closed.

b.5 Corrective Action Associated with Violations 05200012/2009-201-03 and 05200013/2009-201-03

During an inspection in January 2009, the NRC found that STPNOC Procedure U7-P-AD02-0003, "STP Units 3 & 4 Corrective Action and Tracking Program," Revision 0, dated November 20, 2008, did not include any instructions for notifying appropriate levels of management when a SCAQ is identified. In addition, Revision 0 of U7-P-AD02-0003 required that at least one corrective action be implemented to address the root cause of a SCAQ. It did not specify, however, that the corrective action should be implemented to preclude repetition, as is required by Criterion XVI of Appendix B to 10 CFR Part 50.

During this current inspection, the NRC inspection team reviewed the licensee's response to these violations and the corrective action taken. In its response to the violations, STPNOC stated that it revised Procedure U7-P-AD02-0003, "ABWR Corrective Action Program," to include the following requirements: (1) to notify the appropriate division manager in the event that a SCAQ is identified; and (2) to specifically state: "Corrective actions shall be developed to correct or eliminate the root cause(s) and preclude recurrence."

The inspectors reviewed U7-P-AD02-0003, Revision 6, and found that procedural step 4.3.3 directed the CAP supervisor to notify the appropriate manager when a SCAQ is identified. Procedural step 4.5.3.6 stated that corrective actions shall be developed to correct or eliminate identified root causes and preclude recurrence. Corrective actions selected to address apparent causes should minimize the likelihood of recurrence. Based on the review by the NRC inspection team, these violations are closed.

b.6 Corrective Action Associated with Violations 05200012/2009-201-04 and 05200013/2009-201-04

During an inspection in January 2009, the NRC found that Quality Audit Report U7-A-08-004, dated November 25, 2008, which contained the results of the internal audit of STPNOC Units 3 and 4 Regulatory Affairs (Licensing), identified two recommendations that were not entered into the Action Tracking System, as required. Additionally, the STPNOC audit staff had no documentation or record of the status of any corrective actions completed or underway to resolve the recommendations. The NRC inspection team also noted that Procedure U7-P-QP02-0003 did not clearly describe the process for documenting audit recommendations.

During this current inspection, the NRC inspection team reviewed the licensee's response to these violations and the corrective actions taken. In its response to the violations, STPNOC stated that the two recommendations identified in Quality Audit Report U7-A-08-004 were entered into the ABWR CAP as a condition not adverse to quality (CR 09-861). STPNOC documented the actions taken in response to the recommendations and closed CR 09-861. STPNOC conducted QA group training on March 2, 2009, reminding auditors of the Procedure U7-PQP02-0003 requirements for documenting recommendations in the CAP. The NRC inspectors verified that STPNOC entered the recommendations into the ABWR CAP, that the QA personnel received training, and that STPNOC was adequately documenting audit recommendations as

conditions not adverse to quality. Based on the review by the NRC inspection team, these violations are closed.

c. Conclusions

With the exception of NOVs 05200012/2010-201-01 and 05200013/2010-201-01 for ineffective corrective action related to the inadequate documentation of personnel training and qualifications, the NRC inspection team found that the STPNOC CAP conformed to the requirements of Criterion XVI of Appendix B to 10 CFR Part 50.

10. Quality Assurance Records

a. Scope

The NRC inspection team reviewed the STPNOC QAPD and implementing policies and procedures that govern the control of documents to verify compliance with the requirements of Criterion XVII of Appendix B to 10 CFR Part 50.

Specifically, the NRC inspection team reviewed the following documents:

- U7-P-QP01-QAPD, "STP 3 & 4 Quality Assurance Program Description," Revision 3, dated April 12, 2010
- U7-P-RM02-0001, "Units 3 & 4 Records Management and Document Control," Revision 5, dated September 30, 2009
- U7-P-AD02-0002, "Units 3 & 4 Procedure Development, Review and Approval," Revision 1, dated September 15, 2008
- CTR No. 09-8960, dated June 9, 2009
- CTR No. 09-721, dated January 14, 2009
- CTR No. 09-8961, dated June 9, 2009
- CTR No. 09-8962, dated June 9, 2009
- CTR No. 09-902, dated January 15, 2009
- CTR No. 09-8036, dated May 20, 2009
- training, qualification, and certification records for Units 3 and 4 licensing personnel
- training records for engineering personnel
- training records for QA personnel
- training records for supply chain personnel

b. Observations and Findings

Section 17 of the QAPD describes measures and governing procedures in place to ensure that STPNOC develops, reviews, approves, issues, uses, and revises sufficient records of items and activities affecting quality to reflect completed work. The provisions of such procedures establish the scope of the records retention program for STPNOC and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

Procedure U7-P-RM02-0001 establishes the requirements for managing and transferring controlled documents into the official RMS. It specifically delegates Filenet as STPNOC's RMS to list and track stored records. Procedure U7-P-AD01-0002 describes the importance of ensuring that training records are completed and forwarded to the RMS for retention.

The NRC inspection team's review verified that STPNOC had implemented a document records system that provided measures for the identification, classification, validation, and distribution controls of records. Procedures were in place to verify the process for receipt control, processing, corrections, and safekeeping for all documented records.

The NRC inspection team verified that the QA program provided for the administration, identification, receipt, storage, preservation, safekeeping, and disposition of all records and that STPNOC had developed procedures and policies to adequately implement the requirements for record retention. STPNOC staff indicated that measures were in place so that every controlled document would be delegated as a lifetime document and stored in the RMS for retrieval. The records and retention times complied with Regulatory Position C.2 and Table 1, of Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 3, for design, construction, and initial startup.

When performing a followup review of CTR No. 09-902, the NRC determined that STPNOC had adequate procedures for numbering formats for various documents. It also verified that the STPNOC RMS maintained the integrity, authenticity, and acceptability of QA records during their required retention period, in accordance with NRC requirements.

c. Conclusions

The NRC inspection team concluded that the STPNOC QA records program requirements were consistent with the regulatory requirements of Criterion XVII of Appendix B to 10 CFR Part 50. Based on the QA records reviewed, the NRC inspection team also determined that STPNOC adequately implemented the QAPD and implementing procedures. No findings of significance were identified.

10. Audits

a. Scope

The NRC inspection team reviewed the STPNOC QAPD and implementing policies and procedures that govern the audit process to verify compliance with the requirements of

Criterion XVIII of Appendix B to 10 CFR Part 50. The NRC inspection team also evaluated a sample of internal audit reports to verify compliance with the program requirements and adequate implementation of those requirements. Specifically, the NRC inspection team reviewed the following documents:

- U7-P-QP01-QAPD
- U7 STP- 3 & 4 Quality Assurance Program Description,” , Revision 3, dated April 12th, 2010
- U7-C-STP-100001, “Units 3 & 4 Internal Audits Schedule 2010,” dated January 5, 2008
- U7-P-QP02-0001, “Units 3 & 4 Expectations for Quality Activities,” Revision 1, dated October 6, 2008
- U7-P-QP02-0003, “Units 3 & 4 Internal Audits,” Revision 3, dated February 23, 2010
- 0PQP01-ZA-0003, “Vendor Overview Activities,” Revision 5, dated March 27, 2008
- U7-A-09-002, Quality Audit Report, “Units 3 & 4 Records Management and Document Control,” dated May 6, 2009
- U7-A-10-001, Quality Audit Report, “Units 3 & 4 Supply Chain”, dated April 20, 2010
- U7-A-09-001, Quality Audit Report, “Units 3 & 4 Supply Chain”, dated April 9, 2009
- U7-A-09-003, Quality Audit Report, “Units 3 & 4 ABWR Corrective Action Program,” dated May 14, 2009
- Apparent Cause Evaluation for CR 09-887
- CTR No. 09-4010, dated March 18, 2009
- CTR No. 09-8959, dated June 9, 2009
- CTR No. 09-10194, dated July 2, 2009
- CTR No. 09-887, dated January 15, 2009

b. Observations and Findings

STPNOC had established an internal audit program under Chapter 18 of the QAPD, as implemented by Procedure U7-P-QP02-0003. The QAPD provided general timeliness requirements for the conduct of audits and identified requirements for audit team composition and qualifications. Procedure U7-P-QP02-0003 provided guidance for preparing audit plans, making audit notifications, performing audits, and reporting conditions, and for audit closeout and documentation. The procedure also referred to Procedure U7-P-QP02-0001 for guidance on implementing the internal audit program.

Procedure U7-P-QP02-0001 set forth the expectations for quality activities, including internal audit planning, conduct, pre- and post-audit meetings, and condition reporting.

As of the date of this inspection, STPNOC had completed ten internal audits that covered the areas of records management and document control, supply chain management, corrective actions, engineering, training, and licensing, records management and document control, supply chain management, corrective actions, engineering, training, and licensing.

The NRC inspection team verified the following for a sample of four internal audits:

- (1) An audit notification letter had been sent to the affected organization at least 2 weeks before the audit started.
- (2) An audit plan was prepared and signed by the audit team leader and approved by responsible management.
- (3) An audit report was issued and sent to the audited organization, senior management, and the President and CEO within 30 days of the post-audit conference
- (4) An audit checklist was completed and identified the applicable STPNOC quality requirement, source regulatory requirement or criteria, and current and future implementing document for each area audited.
- (5) The procedures in use for internal audits had been approved and the personnel who led and conducted the audits held the appropriate qualifications.

The NRC inspection team verified that audit teams selected by STPNOC were sufficiently qualified and that these auditors were not auditing their own work. When performing a followup review of CTR No. 09-887, it was determined that STPNOC was adequately documenting audit recommendations as conditions not adverse to quality.

The NRC inspection team also verified that STPNOC had established a 2010 audit schedule and that the schedule included all functional areas currently being performed by STPNOC, with the applicable quality criteria from Appendix B to 10 CFR Part 50. The schedule met the frequency requirements delineated in the STPNOC QAPD and implementing procedures.

c. Conclusions

The NRC Inspection Team concluded that the internal audits provided by STPNOC are consistent with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. Based on the internal audit reports reviewed, the NRC inspection team also determined that STPNOC was adequately applying the QAPD and implementing procedures. No findings of significance were identified.

12. Entrance and Exit Meetings

On April 19, 2010, the NRC presented the inspection scope during an entrance meeting with STPNOC staff. On April 22, 2010, the NRC presented the inspection results during an exit meeting with Mark Burnett, Vice President, Oversight and Regulatory Affairs, and other STPNOC personnel. The entrance and exit meeting attendees are listed in the attachment to this report.

On May 26, 2010, the NRC inspection team conducted a subsequent exit meeting with Mark Burnett, Vice President Oversight and Regulatory Affairs, and other STPNOC personnel to discuss a change in the NRC's position on the inspection results presented at the April 22, 2010 exit meeting.

ATTACHMENT 1

1. ENTRANCE/EXIT MEETING ATTENDEES

<u>Name</u>	<u>Title</u>	<u>Affiliation</u>	<u>Entrance</u>	<u>4/22/10 Exit</u>	<u>5/27/10 Exit</u>	<u>Interviewed</u>
Mark McBurnett	VP Oversight and Regulatory Affairs	STPNOC	X	X	X	
Fred Puleo	Plant Protection Coordinator	STPNOC	X	X	X	X
Roger Lanksbury	Sr. Project Manager	NRC/R-II	X	X		
Robert Prato	Sr. Reactor Operations Engineer	NRC/NRO	X	X		
Ron Ballenger	Supervisor Supply Chain	STPNOC	X	X		X
Scott Cameron	Supervisor Vendor Oversight	STPNOC	X	X	X	X
Samantha Crane	Reactor Operations Engineer	NRC/NRO	X	X	X	
Bill Mookhoek	Licensing Supervisor	STPNOC	X	X	X	X
Shavon Edmonds	Reactor Engineer	NRC/NRO	X	X	X	
John Bartleman	Sr. Construction Inspector	NRC/R-II	X	X		
Tim Walker	Manager, Quality	STPNOC	X	X	X	X
Terry Casteel	Manager, Quality	TANE	X	X		X
Dick Scheide	Licensing Engineer	STPNOC	X	X		X
Crystal Jackson	Quality Specialist	STPNOC	X			
Kyle Ulassin	Quality Specialist	STPNOC	X	X	X	X
Evans Heacock	Design Engineer Lead	STPNOC	X	X	X	X
Linda Dyer	Document Control Lead	STPNOC		X		X
Scott Head	Manager Regulatory Affairs	STPNOC		X	X	X
Paul Kallan	Project Manager	NRC/NRO		X	X	
Michael Morgan	Reactor Operations Engineer	NRC/NRO	X	X		
Nanette Gilles	Senior Policy Analyst	NRC/NRO			X	
Richard Rasmussen	Chief, Quality and Vendor Branch	NRC/NRO			X	

The following individual observed the inspection from April 19-22, 2010:

Paul Kallan, Project Manager, NRC Office of New Reactors

2. PERSONS CONTACTED

F. Puleo, Plant Protection Coordinator, South Texas Project Nuclear Operating Company (STPNOC)

J. Dixon, Training Coordinator, STPNOC

M. McBurnett, Vice President Oversight & Regulatory Affairs Unit 3&4, STPNOC

S. Cameron, Supervisor Vendor Oversight, STPNOC

K. Ulassin, Quality Specialist, STPNOC

R. Ballenger, Supervisor Contracts Administration, STPNOC

T. Walker, Manager Quality, STPNOC

W. Mookhoek, Licensing Supervisor, STPNOC

F. Hayes, Principal Engineer, Westinghouse Electric Company

T. Casteel, Quality Assurance Manager, TANE

R. Scheide, Licensing Engineer, STPNOC

E. Heacock, Design Engineering Lead, STPNOC

L. Dyer, Document Control Lead, STPNOC

S. Head, Manager Regulatory Affairs, STPNOC

3. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection"

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

4. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

The NRC previously conducted an inspection at STPNOC's facility in Bay City, TX, from January 13–15, 2009, and documented it in Inspection Reports 05200012/2009-201 and 05200013/2009-201. All open items from that inspection have been closed.

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
05200012/2010-201-01 and 05200013/2010-201-01	Opened	NOV	Criterion XVI
05200012/2009-201-01 and 05200013/2009-201-01	Closed	NOV	Criterion II Criterion V Criterion VI
05200012/2009-201-02 and 05200013/2009-201-02	Closed	NOV	Criterion VI
05200012/2009-201-03 and 05200013/2009-201-03	Closed	NOV	Criterion XVI
05200012/2009-201-04 and 05200013/2009-201-04	Closed	NOV	Criterion XVIII