

April 13, 2006

Mr. Paul Mesmer, Director
Quality Assurance
Invensys/Triconex
15345 Barranca Parkway
Irvine, California 92618

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
99901357/2006201

Dear Mr. Mesmer:

This letter addresses the Nuclear Regulatory Inspection (NRC) inspection of your facility at Irvine, California, conducted by Bill Rogers and Victor Hall of this office on March 14 through March 15, 2006. Mr. Rogers held an exit meeting and discussed his conclusions with you and your staff at the conclusion of the inspection.

This inspection consisted of an examination of procedures and representative records, interviews with personnel, and observations by the NRC inspectors. The NRC staff reviewed selected portions of your quality assurance program, and its implementation, as it relates to your safety-related control and display systems for the nuclear industry and other nuclear related activities. The areas examined during the inspection are discussed in detail in the enclosed report.

During this inspection, it was found that the Invensys/Triconex quality assurance program was, in general, well documented and being adequately implemented in the areas reviewed. However, during this inspection it was found that the implementation of your quality assurance program failed to meet certain NRC requirements in one area. For numerous Action Request Reports (ARRs) applicable to a safety-related purchase order, the ARR remained open for an excessive period of time, the corrective actions listed in the "Problem Description" section did not clearly or specifically correlate with items in the "Problem Fix" section, and the specific basis for closure of the items listed in the "Problem Description" section was not adequately documented in the "Problem Fix" section or included in the ARR package.

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

Docket No. 99901357

P. Mesmer

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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room (PDR).

Sincerely,

\RA

Hossein Hamzehee, Chief
Quality and Vendor Branch B
Division of Engineering
Office of Nuclear Reactor Regulation

Enclosures:

- (1) Notice of Nonconformance
- (2) Inspection Report 99901357/2006201

P. Mesmer

-2-

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OFFICE	NRR/EQVB	C	BC:NRR/EQVB	
NAME	BRogers		HHamzehee	
DATE	04/13/2006		04/13/2006	

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NOTICE OF NONCONFORMANCE

Invensys/Triconex, Irvine, California
Docket Number 999-01357

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted on March 14 -15, 2006, of activities supporting safety-related purchase orders, it appears that certain activities were not conducted in accordance with NRC requirements.

Criterion XVI, "Corrective Action," of 10 CFR Part 50, Appendix B, states, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

Criterion XVII, "Quality Assurance Records," of 10 CFR Part 50, Appendix B, states, in part, that sufficient records shall be maintained of activities affecting quality.

Contrary to the above, for numerous Action Request Reports (ARRs), applicable to a safety-related Florida Power & Light purchase order for Qualified Safety Parameter Display Systems: (1) the ARR's remained open for an excessive period of time; (2) the corrective actions listed in the "Problem Description" section did not clearly or specifically correlate with items in the "Problem Fix" section; and (3) the specific basis for closure of the items listed in the "Problem Description" section was not adequately documented in the "Problem Fix" section or included in the ARR package. This issue is identified as Nonconformance 99901397/2006201-1.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Chief, Quality and Vendor Branch B, Division of Engineering, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to Notice of Nonconformance" and should include for each nonconformance: (1) the reason for the nonconformance, or if contested, the basis for disputing the nonconformance, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further noncompliances and (4) the dates your corrective action will be completed. Where good cause is shown, consideration will be given extending the response time.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system, Agency-wide 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

ENCLOSURE 1

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 2.790(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.

Dated this 13th day of April 2006.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION

COMPANY: Invensys/Triconex
 15345 Barranca Parkway
 Irvine, CA 92618

CONTACT: Paul Mesmer, Qualify Assurance Director
 Invensys/Triconex
 (949) 885-0700

NUCLEAR ACTIVITY: Designs and manufactures safety-related control systems.

DATES: March 14 - 15, 2006

REPORT NO: 99901357/2006201

NRC inspectors: Bill Rogers
 Quality and Vendor Branch B
 Division of Engineering
 Office of Nuclear Reactor Regulation
 U.S. Nuclear Regulatory Commission

 Victor Hall
 Division of Engineering
 Office of Nuclear Reactor Regulation
 U.S. Nuclear Regulatory Commission

APPROVED BY: Hossein Hamzehee, Chief
 Quality and Vendor Branch B
 Division of Engineering
 Office of Nuclear Reactor Regulation
 U.S. Nuclear Regulatory Commission

ENCLOSURE 2

1. INSPECTION SUMMARY

On March 14 - 15, 2006, the U.S. Nuclear Regulatory Commission (NRC) performed an inspection at the Invensys/Triconex facility in Irvine, California. The purpose of the inspection was to verify compliance with the regulations contained in 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

The scope of the inspection focused on selected portions of the Invensys/Triconex quality assurance program and the implementation of the program used in the design and manufacture of safety-related control systems.

1.1 Nonconformances

Nonconformance 99901357/2006201-1 is discussed in Section 3.3.

2. STATUS OF PREVIOUS INSPECTION FINDINGS

There were no previous inspection findings. This was the initial NRC inspection of Invensys/Triconex.

3. INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Review of Safety-Related Purchase Order Quality Assurance Activities

a. Inspection Scope

The NRC inspectors reviewed Invensys/Triconex activities supporting the safety-related Florida Power & Light (FP&L) purchase order 000060611 for Class 1E Qualified Safety Parameters Display Systems (QSPDS). The NRC inspectors reviewed Quality Surveillances associated with the purchase order, relevant parts of the Invensys/Triconex Quality Assurance Manual (QAM), Quality Procedures Manual (QPM), and Project Procedures Manual (PPM). In addition, the NRC inspectors reviewed portions of the documentation and implementation of the ongoing Factory Acceptance Test (FAT) for the QSPDS order.

b. Observations and Findings

The FP&L QSPDS purchase order is for safety-related controller upgrades built on the Invensys/Triconex TRICON control system. The NRC inspectors reviewed the purchase order for four QSPDS systems: two for St. Lucie Units 1 and 2, and two for Turkey Point Units 3 and 4. The purchase order requires Invensys/Triconex to conform to their 10 CFR Part 50, Appendix B, (Appendix B) Quality Assurance program. Section 1.4 "Project Activities" of the purchase order states that "All project activities shall be conducted in accordance with the Invensys/Triconex Quality Assurance Manual (QAM), the Project Procedures Manual (PPM), and the Project Quality Plan."

Quality Surveillances

Quality Surveillances, QAM 17.0, "Audit Program," requires that quality surveillances be performed in accordance with QPM 17.2, "Quality Surveillances." In addition, QAM 17.0, Section 4.5, "Quality Program Surveillance," states in part:

"The Invensys/Triconex audit program may be augmented by other documented quality surveillance activities. Surveillance Reports and Self-assessment Reports may be used as a means to plan, conduct, and document independent verifications or the monitoring of selected activities for compliance with quality program requirements. Quality Surveillances are conducted in accordance with QPM 17.2"

The NRC inspectors also reviewed QPM 17.2 which states: "Triconex Quality Assurance should conduct two surveillances each month to verify the quality of selected activities in progress." The NRC inspectors noted that the procedure calls for a surveillance schedule to be kept by the Quality Director. The NRC inspectors reviewed the Invensys/Triconex Quality Surveillance Schedule, Log, and a sample of Surveillances. The NRC inspectors verified that Invensys/Triconex performed Quality Surveillances in accordance with the periodicity requirements of the QAM.

Factory Acceptance Testing

The NRC inspectors reviewed the procedures developed for performance of the FAT. The tests performed for the FP&L QSPDS order included several distinct tests. Preliminary Test Verification (PTV) was a hardware test using a test program which exercised the full range of all of the inputs and outputs to verify functionality. The FAT was an integrated test of the actual final application program and verified interfaces using customer developed software. The System Performance Test (SPT) verified time response, data throughput and printer and screen functionality. The Integrated System Availability (ISA) was a 120-hour system exercise under normal operating conditions. The NRC inspectors reviewed the PTV, FAT, and ISA procedures, observed the actual equipment in the testing configuration and verified the quality controls supporting the test. In addition, the NRC inspectors reviewed the qualification requirements for the individuals performing the test, determined that adequate training and qualification requirements were in place, and that the personnel managing and performing the test activities were qualified to perform their tasks. The NRC inspectors did not identify any issues related to procedures, documentation, configuration, or training and qualification.

c. Conclusions

The NRC inspectors did not identify any instances where Invensys/Triconex was not in compliance with the requirements of their customer's purchase order.

3.2 10 CFR PART 21 PROGRAM

a. Inspection Scope

The NRC inspectors reviewed Invensys/Triconex Products Quality Assurance Manual (QAM) 13.3, “10CFR Part 21 Reporting of Defects and Noncompliance,” and associated documents related to the implementation of its program.

b. Observations and Findings

Invensys/Triconex QAM 13.3 was developed to implement the requirements of 10 CFR Part 21 (Part 21). QAM 13.3 describes the Invensys/Triconex process for identifying and evaluating “defects and/or deviations” and reporting to the NRC when required. The NRC inspectors determined that QAM 13.3 defined the terms “defect” and “deviation” consistent with the definitions in Part 21; however, the terms are incorrectly used (interchanged) elsewhere in Invensys/Triconex procedures. In particular, Step 1 of the Invensys/Triconex Part 21 Evaluation worksheet (Figure 1 of QAM 13.3), is labeled: “Defect [emphasis added] in product discovered.”

The NRC inspectors noted that Part 21.21 states, in part: “A dedicating entity is responsible for identifying and evaluating deviations [a departure from the technical requirements in a procurement document] and reporting defects [in part, a deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to this part if on the basis of an evaluation, the deviation could create a substantial safety hazard].” In accordance with Part 21, the vendor is responsible for identifying and evaluating deviations (or notifying the purchasers or affected licensees if the supplier does not have the capability to perform the evaluation) to determine if the deviation meets the definition of a defect.

QAM 13.3 states that all Invensys/Triconex employees are responsible for identifying potential product deficiencies which are reported to the Quality Assurance Review Board (QARB). The QARB is responsible for evaluating deficiencies, which can be identified on Product Discrepancy Reports (PDRs), Quality Discrepancy Reports (QDRs), and Action Request Reporting (ARRs). In addition, the QARB reviews System Integration Discrepancy Reports (SIDRs), Material Review Reports (MRRs), and Corrective Action Request (CARs) for Part 21 reportability. QPM 14.0 requires that QARB meeting minutes be kept, and are regarded as quality records. In addition, QAM 13.3 requires that evaluations, notifications, and records be kept, consistent with Part 21. The NRC inspectors reviewed a sample of MRRs, PDRs, and SIDRs for potential Part 21 reportability issues and did not identify any concerns. In addition, the NRC inspectors verified that the Invensys/Triconex procedure included the required time limits and that the Part 21 posting requirements had been met.

c. Conclusions

The NRC inspectors concluded that the Invensys/Triconex procedures met the intent of Part 21. However, Part 21 terminology for deviations and defects was used incorrectly in certain procedures. This was identified as a minor weakness.

3.3 Corrective Action Program

a. Inspection Scope

The NRC inspectors reviewed portions of the Invensys/Triconex corrective action program. Invensys/Triconex used several processes to identify manufacturing, material, and process issues which needed review. The NRC inspectors focused on Action Request Reports (ARRs) which primarily documented program and process deficiencies.

b. Observations and Findings

The NRC inspectors reviewed the organizational chart and quality records, observed activities, and discussed documentation of quality issues with Invensys/Triconex management and staff to determine whether the QA organization had sufficient authority and organizational independence to identify quality problems, recommend or provide solutions, and verify implementation of the solutions. The NRC inspectors reviewed ARR associated with the FP&L QPDS to determine the nature of issues being identified and documented. It was determined that the Invensys/Triconex QA management and staff were documenting substantive issues and aggressively using the ARRs to identify process issues arising from various sources. Based on review of the ARRs and discussion with QA management and staff and production management and staff, the NRC inspectors concluded that Invensys/Triconex personnel were freely documenting issues in support of a quality assurance structure which is adequate for providing safety-related products and services.

The NRC inspectors reviewed the requirements for timeliness of closure of ARRs contained in the Invensys/Triconex documents Quality Assurance Manual (QAM) section 14.0, "Corrective Action and Preventative Action," and the Quality Procedures Manual (QPM) 14.2, "Corrective Action Document Processing." QPM 14.2 stated that the due date for closure was fourteen to thirty days, if not closed within sixty days the item would be forwarded to the executive staff for action, and ARRs open beyond six months would be highlighted in a management meeting minutes for visibility. The NRC inspectors reviewed the ARRs associated with the safety-related FP&L QPDS order and determined that there were numerous ARRs, open well over thirty days with several extending up to a year. The NRC inspectors also noted that Invensys/Triconex had documented the ARR timeliness issue in an ARR 496, "Overdue Corrective Actions for Quality Program Deficiencies on Florida Power & Light Projects," dated March 12, 2006. The NRC inspectors concluded, based on a review of the ARRs, that adequate corrective actions had not yet been put in place to address the issue.

ARRs were typically composed of two pages, the first page which documented the "Problem Description," "Problem Cause," and the "Problem Fix" and the second page an extension of the "Problem Fix" section. The NRC inspectors noted that the "Problem Fix" information generally consisted of a running chronology of dated items such as recommendations, action items, due dates, and excerpts of meeting notes. There was often no clear, specific reference between the initial "Problem Description" (which often consisted of multiple items) and the information listed in the "Problem Fix" section. For numerous ARRs reviewed, the NRC inspectors were unable to consistently correlate the "Problem Description" items with "Problem Fix" items to determine the existence or adequacy of corrective actions. The NRC inspectors also noted that the "Problem Fix" field often maintained a very casual, conversational tone which made the

section difficult to comprehend and also contained superfluous information, inappropriate for a quality document.

In addition, for many of the closed ARR's which were reviewed, the NRC inspectors were unable to determine the existence or adequacy of a basis for closure of the ARR. Discussion with Invensys/Triconex management indicated that the basis for closure, if not documented in the "Problem Fix" section, was documented in management board meeting notes where ARR closures were discussed. However, based upon a review of applicable meeting notes the NRC inspectors were unable to determine the existence or adequacy for a documented basis for closure in many cases in either the "Problem Fix" section or meeting notes. The failure to promptly address identified issues and close ARR's, the lack of correlation between the "Problem Description" and the "Problem Fix" sections, and the inadequate documentation for the basis of ARR closure was identified as Nonconformance 99901357/2006201-1.

c. Conclusions

The NRC inspectors concluded that Invensys/Triconex have adequately documented process issues in the ARR process in accordance with the quality assurance program and did not identify any instances where the Invensys/Triconex Quality Assurance organization did not have sufficient independence from Invensys/Triconex Project Management. However, timeliness, correlation of issues with corrective actions, and documenting the basis for closure were determined to be areas of the Invensys/Triconex corrective action program which did not meet the requirements of 10 CFR Part 50, Appendix B.

4 PERSONS CONTACTED

David Golden, Global Director of Quality
Bob Rasmussen, Manufacturing and Site General Manager
Gary Hufton, Director of Engineering
Gary McDonald, Director Nuclear Quality
Paul Mesmer, Director Quality
Michael Phillips, Nuclear Program Director
George Vaslos, Senior Nuclear Quality Engineer
Brian Haynes, Project Manager