August 28, 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 05200012/2009-202 AND 05200013/2009-202

Dear Mr. McBurnett:

On July 13-17, 2009, U.S. Nuclear Regulatory Commission (NRC) inspectors conducted an inspection at Toshiba Corporation's (Toshiba) Isogo Nuclear Engineering Center in Yokohama, Japan. The enclosed report presents the results of this inspection.

The purpose of this inspection was to independently assess the basis upon which South Texas Project Nuclear Operating Company (STPNOC) determined that Toshiba is capable of providing the certified Advance Boiling Water Reactor (ABWR) for STPNOC Units 3 & 4. The inspection team examined Toshiba's compliance with the provisions of Title 10, Part 21 of the *Code of Federal Regulations* (10 CFR Part 21), "Reporting of Defects and Noncompliance," and selected portions of Appendix B to 10 CFR Part 50, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The inspection team also examined Toshiba's design control processes for digital instrumentation and control (I&C) systems and containment analysis and Toshiba's implementation plans for the Initial Test Program. While the NRC did review the implementation of portions of Toshiba's quality assurance (QA) and Part 21 programs, this NRC inspection report does not constitute NRC endorsement of these programs.

Based on the inspection, the NRC independently confirmed STPNOC's due diligence review of Toshiba and concluded that it adequately demonstrated Toshiba's qualification to supply the certified U.S. ABWR for STP Units 3 & 4. However, during the course of the inspection, the inspection team identified 3 findings related to the effective implementation of Toshiba's QA program. Specifically, the findings were identified in the following areas: (1) training records database implementing procedures, (2) timeliness of corrective actions, and (3) adherence to the procedural requirements for the conduct of internal audits. None of these findings affects the capability of Toshiba to provide the certified U.S. ABWR design for STPNOC Units 3 & 4.

The staff requests that STPNOC provide the NRC with the status of Toshiba's corrective actions regarding the three findings identified above.

In accordance with 10 CFR 2.390, "Public Exemptions, Requests for Withholding," the agency will make a copy of this letter, its enclosures, and your response available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide

Documents Access and Management System (ADAMS), accessible 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

Enclosure: Inspection Report Nos. 05200012/2009-202 and 05200013/2009-202

cc: Kiyoshi Iwasawa

Documents Access and Management System (ADAMS), accessible 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
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Docket Nos. 05200012 and 05200013

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cc: Kiyoshi Iwasawa

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

Docket Nos.:	05200012 and 05200013
Report Nos.:	05200012/2009-202 and 05200013/2009-202
Applicant:	South Texas Project Nuclear Operating Company (STPNOC) P.O. Box 289 Wadsworth, TX 774879
Applicant Contact:	Timothy Walker Quality Assurance Manager
Background:	By letter dated September 20, 2007, STPNOC submitted its Combined Operating License application (COLA) for two Advance Boiling Water Reactors (ABWRs) (STPNOC Units 3 & 4) to be constructed adjacent to South Texas Project (STP) Units 1 & 2 near Bay City, Texas. By letter dated August 19, 2008, STPNOC submitted a Due Diligence Report (DDR) that provided the qualification assessment to determine whether Toshiba Corporation (Toshiba) is qualified to supply the design of the ABWRs for STP Units 3 & 4. STPNOC awarded the engineering, procurement, and construction (EPC) contract to 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.
Inspection Dates:	July 13-17, 2009

Inspectors:			
	John A. Nakoski	NRO/DCIP/CQVB	Team Leader
	Belkys Sosa	NRO/DNRL/DDLO	
	Richard P. McIntyre	NRO/DCIP/CQVB	
	Aida Rivera-Varona	NRO/DCIP/CQVB	
	Frank X. Talbot	NRO/DCIP/CQVB	
	Yamir Diaz-Castillo	NRO/DCIP/CQVB	
	Andrzej Drozd	NRO/DSRA/SBCV	
	Dinesh Taneja	NRO/DE/ICE2	
	Jack Y. Zhao	NRO/DE/ICE2	

	/RA/	***8/28/2009***
Approved by:	John A. Nakoski, Chief Quality & Vendor Branch 2 Division of Construction Inspection & Operational Programs Office of New Reactors	Date

ENCLOSURE

EXECUTIVE SUMMARY

STPNOC
05200012/2009-202 and 05200013/2009-202

The purpose of this inspection was to independently assess the basis upon which South Texas Nuclear Operating Company (STPNOC) determined that Toshiba is capable of providing the certified ABWRs for STP Units 3 & 4. This was accomplished by verifying that Toshiba has implemented a quality assurance (QA) program that complies with the requirements of Appendix B to 10 CFR Part 50 of the *Code of Federal Regulations*, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" (Appendix B) and a program for reporting defects and nonconformances consistent with the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance," in a manner that provides reasonable assurance that they are capable of supplying the design of the ABWRs for STPNOC Units 3 & 4. The inspection team also examined Toshiba's design control processes for digital instrumentation and control (I&C) systems and containment analysis and Toshiba's implementation plans for the Initial Test Program (ITP).

The NRC inspection bases were:

- Appendix B
- 10 CFR Part 21

The NRC inspectors implemented Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection" in combination with IP 43002, "Routine Vendor Inspection," and IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance" during the conduct of this inspection.

There were no NRC inspections performed at Toshiba's facility in Yokohama, Japan prior to this inspection.

During the course of the inspection, the inspection team identified 3 findings related to the effective implementation of Toshiba's QA program. Specifically, the findings were identified in the following areas: (1) training records database implementing procedures, as discussed in Section 10 of this report; (2) timeliness of corrective actions, as discussed in Section 9 of this report; and (3) adherence to the procedural requirements for the conduct of internal audits, as discussed in Section 7 of this report. None of these findings affects the capability of Toshiba to provide the certified U.S. ABWR design for STPNOC Units 3 & 4.

The NRC inspectors concluded that Toshiba's QA policies and procedures were in compliance with the applicable requirements of 10 CFR Part 21 and Appendix B, and that Toshiba personnel were implementing these policies and procedures effectively. Furthermore, no issues were identified that raised concerns with STPNOC's demonstration that Toshiba is qualified to provide the certified U.S. ABWRs for STP Units 3 & 4. As such, the NRC has reasonable assurance that Toshiba has the capabilities and technical competence necessary to support STP Units 3 & 4 as the nuclear steam supply system (NSSS) vendor.

REPORT DETAILS

1. Alternate Vendor Qualification

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspectors reviewed ABWR engineering documents, licensing technical reports referenced in the ABWR Design Control Document (DCD) and applicable test data to independently confirm that Toshiba has access to the ABWR engineering documents that form the design basis documents for the certified U.S. ABWR design.

b. Observations and Findings

The NRC inspectors examined Toshiba's internal processes developed to control the ABWR project and the specific use and handling of General Electric's (GE) proprietary information contained in the U.S. ABWR design certification. The proprietary documents necessary to support the ABWR STP COLA are available to Toshiba subject to the restrictions specified in technical cooperation agreements. These agreements specify that Toshiba has a right to use the proprietary information received under the agreements and developed derivative documents. The derivative documents are prepared by Toshiba's engineering design group and are reviewed and approved by Toshiba for use in activities related to the design and licensing of ABWRs in the U.S. The derivative documents contain the necessary technical information to support the ABWR licensing and design activities with appropriate references to the original proprietary documents and they also explain the licensing context for the proprietary material. The derivative documents also include additional technical information developed independently by Toshiba, for example: relevant supporting test data and ABWR specific analytical results derived by using methodologies in the ABWR DCD, as necessary, to support the U.S. ABWR licensing and design efforts.

In general, Toshiba demonstrated a long history of involvement with the ABWR technology as well as access to the documentation necessary to support ABWR design and licensing activities for the STP COLA.

c. Conclusions

Based on the areas reviewed during the inspection, the NRC inspectors were able to independently confirm STPNOC's due diligence review of Toshiba. The NRC inspectors concluded that STPNOC's due diligence review adequately demonstrates that Toshiba is qualified to supply the ABWR certified design, as required by 10 CFR 52.73(a). The results of the alternate vendor qualification inspection provide the staff with reasonable assurance that Toshiba has the capabilities and technical competence necessary to assume the duties normally assigned to the design vendor.

2. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspectors reviewed Toshiba's policies and implementing procedures that govern the 10 CFR Part 21 program to verify compliance with the requirements of 10 CFR Part 21,

"Reporting of Defects and Noncompliances." Specifically, the NRC inspectors reviewed the following procedures established by Toshiba:

- Document Number (DN) 4401-4, Nuclear Energy Quality Assurance Program Description (QAPD), Section 5, "Procurement Document Control," Revision 2, dated June 8, 2009.

- DN 4401-5, Quality Assurance Manual (QAM), Section 5, "Procurement Document Control," Revision 2, dated June 19, 2009.

- Power Systems Company Nuclear Energy (PSNE) Regulations and Procedures, DN 4810, "Reporting Procedure for Defects and Noncompliance under 10CFR21," Revision 2, dated May 20, 2008.

In addition, the NRC inspectors evaluated Toshiba's 10 CFR Part 21 postings for compliance with the requirements of 10 CFR 21.6, "Posting Requirements," and reviewed a sample of Toshiba's purchase orders (POs) to verify compliance with 10 CFR 21.31, "Procurement Documents".

b. Observations and Findings

b.1 Postings

The NRC inspectors evaluated Toshiba's compliance with the posting requirements of 10 CFR 21.6. The NRC inspectors found that Toshiba had posted notices that included a copy of Section 206 of the Energy Reorganization Act of 1974, a description of 10 CFR Part 21 and the procedure that implements the regulation, the location where the 10 CFR Part 21 regulation and implementing procedures may be examined, and a notice that included the telephone number of Toshiba's 10 CFR Part 21 contact: the Senior Manager of the Nuclear Quality Assurance (NQA) Department.

b.2 10 CFR Part 21 Procedure and Implementation

The NRC inspectors discussed Toshiba's 10 CFR Part 21 program with Toshiba's NQA Senior Manager. The NRC inspectors determined that PSNE 4810 contained adequate procedural guidance to initiate Toshiba's 10 CFR Part 21 process when a corrective action request or nonconformance evaluation determined that a reportable defect exists.

In accordance with 10 CFR 21.21, the NRC inspectors requested copies of 10 CFR Part 21 records of evaluations that Toshiba had completed. During discussions with Toshiba staff, the NRC inspectors discovered that Toshiba had not performed a 10 CFR Part 21 evaluation. However, the NRC inspectors verified that Toshiba's staff was knowledgeable about the conditions that would warrant a 10 CFR Part 21 evaluation. The NRC inspectors also determined that Toshiba's 10 CFR Part 21 procedure included all the requirements of Part 21 for evaluating and reporting defects and failures to comply.

b.3 Purchase Orders

The NRC inspectors reviewed a sample of Toshiba's POs and verified that Toshiba had implemented a program consistent with the requirements described in 10 CFR 21.31 regarding specifying the applicability of 10 CFR Part 21 in its POs for basic components.

Subsection 5.1.6 of Toshiba's QAPD and subsection 5.3.6 of Toshiba's QAM requires POs to contain 10 CFR Part 21 requirements as appropriate. Toshiba imposes the requirements of 10 CFR Part 21 on its qualified suppliers having programs meeting the requirements of Appendix B. All reviewed POs contained the above 10 CFR Part 21 provision.

c. Conclusions

The NRC inspectors concluded that Toshiba's program requirements for 10 CFR Part 21 were consistent with the regulatory requirements of 10 CFR Part 21 and were being effectively implemented. The NRC inspectors did not identify any issues in this area.

3. Quality Assurance Program

a. Inspection Scope

The NRC inspectors reviewed Toshiba's QA policies and implementing procedures that govern the QA program to verify compliance with the requirements of Criterion II, "Quality Assurance Program," of Appendix B. Specifically, the NRC inspectors reviewed the following policies and procedures established by Toshiba:

- DN 4401-4, Nuclear Energy QAPD, Section 3, "QA Program," Revision 2, dated June 8, 2009.

- DN 4401-5, QAM, Section 3, "QA Program," Revision 2, dated June 19, 2009.

In addition, the NRC inspectors reviewed the QA program commitments and the implementation process that Toshiba performs for STP Units 3 & 4 activities.

b. Observations and Findings

Toshiba's QAPD is a top level policy document that is applied throughout Toshiba's PSNE to the activities affecting safety-related structures, systems, components and services (SSC&Ss). In certain cases, selected elements of the QAPD are also applied to those SSC&Ss that are not classified as safety-related, but support safe, economic, and reliable facility operations, or where other NRC guidance establishes QA requirements. The QAPD commits to meeting the requirements of the American National Institute Standard/American Society of Mechanical Engineers (ANSI/ASME) NQA-1-1994.

Additionally and in support to the QAPD, PSNE activities affecting quality are prescribed and documented in the PSNE regulations, top level policies, procedures, QA Manuals, (in-house) standards, and instructions within each organizational unit. The QAPD and the PSNE top level policies and procedures are commonly applied to the PSNE major organizational units. These include procedures for personnel proficiency in quality-related activities, review of the QA program, and the reporting of defects and noncompliance under 10 CFR Part 21.

The Quality System of the respective organizational units is documented on quality manuals, (down-stream) procedures, (in-house) standards, and instructions within each organizational unit in a manner that meets the QAPD and PSNE Regulations and Procedures to fit the functions of the particular organization.

Toshiba's QAM defines the QA Program of the Nuclear Energy Systems & Services Division (NED) for supplying SSC&Ss in compliance with the applicable Codes, standards, regulations, the QAPD, and PSNE top level policies and procedures. The Vice President of Power Systems Company and the Technology Executive of Nuclear Energy are responsible for the assessment of the QA Program and its effective implementation. For the purpose of supporting the QA Manual and to document detailed procedures and responsibilities, NED issues and maintains Engineering Standards and Work Guides.

The NRC inspectors confirmed that Toshiba's QAPD and NED QA Manual provide an organizational description, interrelationships, and areas of responsibility and authority for all organizations performing quality-related activities in support of safety-related activities.

c. Conclusions

The NRC inspectors concluded that Toshiba's program requirements for the QA program are consistent with the regulatory requirements of Criterion II of Appendix B. Based on the limited sample of documents reviewed, the NRC inspectors also determined that Toshiba's QAM and associated procedures related to the QA Program were being effectively implemented.

4. Design Control

a. Inspection Scope

The NRC inspectors reviewed Toshiba's QA policies and implementing procedures that govern the design control process to verify compliance with the requirements of Criterion III, "Design Control," of Appendix B. Specifically, the NRC inspectors reviewed the following policies and procedures established by Toshiba:

- DN 4401-4, Nuclear Energy QAPD, Section 4, "Design Control," Revision 2, dated June 8, 2009.
- DN 4401-5, QAM, Section 4, "Design Control," Revision 2, dated June 19, 2009.
- NED Engineering Standard (ES) AS-200A001, "Engineering and Design Procedure," Revision 10, dated July 6, 2009.
- NED ES AS-200A002, "Design Verification Procedure," Revision 5, dated November 11, 2000.
- NED ES AS-200A015, "Design Change Control Procedure," Revision 6, dated November 20, 2000.
- NED ES AS-200A104, "Safety/Quality Group Classification Procedure," Revision 1, dated June 23, 2005.
- PSNE 4610, "Equipment Qualification Program for ABWR," Revision 0, dated July 7, 2009.

In addition, the NRC inspectors reviewed the following Design Change Notices (DCNs) and Change Proposed Notices (CPNs) for STP Units 3 & 4:

- DCN-3E51-2101-0001-00001-1, “Reactor Core Isolation Cooling System Piping & Instrument Diagram (P&ID) Sheet 1/3,” dated March 26, 2008.

- DCN-3E51-2101-0001-00002-1, “Reactor Core Isolation Cooling System Piping & Instrument Diagram (P&ID) Sheet 2/3,” dated March 26, 2008.

- DCN-3E51-2101-0001-00003-1, “Reactor Core Isolation Cooling System Piping & Instrument Diagram (P&ID) Sheet 3/3,” dated March 26, 2008.

- DCN-3C41-2101-2101-00001-1, “Design Change Notice for the Standby Liquid Control System P&ID,” dated December 08, 2008.

- CPN-3C12-2101-0001-01, “Control Rod Drive P&ID, Sheet 1/3,” dated March 13, 2009.

- CPN-3C12-2101-0002-01, “Control Rod Drive P&ID, Sheet 2/3,” dated March 13, 2009.

- CPN-3C12-2101-0003-01, “Control Rod Drive P&ID, Sheet 3/3,” dated March 13, 2009.

- CPN-3C41-2101-0001-01, “Standby Liquid Control P&ID Sheet-1/1,” dated January 19, 2009.

b. Observations and Findings

AS-200A001 contained guidance for design control in the following areas:

- Certification of Design Reports
- Design Planning and Scheduling
- Reviewing and Verifying Design Output Documents
- Approval and Issuance of Design Output Documents
- Identification, Documentation and Approval of Design Input
- Specifying and Documenting Design Descriptions and Analysis
- Validation and Storing Design Output Documents as QA Records

AS-200A002 described the design verification process used at Toshiba. The procedure uses a design verifier to perform the independent review of design descriptions and design output documents. Although the verifier may be from the same organization, the verifier is not the one who performed the original design. The verifier completes the design verification report that identified independent methods for verification.

Toshiba performs design verifications of design documents prior to release of procurement, manufacture, construction or release to other organizations for use in design activities. For non-verified portions of design documents, Toshiba controls these design documents through a verification sheet. In all cases, Toshiba completes design verifications prior to relying upon the structure, systems, and components (SSCs) or computer programs to perform its function. As such, AS-200A002, Step 6.2.1, states that “when changes to previously verified designs have been made, the verifier shall review all related verification follow sheets, review the results of these verifications and date in the confirmation column of the verification follow sheet.”

AS-200A015 described the process for authorizing and controlling changes from previously approved designs. When a design change is necessary due to an incorrect design, the design change and verification controls are completed in accordance with procedure AS-300A008, "Nonconformance Control and Corrective Action." The procedure performs and completes change proposals, evaluates change proposals, and authorizes the change. The design change is documented using the DCN. A preparer documents the design change in the DCN and determines the design change classification as Design Change Class I, II, III or None.

If the design change is classified as Design Change Class I, II or III, then Toshiba completes a design verification report. The design verification report documents changes that must meet ASME and safety related requirements. When a Qualification Test is required, the test shall be identified in the design verification report column. AS-300A008 also requires the reviewer(s) to perform a 10 CFR Part 21 evaluation, when the proposed change is the result of an inadequacy in the original design that could create a substantial safety hazard for safety related activities.

AS-200A104 described three safety classifications (SC-1, SC-2 and SC-3) and one non-nuclear safety classification. These SCs meet the SC guidance for Quality Groups A through D in NRC Regulatory Guide (RG) 1.26, "Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants." The Engineering Organization also determines safety class interfaces (e.g., interface barriers or isolation devices) in accordance with Section 3.3.2, "Safety Class Interfaces," of the American National Standards Institute/American Nuclear Society (ANSI/ANS) 52.1, "Nuclear Safety Criteria for the Design of Stationary Boiling Water Reactor Plants."

The NRC inspectors examined four DCNs and four CPNs related to design changes to the reactor core isolation cooling (RCIC) system, the standby liquid control system (SLC) system and the control rod drive (CRD) system. All changes to these systems were properly displayed through line changes in the piping and instrument diagrams (P&IDs). The NRC inspectors did not identify any errors in these P&IDs. The NRC inspectors requested further information related to chemistry control for impurities entering the CRD system from makeup sources. Toshiba provided further details that chemistry control is not an issue for the CRD system since makeup water is only provided by high quality water from the Condensate Storage Tank.

c. Conclusions

The NRC inspectors concluded that Toshiba's program requirements for design control are consistent with the regulatory requirements of Criterion III of Appendix B. Based on the limited sample of design documentation reviewed, the NRC inspectors also determined that Toshiba's QAM and associated design control procedures were being effectively implemented. The NRC inspectors did not identify any issues in this area.

5. Procurement Document Control

a. Inspection Scope

The NRC inspectors reviewed Toshiba's QA policies and implementing procedures that govern the procurement document control process to verify compliance with the requirements of Criterion IV, "Procurement Document Control," of Appendix B. Specifically, the NRC inspectors reviewed the following policies and procedures established by Toshiba:

- DN 4401-4, Nuclear Energy QAPD, Section 5, "Procurement Document Control," Revision 2, dated June 8, 2009.

- DN 4401-5, QAM, Section 5, "Procurement Document Control," Revision 2, dated June 19, 2009.

- NED ES AS-200A007, "Procedure for Procurement Specification Preparation," Revision 10, dated July 10, 2009.

- NED ES AS-200A008, "Procurement Planning Procedure" Revision 8, dated May 19, 2005.

- NED ES AS-200A016, "Subcontracting Procedure from NED to Other Organizations within Toshiba Corporation," Revision 5, dated June 22, 2006.

- NED ES AS-300A001, "Procedure for Preparation of QA Specification," Revision 10, dated May 19, 2008.

b. Observations and Findings

Chapter 5 of Toshiba's QAPD established measures for the documentation, issuance, and control of procurement documents to assure that applicable regulatory requirements, design basis and other requirements necessary to achieve adequate quality are included or referenced in the procurement documents for materials, equipment, or services. This section included:

- Contents and issuance of procurement documents
- Procurement document review and change

Chapter 5 of Toshiba's QAM described the procedure and responsibility for controlling procurement documents to assure that applicable regulatory requirements, design basis and other requirements necessary to achieve adequate quality are included or referenced in the documents for procurement of materials, equipment and services. This section included:

- Contents of procurement documents, including technical and quality requirements
- Procurement document structure and organizational responsibility
- Procurement document review and change

During the review of Section 5.5 of the QAM, the NRC inspectors identified that the QA specification for Measuring and Test Equipment (M&TE) does not include provisions or guidance for the control of suppliers of calibration services. These provisions are also not included in the QA specifications reviewed for other vendors. Section 5.5 is not clear as to the intent of the use of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) for calibration as described in the QAPD. Refer to Section 7.b of this report for more discussion on this issue.

The NRC inspectors examined the implementation of QA program requirements for the issuance of procurement documents for engineering services and activities for five vendors, including two Toshiba vendors:

- Fluor
- Westinghouse Electric
- Toshiba Fuchu Complex
- Toshiba Keihin Product Operations
- Ishikawajima-Harima Heavy Industries (IHI) Co., Ltd.

The NRC inspectors verified that the contents of the procurement documents included the appropriate technical and quality program requirements as required by AS-200A007 and AS-200A016.

The NRC inspectors examined IHI's documentation package supporting procurement of the STP Units 3 & 4 Reactor Pressure Vessel (RPV) including:

- Procurement purchase order and procurement requisition
- Design Specification U3-RPV-M-SPEC-ASME-001
- QA Specification U-7RPV-Q-SPEC-QA-0001
- Materials and Process Control General Design Document A10-0501-003

The NRC inspectors examined a sample of Fluor's 2008 and 2009 task order packages, including the following documentation:

- Procurement Blanket Contract for services and materials provided by Fluor since there are numerous task orders
- Procurement Technical Specification for I&C engineering work for STP 3 & 4
- Procurement Requisitions
- QA Specification of Engineering and Design Activities other than those for Electrical, Control & Monitoring System components (FLUOR) - AS-STP34-2013
- QA Specification of Engineering and Design Activities (Control & Electrical system Design) (FLUOR) - AS-STP34-2013

The NRC inspectors examined Westinghouse Electric's documentation package supporting procurement of the STP Units 3 & 4 COLA Revision of Control and Electrical System design including:

- Procurement purchase order and Blanket Contract procurement requisition.
- Recent Westinghouse responses to PO requirements
- Procurement Technical Specification for Support of Preparation of a COLA Amendment for STP 3 & 4
- QA Specification of Engineering and Design activities (Control and Electrical System Design)

The NRC inspectors also examined the process and controls used by Toshiba for procurement of material, equipment, and services from other Toshiba companies such as Fuchu and Keihin, as opposed to outside vendors.

AS-200A016 described the process for subcontracting the design, manufacturing of items and services to other organizations within Toshiba using the Job Order Sheet (JOS). The JOS is used to subcontract design, manufacturing of items and services to other organizations within Toshiba. The JOS includes specific information such as ASME code, material, QA, technical,

nonconformance, and corrective action requirements. This process will be used for contracts with the Fuchu and Keihin facilities (digital I&C at Fuchu and components such as fine motion CRDs at Keihin).

The NRC inspectors examined a sample JOS for the Fuchu Nuclear Instrumentation and Control Systems Department (NICSD) because there is currently no JOS in place for STP Units 3 & 4 components. The NRC inspectors examined the JOS for the NRW-Field Programmable Gate Array (FPGA)-Based Reactor Trip Isolation System (RTIS) and Neutron Monitoring System (NMS) Qualification Report that was not specific to STP Units 3 & 4 but for generic qualification projects.

In addition, the NRC inspectors examined the procurement and QA specification for the NRW-FPGA-Based RTIS. The QA specification provides the QA requirements and is used as part of the purchase specification (PS) to document specific project QA requirements. In this PS, the supplier refers to the NICSD who has entered the JOS for the performance of the work covered by the PS. This QA Specification includes references to 10 CFR Part 21, Appendix B, Electric Power Research Institute (EPRI) 5652, "Guidelines for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications," and various NRC Generic Letters. The QA specification is very detailed and includes the applicable Appendix B criteria and a section for M&TE.

c. Conclusions

The NRC inspectors concluded that Toshiba's program requirements for procurement document control are consistent with the regulatory requirements of Criterion IV of Appendix B. Based on the limited sample of documents reviewed, the NRC inspectors also determined that Toshiba's QAM and associated procedures for procurement document control are being effectively implemented. The NRC inspectors did not identify any issues in this area.

6. Document Control

a. Inspection Scope

The NRC inspectors reviewed Toshiba's QA policies and implementing procedures that govern the document control process to verify compliance with the requirements of Criterion VI, "Document Control," of Appendix B. Specifically, the NRC inspectors reviewed the following policies and procedures established by Toshiba:

- DN 4401-4, Nuclear Energy QAPD, Section 7, "Document Control," Revision 2, dated June 8, 2009.
- DN 4401-5, Quality QAM, Section 7, "Document Control," Revision 2, dated June 19, 2009.
- NED ES AS-100A004, "Document Control Procedure," Revision 10, dated May 19, 2008.
- NED ES AS-100A005, "Distribution Control Procedure for Maintenance Control Documents," Revision 10, dated February 20, 2009.

- NED ES AS-100A006, “Procedure for Control of Electronic Media Documents,” Revision 5, dated July 21, 2006.

- NED ES AS-200A010, “Control Procedure of Vendor Generated Documents,” Revision 4, dated May 19, 2008.

- NED ES AS-300A017, “Procedure for Control of QA Manuals,” Revision 7, dated May 19, 2008.

b. Observations and Findings

Chapter 7 of Toshiba’s QAPD provided a general description of Toshiba’s document control program, how the documents are classified, and list the documents to be controlled. In addition to providing the same information as the QAPD, Chapter 7 of the QAM also included the procedures and responsibilities for controlling documents to assure that the correct documents are being used. Toshiba’s document control program classified its documents as Project Control Documents (PCDs) and Maintenance Control Documents (MCDs). PCDs are documents that specify quality requirements or prescribe activities affecting quality, for example:

- Procurement documents
- Nonconformance reports
- Corrective action documents
- Design analysis/calculations
- Project design documents/drawings

MCDs are documents that are not categorized as PCDs but must be controlled in order to meet regulatory requirements, for example:

- QAPD
- QAM
- Qualified vendors list
- Audit schedule/plan
- Training plans/records

AS-100A004 established the responsibilities and defined the measures used to control the preparation, review, revision, release, issuance, and disposition of PCDs. This procedure also established the measures to control Topical Reports, which are submitted to the NRC for review and approval. The procedure contained a table that described which documents are to be categorized as PCDs and defined responsibilities for the preparation, review, and approval of the PCDs. The procedure stated that the project engineer (PE) of each Project Organization (Pj) is responsible for activities related to the management of PCDs, such as the preparation of the Project Control Document List (PCDL) and the Submittal Document List (SDL). The Manager of each Engineering/Design Organization (EDO) is responsible for designating a person for the preparation of PCDs based on the registered information in the PCDL. Any changes to the PCDL and SDL shall be made by the Pj, while changes to the PCDs shall be made by the person that developed the PCD.

Each PCD must have a coversheet that includes the document/drawing number, revision number, title, date of issue, job number (if applicable), and signature/stamp with the date that it

was prepared, reviewed and approved. In addition, PCDs shall be identified, stamped, marked or printed as follows, if applicable:

- Controlled copy
- US Safety-related
- Indoctrination or training
- Identification of job number
- Proprietary classification (Class 1, 2 or 3)

AS-100A005 identified the documents to be controlled as MCDs and the responsibilities for the preparation, review, approval, and issuance of these documents. Controlled documents are identified in the Maintenance Control Document List (MCDL). The procedure contained a table that described which documents are to be categorized as MCDs and defined responsibilities for the preparation, review, approval, and issuance of MCDs. Similar to the PCDs, MCDs are identified, stamped, marked or printed as necessary. MCDs are developed in accordance with the applicable procedure described in this standard.

AS-100A006 described the control of Electronic Media Documents (EMDs) classified as PCDs or MCDs. These documents are controlled using the NUPDM System, whose functions include:

- Preparation, review and approval of documents
- Distribution including “read” function at computer terminals for the designated person
- Storage of documents

EMDs are stored with a unique index number called the Document Filing Number to ensure that documents are retrievable and identifiable. An Authorization List of all responsible groups is prepared so that document review and approval can be performed by authorized personnel only. During the process of review, verification and approval; a set of EMDs is used as a circulation unit, and a personnel list is used for forwarding the unit. The personnel list consists of the reviewer, verifier and the approver of the EMDs. When the EMDs are submitted, they are automatically forwarded by the system to the people in the personnel list, and the system will ensure that every review, verification and approval is completed by the designated personnel only. An electronic signature with date can be used for evidence of completion of these actions. All document changes are reviewed and approved by the same group that performed the original review and approval. The NRC inspectors witnessed the use of the NUPDM System by Toshiba’s QA staff and verified that EMDs are controlled in accordance with the procedure.

AS-200A010 described the methods of receiving, reviewing, approving, and returning vendor generated documents. AS-300A017 defined the responsibilities and control methods used for the preparation, distribution, revision, and retention of the following Toshiba QAM:

- ASME QA Manual for ASME Code works
- QA Manual for safety-related items and services in accordance with Appendix B

Both of these manuals are classified as “Controlled” or “Uncontrolled” depending on its use under the responsibility of the QA Manager. “Controlled” copies are distributed within and outside of the NED and are assigned serial numbers for identification. “Uncontrolled” copies are distributed as necessary without serial numbers. Both types of copies are identified on the cover page as “Controlled” or “Uncontrolled.” Both manuals and its revisions are distributed using a QAM Transmittal Slip. Toshiba maintains records of all QAMs and its distributed

revisions by using the QAM Distribution Record form. The NRC inspectors examined a sample of "Controlled" and "Uncontrolled" copies of both manuals and confirmed that they are controlled in accordance with the procedure.

The NRC inspectors examined a sample of PCDs and MCDs and verified that the preparation, review, approval, and issuance of these documents were performed in accordance with the procedure. In addition, the NRC inspectors confirmed that the sampled PCDs and MCDs contained the required identification, stamps, and markings as necessary. Through discussions with the QA Manager and his staff, the NRC inspectors verified that Toshiba's personnel were knowledgeable of the document control process and the associated procedural requirements.

c. Conclusions

The NRC inspectors concluded that Toshiba's program requirements for document control are consistent with the regulatory requirements of Criterion VI of Appendix B. Based on the limited sample of documents reviewed, the NRC inspectors also determined that Toshiba's QAM and associated document control procedures were being effectively implemented. The NRC inspectors did not identify any findings in this area.

7. Control of Purchased Material, Equipment and Services

a. Inspection Scope

The NRC inspectors reviewed Toshiba's QA policies and implementing procedures that govern the control of purchased material, equipment, and services to verify compliance with the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B. Specifically, the NRC inspectors reviewed the following policies and procedures established by Toshiba:

- DN 4401-4, Nuclear Energy QAPD, Section 8, "Control of Purchased Material, Equipment and Services," Revision 2, dated June 8, 2009.
- DN 4401-5, QAM, Section 8, "Control of Purchased Material, Equipment and Services," Revision 12, dated February 20, 2009.
- NED ES AS-300A002, "Procedure for Evaluation of Vendors," Revision 10, dated May 19, 2008.
- NED ES AS-300A012, "Internal Audit Procedure," Revision 11, dated February 20, 2009.
- NICSD NQ-3005, "Procedure for Evaluation of Suppliers," Revision 2, dated April 19, 2009.
- NICSD NQ-3017, "Measuring and Test Equipment Control Standard," Revision 2, dated January 19, 2009.

b. Observations and Findings

Chapter 8 of Toshiba's QAPD described the measures to assure that purchased material, equipment, and services, whether purchased directly or through vendors, conform to the procurement documents. These measures include provisions for (1) source evaluation and selection, (2) objective evidence of quality furnished by the vendor, (3) audit or inspection at the vendor source, and (4) examination or review of the materials, equipment, or services upon delivery or completion. This section includes:

- Procurement planning
- Source evaluation
- Maintenance of qualified vendors list
- Bid evaluation and vendor selection
- Vendor performance evaluation
- Control of vendor generated documents
- Acceptance methods for purchased material, equipment, and services
- Control of vendor nonconformances
- Commercial grade dedication program verification

Chapter 8 of Toshiba's QAM described the procedures and responsibilities for procurement of items and services. The Group Manager (GM) in the Sourcing Department is assigned responsibility for the procurement of material, equipment and services except for cases when materials, equipment and services are subcontracted to IHI Corporation and Toshiba Plant Systems & Services Corporation (TPSC), in which case the GM in the Plant Business Management Department (PBMD) is responsible for the procurement source selection, bid evaluation, and award.

The GM in the applicable EDO and the project QA are responsible for procurement activities except for the procurement source selection, bid evaluation and award. When design and manufacturing of equipment and services are subcontracted to other organizations within Toshiba, the GM of the applicable EDO is responsible for issuing the JOS in accordance with AS-200A016.

Section 8 of the QAM includes:

- Procurement planning
- Source evaluation
- Maintenance of a qualified vendors list
- Bid evaluation and vendor selection
- Vendor performance evaluation
- Control of vendor generated documents
- Acceptance methods for purchased material, equipment, and services such as product quality certificate, source verification, receiving inspection, and post installation testing
- Control of vendor nonconformances
- Commercial grade dedication program verification

The NRC inspectors examined the NED 2009 survey/audit schedule and the most recent Qualified Vendors Lists (QVL) for NED and NICSD and confirmed that both were up to date and included the audit schedule for selected vendors (IHI, Westinghouse, Fluor, Keihin and Fuchu)

for 2009. All the scheduled audits for 2009 had either been completed or were scheduled to be completed.

During the inspection at the Fuchu NICSD facility, the NRC inspectors inquired about how NCISD qualified its commercial suppliers of calibration services. Toshiba advised that these suppliers were qualified based only on a review of documentation received from the suppliers. The NRC inspectors examined the QAPD, QAM, AS-300A002, and NICSD NQ-3005 to determine if guidance existed for these activities and whether it was included in the appropriate documents. The NRC inspectors identified that Section 6 of AS-300A002, and Section 11 of NICSD NQ-3005 did not include guidance relative to the evaluation of commercial calibration service vendors based on the NRC provisions for use of the ILAC MRA certification as explained in the Arizona Public Service (APS) Safety Evaluation Report (SER), dated September 28, 2005.

AS-300A002 did not include all of the appropriate exceptions documented in the APS SER for use of such commercial calibration laboratories. Furthermore, it did not include any information relative to the applicability to only using these provisions as related to domestic U.S. calibration laboratories certified by the five domestic U.S. Accrediting Bodies (ABs) recognized by the NRC. NICSD NQ-3005 did include all of the exceptions documented in the APS SER.

NED and NISCD personnel indicated that STP had previously identified this process weakness to Toshiba during a June 20, 2009, video conference call, and that Toshiba began processing a Corrective Action Request (CAR) to require Toshiba and its safety-related Appendix B suppliers such as IHI, Keihin, and Fuchu, to perform audits/surveys of these calibration suppliers if they have not been certified by any of the U.S. ABs. The NRC inspectors advised Toshiba that it would also be required to include the level of detail that is already included in NQ-3017, Section 6.2 relative to procurement control of calibration work, in both AS-300A002, Section 6, and NICSD NQ-3005, Section 11, and most importantly into the QAPD/QAM.

The NRC inspectors examined CARs 09-129, 130, 131, dated July 15, 2009, with proposed corrective actions for Toshiba to revise its QAPD/QAM and implementing procedures for addressing IHI, Keihin, and Fuchu and concluded this was responsive to NRC and STP concerns.

The NRC inspectors examined the Internal Audit report No. 08SR-034, Revision 0, dated March 6, 2009 of Fuchu. This was a four person audit that was observed by STP. This audit was documented as being an internal audit since it was performed at another Toshiba organization contracted through a JOS and not as a PO that would be the case with external suppliers.

AS-300A012, section 4.2 includes requirements to utilize a checklist written specific to the performance of internal audits of Toshiba QA program requirements. However, since the audit of Fuchu was intended to review the implementation of its newly implemented Appendix B QA program, the audit used the checklist for the Evaluation of Vendors, which is used for performing external audits (referenced and attached in AS-300A012). Toshiba presented the NRC inspectors with CAR No. 09-136 dated July 16, 2009, that revised AS-300A012 to allow for other checklists that are appropriate depending on the type of audit.

c. Conclusions

Except for the finding related to using an external audit checklist for performing internal audits, the NRC inspectors concluded that Toshiba's program requirements for the control of

purchased material, equipment and services are consistent with the regulatory requirements of Criterion VII of Appendix B. Based on the limited sample of documents reviewed, the NRC inspectors also determined that Toshiba's QAM and associated procedures for the control of purchased material, equipment and services were being effectively implemented.

8. Nonconforming Materials, Parts, or Components

a. Inspection Scope

The NRC inspectors reviewed Toshiba's QA policies and implementing procedures that govern the nonconforming materials, parts or components to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts or Components," of Appendix B. Specifically, the NRC inspectors reviewed the following policies and procedures established by Toshiba:

- DN 4401-4, Nuclear Energy QAPD, Section 16, "Nonconforming Materials, Parts or Components," Revision 2, dated June 8, 2009.
- DN 4401-5, QAM, Section 16, "Nonconforming Materials, Parts or Components," Revision 2, dated June 19, 2009.
- NED ES AS-300A006, "Control Procedure for Procured Items and Services," Revision 5, dated May 19, 2008.
- NED ES AS-300A008, "Nonconformance Control and Corrective Action Procedure," Revision 12, dated February 20, 2009.
- PSNE Regulations and Procedures, DN 4810, "Reporting Procedure for Defects and Noncompliance under 10CFR21," Revision 2, dated May 20, 2008.

In addition, the NRC inspectors reviewed Nonconformance Notice Reports (NNRs) initiated during the last two years.

b. Observations and Findings

Section 15.0 of Toshiba's QAPD defined the measures for controlling items that do not conform to specified requirements in order to prevent their inadvertent use or installation. Toshiba's nonconformance program is a closed-loop system that starts with the identification and documentation of the nonconformance and continues through the verification of actions that are to be taken to further investigate and then identify the root cause of the nonconformance.

AS-300A006 described the responsibilities and measures for controlling items and services that do not meet the requirements of procurement documents issued to NED or documents approved by NED.

AS-300A008 included provisions for addressing (1) nonconforming items manufactured by Toshiba Shop Organizations such as the Nuclear Energy Equipment Manufacturing Department (NEEMD) using inadequate NED specifications, or (2) nonconforming documents such as specifications, instructions and drawings, and data used by NED.

Both procedures included provisions for evaluating significant conditions adverse to quality and nonconformances reported from vendors to determine whether these conditions are reportable in accordance with 10 CFR Part 21 DN 4810, "Reporting Procedure for Defects and Noncompliance under USNRC 10CR21."

AS-300A008 stated that a person who identifies a nonconformance must notify the QA staff and/or project QA. The QA staff or project QA will determine if the nonconformance should be disposition using AS-300A006 or AS-300A008. If disposition is made by using AS-300A008, the senior manager (SM) of the NED QA Department (NQAD) assigns a QA staff for matters concerning the QA program or a project QA for matters concerning the project activities to prepare the NNR Phase I (NNR-1). If there is a condition adverse to quality identified in an NNR-1 that requires corrective action (e.g., condition that has negative impact on health and safety of the public or environment, a condition that has a negative impact on reliability, availability, or maintainability or the equipment of facility), the root cause and the impact of those conditions on completed and/or related items must be determined, evaluated, and documented in NNR Phase II (NNR-II).

During the review of NNRs, the NRC inspectors noted that for five NNR-1s (NNR-08-001-I, NNR-08-002-I, NNR-08-003-I, NNR-09-001-I, NNR-09-002-I): (1) the nonconformances were identified and adequate dispositions were taken in accordance with Toshiba's approved procedures; (2) appropriate technical justifications were presented for each disposition; and, (3) adequate actions were taken by Toshiba in regard to the nonconforming condition. The NRC inspectors also noted that the NNR-1s contained the appropriate review and disposition by Toshiba personnel.

The NRC inspectors also examined three NNR-IIs that Toshiba determined to be significant conditions adverse to quality. The NRC inspectors found that actions taken by Toshiba were fully appropriate in addressing these NNR-IIs, including the determination of whether these conditions were reportable in accordance with 10 CFR Part 21.

c. Conclusions

The NRC inspectors concluded that Toshiba's program requirements for the control of nonconforming materials, parts or components are consistent with the regulatory requirements of Criterion XV of Appendix B. Based on the limited sample of documents reviewed, the NRC inspectors also determined that Toshiba's QAM and associated procedures for the control of nonconforming materials; parts or components were being effectively implemented. The NRC inspectors did not identify any findings in this area.

9. Corrective Action

a. Inspection Scope

The NRC inspectors reviewed Toshiba's QA policies and implementing procedures that govern the corrective action process to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B. Specifically, the NRC inspectors reviewed the following policies and procedures established by Toshiba:

- DN 4401-4, Nuclear Energy QAPD, Section 17, "Corrective Action," Revision 2, dated June 8, 2009.

- DN 4401-5, QAM, Section 17, "Corrective Action," Revision 2, dated June 19, 2009.

- NED ES AS-300A009, "Corrective Action Request Application Procedure," Revision 10, dated February 20, 2009.

In addition, the NRC inspectors also reviewed a sample of CARs initiated in 2008 and 2009, as well as the CAR log. These CARs were primarily the result of deficiencies identified by Toshiba's customers and by Toshiba's external audit findings.

b. Observations and Findings

Section 16.0 of Toshiba's QAPD defined the measures for generating, tracking, and closing CARs. Toshiba's corrective action program is a system that provides measures to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective materials and equipment, and nonconformances are promptly identified and corrected. Toshiba's NQAD, as the key QA organization, is responsible to issue CARs in response to an identified problem from a variety of sources such as vendor's nonconformance report, external audit reports, internal audit reports and other information, such as adverse trends.

AS-300A009 described the responsibilities and measures for establishing that the conditions adverse to quality are promptly identified, documented, and corrected as soon as practical. AS-300A009 describes the responsibilities and measures for identifying, documenting the cause, the corrective action taken to preclude recurrence and follow-up actions taken to verify implementation of the corrective action. The procedure also provided guidance for reporting to appropriate level of management. It indicated that it is the overall responsibility of the SM of NQAD to assure that corrective actions are taken to correct conditions adverse to quality and to prevent recurrence. Moreover, the overall responsibility includes monitoring corrective action processes through the attendance at a regular Corrective Action Review Board, and providing additional management attention where needed.

The NRC inspectors examined the log for CARs generated between January 1, 2008, and July 12, 2009, as well as CARs generated as a result of activities associated with U.S. safety-related projects. The NRC inspector found that actions taken by Toshiba were fully appropriate for these CARs, including determining whether these conditions were reportable in accordance with 10 CFR Part 21. Although the NRC inspectors noted that there are no expectations for the timeliness implementation of the corrective action program within AS-300A009, they identified many instances where corrective action reports were closed after the due dates.

The NRC inspectors examined the corrective actions trending report QPR-09-02 and noted that one of the seven recommendations of this report included senior management awareness to accelerate the closure of 29 CARs that were already late at the time. The NRC inspectors discussed the issue with Toshiba QA personnel who explained that this recommendation was not tracked in a CAR.

Based on the discussions on this issue and questions raised by the NRC inspectors, Toshiba performed a trend analysis during the time of the inspection on the timeliness of the corrective actions. This trend analysis divided the causes for the late closure of these corrective actions into six different categories. The Toshiba QA manager met with the NRC inspectors and explained that as a result of the trend analysis, Toshiba will be revising procedure AS-300A008 to establish guidance to determine due dates for completion of CARs and the control of extensions of completion dates. Toshiba initiated CAR No. 09-135 to address this finding.

c. Conclusions

Except for the finding related to the timeliness of corrective actions, the NRC inspectors concluded that Toshiba's program requirements for corrective actions are consistent with the regulatory requirements of Criterion XVI of Appendix B. Based on the limited sample of documents reviewed, the NRC inspectors also determined that Toshiba's QAM and associated corrective action procedures were being effectively implemented.

10. Training and Qualification

a. Inspection Scope

The NRC inspectors reviewed Toshiba's QA policies and implementing procedures that govern the control of training and qualification of personnel performing activities affecting quality to verify compliance with the requirements of Criterion II, "Quality Assurance Program," of Appendix B. Specifically, the NRC inspectors reviewed the following policies and procedures established by Toshiba:

- DN 4401-4, Nuclear Energy QAPD, Section 3, "QA Program," Revision 2, dated June 8, 2009.
- DN 4401-5, QAM, Section 3, "QA Program," Revision 2, dated June 19, 2009.
- PSNE Regulations and Procedures, DN 3830, "Personnel Proficiency in Quality-Related Activities," Revision 4, dated July 7, 2009.
- NED ES AS-100A008, "Procedure for Indoctrination and Training," Revision 12, dated July 6, 2009.
- NED ES AS-300A013, "Auditor Qualification Procedure," Revision 8, dated November 6, 2008.
- NED ES AS-300A015, "Qualification Procedure of Test Personnel and Witness Inspector for Mechanical Items and Services," Revision 6, dated November 6, 2008.
- NED ES AS-300A102, "Qualification Procedure of Test Personnel and Witness Inspector for Instrumentation and Electrical Items and Services," Revision 2, dated November 6, 2008.

b. Observations and Findings

Section 3.4 of Toshiba's QAPD provided a general description of Toshiba's requirements for the indoctrination, training and qualification of personnel performing activities affecting quality. Section 3.4 of Toshiba's QAM included the procedures used for the indoctrination and training of personnel.

PSNE DN 3830 outlined the indoctrination and training program for personnel affecting quality, including safety-related activities. Specific indoctrination and training programs are developed in accordance with the scope, complexity and nature of each major organizational unit (MOU)

within Toshiba. There are four MOUs: (1) NED, (2) Shop Organization, (3) Regional Organization, and (4) Site Organizations for particular site construction and/or field services. Toshiba's indoctrination and training program is also divided into two parts: common and specific subjects.

Common subjects are regulatory requirements, Codes, and Quality Systems Documents that are considered to be the top level QA documents for U.S. safety-related activities. The QA organization is responsible for providing training on these QA documents for all personnel. In addition, the Vice President and the Technology Executives are also trained on these topics. Examples of common subjects are:

- 10 CFR Part 21
- 10 CFR Part 50.34(a)(7)
- 10 CFR Part 50.55a
- 10 CFR Part 50.55(e)
- 10 CFR Part 50 Appendix A
- 10 CFR Part 50 Appendix B
- NRC Regulatory Guides 1.26, 1.28 and 1.29
- Applicable edition/addenda of ASME NQA-1
- Quality Systems Documents

Specific subjects depend on the nature of activities performed by the MOU and may include inspection, testing, special processes, audit and design activities. The procedure also stated that all personnel shall have an indoctrination/training plan and that any training activities shall be conducted in accordance with the employee's indoctrination/training plan.

AS-100A008 described the process for indoctrination and training for NED personnel. This procedure identified the different types of courses for indoctrination and training of personnel as follows:

- Codes and Standards
- QA Program
- Lead Auditor/Auditor
- Inspection and Test Personnel and Witness Inspector
- Project Specific

Toshiba's indoctrination and training may be in the form of lecture, document circulation or self-study. For each type of training, its implementation and satisfactorily completion is documented in the applicable form with the date and stamp of the instructor for lecture type training and the date and stamp of the manager responsible for indoctrination and training (MRIT) for document circulation or self-study type training. The MRIT establishes an indoctrination and training plan for each employee on an annual basis and it is recorded in the "Personnel Indoctrination, Training Plan and Evaluation Record." Once the employee has completed the training specified in their plan, then he or she is registered on the "Personnel List for Performing Safety-Related and/or ASME Code Work."

AS-300A013 established the requirements for qualification of Lead Auditors and Auditors who conduct internal and external audits.

AS-300A015 established the methods for qualification of test personnel for the pressure test of the ASME Code Items and the witness inspector of procured mechanical items and services.

NED ES AS-300A102 established the methods for qualification of test personnel and witness inspector for instrumentation and electrical items and services.

The NRC inspectors examined indoctrination, training and qualification records for a sample of lead auditors, auditors, senior management and the following personnel: QA, testing, and witness inspectors. The NRC inspectors verified that all personnel performing activities affecting quality had completed the required training and met all the specified requirements in accordance with the applicable procedural requirements. During the review of the training records, the NRC inspectors were informed by Toshiba personnel that beginning from the current fiscal year, indoctrination and training plans and records were going to be tracked and stored using an electronic database called Indoctrination and Training Management System (ITMS). The NRC inspectors inquired about the procedure used for managing the ITMS database and whether the use of the database was captured in AS-100A008. Toshiba's QA staff stated that no procedure exists for the use of the database. Although no procedure exists for the use of the database, through discussions with Toshiba's QA staff and a demonstration on how the database works, the NRC inspectors were able to confirm that Toshiba's QA staff was knowledgeable regarding the use of the database. Toshiba initiated CAR No. 09-132 to address the lack of procedural guidance on the use of ITMS.

c. Conclusions

Except for the finding related to not having implementing procedures for the new training database, the NRC inspectors concluded that Toshiba's program requirements for training and qualification of personnel performing activities affecting quality are consistent with the regulatory requirements of Criterion II of Appendix B. Based on the limited sample of training and qualification records reviewed, the NRC inspectors also determined that Toshiba's QAM and associated training and qualification procedures were being effectively implemented.

11. Initial Plant Test Program

a. Inspection Scope

The NRC inspectors reviewed Toshiba's QA policies and implementing procedures that govern the process used to develop and implement the STP Units 3 & 4 initial plant test program (ITP). Specifically, the NRC inspectors reviewed the following policies and procedures:

- U7-P-SU01-0001, "STP Units 3 & 4 Startup Administrative Manual," Revision 1, dated February 12, 2009.

- U7-P-SU02-0004, "STP Units 3 & 4 Inspections, Tests, and Acceptance Criteria (ITAAC) Closure Process", Revision 1, dated June 9, 2009.

- ABR-AE-07000004, "STP Units 3 & 4 Quality Assurance Program Description," Revision 1, dated September 10, 2007.

- Toshiba Project Document Number (TPDN) 7A-90-0301-0001, STPNOC Units 3 & 4, "COLA Change Procedure," Revision 0, dated March 26, 2008.

- TPDN 7A-95-0301-0001, STPNOC Units 3 & 4, "ITAAC Implementation Procedure," Revision A, dated April 1, 2009.

- TPDN 7A-95-0301-0002, STPNOC Units 3 & 4, "General ITAAC Closure Procedure," Revision A, dated April 1, 2009.

- NED RS-5128570, "COLA Change Validation Package Departure Number STD DEP 14.2-1," Revision 0, dated June 11, 2008.

b. Observations and Findings

b.1 STP Units 3 & 4 ITP

The NRC inspectors discussed Toshiba's development plans for conducting the STP Units 3 & 4 ITP. Toshiba provided the inspectors with an overview of the following topics:

- ITP Organization, Schedule, and Guidelines
- Past ITP Operating Experience from Japanese ABWR Plants
- ITP First-Of-A-Kind (FOAK) Tests
- Startup Test Analysis Plans
- Test Engineer Training and Qualification Plans
- Development of:
    - ITP Plan
    - Licensing Documents and Design Specifications
    - ITP Test Requirements and Acceptance Criteria
    - Test Instructions, Procedures and Reports

The ITP Guidelines included the following programs and procedures:

- Management of the Test Program
- Conduct of the Test Program
- Lock Out/Tag Out (LOTO) Program
- Corrective Action Program
- System Turn Over Procedure
- Plant Operation Supports Program

Toshiba also presented details regarding past Japan ABWRs ITP experience. As part of this experience, Toshiba incorporated the following into the STP Units 3 & 4 ITP:

- ITP Best Practices
- Problem Identification/Nonconformance/Corrective Action
- Lessons Learned Program/ Database
- Design Effort (Design Verification/DCN), Test Planning and Effort

In the area of FOAK tests, the NRC inspectors inquired about why STPNOC, Fluor, and Toshiba identified the Combustion Turbine Generator (CTG) system preoperational test as a FOAK test. The NRC inspectors noted that a number of U.S. Boiling Water Reactors (BWRs) use CTG to meet the Station Blackout (SBO) rule (10 CFR 5.63), and therefore did not consider the CTG preoperational test to be a FOAK test. Toshiba stated that the Japanese plants use offsite power sources rather than an onsite CTG to meet the SBO rule requirements. The supplier of the CTG, Fluor, stated that it would gather more information regarding unique design features related to the CTG system test to verify if this justified its identification as a FOAK test. After further discussions with STPNOC and Fluor, they were not able to confirm the reason for identifying the CTG test as a FOAK test. However, the STPNOC stated that for conservative reasons, they preferred identifying the CTG preoperational test as a FOAK test.

b.2 Change Control Process for Departures

The NRC inspectors reviewed the basis for standard Tier 2 departure 14.2-1 (STD DEP 14.2-1) as documented in TPDN 7A-90-0301-0001. STD DEP 14.2-1 eliminated the requirement for performing CRD System Performance friction testing at rated pressure as described in Section 14.2.12.2.5 of the ABWR DCD because of new position monitoring instrumentation for the control rods. The new positioning method uses an electric motor as compared to the old method of using hydraulic pressure. STP Units 3 & 4 Final Safety Analysis Report (FSAR) states that a continuous monitoring system will detect the presence of friction in the drive mechanism. During the STP COLA review of Tier 2 departure STD DEP 14.2-1, the staff questioned whether elimination of the CRD friction test requirement at full pressure may:

- Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a SSC important to safety previously evaluated in the plant specific DCD, or

- Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD.

If either of the condition were met, STD DEP 14.2-1 would require prior NRC approval in accordance with the change control process described in 10 CFR Part 52, Appendix A, Sections VIII.B.5.b, Criterion 2 and 4. The NRC inspectors requested STPNOC and Toshiba to provide further details on the evaluation used to determine if departure STD DEP 14.2-1 required prior NRC approval. In response to this request, STPNOC and Toshiba directed the NRC inspectors to NED RS-5128570 that indicated friction testing on four selected CRDs at rated pressure and temperature conditions during initial heat up of the startup test program was deleted. Friction testing at cold conditions is only required for the Fine Motion Control Rod Drive (FMCRD). CRD friction testing is a traditional requirement performed for older BWR designs with CRD positioned using hydraulic pressure.

The ABWR design feature includes normal rod positioning using an electric motor. Friction in an ABWR CRD will result in blade separation from the ball-nut that would be detected by permanently installed instrumentation (i.e., Separation Indicator Probe (SIP)) which is a special feature of the FMCRD described in the ABWR DCD. STPNOC evaluated STD DEP 14.2-1 against the 10 criteria in 10 CFR Part 52, Appendix A, Sections VIII.B.5.b and VIII.B.5.c. The NRC inspectors also examined the STPNOC's evaluation and found CRD normal rod positioning is performed by an electric step motor driving a ball-nut and rotating ball-screw instead of hydraulics used in earlier BWRs. If excessive friction of the drive occurs, the SIP would detect blade separation from the ball-nut; therefore, the CRDs are monitored for performance degradation during normal operation. As such, the NRC inspectors concluded that

the change does not change or increase the likelihood or consequences of an SSC malfunction in the CRD system. Based on this information, the NRC inspectors found that none of the criteria in 10 CFR Part 52, Appendix A, Sections VIII.B.5.b and VIII.B.5.c are met; therefore, prior NRC approval is not required.

b.3 Administrative Controls for ITP Performance

During the review of the ITAAC implementation procedure, the NRC inspectors identified that the procedure did not provide guidance in the ITAAC closure process to include preoperational tests that also satisfy ITAAC acceptance criteria. STPNOC and Toshiba stated that the ITAAC closure process for STP Units 3 & 4 will ensure ITAAC acceptance criteria are met in the appropriate preoperational testing, where applicable, so that there is no need to run tests again only for the purpose of satisfying ITAAC.

The NRC inspectors observed that STP Units 3 & 4 Startup Administrative Manual (SAM) complements the ITAAC program. SAM Section 1.2, "Scope," states: "The ITP will also include ITAAC that are a requirement of 10 CFR Part 52 and are documented in the ABWR DCD and STP Units 3 & 4 COL Application. ITAAC may be completed during construction testing and preoperational testing but must be completed and accepted by the NRC before fuel load and startup testing can begin." The NRC inspectors also noted that SAM section 3.2.2 states that the Joint Test Group is an integrated group that reviews and approves all preoperational test procedures and results. SAM section 4.5.2 states "preoperational test procedures will state ITAAC requirements it satisfies and documents completion of ITAAC," while section 4.6.1 states that "preoperational test procedures include test criteria for ITAAC." SAM Section 4.9.2 also states "preparation of the test package identifies which testing completes ITAAC." Based on this information, the NRC inspectors determined that Toshiba's SAM adequately covers ITAAC overlap with the ITP.

The NRC inspectors discussed with STPNOC and Toshiba the roles and responsibilities for conducting the ITP consistent with the information in the COLA and the STP Units 3 & 4 QAPD. The pre-operational test procedure preparation, procedure approval, performance, and approval of test results will be performed under Toshiba's QA program. STPNOC has reviewed Toshiba's QA program and found that it is consistent with STPNOC review and oversight of the pre-operational test program. The COLA also refers to the Pre-operational Test Organization in Section 14.2 and refers to the SAM for the performance of the program. The SAM provided details that Toshiba will have the lead for the performance of the pre-operational test program and STPNOC will provide review and oversight. As discussed in the SAM, STPNOC will have the lead for the startup test program and Toshiba will provide support. The SAM is a STPNOC QA document that is consistent with the guidance in RG 1.28, "Quality Assurance Program Requirements (Design and Construction)" and the STP Units 3 & 4 QAPD.

c. Conclusions

The NRC inspectors concluded that STPNOC and Toshiba have adequate design and change controls for documenting changes and/or Tier 2 departures made to the STP Units 3 & 4 ITP. The NRC inspectors also concluded that STPNOC and Toshiba provided adequate procedures to document overlap activities between the ITP and the ITAAC. The NRC inspectors did not identify any issues in this area.

10. Containment Analysis

a. Inspection Scope

The NRC inspector reviewed several technical issues associated with containment licensing analysis to verify Toshiba's capabilities to perform licensing containment safety analysis. Specifically, the NRC inspectors examined the following documents established by Toshiba:

- GE, NEDE-25100-P, "Caorso Safety Relief Valve Discharge Tests Phase 1 Test Report," dated May 1979.
- GE, NEDC-30623, "Advanced Boiling Water Reactor Building/Containment Design Study", dated June 1984.
- GE NEDO-30832, "Elimination of Limit on BWR Suppression Pool Temperature for SRV Discharge with Quenchers," dated December 1984.
- GE, NEDC-31393, "ABWR Containment Horizontal Vent Confirmatory Test, Part I," dated March 1987.
- Japan Atomic Power Co., Ltd., "Dynamic Load in Suppression Pool during BWR Main Steam Safety Valve Actuation," Karyoku-Gensiryoku Hatsuden, Volume 30, Revision 8, dated August 1979.
- Joint Study Report, "Containment Horizontal Vent Confirmatory Test, Part II," dated March 1987.
- K-6/7 Common Engineering Document, 1.D.7, "Containment Load Report", Revision 3, dated February 16, 1989.

b. Observations and Findings

The NRC inspector's review focused on the following containment technical issues: maximum Pressure/Temperature (P/T) calculation, pool swell analysis and definition of hydrodynamic loads.

The P/T calculation will be performed by WEC using the GOTHIC computer code. Toshiba would not be providing any specific test data as a basis for the GOTHIC qualification; however, the selected Horizontal Vent Tests (HVT) will be used for the code verification. The NRC inspectors confirmed that Toshiba has access to the HVT test data to be used to verify the GOTHIC code for the P/T calculation.

Pool swell analysis will be performed by WEC using the GOTHIC code. The code will be benchmarked against GE Pressure Suppression Test Facility (PSTF) test data. Toshiba will provide the test data in the form of an internal document developed based on GE's data. The NRC inspector confirmed that Toshiba has access to GE's PSTF test data and that the process being used to develop the Toshiba's internal document is acceptable.

Hydrodynamic loads will be defined by Toshiba and will be provided to STP to be used in a licensing structural analysis. The definition of the pressure forcing functions for the condensation oscillation (CO) and chugging loads will be based on the HVT test data (full scale (FS) and sub-scale (SS)), as defined in the internal document. Toshiba's internal document for CO and chugging loads has not yet been completed. The SS data will be used for CO, and FS data will be used for the chugging loads.

For the safety relief valve loads, Toshiba will use GE's empirical correlation developed for the X-quenchers, which are to be used in the STP ABWR. This correlation was previously approved by NRC for the ABWR licensing applications. The NRC inspectors confirmed that Toshiba has access to GE's data developed for the X-quenchers.

c. Conclusions

The NRC inspectors concluded that Toshiba has the experience and the capability to perform licensing containment safety analysis for STP Units 3 & 4. The NRC inspectors did not identify any issues in this area.

11. Digital I&C Systems

a. Inspection Scope

The NRC inspectors reviewed Toshiba's QA policies and implementing procedures that govern the process used to develop and implement the STP Units 3 & 4 I&C systems. Specifically, the NRC inspectors reviewed the following policies and procedures established by Toshiba:

- 7A90-0301-0001, "Project Requirements Document - COLA Change Procedure," Revision 1, dated January 13, 2009.
- 7C51-1001-0001, "STP 3&4 NMS System Design Description (SDD)," Revision 0, dated December 26, 2008.
- 7C71-1001-0001, "STP 3&4 RTIS SDD," Revision 1, dated July 11, 2009.
- 7C71-1001-0002, "STP 3&4 Reactor Protection System SDD," Revision 1, dated July 11, 2009.
- AS-200A111, "Acceptance Procedure for Commercial Grade Dedication," Revision 1, dated November 22, 2006.
- NQ-2036, "Procedure for Design Control," Revision 2, dated November 15, 2008.
- NQ-2033, "Procedure for Configuration Management of FPGA," Revision 1, dated August 18, 2008.
- NQ-2010, "Preparation Procedure for FPGA Design Specification," Revision 2, July 31, 2008.
- NQ-4001, "Commercial Grade Dedication (Digital I&C)," Revision 3, dated January 15, 2009.

- FPG-PLN-C51-3001, “Procurement Specification of NRW-FPGA Based NMS Qualification” Revision. 0, dated February 26, 2009.

- FPG-RQS-C51-3001, “NRW-FPGA Based NMS SDD” Revision 0, dated January 21, 2009.

- 3C51-2205-0001, STP 3 NMS Interlock Block Diagram,” Revision 0, dated, December 26, 2008.

- NP-5101080, “STP 3 NMS Instrument Electrical Diagrams,” Revision 1, dated February 20, 2009.

- DVR-C51-1001-0001-0, “STP Units 3 & 4 NMS SDD Design Verification Report,” Revision 0, dated December 26, 2008.

- C51-0901-0001, “STP 3&4 NMS Design Input Sheet,” Revision 1, dated July 11, 2009.

- ECS-JH1-013738, “Interface Specifications between TOSMAP and Ovation for Ovation Gateway Development.”

- 5B8H7094, “Design Specification for O/E Converter Communication data Format.”

- Toshiba America Nuclear Energy (TANE)-STP-2009-0407, TOSMAP-C2000, “General Information Manual,” Revision 10, march 16, 2007.

- TANE-STP2009-0408, “TOSMAP-DS/High Speed Controller General Description Manual,” Revision 0, dated November 2007.

- TANE-STP2009-0420, “Toshiba I&C Platform Integration Experiences,” Revision 0, dated July 2009.

- TANE-STP2009-0423, “TOSMAP C2000/High-Speed Controller Experience,” Revision 0, dated July 2009.

b. Observations and Findings

The NRC inspectors examined Toshiba’s technical capabilities and qualifications to:

- Specify, manufacture, test, and implement a FPGA based safety related NMS, which includes oscillation power range monitor (OPRM), startup range neutron monitoring (SRNM), power range monitoring system (PRNM), and other non-safety related components. The NRC inspectors focused on two primary areas: (1) development of an OPRM system, which is a first-of-a-kind product for Toshiba; and (2) use of FPGA technology, which is a first-of-a-kind technology to be used in a safety related application for the US nuclear industry.

- Specify, manufacture, test, and implement a FPGA based RTIS, which is a FOAK product for both Toshiba and the U.S. nuclear power industry.

- Design and integrate several different digital I&C platforms for both safety and non-safety related systems for STP Units 3 & 4, which include the new TOSDIA-FPGA, Westinghouse Common-Q, TOSMAP-C2000, TOSMAP-HCNT, Ovation, and other third party platforms for the safety-related radiation monitoring system (RMS), and non-safety related balance of plant systems.

Toshiba provided a number of presentations that focused on the I&C areas, and the NRC inspection team examined various design documents generated by Toshiba's NED and NICSD. Some of these documents have been specifically generated for STP 3 & 4 I&C systems, while others were prepared for development of the RTIS and NMS prototype modules.

At Toshiba's Fuchu complex, the NRC inspectors witnessed demonstrations of the prototype OPRM and RTIS components that represent the proposed systems for STP Units 3 & 4. The NRC inspectors also observed the fabrication facilities where the FPGA chips are programmed and assembled onto the circuit boards for RTIS and NMS components.

Based on GE's publically available algorithms and logic for the OPRM system, Toshiba has already developed an OPRM prototype using the FPGA technology. This OPRM design has a wide available range for the OPRM trip set point. Westinghouse Electric Company (WEC) analysis group is performing the stability analysis based on the new fuel design (as a part of the post-COL fuel amendment). WEC's analysis will be validated by the instability data from the Oskarshamn-3 event in February 1998. The OPRM trip set point data will be provided as part of the validation package from the WEC analysis group to Toshiba's NICSD at the Fuchu Complex. The OPRM Appendix B validation test will use this data. The NRC inspectors also inspected Toshiba's documents related to the use of FPGA technology for developing the RTIS and NMS. Toshiba is essentially following the software QA process suitable for developing safety related CPU based digital I&C systems in accordance with EPRI Topical Report (TR)-107330, "Generic Requirements Specification for Qualifying a Commercial PLC for Safety-Related Applications in Nuclear power Plants."

After conducting the evaluation of Toshiba's capabilities as an alternate vendor for STP Units 3 & 4, STPNOC recognized that the integration of multiple I&C platforms would be challenging. Accordingly, Toshiba's lead EPC team has started to address the issue of integrating the multiple I&C platforms. Toshiba presented two preliminary documents that address the integration of multiple I&C platforms proposed for the U.S. ABWR design. Toshiba also shared its experiences of integrating various I&C platforms in nuclear and non-nuclear applications. Although its integration experience is not on systems as complex as what is required for the U.S. ABWR design, it does provide a level of confidence in Toshiba's capabilities for integrating the multiple I&C systems being proposed. The NRC inspectors concluded that the integration of multiple I&C platforms remains a significant challenge issue for Toshiba and its EPC team.

During the review of AS-200A111 and NQ-4001, the NRC inspectors noted that both procedures reference Toshiba's commitment to implement their commercial grade dedication (CGD) program in accordance with EPRI NP-5652 and EPRI 106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Related Applications."

c. Conclusions

The NRC inspectors concluded that Toshiba has the experience and the capability for supplying the OPRM system for STP Units 3 & 4. Toshiba also demonstrated through its past experience in Japan and its ongoing efforts on STP Units 3 & 4 that its capable of integrating the various I&C safety and non-safety platforms for the entire plant. The NRC inspectors did not identify any issues in this area.

12. Entrance and Exit Meetings

On July 13, 2009, the NRC inspectors presented the scope of the inspection during an entrance meeting with Kiyoshi Okamura, Toshiba's Nuclear Energy Systems & Services Division Vice President; and other STPNOC and Toshiba personnel. On July 17, 2009, the NRC inspectors presented the results of the inspection during an exit meeting with Kiyoshi Okamura, Toshiba's Nuclear Energy Systems & Services Division Vice President; Mark McBurnett, STPNOC Oversight and Regulatory Affairs Vice President; John Crenshaw, STPNOC Engineering & Construction Vice President, and other STPNOC and Toshiba personnel. A list of entrance/exit meeting attendees is included as an attachment to this report.

ATTACHMENT

1. PERSONS CONTACTED

NAME	COMPANY	TITLE	ENTRANCE	EXIT	INTERVIEWED
K. Okamura	Toshiba	Nuclear Energy Systems & Services Division Vice President	√	√	
A. Shiori	Toshiba	Power Systems Company Technology Executive	√	√	
S. Iwamoto	Toshiba	Isogo Nuclear Engineering Center General Manager	√	√	
S. Suzuki	Toshiba	Nuclear Energy Division General Manager's Assistant	√	√	√
H. Iwasa	Toshiba	Nuclear Energy Division General Manager's Assistant	√	√	
A. Fukumoto	Toshiba	Nuclear Energy Division Senior Fellow	√	√	√
K. Oshima	Toshiba	Light Water Reactor Plant Engineering Department Senior Manager	√	√	
T. Ono	Toshiba	Overseas Project Promotion Department Senior Manager	√	√	
T. Yamamoto	Toshiba	Quality Assurance Department Senior Manager	√	√	√
K. Iwasawa	Toshiba	Quality Assurance Department Chief Specialist	√	√	
R. Kudo	Toshiba	Quality Assurance Department, Project Quality Assurance Group 1 Group Manager	√	√	√
H. Takeda	Toshiba	Quality Assurance Department Project Quality Assurance Group 2, Chief Specialist			√
K. Arai	Toshiba	System Design & Engineering Department Senior Manager	√	√	
H. Oikawa	Toshiba	System Design & Engineering Department, Safety Engineering Group's Group Manager	√	√	√
H. Imaruoka	Toshiba	System Design & Engineering Department BWR System Planning Group (Licensing) Group Manager	√	√	
K. Kitsukawa	Toshiba	Plant Design & Engineering Department Senior Manager	√	√	
M. Shimmura	Toshiba	Plant Design & Engineering Department Chief Specialist	√	√	
T. Miyagawa	Toshiba	Plant Design & Engineering Department Containment Design Group's Group Manager	√	√	
N. Asano	Toshiba	Control & Electrical Systems Design & Engineering Department Senior Manager	√	√	
M. Tahira	Toshiba	Control System Engineering Group Manager	√	√	√
S. Yukinori	Toshiba	Plant Project Engineering Senior	√	√	

		Manager			
NAME	**COMPANY**	**TITLE**	**ENTRANCE**	**EXIT**	**INTERVIEWED**
K. Naruse	Toshiba	Mechanical Technology & Engineering Department Senior Manager	√	√	
K. Mastunaga	Toshiba	Mechanical Technology & Design Department, Vessel & Components Engineering Group Senior Specialist	√	√	
S. Fuchino	Toshiba	Field Engineering Department Senior Manager	√	√	
Y. Ohta	Toshiba	Field Engineering Department Chief Specialist	√	√	
C. Miyamoto	Toshiba	Field Engineering Department, Pre-Operation & Start-Up Test Group, Senior Specialist		√	
Y. Mori	Toshiba	Field Engineering Department, Pre-Operation & Start-Up Test group, Specialist	√	√	
M. Iguchi	Toshiba	Nuclear I&C System Department Senior Manager			
T. Sato	Toshiba	Nuclear I&C System Department Chief Specialist	√	√	√
M. Horiguchi	Toshiba	First Overseas Light Water Reactor Plant Project Engineering Group's Group Manager	√	√	
M. McBurnett	STPNOC	Oversight & Regulatory Affairs Vice President		√	
J. Crenshaw	STPNOC	Engineering & Construction Vice President		√	
T. Walker	STPNOC	Quality Assurance Manager	√	√	
M. Smith	STPNOC	Quality Assurance Supervisor	√	√	
S. Head	STPNOC	Regulatory Affairs Manager	√	√	√
C. Chappell	STPNOC	Licensing Engineer	√	√	
M. Murray	STPNOC	I&C Manager	√	√	√
C. Schlaseman	TANE	Project Manager	√	√	√
F. Ishibashi	TANE	Licensing Vice President	√	√	
D. Poole	TANE	EPC Lead	√	√	
C. Swanner	TANE	EPC Lead	√	√	√
K. Kondo	TANE	EPC Technical Support	√	√	
H. Nishiyama	TANE	EPC Technical Support	√	√	
D. Herrell	TANE	EPC Technical Support	√	√	√
F. Hayes	WEC	EPC Lead	√	√	
C. Tang	WEC	EPC Technical Support	√	√	√
N. Jain	WEC	EPC Technical Support	√	√	√
L. Dusek	Fluor	EPC Lead	√	√	

J. Cagle	Fluor	EPC Technical Support		√	
NAME	**COMPANY**	**TITLE**	**ENTRANCE**	**EXIT**	**INTERVIEWED**
M. Hokazono	Fluor	EPC Technical Support	√	√	
J. Nakoski	NRC	Inspection Team Leader	√	√	
B. Sosa	NRC	Inspection Assistant Team Leader	√	√	
R. McIntyre	NRC	NRC Vendor Inspector	√	√	
A. Rivera-Varona	NRC	NRC Vendor Inspector	√	√	
Y. Diaz-Castillo	NRC	NRC Vendor Inspector	√	√	
F. Talbot	NRC	NRC Vendor Inspector	√	√	
D. Taneja	NRC	NRC Technical Specialist	√	√	
J. Zhao	NRC	NRC Technical Specialist	√	√	
A. Drozd	NRC	NRC Technical Specialist	√	√	

2. INSPECTION PROCEDURES USED

Inspection Procedure 35017, “Quality Assurance Implementation Inspection.”

Inspection Procedure 43002, "Routine Inspection of Nuclear Vendors."

Inspection Procedure 36100, “Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance.”

3. LIST OF ACRONYMS USED

AB	Accrediting Body
ABWR	Advance Boiling Water Reactor
ANSI	American National Standards Institute
ANS	American Nuclear Society
APS	Arizona Public Service
ASME	American Society of Mechanical Engineers
BWR	Boiling Water Reactor
CAR	Corrective Action Request
CGD	Commercial Grade Dedication
CFR	Code of Federal Regulation
CO	Condensation Oscillation
COLA	Combined Operating License Application
CPN	Change Proposed Notice
CRD	Control Rod Drive
CTG	Combustion Turbine Generator
DCD	Design Control Document
DCN	Design Change Notice
DDR	Due Diligence Report
DN	Document Number
DVR	Design Verification Report
EDO	Engineering/Design Organization
EMD	Electronic Media Document

EPC	Engineering, Procurement, Construction
EPRI	Electric Power Research Institute
ES	Engineering Standard
FMCRD	Fine Motion Control Rod Drive
FPGA	Field Programmable Gate Array
FOAK	First of a Kind Test
FS	Full Scale
FSAR	Final Safety Analysis Report
GE	General Electric Company
GM	Group Manager
HVT	Horizontal Vent Test
I&C	Instrumentation and Control
IHI	Ishikawajima-Harima Heavy Industries
ILAC	International Laboratory Accreditation Cooperation
IP	Inspection Procedure
ITAAC	Inspection, Tests, Analysis and Acceptance Criteria
ITMS	Indoctrination and Training Management System
ITP	Initial Test Program
JOS	Job Order Sheet
LOTO	Lock Out/Tag Out
MCD	Maintenance Control Documents
LCDL	Maintenance Control Document List
MOU	Major Organizational Unit
MRA	Mutual Recognition Agreement
MRIT	Manager responsible for Indoctrination & Training
M&TE	Measuring and Test Equipment
NED	Nuclear Energy Division
NEEMD	Nuclear Energy Equipment Manufacturing Department
NICSD	Nuclear Instrumentation and Control Systems Department
NMS	Neutron Monitoring System
NNR	Nonconformance Notice Report
NQA	Nuclear Quality Assurance
NQAD	NED Quality Assurance Department
NRC	Nuclear Regulatory Commission
NSSS	Nuclear Steam Supply System
OPRM	Oscillation Power Range Monitor
PBMD	Plant Business Management Department
PCD	Project Control Document
PCDL	Project Control Document List
PE	Project Engineer
P&ID	Piping and Instrument Diagram
Pj	Project Organization
PO	Purchase Order
PRNM	Power Range Monitoring System
PS	Purchase Specification
PSNE	Power Systems Company Nuclear Energy
PSTF	Pressure Suppression Test Facility
P/T	Pressure/Temperature
QA	Quality Assurance
QAM	Quality Assurance Manual
QAPD	Quality Assurance Program Description

QVL	Qualified Vendors List
RCIC	Reactor Core Isolation Cooling
RG	Regulatory Guide
RMS	Radiation Monitoring System
RPV	Reactor Pressure Vessel
RTIS	Reactor Trip Isolation System
SAM	Start Up Manual
SBO	Station Black Out
SC	Safety Classification
SDD	System Design Description
SDL	Submittal Document List
SER	Safety Evaluation Report
SIP	Separation Indicator Probe
SLC	Standby Liquid Control
SM	Senior Manager
SRNM	Startup Range Neutron Monitoring
SS	Sub Scale
SSC	Structure, System, and Component
SSC & SS	Structure, System, Component and Service
STDDEP	Standard Departure
STP	South Texas Project
STPNOC	South Texas Project Nuclear Operating Company
Toshiba	Toshiba Corporation
TR	Topical Report
TPSC	Toshiba Plant Systems & Services Corporation
WEC	Westinghouse Electric Company