April 9, 2010

MEMORANDUM TO: Glenn M. Tracy, Director
Division of Construction, Inspection
& Operational Programs
Office of New Reactors

THRU: Richard A. Rasmussen, Chief ***/RA/***
Quality and Vendor Branch B
Division of Construction Inspection
& Operational Programs
Office of New Reactors

FROM: Daniel Pasquale, Inspection Team Leader ***/RA/***
Quality and Vendor Branch B
Division of Construction Inspection
& Operational Programs
Office of New Reactors

SUBJECT: TRIP REPORT ON THE JOINT UTILITY TEAM AUDIT AT ENGINE SYSTEMS, INC., BY NRC INSPECTORS FROM THE DIVISION OF CONSTRUCTION INSPECTION AND OPERATIONAL PROGRAMS

From March 1 to March 5, 2010, U.S. Nuclear Regulatory Commission (NRC) Inspectors Daniel Pasquale and Milton Concepcion observed a Nuclear Procurement Issues Committee (NUPIC) joint utility audit at the Engine Systems, Inc. (ESI) facility in Rocky Mount, NC. Mr. Pasquale (Quality and Vendor Branch B) and Mr. Concepcion (Quality and Vendor Branch A) are both from the NRC's Office of New Reactors, Division of Construction Inspection and Operational Programs. Using the most current version of the NUPIC audit checklist, a representative of Florida Power & Light (FPL) led the audit, with participation from representatives of Constellation Energy (CEG), Luminant Energy (LUM), Omaha Public Power District (OPPD), Progress Energy (PGN), and the South Texas Project Operating Company (STP). A member of the NRC Office of the Inspector General attended the entire inspection. In addition, the NRC Branch Chief for the Quality and Vendor Branch 2, Division of Construction Inspection and Operational Programs, Office of New Reactors attended the final 2 days of the inspection, including FPL's formal exit meeting with the supplier's representatives.

The NRC inspectors observed the audit in order to assess the implementation of the NUPIC audit process used for suppliers of safety-related components to the nuclear industry. The enclosed trip report contains the inspectors' observations and a list of the persons contacted.

Enclosure:
As stated

CONTACT: Daniel Pasquale, NRO/DCIP/CQVB
301-415-2498

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DISTRIBUTION:
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ADAMS Accession No.: **ML100850425**

OFFICE	NRO/DCIP/CQVB	NRO/DCIP/CQVA	NRO/DCIP/CQVB:BC
NAME	DPasquale	MConcepcion	RRasmussen
DATE	04/09/2010	04/08/2010	04/09/2010

OFFICIAL RECORD COPY

NRC TRIP REPORT

Subject

This trip report documents observations by inspectors from the U.S. Nuclear Regulatory Commission (NRC) Office of New Reactors (NRO), Division of Construction Inspection & Operational Programs (DCIP), of a Nuclear Procurement Issues Committee (NUPIC) joint utility audit conducted from March 1 to March 5, 2010, at Engine Systems, Inc. (ESI), in Rocky Mount, NC.

Dates of Audit and Organization Visited

March 1-5, 2010
Engine Systems, Inc.
175 Freight Road
Rocky Mount, NC 27804

Author, Title, and Agency Affiliation

Daniel Pasquale, Vendor Inspector
Sr. Operations Engineer
Quality and Vendor Branch B (CQVB)
Office of New Reactors (NRO)

Sensitivity

There were no documents removed from the facility during the conduct of the audit. This document is available to the public (Agencywide Documents Access and Management System (ADAMS) Accession no. **ML100850425**).

Background/Purpose

NUPIC was formed in 1989, as a partnership involving all domestic and several international nuclear utilities. The NUPIC program evaluates suppliers furnishing safety-related components and services and commercial-grade items to nuclear utilities. The audit team followed the NUPIC audit process and plans to provide the results to NUPIC members that procure parts and services from ESI.

This trip report documents the NRC inspectors' assessment of a Florida Power & Light-led, NUPIC joint utility audit conducted at the ESI facility located in Rocky Mount, NC from March 1 to March 5, 2010. ESI provides basic components and safety-related services to the commercial power industry, primarily as a supplier of emergency diesel generator parts, sourced mostly from commercial manufacturers and dedicated. ESI's quality program is based on Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," 10 CFR Part 21, "Reporting of Defects and Noncompliance," and ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications" and ISO (International Organization for Standardization) standard ISO 9001-2008, "Quality Management Systems". ESI is a 10 CFR 50 Appendix B supplier of emergency diesel parts and services, including new, refurbished, and commercially dedicated replacement parts; system design, modification and fabrication; and onsite field services. Additionally, ESI is the sole 10

CFR 50 Appendix B supplier of Woodward Governors and governor controls, including repair and refurbishment.

NRC observes NUPIC audits to verify the effectiveness and implementation of the NUPIC joint utility audit process. The NRC inspectors followed Inspection Procedure (IP) 43005, "NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements," to assess the third-party organization's independent oversight activities to qualify vendors. IP 43005 directs inspectors to perform an inspection of the supplier's 10 CFR Part 21 process, including effective implementation of that program. In this audit, the NUPIC team assumed these responsibilities, as detailed in revision 14 of the NUPIC audit checklist. The inspectors observed the NUPIC audit team as they independently evaluated ESI's 10 CFR Part 21 program in accordance with revision 14 of the NUPIC checklist. The agency is currently revising IP 43005 to provide staff with the option to choose when it will perform a 10 CFR Part 21 inspection at a supplier's facility. Prior to the beginning of the NUPIC audit, NRC inspectors informed the NUPIC audit team leader (ATL) and the supplier's manager of quality assurance that the NRC would not be performing the 10 CFR Part 21 attribute of IP 43005. The NRC lead inspector also repeated this point during the formal entrance meeting at ESI.

A member of the NRC Office of the Inspector General also observed of the inspection. In addition, the Branch Chief for the Quality and Vendor Branch B, (DCIP, NRO) attended the final 2 days of the inspection, including FPL's formal exit meeting with the supplier's representatives.

Discussion

The NUPIC audit scope evaluated the acceptability of ESI's quality assurance (QA) program and included a performance based verification of the effective implementation of that program in accordance with the requirements of Appendix B to 10 CFR Part 50, 10 CFR Part 21, and ASME NQA-1-1994.

The performance-based attributes, included observations by the audit team of shop activities associated with commercial-grade dedication, fabrication, assembly, special processes (welding and nondestructive examination), tests, and inspection activities.

The NUPIC audit team was comprised of an audit team leader (ATL), six utility auditors, and a technical specialist. A representative of Florida Power & Light (FPL) led the audit with assistance by representatives from Florida Power & Light (FPL), Constellation Energy (CEG), Luminant Energy (LUM), Omaha Public Power District (OPPD), Progress Energy (PGN), and the South Texas Project Operating Company (STP).

The audit team assessed the adequacy of ESI's QA program by reviewing the ESI QA manual and related, lower-tier implementing documents such as procedures, commercial-grade dedication reports, and associated drawings. The auditors used the NUPIC audit checklist as a tool to perform these reviews. The NUPIC audit checklist is divided into the 18 criteria of Appendix B to 10 CFR Part 50. Additionally, the checklist includes verification for the incorporation and implementation of the requirements of 10 CFR Part 21. This checklist (1) defines the audit attributes to be examined within each section, and (2) describes how the auditor should utilize the data sheets included with the checklists to record the supporting objective evidence. The inspectors observed that the NUPIC audit team had utilized the most current version (revision 14) of the NUPIC audit checklist for this audit. The NUPIC audit checklist can be downloaded from the NUPIC Web site (www.nupic.com)

Observations and Assessment

The NRC inspectors observed all aspects of the NUPIC audit team's performance starting with the audit team meeting held on February 28, 2010 (1 day before the formal audit entrance meeting). The purpose of this meeting was to review the details of the audit, including a statement of the lead auditor's expectations. Beginning with this pre-audit meeting and extending throughout the week, the inspectors observed that audit activities flowed smoothly and all planned activities were effectively assessed. NRC inspectors found that the audit team leader had adequately prepared for the audit. The inspectors also observed the audit team's internal daily meetings, the daily debriefs with ESI management, and the formal exit meeting where the audit team presented its results. The ATL conducted the entrance meeting professionally and clearly articulated the scope of the audit to the supplier's representatives. As the audit team identified daily issues, the inspectors noted that the audit team appropriately communicated issues amongst team members and also to the supplier's representatives.

The ATL divided the NUPIC checklist sections among the six auditors as part of the audit planning processes. NRC inspectors observed each individual NUPIC audit team member on their portion of the audit. NRC staff specifically noted the individual auditor's assessment of the ESI QA Manual, implementation of procedures, and in-progress/completed documentation. NRC inspectors also observed the individual auditors as they conducted the various activities associated with the reviews of their assigned checklist sections. Observations by the staff of in-progress audit activities included an evaluation of ESI's contract review process, internal and external audits, design control, examinations of commercial-grade item dedication activities, calibration records for measuring and test equipment, nonconformance reports, corrective action reports, software QA, record retention, procurement controls to sub-suppliers, and field service activities. The NRC inspectors also accompanied the NUPIC auditors onto the shop floor and observed ongoing work activities including dedication testing, fabrication and assembly activities, seismic "shake" testing in support of equipment qualification (EQ) requirements, receipt inspection activities and handling, storage, and shipping activities as part of the NUPIC performance-based audit process. Additionally, the staff observed the NUPIC audit team as they reviewed the areas of repair/rework, returned goods authorization (RGA), and 10 CFR Part 21 posting and reporting.

The inspectors observed NUPIC's assessment for program adequacy and implementation of ESI's 10 CFR Part 21 program. This was the first time the inspectors had observed NUPIC auditors perform this inspection independently, without a concurrent inspection being performed by members of the NRC staff. The inspectors noted that the NUPIC auditor utilized NUPIC's newly added 10 CFR Part 21 section, introduced in revision 14 of the NUPIC audit checklist. The inspectors concluded that the auditor had executed an effective assessment of ESI's 10 CFR Part 21 program using this new checklist.

The inspectors noted the depth of skill and experience of the NUPIC auditors and concluded they were appropriately qualified to perform the evaluation of the ESI QA program. The auditors exhibited an appropriate "questioning attitude" for the level of complexity associated with the various NUPIC checklist sections. One exception to this was noted in the review of ESI's internal audits. The inspectors noted that the audit team failed to conclude that ESI's internal audit process was ineffective, even though, at the conclusion of the audit, 28 issues had been identified resulting in 10 potential findings. The NRC inspector observed the review of this section in more detail after it was evident that ESI's internal audit program had not been effective in capturing these issues. Upon further review, the inspectors noted that as early as 2006, ESI had been employing independent contractors to perform their internal audits. The

inspectors also noted that each subsequent annual audit used fewer resources, took less time, and found fewer issues. In 2008, ESI changed out their original contractor for another. Even fewer issues were identified in the 2 years following the change out. These observations were discussed with the responsible auditor and with the ATL prior to the formal exit meeting with ESI. The ATL stated from these discussions that, since each of these internal audit reports had a reasonable amount of documented objective evidence, and a NUPIC style checklist had been used to guide the audit, that NUPIC's internal audit section should be deemed satisfactory. A review of the final NUPIC Inspection Report indicated that Section 12, "Internal Audits," was submitted as being "satisfactory". In follow-up conversations with the ATL and with the NUPIC auditor assigned to Section 12, relative to this conclusion, they indicated that their reasoning for declaring this section satisfactory originates in the way the NUPIC audit checklist is structured. The checklist attributes for Section 12 require the auditor to collect and review objective evidence in support of the supplier's performance of internal audit activities. These attributes however, never require the auditor to assess the effectiveness of these internal audits. This is inconsistent with the guidance presented in Appendix B to 10 CFR 50, Criterion XVIII, "Audits," which states, in part, "A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program." In the case of this audit of ESI, the NUPIC team issued 10 findings to the supplier, and noted a degrading trend in internal audit quality over the years spanned during the audit. The inspectors determined that the supplier's internal audit program failed to adequately assess the effectiveness of ESI's implementation of their QA program. The ATL did make mention of a degrading trend in internal audit quality during the formal exit meeting with ESI management, documented the issue in the final audit report, and required the supplier to respond in writing to this observation. The inspectors agree that these efforts will direct ESI to re-evaluate their internal audit strategy, but feel that this is a weakness in the NUPIC vendor oversight program; in that it does not take into account the benefits of trending degrading performance as a predictor of more significant programmatic breakdowns.

The NUPIC audit team's technical specialist was observed by the inspectors, using the NUPIC performance based supplier audit (PBSA) worksheet to review technical characteristics such as the following: (1) control of design from OEM specifications, (2) the evaluation of seismic and environmental qualification activities, (3) commercial-grade dedication, (4) material and mechanical testing activities, (5) electrical testing, (6) adequacy of commercial grade audits and surveys, (7) governor calibration, (8) foreign material exclusion (FME) practices, and (9) evaluation of obsolete components including recommendations of substitute components to the utilities. He used the PBSA to review the physical and technical characteristics of various products and services provided by the supplier. He had compiled the PBSA worksheet prior to arriving at ESI, from feedback received from the various utility users. Each PBSA attribute had corresponding acceptance criteria listed. The PBSA worksheets were written specific to ESI-supplied safety-related materials (material specification, traceability, fabrication, nondestructive examination, and testing). The inspectors found this section satisfactory

The NRC inspectors noted that discrepancies existed between the scope of supply listed in the Audit Notification letter, the Audit Plan, the Audit Report, the PBSAs, and what was actually audited by the NUPIC team while at ESI. Specific areas in conflict include: 1.) The supply of Weschler Instruments, 2.) the supply of Honeywell QX/SX Recorders, and 3.) the supply of on-site services including repair and modification of diesel generators. It is unclear from the published audit documentation which products supplied by this vendor were evaluated during the audit. A review of the Audit Report section titled, "Documents reviewed in support of this evaluation,' proved inconclusive in presenting sufficient objective evidence to determine if either

the supply of Weschler Instruments, or the supply of Honeywell QX/SX Recorders, were evaluated by the NUPIC team. Objective evidence to support the evaluation of the supply of on-site services including repair and modification of diesel generators was well documented, but the presentation of the scope of supply was not consistent throughout the audit documentation.

A review of the final NUPIC audit report listed the NRC staff that observed the NUPIC audit team, as "persons participating in the audit." It should be noted, that the inspectors were at ESI to observe and evaluate the NUPIC audit process, not as participants.

Summary of NUPIC Findings:

As a result of their efforts, the NUPIC audit team identified numerous issues associated with ESI's QA program and identified 10 preliminary findings. These preliminary findings and the audit team's recommendations were discussed in detail; the audit team also presented drafts of the findings to ESI management during the exit meeting. The inspectors observed that prior to the exit meeting, the audit team had already effectively communicated each finding to ESI and that ESI personnel understood the issues. The NUPIC audit report was issued to ESI on April 02, 2010, and included findings for failures in the areas of commercial-grade dedication, control of measurements and test equipment, document control/procedural adequacy, control of nonconforming conditions and corrective actions, supplier selection, QA records, and 10 CFR Part 21. The NUPIC lead auditor adequately documented each finding in the audit report.

FPL Audit PQA-10-01 Findings:

1.	Criterion IV	Licensee not notified of product change
2.	Criterion XII	No Calibration of Meter and Test Equipment (M&TE) Equipment
3.	(Multiple) Criterion III Criterion IV Criterion V Criterion VII Criterion XVII 	Commercial grade dedication issues: - Supplier's process controls listed as a critical characteristic - No basis for source of dimensional tolerances - Omitted critical characteristic without justification - Manufacturer's solder specification were used for acceptance while being several revisions out of date - Dedication package three revs out of date - Inadequate commercial-grade surveys (2) - Errors in lot/batch sampling assumptions
4.	Criterion III	Commercial-grade dedication issue: - Failure mode of basic component not listed in dedication package.
5.	Criterion VII	Use of an unapproved supplier by ESI
6.	Criterion VII	Use of an unapproved supplier by a sub-supplier of ESI
7.	Criterion XVIII	No justification to disregard auditor's recommendations listed in the supplier audit.
8.	Criterion XVII	QA records not maintained in an appropriate fire file
9.	Criterion III	Commercial-grade dedication issue: - Inadequate commercial-grade survey
10.	Criterion XVII	Missing inspector qualification records

Conclusions

Based on the NRC inspectors' assessment of the performance of the NUPIC joint utility audit team, the inspectors concluded that, with the exceptions of the internal audit assessment issue, and the discrepancy between the reported scope of supply and the actual audit activities as identified above, the NUPIC audit team effectively implemented the NUPIC audit process and thoroughly reviewed the areas covered by the audit.

Pending Actions/Planned Next Steps for NRC

This NRC assessment was one of at least two planned for FY 2010. Depending on the adequacy of ESI's responses to the NUPIC findings, the staff may conduct a followup inspection. At the next NUPIC general meeting, staff will discuss NRC observations related to the performance of this audit with NUPIC leadership.

Points for Commission Consideration/Items of Interest

None.

List of Meeting Participants

			Entrance	Exit
Daniel Pasquale	Lead Inspector	NRC	X	X
Milton Concepcion	Inspector	NRC	X	X
Mike Zeiter	Observer	NRC	X	X
Rick Rasmussen	Observer	NRC		X
Jose Magalhaes	Team Lead Auditor	FPL	X	X
Jeffrey Baysinger	Auditor	FPL	X	X
John Simmons	Auditor	LUM	X	X
Joe Davis	Auditor	OPPD	X	X
Brian Vickery	Auditor	PGN	X	X
Phil Sullivan	Auditor	STP	X	X
Doug Weeks	Technical Specialist	FPL	X	X
John A. Manno	Vice President	KIRBY ENGINE SYSTEMS, Inc	X	X
Paul Stepantschenko	Manager , QA	ESI	X	X
John Kriesel	Dedication Engineering Supervisor	ESI	X	X
	Nuclear Governor Coordinator, Supervisor of Dedication Testing	ESI	X	X
Kevin Broussard	Quality Assurance	ESI	X	X
Darryl Hartley	Customer Service Manager	ESI	X	X