July 11, 2008

Mr. Jeff Larson, Director
Nuclear Quality Assurance
Invensys Process Systems
15345 Barranca Parkway
Irvine, CA 92618

SUBJECT: NRC INSPECTION REPORT NO. 99901357/2008-201, NOTICE OF VIOLATION

Dear Mr. Larson:

On May 19–22, 2008, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Invensys Process Systems (IPS) facility in Irvine, California. The enclosed report presents the results of this inspection.

This was a limited scope inspection that focused on assessing your compliance with the provisions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10, Part 50, Domestic Licensing of Production and Utilization Facilities," of the *Code of Federal Regulations* (10 CFR Part 50) and 10 CFR Part 21, "Reporting of Defects and Noncompliance." This NRC inspection report does not constitute NRC endorsement of your overall quality assurance or10 CFR Part 21 programs.

Based on the results of this inspection, the NRC determined that one violation of NRC requirements occurred. Specifically, IPS did not provide adequate procedural guidance for the evaluation of deviations and failures to comply associated with substantial safety hazards. The enclosed Notice of Violation (Notice) cites the violation, and the subject inspection report describes in detail the circumstances surrounding it.

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

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," the NRC will place a copy of this letter, its enclosures, and any associated correspondence in the NRC's Public Document Room or in the NRC's Agencywide Documents Access and Management System, which is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that the agency can make the response available to the public without redaction.

Sincerely,
/RA/

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

Docket No.: 99901357

Enclosures: 1. Notice of Violation
2. Inspection Report 99901357/2008-201

Sincerely,
/RA/

Juan Peralta, Chief
Quality and Vendor Branch 1
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2. Inspection Report 99901357/2008-201

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DATE	07/10/2008	07/10/2008	07/11/2008

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NOTICE OF VIOLATION

Invensys Process Systems
15345 Barranca Parkway
Irvine, CA 92618

Docket Number 99901357
Inspection Report No. 99901357/2008-201

Based on the results of the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on May 19–22, 2008, of activities performed at Invensys Process Systems (IPS), the agency has identified one violation of NRC requirements. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR Part 21, Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," paragraph 21.21(a), requires, in part, that each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to (1) evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable.
>
> IPS 10 CFR Part 21 implementing procedure Quality Assurance Manual (QAM) 13.3, “10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 9, dated May 18, 2007, describes the process for identifying and evaluating deviations and reporting to the NRC when required.
>
> Contrary to the above, as of May 22, 2008:
>
> The IPS 10 CFR Part 21 implementing procedure QAM 13.3 did not provide adequate procedural guidance to evaluate deviations and failures to comply associated with substantial safety hazards.

This issue has been identified as Violation 99901357/2008-201-01.

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

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," IPS is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality and Vendor Branch 1, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated at Rockville, Maryland this 11th day of July 2008.

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

Docket No.:	99901357
Report No.:	99901357/2008-201
Vendor:	Invensys Process Systems 15345 Barranca Parkway Irvine, CA 92618 (949) 885-0716
Vendor Contact:	Jeff Larson Director, Nuclear Quality Assurance Jeff.Larson@ips.invensys.com
Nuclear Industry:	Invensys Process Systems is a global supplier of products, systems, and services for safety, critical control, and turbomachinery applications. Invensys, with its Foxboro business unit, has been a major supplier to the nuclear industry for nearly 50 years.
Inspection Dates:	May 19–22, 2008

Inspection Team:			
	Milton Concepcion	NRO/DCIP/CQVP	Lead Inspector
	Greg Galletti	NRO/DCIP/CQVP	
	Dori Votolato	NRO/DCIP/CQVP	
	Andrea Keim	NRO/DCIP/CQVB	
	Victor Hall	NRR/DE	
	Dinesh Taneja	NRO/DE/ICE2	

Approved by: ***/RA/*** 7/11/2008

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

Date

ENCLOSURE 2

EXECUTIVE SUMMARY

Invensys Process Systems
99901357/2008-201

The purpose of this inspection was to verify the implementation of the Invensys Process Systems (IPS) quality assurance (QA) program and the program under Title 10, Part 21, "Reporting of Defects and Noncompliance," of the *Code of Federal Regulations* (10 CFR Part 21). The U.S. Nuclear Regulatory Commission (NRC) inspectors reviewed selected portions of the IPS QA and 10 CFR Part 21 controls established and implemented to meet the regulations set forth in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Process and Utilization Facilities," and 10 CFR Part 21, respectively. The NRC conducted the inspection at the IPS facility in Irvine, California.

The following were the NRC inspection bases:

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

The NRC performed an inspection of IPS on March 14–15, 2006, and identified a nonconformance with NRC requirements associated the IPS corrective action program. During this inspection, the NRC inspectors reviewed the corrective and preventive actions associated with this nonconformance. This issue has been closed. Section 4 of this report discusses this issue in more detail.

The results of the inspection are summarized below.

10 CFR Part 21 Program

The NRC inspectors identified one violation for failure to meet the requirements of 10 CFR Part 21. Violation 99901357/2008-201-01 was cited because IPS did not provide appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards.

REPORT DETAILS

1. 10 CFR PART 21 PROGRAM

   a. Inspection Scope

   The NRC inspectors reviewed the IPS QA policies and implementing procedures that govern the 10 CFR Part 21 process to determine compliance with 10 CFR Part 21. The NRC inspectors also sampled the vendor's 10 CFR Part 21 program implementation activities.

   b. Observations and Findings

   Quality Assurance Manual (QAM) 13.3, "10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 9, dated May 18, 2007, described the IPS process for complying with the requirements of 10 CFR Part 21. The NRC inspectors noted that QAM 13.3 provided adequate interface of the corrective action and nonconformance reporting processes with the 10 CFR Part 21 program to ensure effective identification of deviations and failures to comply associated with substantial safety hazards. The NRC inspectors noted that QAM 13.3 correctly defined the following terms relevant to 10 CFR Part 21—defect, deviation, basic component, commercial grade item, and dedication. The NRC inspectors also noted that QAM 13.3 properly addressed all the timeliness requirements of 10 CFR Part 21 and found that IPS procedure QAM 16.0, "Quality Records," Revision 16, dated February 29, 2008, provided adequate controls for the retention of 10 CFR Part 21 evaluations or notifications.

   During the review of QAM 13.3, the NRC inspectors noted that the Quality Assurance Review Board (QARB) is responsible for evaluating whether deficiencies and deviations warrant a 10 CFR Part 21 evaluation. QAM 13.3 provided five screening criteria and a flowchart to determine whether a deviation or deficiency is reportable under 10 CFR Part 21. However, the NRC inspectors noted that the procedure did not describe how to perform a Part 21 evaluation to determine if the identified deviation or failure to comply could cause a substantial safety hazard. After discussions with IPS personnel, the NRC inspectors determined that QAM 13.3 did not provide adequate procedural guidance for the evaluation of deviations and failures to comply associated with substantial safety hazards. The NRC inspectors further noted that the flowchart in QAM 13.3 incorrectly screens all deviations as defects. The NRC inspector's identified lack of adequate guidance for the evaluation of deviations or failures to comply as Violation 99901357/2008-201-01.

   To verify adequate implementation of the 10 CFR Part 21 process, the NRC inspectors requested copies of 10 CFR Part 21 records of evaluations and reports that IPS has completed. IPS had performed three 10 CFR Part 21 evaluations of deviations, as documented in Action Request Reports (ARRs) 539, 579, and 580. The NRC inspectors noted that the ARRs did not document the 10 CFR Part 21 screening process required in QAM 13.3. ARRs 539 and 580 provided adequate objective evidence to determine that the identified deviations were not reportable defects. However, the evaluation for ARR 579 did not provide objective evidence to demonstrate that an identified deviation was not a defect. The NRC inspectors determined that this deficiency was caused by the

lack of adequate procedural guidance from IPS to evaluate deviations as noted above in Violation 99901357/2008-201-01. During the inspection, IPS entered this issue into its corrective action program.

Based on a sample of procurement documents for safety-related parts and services from sub-suppliers, the NRC inspectors verified that IPS had specified the applicability of 10 CFR Part 21 as required in 10 CFR 21.31, "Procurement Documents." However, the NRC inspectors noted that Purchase Orders 120487, 120488, and 120614 to the IPS Reynosa, Mexico, facility for nonsafety-related parts incorrectly invoked the requirements of Appendix B to 10 CFR Part 50. The NRC inspectors noted that IPS self-identified this issue during an internal audit and took appropriate corrective action. The NRC inspectors also verified that IPS posted notices describing the 10 CFR Part 21 regulations and procedures consistent with the requirements of 10 CFR Part 21.6 "Posting Requirements."

c. Conclusions

The NRC inspectors identified one violation for failure to meet the requirements of 10 CFR Part 21. Violation 99901357/2008-201-01 was cited because IPS did not provide adequate procedural guidance to evaluate deviations and failures to comply associated with substantial safety hazards. Except for the violation identified, the NRC inspectors concluded that the IPS 10 CFR Part 21 program and implementation are consistent with the regulatory requirements.

2. DESIGN CONTROL

a. Inspection Scope

The NRC inspectors reviewed the IPS policy and procedures governing design control activities as they relate to the development of the Triconex software and hardware to ensure that those guidelines adequately described the process as required in Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. The NRC inspectors also reviewed a representative sample of design packages and observed testing activities at the IPS manufacturing facility to verify effective implementation of such requirements.

b. Observations and Findings

b.1 Tricon v10 Nuclear Qualification Project

The NRC inspectors reviewed the documentation associated with the Tricon v10.2.1 qualification project to verify whether the process implemented by IPS is consistent with applicable regulatory requirements and relevant industry standards. In addition to reviewing the documents governing the process, the NRC inspectors also interviewed IPS personnel to ensure that activities performed were commensurate with their responsibilities.

The Tricon PLC system has continued to evolve since the nuclear qualification of Tricon v9.5.3. For various reasons, such as enhanced response time requirements, obsolete components, circuit board fabrication technology, and other considerations, IPS initiated

the Tricon v10.2.1 nuclear qualification project and completed it in May 2008, but it has not yet been approved by the NRC for use in safety-related applications.

The NRC selected this project for inspection of the IPS design control process. The NRC inspectors noted that a number of documents were created for the v10.2.1 nuclear qualification project, consistent with the IPS QAM and Engineering Department Manual (EDM). The NRC inspectors reviewed the documents listed in Table 1 related to the v10.2.1 qualification project:

Table 1 Documents Reviewed

Ref. No.	Document No.	Rev.	Date	Title
1	9600164-002	3	11/08/2006	Nuclear Qualification Quality Plan; provides an overview of the nuclear qualification process.
2	9600164-500	5	05/10/2008	Master Test Plan
3	9600164-535	0	July 2007	Software Quality Report
4	9600164-537	0	07/24/2006	Software QA Plan
5	9600164-539	0	July 2007	Critical Digital Review of the Triconex Tricon v10.2.1
6	9600164-540	21	05/10/2008	Master Configuration List (MCL)
7	9600164-542	0	07/15/2007	Change Impact Analysis (CIA) Tested vs. Current Production
8	9600164-545	1	05/10/2008	Equipment Qualification Summary Report Appendix A—EPRI TR-107330 Compliance Traceability Matrix Appendix B—Application Guide Appendix C—Evaluation of IEEE Std. 323-2003
9	9100150-001	2.0	April 2008	Tricon v10 Nuclear-Qualified Equipment List (NQEL)

The NRC inspectors reviewed the equipment qualification summary report and noted that the v10.2.1 qualification project included the following Tricon PLC system modules:

- enhanced main processor (MP) (model 3008)
- Next Generation Differential Analog Input module
- Next Generation Differential Digital Output module
- surface mount technology versions of previously qualified input/output (I/O) modules
- Tricon Communication Module

EDM 12.00, "Product Development Process," Revision 4.3, dated April 20, 2007, documents the Triconex product development process, which is designed to comply with the following industry standards:

- IEC 61508 (international standard for electronic safety system) intended to satisfy the process requirements of Safety Integrity Level 3
- ISO 9001:2000
- Institute of Electrical and Electronics Engineers (IEEE) Std. 1012-1998, "Verification and Validation"

The NRC inspectors noted that EDM 12.00 groups lifecycle activities and includes the following phases:

- requirements—including marketing requirements/design inputs, engineering project plan, system requirements

- design—including system design, module requirements, module design

- implementation—including creation of prototype modules, prototype fabrication, assembly, test benches and simulation processes for prototype testing

- verification – including module test, module integration and verification, system integration and verification (design verification performed by qualified personnel not directly involved in the design of the product)

- validation—including system validation and pilot release, system certification (third party, etc.), and product release to manufacturing

- active—including production and sales, product configuration control and change management, product withdrawal

- retirement—product deactivation and retirement

The NRC inspectors also noted that IPS followed Triconex engineering procedure EDM 74.00, "Nuclear Qualification of Triconex Products," Revision 1.1, dated February 20, 2008, along with EDM 12.00 for qualification of v10.2.1 modules for nuclear-safety-related applications. Upon successful completion of the qualification program, the qualified components were documented in the Tricon v10.2.1 Nuclear

Qualified Equipment List (NQEL). Tricon components identified in NQEL are the only components allowed to be used in safety-related nuclear applications.

Using the NQEL, the NRC inspectors selected the enhanced nuclear-qualified MP 3008N module as a sample to verify the implementation of the design control process. IPS first introduced this module in v9.6 of the Tricon PLC system, and it is considered an upgrade from the MP 3006N used in the NRC-approved v9.5.3 of the Tricon PLC system. Each MP 3008N uses two Motorola processors that provide increased performance. IPS is using the MP 3008N module in the v10.2.1 qualification project.

The MCL prepared for the v10.2.1 qualification project identifies all the components that are part of the v10.2.1 qualification activities. The specifications of the MP are as follows:

MP 3008 Enhanced MP III, v10, 16Mb
Part Number 3000710-100, Revision D
Printed Circuit Board Number 7400222-100, Revision B2

The NRC inspectors noted that IPS documented a critical digital review (CDR) of Tricon v10.2.1 and TriStation 1131 v4.1, Build 437, to support the v10.2.1 qualification project. This CDR documents changes to the Tricon PLC system, including microprocessor, simplified architecture, faster speed, and simpler communication network between the MP modules.

A section of the CDR was devoted to the evaluation of the MP evolution from 3006N (qualified as part of v9.3.1 original qualified system) to the current version of MP 3008N. The NRC inspectors noted that the change in MP module also required changes to other components within the Tricon PLC system, including the communications scheme, memory type and size, and others. The CDR considered and documented all of these changes. The CDR also offers various cautions, including application cautions, recommendations for use, and QA process enhancements. The NRC inspectors noted that the various recommendations provided in the CDR are now included in EDM 74.00.

The NRC inspectors noted that all of the Tricon v10.2.1 modules were put through an environmental qualification process in accordance with IEEE Std. 323, “IEEE Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations,” which included seismic, radiation, environmental, and electromagnetic tests. The equipment qualification summary report documents the test results. Subsequent to these qualification tests, IPS performed a CIA that documented the changes between the tested and the production versions of the MP modules. This analysis evaluated changes to radiation, seismic, environmental, and electromagnetic characteristics of the components in the MCL for the v10.2.1 nuclear qualification project. The NRC inspectors reviewed the CIA and noted that the production 3008N module evolved from tested part no. 7400222-100, Revision B2, to production part no. 7400222-100, Revision B5. The NRC inspectors reviewed the NQEL to verify that the correct information was documented for the 3008N module, consistent with IPS procedural guidance. After reviewing the NQEL, the NRC inspectors noted that it did not document the revision number of the MP module qualified in accordance with the CIA. In absence of this information, the system integrator would have to use the CIA along with the NQEL

to determine the correct revision number of the nuclear-qualified MP that will be used in safety-related applications. The NRC inspectors discussed this issue with IPS engineering personnel and learned that this issue had already been identified and an ARR was initiated in September 26, 2007, to address document inconsistencies in the v10 NQEL. The NRC inspectors found this acceptable.

The NRC inspectors reviewed the Technischer Überwachungs-Verein (TÜV) validation and certification documents, which are part of the v10.2.1 qualification project documentation. TÜV is an independent German organization that performed third-party validation and certification of v10.2.1 of the Tricon PLC system. The NRC inspectors reviewed the approved components list for the Tricon v10.2.1, which is available at the TÜV Web site. The NRC inspectors noted that the certificate only listed the MP module model 3008 and did not list the nuclear-qualified model 3008N. For various other modules, TÜV listed both the commercial and nuclear version of the modules. The NRC inspectors held multiple discussions with IPS engineering personnel to clarify this issue. IPS engineering personnel stated that documentation was submitted to TÜV to support the certification of the MP 3008N module. After conversations with IPS personnel, the NRC inspectors learned that this issue had been entered in the IPS corrective action program, and engineering personnel prepared a letter to TÜV requesting issuance of the Tricon v10.2.1 certification with the list of components submitted by IPS for certification, including the MP 3008N module. In a followup conference call with the IPS Nuclear Quality Director, the NRC inspectors learned that TÜV, as requested by IPS, updated the approved components list for the Tricon v10.2.1 to reflect the nuclear-qualified 3008N module. The NRC inspectors found this acceptable.

b.2 Review of Project-Specific Application of the Triconex System

Project Procedures Manual (PPM) 1.0, “Application Project Administrative Controls,” Revision 008, dated May 12, 2008, provides the administrative controls for projects that incorporate Tricon products into fully operational integrated systems, consistent with the IPS QAM. This procedure contains provisions for the review of project-specific purchase order specifications; development of hardware requirements specifications (HRS), software requirements specifications (SRS), quality plans/project plans, and the system design basis (SDB); development of functional drawings and function block diagrams, development of test specifications, test plans, and test procedures for the acceptance test phase; and system integration implementation activities.

PPM 2.0, “Design Control,” Revision 006, dated May 2, 2005, describes the design control process used by IPS in Tricon application projects. This procedure implements design QA requirements established in Section 4.0 of the IPS QAM. This procedure controls design development, design review, design verification and validation (V&V), approval and release of the design documents, design changes, and final as-built design products.

The NRC inspectors reviewed the design process used by IPS for the qualification of Tricon PLC system for project-specific applications. The NRC inspectors focused the design review on the Florida Power and Light (FP&L) documentation related to the digital qualified safety parameter display system (QSPDS) replacement project. The QSPDS is a nuclear safety-related monitoring device that performs the following functions in support of Inadequate Core Cooling System (ICCS) monitoring:

- Subcooled Margin Monitor (SMM) parameter indication
- Reactor Vessel Level Monitoring System (RVLMS), including reactor vessel level indication and control of heater controller
- Qualified Core Exit Thermocouple (CET) Temperature Indication
- Transmission to and display of QSPDS data on a control room flat screen display
- Communication data link for transmission of QSPDS data to the non-Class 1E emergency response data acquisition and display system (ERDADS) for the purposes of alarm and alarm history; data history, trending, and reporting; sequence of events processing; and display on the ERDADS graphic displays
- Additional interface communication functions to laptops, workstations, printers, and associated software

The NRC inspectors selected the CET system as a sample within the ICCS to verify the adequacy of the design process implemented by IPS. The CET system uses 51 thermocouples positioned to measure fuel assembly coolant outlet temperature at preselected core locations. The NRC inspectors reviewed the process used to design, manufacture, qualify, and test the Tricon software and hardware platform, starting from general and functional requirements contained in the FP&L final safety analysis report (FSAR), the translation of these requirements into system processing requirements and function specifications, and the incorporation of these requirements into functional diagrams, generation of software code, software validation, and the factory acceptance testing (FAT). To this end, the NRC inspectors reviewed a sample of project-specific procedures and reports that documented different activities associated with the qualification of the Tricon PLC system to verify compliance with administrative requirements contained in the IPS design control process. Additionally, the NRC inspectors held numerous discussions with IPS personnel to ensure that activities performed were commensurate with their responsibilities.

IPS developed several QA-related documents for the design of the QSPDS, including a project quality plan and software and hardware quality plans. These plans complement the IPS QA plan with measures that are specific to instrumentation and control (I&C). Design procedures describe the engineering process for I&C activities that need to be performed for a specific project. The process developed by IPS ensures that the Tricon PLC system is qualified for each project.

Project-Specific Quality Plan

The NRC inspectors reviewed the FP&L quality plan for the QSPDS replacement project; Document No. 488547-1-900, "Quality Plan/Project Plan," Revision 13, dated March 12, 2007. This plan documents the project activities in accordance with the IPS QA program and applicable industry standards. The plan covers design, fabrication, integration, and test activities associated with the QSPDS project. This includes the Tricon system interface with the Foxboro Intelligent Application (I/A) distributed control system (DCS), the ERDADS, and the Westinghouse safety-related human machine interface (SR HMI) display panel. The quality plan covers organizational responsibilities, qualification requirements, and interfaces with customers to ensure the quality of hardware/software and project deliverables. In addition, the quality plan covers equipment qualification requirements such as environmental, seismic, electromagnetic

interference/radio frequency interference (EMI/RFI), surge withstands capability, and electrostatic discharge (ESD) withstands capability.

The quality plan requires the development and issuance of project plans and documents for all the phases of the design process, including planning, design, drawings, software, verification testing, and system validation testing activities. For the FP&L QSPDS replacement project, the NRC inspectors reviewed the following documentation:

- System Software and Hardware Quality Assurance Plan (SQAP)
- System Software and Hardware Verification and Validation Plan (SVVP)
- SDB
- HRS
- Functional diagrams and functional block diagrams
- FAT Procedures
- Validation test report of the QSPDS

Details of the review of these documents are provided below.

System Software and Hardware Quality Assurance Plan

The NRC inspectors reviewed Document No. 488547-1-801, "System Software and Hardware Quality Assurance Plan (SQAP)," Revision 5, dated March 6, 2007. This plan describes the requirements and methodology to be followed in designing and developing the integrated system for the FP&L QSPDS replacement project. It covers the design of application program software and system hardware and its verification during the project engineering design phase. The plan also covers validation testing during the preliminary test verification (PTV), pre-FAT, FAT, and system performance test (SPT) activities. Specifically, the SQAP covers the following design activities:

- embedded operating system software, including operating systems, communications software, and chip-based firmware procured as a standalone component or as a subassembly that is under configuration control by others

- application software development tools, including the Triconex TriStation 1131 and other software used for applications programming and graphic display development

- application software, including the TriStation Application Project (TSAP) resident on the Tricon PLC system

- application software verification tools, including custom test drivers and software verification test cases used to document software verification testing of the TSAP, QSPDS library, and other software

The NRC inspectors noted that the SQAP describes management responsibilities and project tasks; documentation requirements; reviews and audit requirements; problem reporting and corrective action; code, media, and supplier control; record retention requirements; and training and risk management requirements. Output documentation required by the SQAP include the SRS, Software Design Description (SDD), SVVP, System Software and Hardware Verification and Validation Report (SVVR), user

documentation, software configuration management plan, project management plan, project traceability matrix, software installation and integration plan, and HRS. The NRC inspectors verified that these output documents were consistent with the project quality plan. No issues were identified in this area.

System Software and Hardware Verification and Validation Plan

The NRC inspectors reviewed Document No. 488547-1-802, "System Software and Hardware Verification and Validation Plan (SVVP)," Revision 9, dated June 5, 2007. This document establishes the requirements for the V&V process to be applied to the Triconex TriStation application project (TSAP) software and system hardware developed for the FP&L QSPDS replacement project. The NRC inspectors noted that the SVVP includes verification activities for application program software, system hardware interfaces with the Westinghouse display panel, and Foxboro I/A workstations. It also specifies the methodology for the performance of specific V&V activities to verify QSPDS system reliability and availability.

The SVVP provides an overview of the V&V process and includes organizational responsibilities and a description of the tools and techniques used during the different lifecycle phases. It provides the verification process, including the requirement phase, design phase, implementation phase, test phase (validation), and preship checkout. The NRC inspectors verified that the description of each phase includes the input, tasks, and outputs required to complete the phase. In addition, the plan describes V&V administrative requirements, including anomaly reporting and resolution, task iteration and deviation policy, and control procedures applied to the V&V effort. Section 2 of the V&V plan describes the software safety plan and provides procedures and methodologies for the development of safety-critical software and hardware to help mitigate the introduction of software errors and system defects. Additionally, the NRC inspectors noted that the plan includes organizational responsibilities, qualification and training requirements, configuration management, and QA requirements. The NRC inspectors verified that the SVVP was developed consistent with the guidance contained in IEEE 1012-1998, "Software Verification and Validation," and IEEE 1028-1997, "Software Reviews." No issues were identified in this area.

System Design Basis

The NRC inspectors reviewed Document No. 488547-1-805, "System Design Basis," Revision 4, dated March 26, 2007. This document describes the current design and licensing basis requirements for the QSPDS at Turkey Point and provides information necessary to describe how the new Tricon PLC system complies with those requirements. It further translates specific technical requirements (design inputs) identified in the Turkey Point FSAR, technical specifications, American National Standards Institute (ANSI)/IEEE standards and specifications, applicable Electric Power Research Institute (EPRI) reports, and regulatory requirements, into Tricon project documents (design outputs). PPM 2.0 describes the process used by IPS to identify design inputs and develop design outputs.

The NRC inspectors noted that the SDB provides a system design overview, describing the system software and hardware platforms; detailed design functions, including considerations of safety assessments contained in the Turkey Point final safety

evaluation report (FSER), and input, operation, and output descriptions; a detailed description of system interlocks and interfaces; and design-basis considerations such as redundancy, separation and isolation, seismic, environmental factors, EMI/RFI, and reliability. Section 6 of the SDB provides performance specifications for the seismic qualification of the safety-related components of the system. The Tricon PLC system must be seismically qualified and capable of operating within stated environmental limits of these performance specifications. These conditions bound the worst case environmental and seismic conditions anticipated during any plant operating mode and design-basis accident. Since all of the Tricon equipment provided to FP&L is being mounted in locations classified as mild environments, IPS determined that it did not need environmental qualification as required in 10 CFR 50.49, "Environmental Qualification of Electric Equipment Important to Safety for Nuclear Power Plants." The NRC inspectors did not identify any issues in this area.

The SDB also describes the hardware to be used and how it interfaces with existing equipment and other plant systems. The NRC inspectors reviewed the HRS and SDD, as summarized below, for details pertaining to the actual hardware and software to be used (including algorithm development).

Hardware Requirements Specification

The NRC inspectors reviewed Document No. 488547-1-807, "Hardware Requirements Specification," Revision 6, dated March 13, 2007. This document provides hardware requirements for the Tricon PLC system being supplied for the QSPDS upgrade. The HRS provides detailed descriptions of hardware specifications, including power distribution, grounding, configuration requirements, heat load calculations, interfaces with other hardware platforms, thermocouple input modules, digital input modules, analog input modules, and interfaces with other I/O data link components. It also describes the installation details and mounting configuration of equipment contained within the existing main QSPDS cabinets. Since the Tricon PLC system interfaces with the qualified flat panel display manufactured by Westinghouse, the HRS provides a detailed description of the hardware integration and operation of the Westinghouse equipment and the Tricon PLC system for overall completeness.

The NRC inspectors reviewed hardware configuration descriptions, design output documents, and cabinet drawings to verify compliance with program requirements. To this end, the NRC inspectors also reviewed drawings developed for the FP&L project and associated with the CET system. Specifically, the NRC inspectors reviewed drawing nos. 488-543-1-366 and
488547-1A-203, which provide hardware specifications for the QSPDS cabinets. The NRC inspectors noted that thermocouple inputs are identified, where CET inputs from the field are connected to the I/O chassis. These drawings provide references to the SDB document and specific interfaces with other systems within the Tricon PLC system. Supporting documentation describes the configuration of the equipment, minimum power supply requirements, and I/O functional requirements, as required in PPM 2.0. The NRC inspectors identified no issues in this area.

Software Requirements Specification

The NRC inspectors reviewed Document No. 488547-1-809, "Software Requirements Specification," Revision 9, dated June 1, 2007. This document describes the functionality of the TSAP developed to monitor and analyze core safety parameters and transmit these results to the SR HMI and ERDADS. TSAP also receives operator inputs for setpoint control and bypass settings from SR HMI, which the Foxboro Intelligent Application (I/A) series system controls. Section 2 of the SRS provides a general description of the TSAP software and software function and a discussion of identified constraints, assumptions and dependencies. The NRC inspectors noted that FP&L specified TSAP software requirements for monitoring and analyzing reactor core safety parameters and transmitting the data to the SR HMI and ERDADS, as documented in the Turkey Point FSAR. Section 3 of the SRS provides the specific requirements as presented by FP&L for this project. These include functional requirements, communication data links, user interfaces, external interfaces, attributes, and other requirements. These software design specifications were translated in software design and functional requirements for the design of the QSPDS, consistent with PPM 2.0.

The NRC inspectors reviewed the functional description of the CET_Monitor program module, which is used to calculate CET temperatures, perform statistical comparisons, determine alarm status, and provide data to the Saturation and SMM program module. The NRC inspectors noted that the SRS includes a detailed description of the measurement and analysis of process input signals, transmission of data for the display of CET temperatures, results of CET temperature monitoring calculations, and transmission of data for the alarming of high CET temperature values. The SRS also includes a detailed description of the algorithm that monitors, detects, and provides alarm indications when inadequate core cooling conditions exist. No issues were identified in this area.

Software Design Description

The NRC inspectors reviewed Document No. 488547-1-810, "Software Design Description," Revision 9, dated June 1, 2007. The SDD translates the design requirements of the SRS into a description of the functional requirements, system architecture, control logic, data structures, I/O formats, interface descriptions, and specific algorithms for the QSPDS. The SDD provides a detailed description of the QSPDS software for the Tricon PLC system and the interfaces with the Westinghouse node box connecting the Tricon PLC system and the Westinghouse common Q display. The SDD also describes the two software programs associated with the Foxboro I/A data link, which connects the Tricon PLC system to the existing ERDADS.

The NRC inspectors reviewed the algorithm description related to the CET_Module program. The NRC inspectors noted that the CET_Module program includes formulas, assumptions, and comparison analyses with the different data obtained from other modules. The NRC inspectors also reviewed Section 4 of the SDD, which describes the Tricon detailed module design, and focused on the description associated with the CET_Monitor used by the CET system. The NRC inspectors noted that the SDD provides a description the module, the functions and function blocks used by the CET_Monitor, dependencies of other modules for the CET_Monitor, a description of the interfaces with field thermocouples, and a detailed graphical representation of the

processing of the CET_Module and the relationship between other functions/modules. The description also includes timing, sequencing of events or processes, prerequisites for process initiation, priority of events, processing level, actual process steps, and all of the resources external to the design that this module needs to perform its function.

The NRC inspectors reviewed a sample of the subroutines included in the custom function library used by the CET_Monitor. The NRC inspectors also reviewed functional descriptions and function block diagrams associated with the CET monitoring system, contained in drawing no. 488547-1A-037 for channel A of the QSPDS. These functional diagrams describe the digital signal processing performed by the QSPDS, from the acquisition of the CET temperature sensors to the transmission and display of data on the control room flat screen display. The NRC inspectors identified no issues in this area.

Factory Acceptance Tests

The NRC inspectors reviewed Document No. 488547-1A-902-2, "Factory Acceptance Test (FAT) Procedure for Channel A," Revision 0, dated September 23, 2005. This document outlines the steps to perform the FAT for the FP&L QSPDS replacement project to verify that the QSPDS hardware and software functions are designed in an operating integrated system environment. The FAT procedure includes verification that each of the functions within the application program, as described in FL&P specifications, meets the specified acceptance criteria.

The NRC inspectors reviewed Section 9 of the FAT procedure, which includes the test methodology used to demonstrate the functionality of the QSPDS. Specifically, Section 9.2 describes the methodology for the test cases developed to demonstrate the CET functions. The test analysis provides the test case used for the validation of, among other functions within the QSPDS, the channels used by the CET, which the NRC inspectors selected as a review sample. For this activity, the NRC inspectors reviewed Appendix A.29 to the FAT procedure to verify the results of the out-of-range and open thermocouple testing, and Appendix A.30 to the FAT procedure to verify the results of the CET suspect testing. The NRC inspectors verified that the test cases were executed as described in the FAT procedure, and that the structure of each test case included the scope, validation requirements, I/O signals, service parameters to be used during the test, and the expected results, as required in PPM 6.0, "Test Control." No issues were identified in this area.

Validation Test Reports

The NRC inspectors reviewed Document No. 488547-1-854, "Validation Test Report," Revision 0, dated June 18, 2007. This report lists all executed test documents related to the system- and acceptance-level testing of the FP&L QSPDS replacement project. The validation test report includes a summary of the system- and acceptance-level test results; documents test failures from test documents, and document the review and approval of the system- and acceptance-level testing.

The NRC inspectors reviewed a sample of the interim change notices (ICNs) and system integration deficiency reports (SIDRs) contained in the validation test report associated with the CET system. The NRC inspectors noted that, while performing testing of the

CET suspect test case contained in Appendix A.30 to the FAT procedure, IPS test personnel identified an issue and issued an SIDR. Specifically, IPS wrote SIDR 172 to document an issue associated with the test parameters established in the procedure. The SIDR states that the test was suspended when testing personnel observed that one of the tested parameters did not respond as expected. In the SIDR evaluation of the issue, IPS staff determined that the test procedure was in error because the instructions were incorrectly established. The analysis conducted by IPS personnel concluded that this discrepancy had no functional impact on the system. The NRC inspectors noted that this issue was captured in two other ICNs that were open to correct the identified procedure deficiencies. The NRC inspectors found this action acceptable and consistent with the procedural guidance. No other issues were identified in this area.

Tour of Triconex Manufacturing Department

During the inspection, the NRC inspectors toured the Triconex manufacturing facility. Highlights of the tour included observation of receipt inspection, QA, and test activities, including a demonstration of a Tricon PLC system implemented on a nonsafety-related monitoring system, observation of software/hardware integration tests, environmental qualification activities in progress, and a visit to the software QA laboratory to observe IPS staff performing board-level automated fault insertion test activities.

c. Conclusions

The NRC inspectors concluded that IPS design control program requirements are consistent with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of Tricon PLC system and application design and testing documentation reviewed, the NRC inspectors determined that the IPS design control procedures were being effectively implemented.

3. COMMERCIAL GRADE DEDICATION

a. Inspection Scope

The NRC inspectors reviewed the IPS implementing policies and procedures that govern the commercial-grade dedication process to ensure that those guidelines adequately described the process as required in 10 CFR Part 21. The NRC inspectors also evaluated a limited sample of dedication packages for safety-related components to verify compliance with program requirements and adequate implementation of those requirements.

b. Observations and Findings

Quality Procedures Manual (QPM) 6.2, “Dedication of Commercial Grade Items,” Revision 006, dated March 31, 2006, provides controls for the dedication of all Triconex products (or third-party items supplied by Triconex) used in safety-related applications. IPS implements this procedure to evaluate and verify the acceptability of items used in the Tricon PLC system that are commercial grade, for the dedication of items designed, manufactured, assembled, and inspected/tested by IPS and for the dedication of items

designed by IPS but manufactured, assembled, inspected/tested by approved vendors for IPS.

The NRC inspectors held several discussions with the IPS Nuclear Quality Director to become familiar with the IPS dedication program and its implementation. The NRC inspectors learned that IPS designed the Tricon PLC system as a commercial-grade system, rather than specifically for use in safety-related systems in nuclear power plants (i.e., a basic component). To ensure that the Tricon PLC system meets the requirements for safety-related systems in nuclear power plants, IPS evaluates and verifies the acceptability of the Tricon PLC system parts and components by implementing quality controls such as design control, test control, inspection, supplier evaluation and selection, and record retention requirements, consistent with the IPS QA program. Dedication of Tricon items also includes qualification in accordance with IEEE Std. 323, "IEEE Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations," and EPRI TR-107330, "Generic Requirements Specification for Qualifying Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants."

The NRC inspectors reviewed the guidance provided in QPM 6.2 and noted that IPS identifies all Tricon parts to be dedicated on the Nuclear Dedicated Parts List (NDPL) and the NQEL. The NDPL contains all dedicated parts evaluations (DPE) maintained by the engineering department. The NQEL includes nuclear-qualified items such as modules, chassis, power supplies, termination assemblies, communication cable, and signal conditioners for termination panels. IPS maintains control of the design, manufacture, assembly, and testing of a number of these components and provides additional controls for the acceptance of items included in the NQEL that are not fully designed, manufactured, assembled, and inspected/tested under the IPS QA program. Once the items are identified in the NQEL, a DPE form is developed to dedicate the item for use in nuclear safety-related applications. The DPE documents the evaluation of the item and defines the method of acceptance used by IPS. This includes the evaluation and selection of critical characteristics based on the item's intended use, safety-related function, important physical and performance characteristics, and traceability requirements. The DPE also provides the method of acceptance for each critical characteristic. Final acceptance of the item is performed during receipt inspection and other required inspections or tests, as specified in the DPE. The NRC inspectors verified that the procedure incorporates the general guidelines of EPRI-5652, "Guidelines for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications," NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulent Marketed Products," dated March 21, 1989, and NRC Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs."

The NRC inspectors reviewed Document No. 9100055-001, "Nuclear Dedicated Parts List (NDPL)," Revision 10, dated May 2008. To verify the effective implementation of the IPS dedication process, the NRC inspectors sampled an item from the NDPL—namely, the Tricon modules/personal computers (PC) boards. These boards were dedicated for two independent projects, a Nuclear Logistics Incorporated (NLI) project and the FP&L project. These items were dedicated using DPE-03, which documents the dedication plan for modules and PC board assemblies. The NRC inspectors verified that DPE-03 identifies the safety function of the boards, the critical characteristics consistent with the

safety function, and the method of acceptance. The NRC inspectors noted that IPS conducted surveys of the pc board supplier in Reynosa, Mexico, and used special test and inspections to verify functionality of all of the PC boards received. In addition, the NRC inspectors noted that IPS performs checks or tests at preestablished phases during the manufacturing process and also before final acceptance.

The NRC inspectors reviewed the following procedures used to perform board-level performance tests and system performance tests on the PC boards:

- Test Procedure No. 76000120-001, "Unit Level Test Procedure for Enhanced Main Processor II Module," Revision 5.1, dated February 22, 2007

- Test Procedure No. 9600051-001, "Tricon System Acceptance," Revision 1.15, dated September 17, 2007

The NRC inspectors noted that both procedures specify test requirements for I/O modules and their respective acceptance criteria. The NRC inspectors also reviewed the functional test data sheet for the NLI and FP&L projects as well as board test records and system test records. The NRC inspectors verified that test results were documented and approved using the appropriate forms, and IPS issued certificates of conformance consistent with procedural guidance. No issues were identified in this area.

c. Conclusions

The NRC inspectors concluded that IPS commercial-grade dedication program requirements are consistent with the regulatory requirements of 10 CFR Part 21. Based on the limited sample of Tricon PLC system and application design and testing documentation reviewed, the NRC inspectors determined that the IPS commercial-grade dedication procedure had been effectively implemented.

4. CORRECTIVE ACTION

a. Inspection Scope

The NRC inspectors reviewed the IPS QAM and implementing policies and procedures that govern the corrective action process to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. The NRC inspectors also evaluated a limited sample of nonconformances, corrective action reports (CARs), and ARRs initiated during the past 24 months to verify compliance with program requirements and adequate implementation of those requirements.

b. Observations and Findings

Three levels of policy and procedures controlled the IPS corrective action process. The nuclear QAM controlled the QA program for all items and services provided by IPS worldwide operations. The QAM described the overall corrective action program elements and goals for all departments at the IPS Irvine operation. QPMs provide guidance for the control of activities affecting quality at the IPS Irvine operation. PPMs provide guidance for the control of nonconformances identified in project activities at the IPS Irvine operation.

Section 16 of the Nuclear QAM IPS-Q2, “Corrective Actions,” Revision 2, dated September 4, 2007, stated that conditions adverse to quality are promptly identified, corrected, documented, and reported to management, and followup action is taken to verify implementation of the corrective actions.

QAM 14.0, “Corrective and Preventive Action,” Revision 14, dated March 31, 2006, described the process for identifying and determining the cause of problems and assigning and monitoring corrective or preventive actions to correct those identified conditions. The QAM stated that any trends noted in the correction of deficiencies that indicated a generic quality program deficiency shall be issued as an ARR for review and evaluation.

QPM 14.2, “Corrective Action Document Processing,” Revision 5, dated September 14, 2007, described the requirements for processing corrective action documents, including ARRs and CARs. Section 4.1.2.3 defined four levels of characterization for QA program deficiencies ranging from Level 1, significant condition adverse to quality, to Level 4, no significance. Table 2 described each level of significance and the required actions necessary to respond to the condition. Section 4.2 described the process for opening, tracking, and resolving CARs generated against suppliers as a result of audits or other defective materials identified by IPS. This section also included requirements to review and screen CARs to determine 10 CFR Part 21 applicability.

QPM 14.0, “Quality Assurance Review Board,” Revision 8 dated March 31, 2006, described the responsibilities of the QARB. The QARB controlled, monitored, and reviewed all ARRs, quality discrepancy reports (QDRs), and product discrepancy reports (PDRs); assigned responsibility for corrective actions to cognizant personnel; assigned appropriate due dates; and reviewed potential 10 CFR Part 21 issues.

QPM 4.2, “Quality Discrepancy Report,” Revision 4, dated April 30, 2004, described the system to process and disposition QDRs. QDRs captured both software and hardware issues. Once a product is released per engineering change order by the change control board, any further discrepancies are captured as PDRs for that product.

QPM 13.2, “Product Discrepancies,” Revision 5, dated March 6, 2008, described the system used to investigate, report, correct, and document product discrepancies inherent to the design of the product. The procedure described the use of the PDR and responsibilities of the QARB with respect to PDRs. The procedure stated that the QARB was responsible for the review of nonconformance documents and determining if it was a PDR or a QDR. Furthermore, the QARB determined the criticality of the issue. Section 4.5.1 of QPM 13.2 defined five criticality levels, from Criticality Level 1, an impact to a safety system, to Criticality Level 5, noted for information only.

PPM 10.0, “Corrective and Preventive Action,” Revision 14, dated March 31, 2006, defined the process for controlling nonconforming items and identifying appropriate corrective actions for project activities. The procedure described requirements related to tasks on application projects and the use of an ARR, CAR, and SIDR to document nonconforming and corrective actions. The Project Material Review Board was responsible for the review and approval of the disposition of all nonconforming conditions, such as those documented on an SIDR.

QAM 13.1, “Control of Non-Conforming Product,” Revision 11, dated April 30, 2004, governed the material review report (MRR) process and described the process to ensure that product and integrated system items that do not conform to specified requirements are prevented from inadvertent use or installation. An MRR documented all nonconforming items, unless they were reworked in-house. Reworked items were required to have documentation to identify the discrepancy, rework instructions, rework inspections, and retest instructions.

The NRC inspectors selected a sample of ARRs to verify that they were completed and reviewed as required by the applicable procedure. The NRC inspectors confirmed that ARRs provided detailed objective evidence including actions taken and the rationale for the acceptance of actions to address the condition. The NRC inspectors also confirmed that the vendor adequately reviewed and evaluated the issues and implemented adequate corrective actions.

c. Conclusions

The NRC inspectors concluded that the IPS corrective action program requirements were consistent with the regulatory requirements of Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50. Based on the limited sample reviewed, the NRC inspectors determined that the IPS QAM and associated nonconformance and corrective action procedures were effectively implemented.

5. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

a. Inspection Scope

The NRC inspectors reviewed the IPS QAM and implementing policies and procedures that govern the purchase of material, equipment, and services to verify compliance with the requirements of Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50. The NRC inspectors also evaluated a limited sample of vendor survey reports to verify compliance with program requirements and adequate implementation of those requirements.

b. Observations and Findings

QAM 6.0, “Purchasing,” Revision 22, dated February 4, 2008, described the IPS process for selecting and approving suppliers. QAM 6.0 required that all suppliers be approved in accordance with QPM 6.1, “Source Evaluations and Supplier Selection,” Revision 13, dated September 26, 2006. Nuclear suppliers were additionally approved in accordance with Manufacturing Department Manual (MDM) 6.2, “Supplier Selection,” Revision 9, dated October 5, 2007, and Corporate Procedures Manual (CPM) C-6, “IPS Nuclear Supplier and Manufacturing Facility Approval,” Revision 1, dated August 24, 2007. IPS recorded and controlled the Approved Supplier List as a quality record. QPM 6.1 further required IPS to perform an audit or survey as part of the approval process for vendors supplying basic components, and it required reauditing at least every 3 years to maintain supplier qualification. QAM 6.0 required a survey of suppliers of commercial-grade items and services. QAM 17.0, “Audit Program,” Revision 13, dated September 25, 2006, described the IPS audit program for internal and external audits.

QAM 10.0, “Inspection and Testing,” Revision 17, dated September 25, 2006, provided controls for independent inspections and testing activities. The NRC inspectors determined that QAM 10.0 provided appropriate receiving inspection requirements to accept basic components from a supplier. The NRC inspectors noted that QPM 10.2, “Receiving Inspection,” Revision 21, dated February 15, 2008, and PPM 5.0, “Materials & Services,” Revision 7, dated September 29, 2006, provided detailed procedures to implement the requirements of QAM 10.0.

The NRC inspectors selected and reviewed a sample of survey and audit reports of nuclear and commercial vendors on the Nuclear Approved Supplier List, dated February 6, 2008, to verify that they had been performed in accordance with procedural guidance and provided adequate oversight for procured items and materials. Audit reports reviewed included those for the Weed Instrument Company, NLI, Invensys Control Systems (Reynosa, Mexico), MPR Associated Inc., Simco Electronics, and United Controls International. The NRC inspectors also noted that IPS participated in Nuclear Industry Assessment Committee (NIAC) audits and used these third-party audits to qualify some of its suppliers. From the sample selected, the NRC inspectors found that the audits were performed in accordance with procedural guidance and included detailed, documented, objective evidence that provided an adequate basis for the conclusions reached in the reports. The NRC inspectors did not identify any issues in this area.

c. Conclusions

The NRC inspectors found that the IPS control of purchased equipment, material and services program requirements are consistent with the regulatory requirements of Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50. Based on the limited sample reviewed, the NRC inspectors also determined that IPS adequately implemented its procedures to qualify vendors supplying basic components.

6. AUDITS

a. Inspection Scope

The NRC inspectors reviewed the IPS QAM and implementing policies and procedures that govern the audit process to verify compliance with the requirements of Criterion XVIII, “Audits,” of Appendix B to 10 CFR Part 50. The NRC inspectors also evaluated a limited sample of internal audit reports to verify compliance with the program requirements and adequate implementation of those requirements.

b. Observations and Findings

QAM 17, “Audit Program,” Revision 13, dated September 15, 2006, describes the process and requirements for performing internal and supplier audits. This procedure further discusses schedules for audit activities, techniques, and reports, and control of the audit process.

QPM 17.1, “Quality Audits,” controls the frequency of internal audits and describes the preparation and content of the audit report, identification and resolution of corrective actions, and closeout of audit findings. At a minimum, internal audits will be conducted on a triennial basis. Within audit reports, an ARR captures internal findings, describes the deficiencies, and assigns responsibility for and dates for resolving the findings. The NRC inspectors noted that QPM 17.1 established adequate requirements for implementing the audit program.

The NRC inspectors reviewed a sample of internal audit reports to verify that audits were performed in accordance with program requirements. Two of the audit reports reviewed included Audit Report A0601, “Annual Invensys Triconex Internal Audit,” dated August 17, 2006, and Audit Report C0703, “Corporate Audit Report,” dated February 25, 2008. During interviews with IPS responsible personnel, the NRC inspectors learned that IPS developed checklists to ensure that all lead auditors use a consistent evaluation system to evaluate supplier and internal programs. The NRC inspectors noted that the audit team lead is responsible for developing findings, proposing corrective actions, and tracking and collecting responses to those corrective actions before closing out the report. The NRC inspectors confirmed that the audit reports reviewed described recommendations and nonconformances identified during the supplier audits. Once audits are completed, the audit team lead and the Quality Director review corrective actions and evaluate the acceptability of such actions. For the audit reports reviewed, the NRC inspectors noted that corrective actions were taken in a timely manner to respond to any identified findings. The NRC inspectors also noted that the Quality Director was cognizant of the findings and of the proposed or completed corrective actions associated with them. No issues were identified in this area.

In addition, the NRC inspectors reviewed the qualification records for a sample of lead auditors and auditors. The inspection team verified that all auditors and audit team leads met the relevant requirements. Section 7 of this report provides additional details on the NRC’s review of training and qualification records.

c. Conclusions

The NRC inspectors concluded that the IPS internal audit program requirements are consistent with the regulatory requirements of Criterion XVIII, “Audits,” of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the NRC inspectors also determined that the IPS QAM and associated audit procedures were being effectively implemented. The NRC inspectors did not identify any issues in this area.

7. TRAINING AND QUALIFICATION OF PERSONNEL

a. Inspection Scope

The NRC inspectors reviewed the IPS QAM and implementing policies and procedures that govern the training and qualification program to verify compliance with the requirements of Criterion II, “Quality Assurance Program,” of Appendix B to 10 CFR Part 50. The NRC inspectors also evaluated a sample of training records of auditors lead auditors, inspectors, and test personnel to verify compliance with the program requirements and adequate implementation of those requirements.

b. Observations and Findings

QAM Section 18.0, "Training," Revision 20, dated February 4, 2008, described the controls for training and certifying employees, including auditors, product inspectors, and production test personnel. The employee's supervisor was responsible for determining the training requirements for each employee. QA staff controlled all records of training as quality documents.

QPM 18.1, "Personnel Certification," Revision 6, dated April 18, 2008, described the process used for the certification of personnel to conduct audits, inspections, and tests. The procedure described specific qualification requirements for auditors, lead auditors, and inspection and test personnel. The procedure also provided evaluation record documents for auditor and inspection and test personnel to be completed and retained in the employee's training records.

The NRC inspectors reviewed the qualification records for a sample of lead auditors, auditors, inspection personnel, and test personnel. The inspections verified that the auditors and audit team leads reviewed had met the requirements and that all audit leads had regular and active participation in the audit process to maintain their qualification in accordance with program requirements. The NRC inspectors noted that the documentation supporting the qualification of each auditor and lead auditor was detailed and provided sufficient objective evidence to support the finding that qualification requirements had been successfully completed and maintained current. The NRC inspectors also noted that the documentation supporting the training and certification of inspection and test personnel was also complete and detailed.

QPM 18.1 states that management will reevaluate inspectors at least every 3 years (plus or minus 2 months). The NRC inspectors noted that the reevaluation signatures for 3 inspection personnel evaluation records were dated 3.5 years after initial qualification in September 2002. The NRC inspectors discussed this issue with QA personnel and noted that IPS had identified the issue, and the reevaluation was conducted and recorded on the evaluation records in March 2006. An ARR was not written at the time the issue was identified; however, the vendor took appropriate measures to ensure that future reevaluations were conducted in the timeframe specified in the procedure. The subsequent inspector triennial evaluation was conducted for each of the three inspection personnel within the 3-year requirement in January 2008. The NRC inspectors found this action acceptable.

c. Conclusions

The NRC inspectors concluded that the IPS training and qualification program was consistent with the regulatory requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. Based on the limited sample reviewed, the NRC inspectors determined that procedures developed by IPS for training and certification were effectively implemented.

8. EXIT MEETING

On May 22, 2008, the NRC inspectors presented the inspection scope and findings during an exit meeting with the IPS Global Quality Director and other IPS personnel.

ATTACHMENT

1. PERSONS CONTACTED

David Golden	IPS Global Quality Director
Jeff Larson	IPS Nuclear Quality Director
Bob Rasmussen	General Manager, Triconex
Mike Phillips	IPS Nuclear Business Development
Clayton Scott	IPS Nuclear Business Development
Paul Mesmer	Quality Director, Triconex Products
George Hughes	Projects Quality Manager
Michael Kieu	Director, Safety & Critical Components
Naresh Desai	Senior Technical Consultant
Frank Kloer	Qualification Engineer
Aad Faber	Product Assurance

2. INSPECTION PROCEDURES USED

IP 43002, "Routine Vendor Inspection."
IP 43004, “Inspection of Commercial Grade Dedication Programs.”
IP 36100, “Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance."

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
99901357/2008-201-01	Opened	NOV	Violation of Part 21

4. LIST OF ACRONYMS USED

ARR	action request report
CAR	corrective action report
CDR	critical digital review
CET	core exit thermocouple
CFR	*Code of Federal Regulations*
CIA	change impact analysis
CQVB	Quality and Vendor Branch 2
CQVP	Quality and Vendor Branch 1
DCIP	Division of Construction Inspection and Operational Programs
DE	Division of Engineering
DPE	dedicated parts evaluation
EDM	Engineering Department Manual
EPRI	Electric Power Research Institute
ERDADS	emergency response data acquisition and display system
FAT	factory acceptance test
FP&L	Florida Power and Light
FSAR	final safety analysis report
HRS	hardware requirements specifications
I/A	Intelligent/Application
I&C	instrumentation and control
I/O	input/output

ICE2	Instrumentation, Controls, and Electrical Engineering Branch 2
IEEE	Institute of Electrical and Electronics Engineers
IP	inspection procedure
IPS	Invensys Process Systems
MP	main processor
MRR	material review report
NDPL	Nuclear Dedicated Parts List
NLI	Nuclear Logistics Incorporated
NON	Notice of Nonconformance
NOV	Notice of Violation
NQEL	Nuclear-Qualified Equipment List
NRC	U.S. Nuclear Regulatory Commission
NRO	Office of New Reactors
NRR	Office of Nuclear Reactor Regulation
PC	personal computer
PDR	product discrepancy report
PPM	Project Procedures Manual
QA	quality assurance
QAM	Quality Assurance Manual
QARB	Quality Assurance Review Board
QDR	quality discrepancy reports
QPM	Quality Procedure Manual
QSPDS	qualified safety parameter display system
SDB	system design basis
SDD	software design description
SIDR	system integration deficiency report
SQAP	System Software and Hardware Quality Assurance Plan
SR HMI	safety-related human machine interface
SRS	software requirements specifications
SVVP	System Software and Hardware Verification and Validation Plan
TSAP	TriStation Application Project
TÜV	Technischer Überwachungs-Verein
V&V	verification and validation