March 2, 2009

Mr. Mark McBurnett, Vice President
Oversight and Regulatory Affairs
South Texas Project Nuclear Operating Company
P.O. Box 289
Wadsworth, TX 77483

SUBJECT: NRC INSPECTION REPORT NOS. 05200012/2009201 AND 05200013/2009201 AND NOTICE OF VIOLATION

Dear Mr. McBurnett:

On January 13-15, 2009, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the South Texas Project Nuclear Operating Company Units 3 & 4 facility in Bay City, Texas. The enclosed report presents the results of this inspection.

This was a limited scope inspection that focused on assessing your compliance with the provisions of selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) program.

Based on the results of this inspection, the NRC has determined that four Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (http://www.nrc.gov/about-nrc/regulatory/enforcement/enforc-pol.pdf).

The violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in this Notice because a review of STP's QA program documentation and implementation identified that (1) STP failed to adequately control and identify the procedures that had been developed and implemented under the Quality Assurance Program for Unit 3 and 4 COL activities, (2) STP's document control practices did not maintain the guidance document for procedure and document numbering as a controlled document, (3) STP's corrective action procedure did not include instructions for notification of appropriate levels of management in the event that a significant condition adverse to quality is identified or specify the requirement to implement corrective actions to preclude repetition, not just to address the root cause, and (4) STP failed to capture internal audit recommendations in the Action Tracking System, as required by STP Procedures.

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, “Public Inspections, Exemptions, Requests for Withholding,” of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC’s document system (the Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, “Requirements for the Protection of Safeguards Information.”

Sincerely,

/RA/

John A. Nakoski, 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. 05200012/2009-201 and 05200013/2009-201 and Attachments

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (the Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

Sincerely,

/RA/

John A. Nakoski, 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. 05200012/2009-201 and 05200013/2009-201 and Attachments

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Date	3/2/2009		3/2/2009		3/2/2009	
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Name	R.McIntyre		R.Pascarelli		J.A.Nakoski	
DATE	2/26/2009		3/2/2009		2/27/2009	

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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.: 2009-201

During an NRC inspection conducted at the South Texas Project Nuclear Operating Company Units 3 and 4 facility in Bay City, Texas on January 13-15, 2009, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are described below.

A. Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50 states, in part, that the applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance (QA) program that complies with the requirements of this Appendix.

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 states, in part, that activities affecting quality shall be prescribed by documented instructions, procedures, and drawings.

Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50 states, in part, that measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings.

Section 5.6, "QA Program Documents," of the South Texas Project Nuclear Operating Company (STPNOC) Operations Quality Assurance Plan (OQAP), Revision 18, dated February 1, 2008, states that the QA program shall be implemented with documented instructions, procedures, and drawings which include appropriate quantitative and qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. To change these controls, the individual procedure must be changed and shall require the same level of review and approval given to the original procedure. Such instructions, procedures, and drawings are reviewed and approved for compliance with requirements appropriate to their safety significance by individuals qualified to do so.

Section 5.8, "Policies and Goals," of the STPNOC OQAP states that it is the responsibility of each organization supporting the STP to ensure that the requirements stated in the QA program are incorporated into procedures. Adherence to those procedures is mandatory for all STP organizations and contractors or vendors providing items or services covered by the QA program.

Contrary to the above, as of January 16, 2009, STPNOC QA program did not include a list of Unit 1 and 2 procedures that were found to be applicable for Units 3 and 4 COL activities. STPNOC had not been keeping a complete list of new Unit 3 and 4 procedures that had been issued to supersede Units 1 and 2 procedures. STPNOC failed to control and identify the procedures that had been implemented and/or developed for Unit 3 and 4 COL activities.

For example, in the area of Records Management and Document Control, STPNOC had implemented approved procedures U7-P-AD02-0001,"Units 3 & 4 Procedure Writer's

Guide," Revision 1, dated September 15, 2008, and U7-P-AD02-0002, "Units 3 & 4 Procedure Development, Review and Approval," Revision 1, dated September 15, 2008. These procedures referenced procedure U7-P-RM02-0001, "Units 3 & 4 Records Management and Document Control," Revision 0, dated January 13, 2009, for further guidance on the management of controlled documents. However, STPNOC had not yet issued and implemented procedure U7-P-RM02-0001. The STP organization was using Units 1 and 2 procedures 0PGP07-ZA-0002 and 0PGP07-ZA-0018 for the document control and records management program instead. STPNOC failed to adequately reference the appropriate approved procedures for records management and document control.

This issue has been identified as Violations 05200012/2009201-01 and 05200013/2009201-01.

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

B. Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50 states, in part, that measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality.

STP Procedure U7-P-AD02-0001 "Units 3 & 4 Procedure Writer's Guide" Revision 1, dated September 15, 2008, describes the methodology for the preparation of Units 3 & 4 procedures used during the phases of COL Application, construction, startup, testing and turnover. The procedure provides references to procedures U7-P-AD02-0002, "Units 3 & 4 Procedure Development, Review and Approval," Revision 1, dated September 15, 2008, and U7-P-RM02-0001, "Units 3 & 4 Records Management and Document Control," Revision 0, dated January 13, 2009, for further guidance on numbering, development, review and approval.

Contrary to the above, STP guidance on numbering is not maintained as a controlled document. Specifically, Procedure U7-P-AD02-0001, Section 4.1, "Procedure Numbering" states that each procedure is given a unique number issued from Records Management/Document Control (RMDC) and formatted per Procedure U7-P-AD02-0002. However, Procedure U7-P-AD02-0002, Section 4.1 indicates that RMDC will provide the number for new procedures. The numbering procedure or description is not available in either of the documents. There is a guidance document for numbering; however this guidance is not a controlled document.

These issues have been identified as Violations 05200012/2009201-02 and 05200013/2009201-02.

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

C. Criterion XVI, "Corrective Action" of Appendix B to 10 CFR Part 50 states that "measures shall be established to assure that conditions adverse to quality are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the

cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

Chapter 13 of the STP Operations Quality Assurance Program (OQAP) requires procedures to be developed for the control of items, services or activities which do not conform to established requirements and states that these procedures shall provide guidance for making notifications to responsible management. The OQAP also states that "For significant conditions adverse to quality, the cause of the condition and the corrective action taken to preclude repetition shall be documented and reported to appropriate levels of management."

Contrary to these requirements:

(1) STP Procedure Number U7-P-AD02-0003, "STP Units 3 & 4 Corrective Action and Tracking Program," Revision 0, dated November 20, 2008, does not include any instructions for notification of appropriate levels of management in the event that a significant condition adverse to quality is identified.

(2) Procedure U7-P-AD02-0003 requires that at least one corrective action be implemented to address the root cause of significant conditions adverse to quality. It does 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.

These issues have been identified as Violations 05200012/2009201-03 and 05200013/2009201-03.

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

D. Criterion XVIII, "Audits" of Appendix B to 10 CFR Part 50 requires that a comprehensive system of planned and periodic audits be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program and states that "Followup action, including reaudit of deficient areas, shall be taken where indicated."

STP Procedure U7-P-QP02-0003, "Units 3 & 4 Internal Audits," Revision1, dated October 6, 2008 states that audit recommendations (conditions not adverse to quality) are "identified" in accordance with the corrective action and tracking program procedure, Procedure U7-P-AD02-0003, "Units 3 & 4 Corrective Action and Tracking Program," Revision 0, dated November 20, 2008. Procedure U7-P-AD02-0003 states that actions to resolve conditions not adverse to quality are entered on the actions form and closed by the condition owner. (i.e. the procedure directs the staff to open a CTR in the Action Tracking System.)

Contrary to this guidance, the NRC Inspection Team found that Quality Audit Report U7-A-08-004, issued November 25, 2008, which contains the results of the internal audit of STP Units 3 & 4 Regulatory Affairs (Licensing) identified two recommendations that were not entered into the Action Tracking System (ATS). Additionally, the STP 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. The only link that identifies the expectation is that Procedure U7-P-QP02-0003 identifies audit recommendations as being conditions not adverse to quality, and Procedure U7-P-AD02-0003 then provides directions for capturing conditions not adverse to quality in ATS.

These issues have been identified as Violations 05200012/2009201-04 and 05200013/2009201-04.

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

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," STP 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 (1) the reason for the violation, or, if contested, the basis for disputing the violation, (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 through the NRC Agencywide Documents Access and Management System (ADAMS), to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

Dated at Rockville, Maryland, this 2nd day of March 2009.

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.:	05200012/2009-201 and 05200013/2009-201
Applicant:	South Texas Project Nuclear Operating Company (STPNOC) P.O. Box 289 Wadsworth, TX 77489
Applicant Contact:	Timothy Walker Quality Manager 361-972-7392 tfwalker@stpegs.com
Background:	By letter dated September 20, 2007, STPNOC submitted its COL Application for two ABWRs (STP Units 3 & 4) to be constructed adjacent to STP Units 1 & 2 near Bay City, Texas. By letter dated August 19, 2008, STPNOC submitted a report that provided the qualification assessment to determine whether Toshiba Corporation (Toshiba) is qualified to supply the design of the ABWR for the STP Units 3 and 4.
Inspection Dates:	January 13-15, 2009

Inspectors:			
	Richard P. McIntyre	NRO/DCIP/CQVB	Lead Inspector
	Aida Rivera-Varona	NRO/DCIP/CQVB	
	Sabrina Cleavenger	NRO/DCIP/CQVB	
	Damaris Arroyo	NRO/DCIP/CQVB	

Approved by: John A. Nakoski, Chief ***/RA/***
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

ENCLOSURE 2

EXECUTIVE SUMMARY

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

This inspection focused on quality activities that South Texas Project Nuclear Operating Company (STPNOC) implemented during the due diligence assessment to determine whether Toshiba Corporation is qualified to supply the design of the Advance Boiling Water Reactor (ABWR) for STPNOC Units 3 and 4 in accordance with Appendix A "Design Certification Rule for the US ABWR" to 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," of the *Code of Federal Regulations* (10 CFR Part 52).

STPNOC, the COL applicant for STP Units 3 & 4, awarded the engineering, procurement, and construction (EPC) contract to Toshiba Corporation (Toshiba). As the holder of the EPC, Toshiba will assume the duties normally assigned to the plant vendor and the entity that originally obtained the design certification. Because Toshiba is not the entity that originally obtained the design certification, they are referred to as an "alternate vendor."

The *Code of Federal Regulations*, specifically 10 CFR 52.73(a), allows for the use of an alternate vendor to supply a certified design; however, the Code requires that such an alternate vendor be demonstrated as qualified to supply that design. To make this demonstration, STPNOC performed a due diligence review and assessment of Toshiba's capabilities. The results of STPNOC's review were submitted for NRC review by letter dated August 19, 2008.

To support the STP Due Diligence review, the Toshiba EPC team performed the Toshiba Capabilities Assessment (TCA) to help to confirm that Toshiba has the necessary capabilities to complete the STP Units 3 & 4 project to NRC standards and STP 3 &4 Owner's requirements without participation of the certified ABWR design sponsor General Electric Nuclear Energy (GENE).

In order to supply a design for the US certified ABWR, Toshiba must translate the design descriptions from the design certification document (DCD) in to a workable design and support the design throughout the licensing process.

Part of the purpose of this QA implementation inspection was to determine if STP was adequately translating the appropriate technical and quality requirements onto Toshiba for Toshiba and its subcontractors to implement for Units 3 & 4 COL activities. The inspection also aimed to assist the NRC with its assessment of Toshiba's qualification to supply the certified ABWR design without participation of the original certified ABWR design sponsor (GENE).

Based on the results of this limited scope QA implementation inspection, it appears that (1) STP is providing adequate oversight to conclude that Toshiba can continue activities related to the supply of the certified ABWR design without participation of the original certified ABWR design sponsor and (2) the inspection results are supportive of an NRC staff determination that the STP Units 3 & 4 design team, led by Toshiba, is qualified to provide the certified ABWR design for this project.

The inspection also sought to verify that STP implemented an adequate quality assurance (QA) program for COL activities that complied with the requirements of Appendix B to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," of the *Code of Federal Regulations* (10 CFR Part 50).

The NRC inspection basis was Appendix B to 10 CFR Part 50, and the NRC Inspection Team utilized Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection," issued July 29, 2008, during the conduct of this inspection.

The NRC had not performed any QA inspections at the STP Units 3 & 4 facility in Bay City, TX prior to this inspection. The NRC Inspection Team concluded that STP's QA policies and procedures were in non-compliance with the applicable requirements of Appendix B to 10 CFR Part 50 in the areas described below.

Quality Assurance Program

The NRC Inspection Team issued Violations 05200012/2009201-01 and 05200013/2009201-01 because STPNOC failed to control and identify the procedures that had been developed and implemented for Unit 3 and 4 COL activities. The NRC Inspection Team found that the STPNOC QA program was not maintaining a list of Unit 1 and 2 procedures that were found to be applicable for Units 3 and 4 COL activities. Additionally, STPNOC failed to adequately reference the appropriate approved procedures for records management and document control.

Also, the staff will issue a request for additional information (RAI) to clarify STP's use of the OQAP for Units 3 & 4 COL activities and describe the transition to the STP Units 3 & 4 QAPD.

Training and Qualification of Personnel

The NRC Inspection Team concluded that the training requirements provided by STPNOC are not consistent with the regulatory requirements of Criterion II of Appendix B to 10 CFR Part 50. STPNOC self-identified several examples where the personnel training and qualification process did not include adequate documentation of training and identified a failure to have a procedure for a consistent training and indoctrination program for organizations performing quality related activities. Since STPNOC self-identified the issue, the NRC Inspection Team identified the issue as a non-cited violation and concluded that training had not been adequately identified, documented, and maintained as required by the QA program.

Document Control

The NRC Inspection Team issued Violations 05200012/2009201-02 and 05200013/2009201-02 as a result of STP's failure to maintain its guidance document for procedure and document numbering as a controlled document.

Corrective Action

The NRC Inspection Team issued Violations 05200012/2009201-03 and 05200013/2009201-03 because STP Procedure Number U7-P-AD02-0003, "STP Units 3 & 4 Corrective Action and Tracking Program," Revision 0, dated November 20, 2008, did not include instructions for notification of appropriate levels of management in the event that a significant condition adverse to quality is identified. Also, the procedure required that at least one corrective action be implemented to address the root cause of significant conditions adverse to quality but did not specify that the corrective action should be implemented *to preclude repetition*, as is required by Criterion XVI of Appendix B to 10 CFR Part 50.

Audits

The NRC Inspection Team issued Violations 05200012/2009201-04 and 05200013/2009201-04 in response to STP's failure to capture internal audit recommendations in the Action Tracking System, as required by STP Procedure U7-P-QP02-0003, "Units 3 & 4 Internal Audits," Revision1, dated October 6, 2008, and STP Procedure U7-P-AD02-0003, "Units 3 & 4 Corrective Action and Tracking Program," Revision 0, dated November 20, 2008.

REPORT DETAILS

1. Quality Assurance Program

a. Scope

The NRC Inspection Team reviewed the South Texas Project Nuclear Operating Company (STPNOC) policies governing quality assurance programs to assure 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 quality assurance (QA) program requirements that STPNOC has implemented for Unit 3 and 4 COL activities, along with the implementing procedures. These documents govern the implementation of quality activities performed by STPNOC for STP Units 3 and 4 COL activities.

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

- STPNOC Operations Quality Assurance Plan (OQAP), Revision 18, dated February 1, 2008
- Letter, J.J. Sheppard to NRC, "Submittal of Operation Quality Assurance Plan Change QA-061," dated August 8, 2006
- Letter, M. McBurnett to NRC, "Submittal of Quality Assurance Program Description," dated March 26, 2007
- Condition Tracking Report 09-721, dated January 14, 2009

b. Observations and Findings:

By letter August 08, 2006, STPNOC submitted Revision 17 of the OQAP to the NRC to include and provide the basis for the control and performance of safety-related and quality-related activities associated with Early Site Permitting/COLA activities for STP Units 3 and 4. As currently stated in Revision 18 of the OQAP, the STP OQAP defines the criteria and establishes the administrative controls for the implementation of the QA program for STP Units 1 and 2. In addition, the OQAP extends the QA program controls to activities associated with the new units by inserting an applicability statement in the Purpose and Scope of selected implementing procedures.

By letter dated March 26, 2007, STPNOC submitted the Quality Assurance Program Description (QAPD) for STP Units 3 and 4 to the NRC. In this letter, STPNOC states that initially the OQAP would be implemented as established for STP Units 1 and 2. The letter further states that these specific QA controls would remain in effect until the NRC staff approves the QAPD specific to Units 3 and 4, and the associated implementing procedures are in place.

By letter dated September 30, 2007, STPNOC submitted the COL application for STP Units 3 and 4 pursuant to 10 CFR Part 52. Chapter 17 of the COL application describes the STPNOC QA program description applied during the COL activities. Section 17.1 of STP COL application states that "the Quality Assurance Program Description [QAPD] has been submitted as a separate document titled 'STP 3 & 4 Quality Assurance Program Description.'" This chapter of the COL application does not provide the reference to the OQAP as mentioned in letter dated March 26, 2007.

Regulatory Guide 1.206 allows for a COL applicant to submit its QAPD in two phases. The first phase could apply to design, fabrication, construction, and testing QA activities, and the second phase could apply to operational QA activities. However, the RG requires that Chapter 17 of the FSAR incorporate the QAPDs by reference. RG 1.206 also allows for COL applicants to use an existing QAPD that the NRC has approved for either or both phases, provided that they identify and justify alternatives to, or differences from, the SRP in effect 6 months prior to the docket date of the application. Under the scope of the COL application review, the staff will issue a request for additional information (RAI) to STPNOC to clarify these items in the COL application for STP Units 3 and 4.

The NRC Inspection Team reviewed the STP OQAP and verified that the scope of the QA program was consistent with the quality-related activities being performed in support of STP Units 3 & 4. At the time of the inspection, some of the STP quality-related activities being implemented included: procurement, quality oversight of suppliers, internal and external audits, corrective actions, and document control.

The NRC Inspection Team evaluated the STPNOC implementing procedures developed under the OQAP that have been applied to Units 3 and 4 COL activities. The NRC Inspection Team met with the QA Supervisor and discussed the selection and development of procedures for use for STP Units 3 and 4 COL activities. As allowed by the OQAP, STPNOC had been using procedures from Unit 1 and 2, and at the same time had been developing procedures specifically for Units 3 and 4 to supersede Units 1 and 2 procedures. The QA Supervisor explained that Units 3 and 4 procedures are completely independent, such that at the moment that Units 3 and 4 procedures are approved for use, Units 1 and 2 corresponding procedures are no longer used for Unit 3 and 4 COL activities unless the new procedure directs or references the Units 1 and 2 procedures.

The OQAP, as specified, commits to the requirements of the American National Standards Institute (ANSI) N45.2-series standards. The QAPD submitted with the COL application commits to the requirements in American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1994, “Quality Assurance Requirements for Nuclear Applications.” Given that these two programs use different standards with different requirements, Units 3 and 4 new procedures had been developed with the most stringent requirement of meeting both QA programs, so that once the QAPD is in place, the procedures are still applicable.

The NRC Inspection Team asked for a complete list of all the procedures that have been used and the procedures that still needed to be developed for STP Units 3 and 4 COL activities. The NRC Inspection Team noted that STPNOC did not have a clear guidance or list of Unit 1 and 2 procedures that were found to be applicable for Units 3 and 4 COL activities. The NRC Inspection Team also noted that STPNOC had not been keeping a complete list of new Unit 3 and 4 procedures that superseded Units 1 and 2 procedures. The failure to control and identify the procedures that have been implemented and/or developed for Unit 3 and 4 COL activities has been identified as an example of Violations 05200012/2009-201-01 and 05200013/2009-201-01. STPNOC opened Condition Tracking Report (CTR) No. 09-0721 to evaluate the condition to determine required actions.

c. Conclusions

The NRC Inspection Team concluded that STPNOC’s quality assurance program requirements are consistent with the regulatory requirements of Criterion II of Appendix B to 10 CFR Part 50.

However, as identified above, the NRC Inspection Team found that STPNOC failed to control and identify the procedures that have been implemented and/or developed for Unit 3 and 4 COL activities. This issue has been identified as Violations 05200012/2009-201-01 and 05200013/2009-201-01.

The staff will issue a request for additional information (RAI) to clarify STP's use of the OQAP for Units 3 & 4 COL activities and describe the transition to the STP Units 3 & 4 QAPD.

2. 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 verified that STPNOC adequately implemented and maintained personnel training and qualification processes to assure that proficiency was achieved and maintained by STP personnel.

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

- STPNOC OQAP, Revision 18, dated February 1, 2008
- U7-P-TR01-001, "Conduct of Training Manual," Revision 0, dated June 18, 2008
- U7-P-TR02-001, "Units 3 and 4 Analysis of Training Programs," Revision 1, dated September 25, 2008
- U7-P-TR02-002, "Units 3 and 4 Design of Training Programs," Revision 1, dated September, 25, 2008
- U7-P-TR02-003, "Units 3 and 4 Development of Training Programs," Revision 1, dated September, 25, 2008
- U7-P-TR02-004, "Units 3 and 4 Implementation of Training Programs," Revision 1, dated September, 25, 2008
- U7-P-TR02-005, "Units 3 and 4 Evaluation of Training Programs," Revision 1, dated September, 25, 2008
- Training, Qualification, and Certification Records for Units 3 and 4 Licensing Personnel
- Engineering Personnel Training Records
- Internal Audit Report No. U7-A-08-005 dated December 16, 2008
- Training Records for QA personnel
- Condition Tracking Report No. 08-19051 dated December 15, 2008
- Condition Tracking Report No. 08-18157 dated November 20, 2008
- Condition Tracking Report No. 08-18158 dated November 20, 2008

b. Observations and Findings

The STPNOC OQAP provides the overall requirements for qualification, training, and certification of personnel whose activities may affect structures, systems, components and activities at STP. The STPNOC OQAP also provides for general indoctrination and training programs for personnel to assure that adequate knowledge in quality programs and requirements is achieved and maintained.

The NRC Inspection Team reviewed the training records for QA, Engineering, and Regulatory Affairs personnel that had been performing Units 3 and 4 COL quality-related activities. The NRC Inspection Team noted that the training records for the Engineering personnel consisted of their resume and minimal training. The NRC Inspection Team were not able to find the required training needs for these personnel or any procedures that would described training requirements for these personnel.

STP QA staff brought to the attention of the NRC Inspection Team that during the course of three separate STPNOC internal audits, similar deficiencies were discovered concerning the documentation of training. The three internal audits (Audit Nos. U7-A-08-010 to Supply Chain, U7-A-08-004 to Regulatory Affairs and U7-A-08-005 to Engineering) identified a lack of documentation to conclude that the training and or experience was deemed adequate for the job description. There was also an absence of a documented procedure that described the process for a consistent training and indoctrination program for these organizations. In all three audits, STP audits identified that paper qualification and training records were minimal and had not been submitted into STPNOC Units 3 and 4 electronic records storage and retrieval system.

STPNOC opened Units 3 and 4 CTR No. 08-19051 to evaluate this condition. This CTR has been presented to senior management team to determine the corrective actions. On January 7, 2009, STPNOC senior management team met and determined that a standard training process needed to be developed for these organizations. Since STPNOC self-identified this deficiency and opened a CTR to resolve it, the NRC Inspection Team identified this issue as a non-cited violation.

During the review of the quality assurance personnel training, the NRC Inspection Team observed that documentation supporting the lead auditors' qualification and annual re-qualification was provided in the training and qualification file. NRC Inspection Team did not identify any issues in this area.

As of the date of this inspection, STPNOC had started developing procedures for reactor operators and personnel involved with maintenance of plant systems, radiological protection, and engineering duties. This training is based on the institute for Nuclear Power Operations (INPO) accreditation activities and regulatory requirements as stated in 10 CFR 50.120, "Training and qualification of nuclear power plant personnel." The NRC Inspection Team reviewed procedures U7-P-TR01-001, U7-P-TR02-001, U7-P-TR02-002, U7-P-TR02-003, U7-P-TR02-004, and U7-P-TR02-005 and did not identify any issues in this area.

c. Conclusions

The NRC Inspection Team concluded that the training requirements provided by STPNOC are not consistent with the regulatory requirements of Criterion II of Appendix B to 10 CFR Part 50. STPNOC self-identified several examples where the personnel training and qualification process did not include adequate documentation of training and identified a failure to have a procedure for a consistent training and indoctrination program for organizations performing quality related activities. Since STPNOC self-identified the issue, the NRC Inspection Team identified the issue as a non-cited violation and concluded that training had not been adequately identified, documented, and maintained as required by the QA program.

3. Document Control and QA Records

a. Inspection Scope

The NRC Inspection Team reviewed the STP OQAP and implementing policies and procedures that govern the control of documents to verify compliance with the requirements of Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50.

Specifically, the NRC Inspection Team reviewed the following documents:

- STP Document Control Program - Operational Quality Assurance Program (OQAP); Chapter 8, "Control and Issuance of Documents," Revision 6, dated February 1, 1998
- STP Procedure U7-P-AD02-0001, "Units 3 & 4 Procedure Writer's Guide," Revision 1, dated September 15, 2008
- STP Procedure U7-P-AD02-0002, "Units 3 & 4 Procedure Development, Review and Approval," Revision 1, dated September 15, 2008
- STP Procedure U7-P-RM02-0001, "Units 3 & 4 Records Management and Document Control," Revision 0, dated January 13, 2009
- STP Procedure 0PGP07-ZA-002, "STP Document Control," Revision 9, dated October 14,2003
- STP Procedure 0PGP07-ZA-001, "STP Records Management," Revision 10, dated September 06, 2008
- STP Procedure 0PGP07-ZA-0018, "STP Electronic Records Management Program," Revision 1, dated December 19, 2007
- STP Procedure 0PGP07-ZA-0007, "STP Protection of Confidential, Proprietary and Sensitive Security Information," Revision 0, dated November 20, 2008

b. Observations and Findings

b.1 Policies and Procedures for Document Control and QA Records

Chapter 8 of the STP OQAP describes the requirements and the responsibilities for the collection, storage, retrieval, and maintenance of records applicable to those records acquired and developed as a result of or in support of STP design, construction, and operations. The NRC inspection team further verified that any changes made to controlled documents were both appropriately reviewed and approved by the same organization that had reviewed and approved the original documents.

STP Procedure U7-P-AD02-0001 describes the methodology for the preparation of Units 3 & 4 procedures used during COL application, construction, startup, testing and turnover. The procedure provides references to procedures U7-P-AD02-0002 and U7-P-RM02-0001 for further guidance on procedure numbering, development, review and approval. It also provides references to U7-P-AD02-0003 for further guidance on the corrective action and tracking program.

STP Procedure U7-P-AD02-0002 provides guidance and personnel responsibilities for procedure development, review, and approval of Units 3 & 4 procedures used during the phases of COL Application, construction, startup, testing and turnover.

Procedure U7-P-AD02-0001, Section 4.1, “Procedure Numbering” states that each procedure is given a unique number issued from Records Management/Document Control (RMDC) and formatted per Procedure U7-P-AD02-0002. In addition, Procedure U7-P-AD02-0002, Section 4.1 indicates that RMDC will provide the number for new procedures. The NRC Inspection Team found that neither procedure contains guidance on the formatting of procedure numbers.

The NRC Inspection Team found that the RMDC Supervisor has an internal guidance document with a detailed process for numbering format for Units 3 & 4. However, this guidance is not part of a controlled document. The failure of STP to maintain appropriate procedural controls for the formatting of procedure numbers has been identified as Violations 05200012/2009201-02 and 05200013/2009201-02.

STP Procedure U7-P-RM02-0001 describes the requirements for transferring completed records to the RMDC organization. This procedure also describes the requirements for the management of controlled documents for Units 3 & 4. The NRC inspection team noted that the approved procedures U7-P-AD02-0001 and U7-P-AD02-0002 referenced procedure U7-P-RM02-0001. The NRC inspector noted that this procedure had not been issued at that time. The procedure was in the approval phase and was approved on January 13, 2009, during the inspection time frame.

The NRC inspector discussed the issue with the RMDC Supervisor, who indicated that the organization was using procedures 0PGP07-ZA-0002 and 0PGP07-ZA-0018 (Units 1 & 2 procedures) for the document control and records management program during the time that the procedure for Units 3 & 4 was in the development and approval phase. STP Procedure 0PGP07-ZA-0002 describes the requirements and methods for managing controlled documents at Units 1 & 2. STP Units 1 & 2 Procedures 0PGP07-ZA-0001 and 0PGP07-ZA-0018 describe the requirements for the transfer, processing, storage and retrieval of required records. The NRC Inspection Team noted that these documents were not referenced in approved procedures U7-P-AD02-0001 and U7-P-AD02-0002.

This issue has been identified as an example of Notices of Violation 05200012/2009201-01 and 05200013/2009201-01. STPNOC opened CTR No. 09-0902 on January 15, 2009, to evaluate the condition to determine required actions.

Also, the NRC team reviewed QA program record controls to verify that the QA program provides for the preparation of sufficient records to furnish documentary evidence of activities affecting quality. Specifically, the NRC inspection team verified that the QA program provides for the administration, identification, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records and that procedures and policies were developed to adequately implement the requirements for record retention.

b.2 Implementation of Document Control Programs

Based upon the review of controlled documents, the NRC Inspection Team confirmed that the STP QA personnel implemented appropriate controls for creating and storing electronic records. The NRC inspection team noted the extensive use of electronic document control programs. The electronic information system, as a minimum, contained the document type, number, description, retention period, classification, storage media and facility, and the effective and distribution dates for each document in the system. The electronic information system is controlled by the RMDC Management, and RMDC Management personnel are the only individuals who can upload, revise, or make any changes to documents in the system. The

documents in the system are “read-only” documents that can be obtained through the organization’s computer system, and hard copy usage is procedurally held to a minimum.

The NRC inspection team verified that all controlled material was properly identified and that the distribution of such material was appropriately specified. The NRC inspection team reviewed a sample of controlled program documents to confirm proper identification and distribution of the organization’s controlled materials and QA records.

The NRC inspection team identified that the STP electronic document control programs were generally effective in maintaining proper identification, adequacy and completeness of all controlled documents. The implementation of these electronic systems was verified by inspection team member observation of the operation, function, and use of these systems.

c. Conclusions

Except for the examples identified in Violation 05200012/2009201-01 and 05200013/2009201-01 and Violation 05200012/2009201-02 and 05200013/2009201-02, the NRC inspection team concluded that the document control and QA records process requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the team, implemented as required by STP procedures to support quality-related activities for the STP COL application.

4. Corrective Action Program

a. Inspection Scope

The NRC Inspection Team reviewed the STP OQAP and implementing policies and procedures that govern the control of corrective action to verify compliance with the requirements of Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50.

Specifically, the NRC Inspection Team reviewed the following documents:

- South Texas Project Electric Generating Station Operations Quality Assurance Plan (OQAP) Chapter 13, “Control of Conditions Adverse to Quality,” Revision 12, dated February 1, 2008
- STP Units 3 & 4 Procedure U7-P-AD02-0003, “STP Units 3 & 4 Corrective Action and Tracking Program,” Rev. 0, dated November 20, 2008
- STP Electric Generating Station Procedure 0PGP03-ZX-0002, “Condition Reporting Process,” Revision 36, dated August 21, 2008
- STP Units 3 & 4 Procedure U7-P-LI02-0006, “NRC Reporting,” Revision 0, dated January 19, 2009
- STP Units 3 & 4 Procedure U7-P-QP02-0005, “Units 3 & 4 Supplier Evaluation, Oversight, and Inspection,” Revision 2, dated December 31, 2008
- STP Electric Generating Station Procedure 0PQP01-ZA-0004, “Vendor Deficiency Reports” Revision 2, dated November 16, 2006 (applies to all units to include ESP and COLA activities for Units 3 & 4 at STP)
- Condition Tracking Report No. 09-176, dated January 6, 2009

The NRC Inspection Team also reviewed a sample of CTRs associated with STP COL application and quality assurance (QA) program development activities to verify compliance with program requirements and adequate implementation of those requirements.

b. Observations and Findings

b.1 Policies and Procedures for the Corrective Action Program

Chapter 13 of the STP OQAP establishes the high level requirements and responsibilities for the control of conditions adverse to quality and requires personnel to report conditions adverse to quality to appropriate management for resolution in accordance with appropriate procedures. The OQAP also sets forth requirements for procedures to have adequate measures in place to identify conditions adverse to quality and the requirements that these conditions violate, notify responsible management, and resolve, disposition, and document these conditions.

Procedure U7-P-AD02-0003 provides both a Corrective Action and an Action Tracking mechanism used for the identification, control, documentation, classification, and correction of conditions adverse to quality as well as conditions not adverse to quality. The procedure applies to licensing, engineering, procurement, and construction activities conducted prior to the operational phase. The procedure asserts that any employee may identify a condition that requires documented review, evaluation, action for resolution, or action tracking. These conditions may be categorized as conditions adverse to quality (failures, malfunctions, deficiencies, defective items, and nonconformances), significant conditions adverse to quality (a condition, which if uncorrected, could have serious effect on safety or operability), or conditions not adverse to quality and are documented on CTRs.

Procedure U7-P-AD02-0003 requires that every significant condition adverse to quality (SCAQ) have a documented root cause investigation and that the investigation report be reviewed by the Action Tracking Review Group (ATRG). It also requires that at least one corrective action be implemented to address the root cause. It does not specify, however, that the corrective action should be implemented to preclude repetition, as does the OQAP and the corrective action procedure for Units 1 and 2 does (0PGP03-ZX-0002). This failure to provide adequate procedural guidance for corrective actions and to appropriately translate requirements of the QA Program Manual into implementing procedures has been identified as part of Violations 05200012/2009-201-03 and 05200013/2009-201-03.

The STP OQAP requires that procedures be developed for the control of items, services or activities which do not conform to established requirements and that these procedures provide for the notification of responsible management. The NRC Inspection Team found that Procedure U7-P-AD02-0003 did not include any instructions for notification of appropriate levels of management in the event that a SCAQ is identified. This failure to provide adequate procedural guidance for corrective actions and to appropriately translate requirements of the QA Program Manual into implementing procedures has been identified as part of Violations 05200012/2009-201-03 and 05200013/2009-201-03.

Upon NRC identification of these issues, STP Units 3 & 4 QA promptly initiated a CTR (CTR 09-672) to revise the procedure. STP staff also identified that CTR 09-176 had been initiated to revise this procedure on January 6, 2009, although the extent of the revision or planned changes were not referenced in the CTR.

The NRC Inspection Team verified that the STP corrective action procedure provided a link to the STP 10 CFR Part 21 program. Corrective Action Tracking Procedure U7-P-AD02-0003 requires the originator of a CTR to notify STP 3 & 4 Regulatory Affairs if there is potential that the condition has reportability under 10 CFR Part 21. If potential reportability is identified, STP Regulatory Affairs implements STP Units 3 & 4 Procedure U7-P-LI02-0006 to conduct the evaluation for Part 21 applicability and complete any requisite reporting and notifications.

The NRC Inspection Team also verified that STP Units 3 & 4 procedures provided requirements to ensure that corrective action controls extended to subcontractors and suppliers where applicable. STP Units 3 & 4 Procedure U7-P-QP02-0005 directs staff to use STP Station Procedure 0PQP01-ZA-0004 to develop a vendor deficiency report (VDR) when deficiencies are identified by quality personnel during external audits, surveillances, surveys, or other external activities. Procedure U7-P-QP02-0005 includes a detailed evaluation checklist for 10 CFR Part 21/ 10 CFR Part 50.55(e) screening to determine reportability of vendor deficiencies. The procedure also specifies that the status of VDRs should be tracked via a CTR issued into the STPNOC (Units 3 & 4) Corrective Action Tracking Program. The CTR is assigned to an owner who is responsible for tracking the vendor corrective actions, verifying their completion, and closing the CR once the vendor has completed the corrective actions.

b.2 Implementation of the Corrective Action Program

The NRC Inspection Team verified that the STP requirements for corrective action set forth in Procedure U7-P-AD02-0003 were being effectively implemented by reviewing a sample of CTRs issued for STP Units 3 & 4. Prior to implementation of the STP Units 3 & 4 Action Tracking System, Condition Reports were issued under the Units 1 & 2 Tracking System. Of these seven condition reports, six were closed. One remained open. The NRC Inspection Team also reviewed all six CTRs issued in the Action Tracking System. The NRC Inspection Team noted, for the records reviewed, that descriptions of the condition were adequate and each CR included a sufficient description of the condition cause, corrective actions taken, action owner, and the type and level of the condition. The team also noted that after the identification of three issues related to training documentation identified in three separate internal audits, STP recognized a trend and initiated a CTR to address the trend.

The NRC Inspection Team verified that the procedural requirements for documenting supplier deficiencies, as described in STP Procedures U7-P-QP02-0005 and 0PQP01-ZA-0004, were in place by reviewing STP Units 3 & 4 CTRs that were initiated as a result of vendor deficiencies identified in a 2008 audit. The six tracking reports identified an action owner who was responsible for the review of the vendor response and the closeout of the CTR upon satisfactory completion of the corrective actions. The CTRs included copies of the vendor deficiency reports issued to the vendor as well as subsequent correspondence between the vendor and STP Units 3 & 4 to reach a satisfactory resolution. The NRC also reviewed a CTR issued as a result of a supplier-identified inadequacy and found that an owner was identified in the CTR, and the owner reviewed and approved the corrective actions prior to closing out the CTR.

c. Conclusions

Except for the examples identified in Violations 05200012/2009-201-03 and 05200013/2009-201-03, the NRC Inspection Team concluded that the STP Units 3 & 4 corrective action program requirements are generally consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50 and that the STP QA policies and procedures for corrective action were being effectively implemented.

5. Audits

a. Inspection Scope

The NRC Inspection Team reviewed the STP OQAP and implementing policies and procedures that govern the audit process to verify compliance with the requirements of Criterion XVIII, "Audits," 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:

- Chapter 15 of the STP OQAP, "Quality Oversight Activities," Revision 11, dated February 1, 2008
- Procedure U7-P-QP02-0003, "Units 3 & 4 Internal Audits," Revision 1, dated October 6, 2008
- Procedure U7-P-QP02-0001, "Expectations for Quality Activities," Revision 1, dated October 6, 2008
- Condition Tracking Report No. 09-861, dated January 15, 2009
- Condition Tracking Report No. 09-887, dated January 15, 2009

b. Observations and Findings

STP has established an internal audit program under Chapter 15 of the OQAP, as implemented by Procedure U7-P-QP02-0003. The OQAP provides general timeliness requirements for the conduct of audits and identifies requirements for audit team composition and qualifications. Procedure U7-P-QP02-0003 provides guidance for preparing audit plans, making audit notifications, performing audits, reporting conditions, audit closeout, and documentation. The procedure also refers to procedure U7-P-QP02-0001 for guidance on implementation of the internal audit program. Procedure U7-P-QP02-0001 sets forth the expectations for quality activities, including internal audit planning, conduct, pre and post-audit meetings, and condition reporting.

Procedure U7-P-QP02-0003 states that deficiencies identified during internal audits are managed in accordance with the corrective action and tracking program procedure, Procedure U7-P-AD02-0003. Procedure U7-P-AD02-0003 provides guidance for initiating CTRs for deficiencies (conditions adverse to quality or significant conditions adverse to quality).

As of the date of this inspection, STPNOC had completed 4 internal audits that covered the areas of Records Management and Document Control, Supply Chain Management, Regulatory Affairs, and Engineering.

The NRC Inspection Team verified that for each internal audit:

(1) An audit notification letter had been sent to the affected organization at least two weeks prior to the audit start
(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 STP 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 all of the four deficiencies identified during the four internal audits that have been conducted to date were captured in the Action Tracking System (ATS) and were adequately documented. For conditions that were still in the open status, none were past the due date, and for conditions that had been closed, the CTR included a sufficient explanation of the condition and the corrective action.

Procedure U7-P-QP02-0003 states that audit recommendations (conditions not adverse to quality) are "identified" in accordance with the corrective action and tracking program procedure, Procedure U7-P-AD02-0003. Procedure U7-P-AD02-0003 states that actions to resolve conditions not adverse to quality are entered on the actions form and closed by the condition owner. (i.e. the procedure directs the staff to open a CTR.)

Contrary to this guidance, the NRC Inspection Team found that only 17 of the 19 recommendations identified during internal audits were captured in tracking CTRs. Quality Audit Report U7-A-08-004, issued November 25, 2008, with the results of the internal audit of STP Units 3 & 4 Regulatory Affairs (Licensing) identified two recommendations that were not entered into ATS. Additionally, the STP audit staff had no documentation or record of the status of any corrective actions completed or underway to resolve the recommendations. This failure to follow established QA procedures has been identified as part of Violations 05200012/2009-201-04 and 05200013/2009-201-04.

The NRC Inspection Team also noted that Procedure U7-P-QP02-0003 did not clearly state the process for documenting audit recommendations. The only link that identifies the expectation is that Procedure U7-P-QP02-0003 identifies audit recommendations as being conditions not adverse to quality, and Procedure U7-P-AD02-0003 then provides directions for capturing conditions not adverse to quality in ATS. The NRC Inspection Team noted that, overall, the recommendations identified in audits were of a nontrivial nature that warranted followup and documentation in the ATS. This failure to provide adequate procedural guidance for capturing the results of internal audits has been identified as an example of Violations 05200012/2009-201-04 and 05200013/2009-201-04.

Upon NRC identification of these issues, STP initiated two CTRs. CTR 09-861, dated January 15, 2009, was issued to evaluate whether or not STP Licensing personnel had taken actions to address the two audit recommendations that were not included in the ATS or if they had declined the recommendations. CTR 09-887, dated January 15, 2009, was issued to initiate actions within QA to (1) ensure that audit personnel understand the expectations for entering recommendations into ATS when reported in audits and (2) determine if enhancements were needed to Procedure U7-P-QP02-0003.

Chapter 15 of the OQAP states that internal audits shall be conducted by the QA department with a frequency commensurate with their safety significance, past performance, and regulatory requirements and are scheduled at least biennially. Procedure U7-P-QP02-0003 states that internal audits for Units 3 & 4 are performed once per year with a 90 day grace period or once during the life of the activity, whichever is shorter. The procedure states that the manager of quality shall approve the schedule.

The NRC Inspection Team verified that a 2009 audit schedule had been established and that all functional areas currently being performed by STP were included in the schedule with the applicable quality criteria from Appendix B to 10 CFR Part 50. The schedule met the frequency requirements delineated in the STP OQAP and implementing procedures.

c. Conclusions

With the exception of the issues identified in Violations 05200012/2009-201-04 and 05200013/2009-201-04, the NRC Inspection Team concluded that the STP internal audit program requirements were consistent with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. Based on the audit reports reviewed, the NRC Inspection Team also determined that the STP OQAP and implementing procedures were being effectively implemented.

6. Procurement Document Control

a. Inspection Scope

The NRC inspection team reviewed the QA program commitments and the implementation of the controls for procurement of material, equipment and services by STP, its primary contractor, Toshiba, and its contractors and subcontractors (such as Westinghouse, Fluor, Sargent & Lundy) for ABWR COL activities to verify compliance with Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed the STP process governing the control of design engineering services for the various suppliers involved with design activities related to the STP Units 3 & 4 ABWR project. Specifically, the NRC inspection team reviewed purchase orders, work scope EPC technical requirements, contract services requirements, project plans, supplier quality assurance program descriptions, and methods used by the purchasing organizations to qualify suppliers of safety-related items and services. The NRC Inspection Team did not review any records related to procurement of material and equipment during this inspection.

Prior to selecting Toshiba as the "alternate vendor," STP selected GE as its principal contractor to assist with preparing the Units 3 & 4 COLA. GE subcontracted with Bechtel to develop several chapters of the COLA that included site characterization activities. Bechtel supplied personnel, systems, project management, and resources to work on an integrated team with GE and STP. Additionally, contractual relationships were established with several specialized consultants to assist in developing the COLA. This information was described in detail in the NRC Audit Report for the South Texas Project Pre-COL Application Review, issued by the Office of New Reactors on July 26, 2007 (ADAMS: ML 071650376). This inspection did not address any of the previous work activities performer by GE and it subcontractors.

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

- OQAP Chapter 7, "Procurement," Revision 10, dated February 1, 2006
- U7-P-SC02-0007, "Units 3 & 4 Procurement of Material, Equipment and Services," Revision 1, dated October 7, 2008
- U7-P-SC02-0008, "Units 3 & 4 Procurement Document Preparation, review, Control and Administration" Revision 1, dated October 7, 2008

- STP Units 3 & 4 EPC Technical Specification 07-001 Document, dated July 30, 2007
- "Master Engineering, Procurement, and Construction Agreement" (between STP and Toshiba), dated December 11, 2008

b. Observations and Findings

Chapter 7 of the STP OQAP establishes the requirements for procurement of items and services for the STP Electric Generating Station. This chapter applies to the procurement of items and services for use at STP that are subject to the QA program controls. These activities include procurement document control, bid evaluation, vendor evaluation, verification of vendor activities, and receiving inspection.

Procedure U7-P-SC02-0007 identifies the responsibilities and requirements for reviewing, approving and submitting requisitions for procurement of material, equipment, and services for STP Units 3 & 4 COL activities.

Procedure U7-P-SC02-0008 establishes controls for the preparation, review, control, and administration of all purchasing activities for Units 3 & 4. These activities include processing requisitions, evaluating proposals, selecting vendors, preparation and issuance of POs, contracts and revisions, and the final security and control of procurement activities.

Discussion with STP personnel identified that Toshiba Corporation established a US office in Virginia in 2008, Toshiba America Nuclear Energy Corp (TANE), to act as the Agent for purchase orders to Toshiba Japan offices.

b.1 STP Procurement Activities with Toshiba and other COL EPC Contractors

To verify program implementation, the NRC inspection team reviewed procurement documents and contracts STP has placed with EPC contractors such as Toshiba, Bechtel, and Sargent & Lundy (S&L) for COL design and support activities. The NRC Inspection Team also reviewed the STP Units 3 & 4 EPC Technical Specification 07-001 document, which identified the various ABWR plant and system technical requirements.

The latest draft of the "Master Engineering, Procurement, and Construction Agreement" document that STP has placed with Toshiba to supply the design of the ABWR for the STP Units 3 & 4 in accordance with 10 CFR Part 52, Appendix A – Design Certification Rule invokes the specific technical and quality requirements for the project. The document includes many exhibits such as BB-1 "Quality Assurance Program" and the STP Units 3 & 4 EPC Technical Specification 07-001, dated July 30, 2007. Exhibit BB-1, in general, includes references to the specific Quality Assurance Program requirements such as ASME NQA-1-1994, Appendix B to 10 CFR Part 50, and 10 CFR Part 21 and also includes specific areas such as commercial grade dedication.

Toshiba TANE is currently utilizing the following Toshiba organizations for COL design activities in and around Yokohama:

- Isogo Engineering Center (IEC) – design engineering and coordination
- Fuchu - digital I&C control systems

- Keihen Production Operations, Nuclear Energy Equipment Manufacturing Department (NEEMD) - manufacturing activities for fine motion control rod drives and other safety related components

Currently, STP has ongoing contract arrangements with Toshiba, Bechtel, Fluor, and S&L and an expired PO with GENE for its previous work activities related to STP 3 & 4 COLA development. The inspection team reviewed contractual arrangements and /or technical services agreements (TSAs) for the following STP Units 3 & 4 COL EPC contractors:

- Toshiba Corporation, Tokyo, Japan: Commercial Purchase Order (STPNOC Requisition 42531) dated July 16, 2007, from NRG South Texas LP (NRG), Princeton NJ. This commercial PO is specific only to the STP Unit 3, reactor pressure vessel.
- Toshiba Corporation, Tokyo Japan: Purchase Order 90715 dated August 8, 2007. This PO includes the "STPNOC quality and technical requirements procurement document attachment," including areas such as technical requirements, commercial grade dedication requirements, quality requirements, documentation requirements, certification, deviation/nonconformances/noncompliances, 10 CFR Part 21 requirements, identification/tagging, rights of access, stop work authority, surveillance or inspection, and purchasers receipt inspection. STP Units 3 & 4 EPC Technical Specification 07-001 is also referenced.
- Toshiba America Nuclear Energy Corp (TANE), Procurement Document Revision 006, dated December 22, 2008. This TSA covers services and/or materials as itemized in the TSA Attachments and addresses all technical and quality requirements and activities as necessary, including EPC Technical Specification 07-001.
- Bechtel, B03771, Revision 1, dated July 7, 2008. The Quality and Technical Requirements Procurement Document attachment describes additional quality and technical requirements to be implemented in fulfilling the contract beyond the standard boiler plate "Agreement and Contract for Consulting Services," which includes the areas discussed above for the NRG TSA.
- Bechtel, B03658, Revision1, dated January 18, 2008. This TSA has been issued for the Post-COLA support work that began when Bechtel was working for GENE under the previous STP arrangement with GENE.
- Sargent & Lundy, B03490, dated February 19, 2008. This TSA was issued for S&L to act as the previous Owners Engineer when the COL primary contractor was GENE. S&L is now a subcontractor to Fluor through Toshiba.

The NRC inspection team determined that the appropriate level of technical and quality requirements had been invoked through the purchase orders and/or contracts to be consistent with the requirements of Chapter 7.0, "Procurement," of the STP OQAP. This included the applicable regulatory, ASME code and design requirements, including material and component identification requirements, drawings, specifications, standards, inspection and test requirements, special process instructions and handling, preservation, cleaning, storage, packaging and shipping requirements. The NRC Inspection Team verified that appropriate QA commitments to NQA-1-1994, Appendix B to CFR Part 50, and the reporting requirements of 10 CFR Part 21 were included in the Master Agreement and TSAs/contract/purchase order requirements from STP to Toshiba and its subcontractors.

c. Conclusions

The NRC inspection team concluded that the procurement document control process requirements are consistent with the regulatory requirements of Criterion IV of Appendix B to 10 CFR Part 50 and have been appropriately implemented as required by the STP's procedures described above to support STP Units 3 & 4 COL EPC procurement activities.

7. Control of Purchased Material, Equipment, and Services

a. Inspection Scope

The NRC inspection team reviewed the implementation of the STP QA program for the control of purchased material, equipment and services for COL activities related to STP Units 3 & 4. Specifically, the NRC inspection team reviewed the STP policies and procedures governing the process to verify the quality of suppliers providing engineering design services and eventually components for STP COL activities. The NRC audit team also verified that the guidelines provided adequate description of the process and implemented requirements consistent with the requirements of 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:

- OQAP Chapter 7, "Procurement," Revision 10, dated February 1, 2006
- U7-P-SC02-0007, "Units 3 & 4 Procurement of Material, Equipment and Services," Revision 1, dated October 7, 2008
- OPQP01-ZA-0003, "Vendor Overview Activities," Revision 5, dated March 27, 2008
- OPQP01-ZA-0004, "Vendor Deficiency Reports," Revision 2, dated November 16, 2006
- OPQP01-ZA-0008, "Quality Department Evaluation of Vendors," Revision 6, dated March 27, 2008
- OPQP02-ZA-0017, "Vendor Inspection," Revision 4, dated November 16, 2006
- OPQP06-ZA-0003, "Preparation and Control of the Approved Vendors List," Revision 3, dated September 10, 2007

b. Observations and Findings

The NRC inspection team reviewed the STP process and policies governing control of design engineering services and activities for the STP COL, including audits performed by STP of Toshiba and a cursory review of the Toshiba Qualified Vendors List and Toshiba's audits of its subcontractors. These documents govern the implementation of quality activities performed for STP COL design activities by STP, Toshiba, and its subcontractors.

The NRC Inspection Team reviewed the above referenced operating unit procedures that are still used to implement the quality activities related to vendor oversight and qualification. Chapter 7 of the STP OQAP also includes the specific requirements for vendor selection and the quality process used for vendor oversight activities. The NRC Inspection Team reviewed the hierarchy of EPC contractors currently providing support for STP Units 3 & 4 COL activities.

Toshiba

Currently, Toshiba is the Prime Contractor with retained responsibility for design and quality activities. They have responsibility for the qualification and oversight of its subcontractors and suppliers (such as Toshiba Keihen and Toshiba Fuchu, Fluor, IHI, Japan Steel Works, and Westinghouse). Toshiba plans to complete the STP 3 & 4 project with an EPC team comprised of the various Toshiba facilities, Fluor, S&L, and Westinghouse. In addition, Westinghouse will provide engineering and components for selected systems, primarily fuel and safety analyses and I&C systems, and MPR Associates will support Toshiba in the areas of project management assistance, licensing, and technical support in selected areas.

Toshiba Isogo Engineering Center is responsible for basic design activities for the primary containment vessel, balance of the reactor building, control building, and the turbine. They are also responsible for the procurement of the reactor pressure vessel (RPV) and the reinforced concrete containment vessel (RCCV). Finally, various Toshiba locations will be responsible for fabrication activities such as the reactor internal pump and the fine motion control rod drives at Toshiba Keihen and a portion of the digital reactor control system at the Toshiba Fuchu facility.

Bechtel

Bechtel is the current Owners Engineer and is providing COL support. They have been audited by STP and are included on the STP Approved Vendors List.

Fluor

Fluor is identified as the constructor and retains responsibility for the qualification of its subcontractors and suppliers such as S&L and MACTEC. Fluor will also be conducting basic and detailed design of part of the turbine building, services building, intake and discharge structure, balance of plant structures and site layout. Fluor will also be involved with module procurement and fabrication and procurement of components and commodities.

Sargent & Lundy

S&L has responsibility for QA activities in design and procurement document development. S&L will qualify direct vendors or contractors and maintain its quality programs to support its work activities. S&L will be conducting basic design of the radwaste building and the ultimate heat sink with reactor service water tunnels. They will also be responsible for the detailed design of the primary containment vessel (with Toshiba), balance of the reactor building, control building and ultimate heat sink. Finally, it should be noted that S&L was the owners' engineer during the time that GENE was the primary contractor for the STP Units 3 & 4 COL preparation.

b.1 Review of STP EPC Supplier Audit Activities

As part of the implementation review for the above EPC contractors, the NRC Inspection Team reviewed quality records such as the purchase order and contractual requirements, Approved Vendors List information, Audit Plans, Audit Reports, audit checklists, supplier responses to audit findings, and STP Condition Record (CR) forms related to the audit findings and deficiencies. This included the audits that STP has performed at the Toshiba IEC in 2007 and 2008.

The NRC inspection team verified that STP had performed an appropriate level of supplier oversight for the above EPC contractors. STP has been auditing EPC contractors since December 2007 and has been active in providing oversight and guidance to Toshiba as Toshiba continues to implement its oversight of subcontractors for support to STP COL activities. The NRC Inspection Team reviewed several of the audit observations/surveillances that STP has performed with Toshiba such as at Japan Steel Works, IHI Heavy industries, and most recently Toshiba Fuchu in December 2008. Fuchu, which is the final stages of implementing its Appendix B quality program, will be performing commercial grade dedication activities as part of its design of digital I&C systems.

The NRC inspection team verified that STP had performed an appropriate level of supplier oversight for the above suppliers. The NRC inspection team did make a general observation that STP should continue its oversight of Toshiba IEC and the other subcontractors' quality programs as they become more familiar with US quality requirements and begin to implement specific design activities for STP Units 3 &4.

c. Conclusions

The NRC inspection team concluded that the requirements for oversight of suppliers for the STP COL activities are consistent with the regulatory requirements of Criterion VII of Appendix B to 10 CFR Part 50 and have been appropriately implemented as required by the STP procedures described above related to the control of purchased material, equipment, and services. The NRC inspection team plans to verify a sample of EPC contractor QA program implementation activities during future inspections to support the STP Units 3 & 4 COL application.

8. Entrance and Exit Meetings

On January 13, 2009, the NRC Inspection Team presented the inspection scope during an entrance meeting with Kevin Richards, Group Vice President, and other STP personnel. On January 15, 2009, the NRC Inspection Team presented the inspection results during an exit meeting with Joe Shepperd, STPNOC President and CEO; Kevin Richards, Group Vice President; and other STP personnel.

ATTACHMENT 1

1. PERSONS CONTACTED

Tim Walker	Manager, Quality, STPNOC
Marion Smith	Supervisor Quality, STPNOC
Lona I. Smith	Records Management/Document Control Supervisor, STPNOC
Linda Dyer	Records Management/Document Control, STPNOC
Scot Stephens	Licensing Engineer and Corrective Action Program Coordinator, STPNOC
Michael L. Marler	Training Manager, STP Units 3 and 4
Scott Head	Manager, Regulatory Affairs, STPNOC

2. INSPECTION PROCEDURES USED

Inspection Procedure 35017, "Quality Assurance Implementation Inspection," issued July 29, 2008.

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

There were no previous NRC QA Implementation inspections performed at the STP Units 3 & 4 facility near Bay City, Texas, prior to this inspection.

Item Number	Status	Type	Description
05200012/2009-201-01 and 05200013/2009-201-01	Opened	Violation	Criterion II Criterion V Criterion VI
05200012/2009-201-02 and 05200013/2009-201-02	Opened	Violation	Criterion VI
05200012/2009-201-03 and 05200013/2009-201-03	Opened	Violation	Criterion XVI
05200012/2009-201-04 and 05200013/2009-201-04	Opened	Violation	Criterion XVIII

ATTACHMENT 2

STP QA Implementation Inspection
Entrance and Exit Meeting Attendance

List of Attendees: (1) Entrance Meeting January 13, 2009, (2) Exit Meeting on January 15, 2009

(1)	(2)		
X	X	Richard McIntyre	NRC Inspection Team Leader
X	X	Aida Rivera-Varona	NRC Inspection Team
X	X	Sabrina Cleavenger	NRC Inspection Team
X	X	Damaris Arroyo	NRC Inspection Team
X	X	Mike Cash	NRC Office of the Inspector General
X	X	Michael Zeitler	NRC Office of the Inspector General
X	X	Kevin Richards	Group Vice President, STP
X	X	Tim Walker	Manager, Quality, STP
X	X	Marion Smith	Supervisor Quality, STP
X	X	Lona Smith	Records Mgmt/Document Control, STP
X	X	Steve Thomas	Engineering Manager, STP
X	X	W.E. Mookhoek	Licensing Supervisor, STP
X	X	Evan Heacock	Electrical Engineering Supervisor, STP
X	X	Michael Marler	Training Manager, STP
X	X	Dennis Alexander	Procurement Supervisor, STP
X	X	Jim Agles	Licensing, STP
X	X	Preston M. Williams	Quality Assurance, STP
X	X	Joe F. Marek	Quality Assurance, STP
X	X	Kyle Vlasson	Quality Assurance, STP
X	X	Hideki Nishiyama	QA Staff, Toshiba
X	X	Danny Leigh	Fluor Nuclear Supplier Quality Manager
X		Caroline Schlaseman	Project Manager for Alternate Vendor Inspection, Tane
X		Mark McBurnett	VP Oversight & Regulatory Affairs, STP
X		William Jump	Plant General Manager, STP
X		Carl Sayko	General Support Services, STP
X		Tom Oaley	Mechanical Engineering Supervisor, STP
X		Jay Phelps	Operations Manager, STP
	X	Joe Shepperd	President & CEO, STP
	X	Scott Head	Manager, Regulatory Affairs, STP
	X	Ron Ballenger	Contracts Administration Supervisor, STP
	X	S.C. Stephens	Licensing Engineer/CAP Coordinator, STP