

December 21, 2010

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

THRU: Richard A. Rasmussen, Chief */RA/ S. Crane for*  
Quality and Vendor Branch 2  
Division of Construction Inspection  
& Operational Programs  
Office of New Reactors

FROM: George Lipscomb, Inspection Team Leader  
Quality and Vendor Branch 2  
Division of Construction Inspection  
& Operational Programs  
Office of New Reactors

SUBJECT: TRIP REPORT ON THE JOINT UTILITY TEAM AUDIT AT EDSA  
MICRO CORPORATION BY NRC INSPECTORS FROM THE  
DIVISION OF CONSTRUCTION INSPECTION AND  
OPERATIONAL PROGRAMS

From October 26 to October 29, 2010, U.S. Nuclear Regulatory Commission (NRC) Inspectors George Lipscomb and Daniel Pasquale observed a Nuclear Procurement Issues Committee (NUPIC) joint utility audit at the EDSA Micro Corporation facility in San Diego, CA. Mr. Lipscomb and Mr. Pasquale are both from the NRC's Office of New Reactors, Division of Construction Inspection and Operational Programs, Quality and Vendor Branch 2. Using the most current version of the NUPIC audit checklist, a representative of Omaha Public Power District led the audit, with participation from representatives of Exelon Generation Company and Nebraska Public Power District.

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 NRC inspectors' observations and a list of the persons contacted.

Enclosure:  
As stated

CONTACT: George A. Lipscomb, NRO/DCIP/CQVB  
(301) 415-6838

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<b>DATE</b>	12/20/2010	12/20 /2010	12/21/2010

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## **NRC TRIP REPORT**

### **Subject**

This trip report documents observations by inspectors from the U.S. Nuclear Regulatory Commission (NRC), Office of New Reactors, Division of Construction Inspection and Operational Programs, of a Nuclear Procurement Issues Committee (NUPIC) joint utility audit conducted from October 26 to October 29, 2010, at the EDSA Micro Corporation (EDSA) facility in San Diego, CA.

### **Dates of Audit and Organization Visited**

October 26–29, 2010  
EDSA Micro Corporation  
16870 West Bernardo Drive, Suite 330  
San Diego, CA 92127

### **Author, Title, and Agency Affiliation**

George Lipscomb, Electronics Engineer  
Quality and Vendor Branch 2 (CQVB)  
Division of Construction Inspection & Operational Programs (DCIP)  
Office of New Reactors (NRO)

### **Sensitivity**

No documents were removed from the facility during the conduct of the observation. This document is available to the public (Agencywide Documents Access and Management System (ADAMS) Accession No. **ML103540062**).

### **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 NUPIC audit team followed the NUPIC audit process and plans to provide the results to NUPIC members that procure parts and services from EDSA.

This trip report documents the NRC inspectors' assessment of a NUPIC joint utility audit, led by the Omaha Public Power District (OPPD) and conducted at the EDSA facility in San Diego, CA, from October 26 to October 29, 2010. EDSA provides basic components and safety-related services to the commercial power industry, primarily as a supplier of electrical system design and modeling software. Additionally, EDSA is the sole supplier of the Paladin DesignBase suite of software products used to simulate and engineer electrical infrastructure in response to unexpected faults or routine system maintenance.

EDSA's Quality Assurance Program (QAP) is comprised of a quality assurance manual that includes both general organizational and administrative procedures, and a software development standard that includes specific software development procedures. The quality assurance manual, the "Quality Assurance Program Version 15," is based on Appendix B,

“Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities”; 10 CFR Part 21, “Reporting of Defects and Noncompliance”; American Society of Mechanical Engineers (ASME) NQA-1a-1989, “Quality Assurance Program Requirements for Nuclear Power Plants”; and International Organization for Standardization (ISO) standard ISO 9001, “Quality Management Systems—Requirements.” The software development standard, “Software Development Standard Version 16,” is based on ASME NQA-2a-1990, “Quality Assurance Requirements for Nuclear Power Plants,” Subpart 2.7. In addition, both parts are based on Institute of Electrical and Electronics Engineers (IEEE) Standard 610.12-1990, “IEEE Standard Glossary of Software Engineering Terminology,” and North Atlantic Treaty Organization (NATO) Allied Quality Assurance Publication (AQAP)-13, “NATO Software Quality Control System Requirements.”

The 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 for qualifying vendors. IP 43005 directs inspectors to inspect 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 15 of the NUPIC audit checklist. The NRC inspectors observed the NUPIC audit team as it independently evaluated EDSA’s 10 CFR Part 21 program in accordance with Revision 15 of the NUPIC checklist. Before the beginning of the NUPIC audit, the NRC inspectors informed the NUPIC audit team that the NRC would not be performing the 10 CFR Part 21 attribute of IP 43005. The NRC lead inspector also stated during the formal entrance meeting at EDSA that the inspectors would be observing the NUPIC audit team and did not intend to perform any direct inspection activities of EDSA during the audit.

## **Discussion**

The NUPIC audit scope evaluated the acceptability of EDSA’s QAP 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, ASME NQA-1-1989, and ASME NQA-2-1990.

The performance-based attributes included observations by the NUPIC audit team of activities associated with development, testing, packaging, and maintenance of software. Since no software production (only maintenance activities) occurred during the period of the audit, all performance-based observations made consisted of EDSA personnel performing simulated activities as requested by the NUPIC audit team (i.e., CD ROM production, testing, and packaging).

The NUPIC audit team comprised an audit team leader (ATL), three utility auditors, and a technical specialist. A representative of OPPD led the audit, with assistance from representatives of Exelon Generation Company and the Nebraska Public Power District.

The NUPIC audit team assessed the adequacy of EDSA’s quality assurance (QA) program by reviewing the EDSA QA manual, software development standard (SDS), and related documentation. EDSA incorporates implementing procedures directly into its QA manual and SDS. The auditors used the NUPIC audit checklist as a tool to perform these reviews. The NUPIC audit checklist is designed to determine a supplier’s compliance with Appendix B to

10 CFR Part 50. Additionally, the checklist includes verification of 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 use the data sheets included with the checklists to record the supporting objective evidence. The NRC inspectors observed that the NUPIC audit team used the most current version (Revision 15) of the NUPIC audit checklist for this audit. The NUPIC audit checklist can be downloaded from the NUPIC Web site ([www.nupic.com](http://www.nupic.com)).

### **Observations and Assessment**

The NRC inspectors observed most of the NUPIC audit team's activities, including the audit team meeting held on October 25, 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 ATL's expectations. Beginning with this pre-audit meeting and extending throughout the week, the NRC inspectors observed that audit activities flowed smoothly and all planned activities were effectively assessed. The NRC inspectors noted the depth of knowledge and experience of the auditors and concluded that it was appropriate to evaluate the EDSA QAP.

The NRC inspectors found that the NUPIC audit team had adequately prepared for the audit by issuing timely audit notifications, completing the draft Performance Based Supplier Audit (PBSA) Worksheet, and referencing NUPIC Document No. 7, "NUPIC Audit Checklist Revision 15," effective August 1, 2010, and NUPIC Document No. 4, "NUPIC Joint Audit Procedure Revision 33," effective August 16, 2010.

The NRC inspectors noted that the NUPIC audit checklist was based, in part, on 10 CFR Part 21, Appendix B to 10 CFR Part 50, and ASME NQA-1-1994 (including Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Application"). EDSA's QAP and SDS were based on 10 CFR Part 21, Appendix B to 10 CFR Part 50, ASME NQA-1a-1989, and ASME NQA-2a-1990. The NRC inspectors found that the NUPIC audit team effectively adapted to the differing NQA-1 standards by gaining access to all required standards and appropriately employing the NUPIC audit checklist.

The NRC inspectors reviewed the draft PBSA Worksheet that the technical specialist compiled with input from other utility users prior to the audit. The NRC inspectors learned that the technical specialist received one response from the eight NUPIC member users and then drafted the PBSA Worksheet using various sections of the ASME NQA-1-1994, Subpart 2.7, as "Technical Characteristics." Related industry guidance, such as Electric Power Research Institute Report 1016157, "Plant Support Engineering: Information for Use in Conducting Audits of Supplier Commercial Grade Item Dedication Programs," effective September 29, 2009, states, in part, that "The PBSA Worksheet should not include generic programmatic attributes that are specifically addressed in the audit checklist." The NRC inspectors determined that Subpart 2.7 provided mainly software programmatic requirements which matched other assigned audit areas and thus did not provide appropriate technical characteristics for evaluation during the audit. The NRC inspectors discussed this weakness with the ATL after the PBSA Worksheet was finalized.

During the audit, the NRC inspectors observed the NUPIC audit team's internal daily meetings, the daily debriefings with EDSA 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 NUPIC audit team

identified daily issues, the NRC inspectors noted that the audit team appropriately communicated issues among team members and also to the supplier's representatives.

As part of the audit planning processes, the ATL divided the applicable sections of the NUPIC checklist and the review of the previous NUPIC audit findings among the four auditors. The NRC inspectors observed each individual NUPIC audit team member during selected portions of the audit and specifically noted each auditor's assessment of the EDSA QA manual, SDS, and in-progress or completed documentation. The NRC inspectors also observed the individual auditors as they audited their assigned checklist sections and conducted interviews. The NRC inspectors observed the following in-progress audit activities: EDSA's examinations of nonconformance and corrective action reports, internal audits, record retention, software control, and organization. The NRC inspectors also accompanied the auditors as they observed a demonstration of safety-related CD ROM production, testing, and packaging as part of the NUPIC performance-based audit process.

The assessment of 10 CFR Part 21 programs was added to the NUPIC audit checklist in early 2010. The NRC inspectors observed NUPIC's assessment of the programic adequacy and implementation of EDSA's 10 CFR Part 21 program and concluded that the assigned auditor had executed an effective assessment of EDSA's 10 CFR Part 21 program using the new checklist elements.

The NRC inspectors noted that the NUPIC auditors effectively adapted to the technical complexity associated with a software vendor, exhibited an appropriate "questioning attitude," and appropriately expanded on key areas of the NUPIC checklist when necessary. Additionally, the technical specialist provided key insights and recommendations to the auditors. The NRC inspectors also noted that the ATL effectively managed all team concerns, preliminary findings, and requests for vendor documentation while maintaining the team's focus throughout the week.

The NRC inspectors noted that the ATL communicated issues of concern by issuing immediate user notifications both during and immediately after the audit. The first notification was a user information notice related to the EDSA software technical library (reference database included with the software). The NUPIC audit team issued the notice because it had determined that the technical product literature did not clearly outline the verification requirements for the software user library. The NRC inspectors determined that the e-mail notification effectively communicated the concern to member users. The NRC inspectors expect that each user will evaluate the concern for individual applicability and appropriate corrective actions, as necessary.

The second immediate notification was issued for significant finding FCS-V-10-20 that related to the product's advertised accuracy.. The NRC inspectors learned that the ATL classified the finding as significant because it could affect a user's regulatory compliance. The NRC inspectors also learned that, since the finding related to a closed previous audit finding (080930009-1), the finding would be considered a potential "missed opportunity" for future NUPIC audit process improvement. The NRC inspectors determined that the notification effectively communicated the significant finding to member users for further evaluation. The NRC inspectors considered the potential classification as a "missed opportunity" to be an appropriate initial step in process improvement.

Summary of NUPIC Findings:

As a result of its efforts, the NUPIC audit team identified preliminary findings including one significant finding (as previously discussed). The audit team discussed these preliminary findings and the team's recommendations in detail with EDSA management during the exit meeting. Additionally, the audit team presented EDSA management with written copies of the preliminary findings. The NRC inspectors observed that before the exit meeting, the NUPIC audit team had already communicated each finding to EDSA and that EDSA personnel understood the issues. The NUPIC audit report was issued to EDSA on November 29, 2010, and updated on December 10, 2010. It included findings of failures in the areas of organizational oversight, configuration control, procedural adequacy, testing adequacy, quality record maintenance, and corrective action and internal audit program effectiveness. The NRC inspectors noted that the ATL adequately documented each finding in the audit report and that the NUPIC audit report findings were consistent with the preliminary findings.

NUPIC Audit 22665/OPPD Audit V10-004 Findings:

- (1) Criterion III Variance for updated software versions not compared to original software baseline (Finding FCS-V-10-20: significant)
- (2) Part 21 Software Maintenance Agreement renewal required for continued software error reporting to users (Finding FCS-V-10-21)
- (3) Criterion I Insufficient documentation of Chief Technical Officer review of Annual Management Review (Finding FCS-V-10-22)
- (4) Criterion XVI Inadequate follow-up actions to repeat internal audit findings (Finding FCS-V-10-23)
- (5) Criterion X Insufficient testing of copied software CD ROMs before shipment (Finding FCS-V-10-24)
- (6) Criterion XVII Improper classification of records and inadequate quality record retrieval (Finding FCS-V-10-25)
- (7) Part 21 Insufficient Part 21 procedures for evaluation of reportability (Finding FCS-V-10-26)
- (8) Criterion XVI Corrective action process does not provide provision for trending of conditions adverse to quality, nor process to elevate significance of condition when ineffective corrective actions are determined (Finding FCS-V-10-27)
- (9) Criterion XVIII Internal audit program ineffective in identification of noncompliance (Finding FCS-V-10-28)

## **Conclusions**

Based on their assessment of the performance of the NUPIC joint utility audit team, the NRC inspectors concluded that, with the exception of the PBSA Worksheet preparation and usage, the NUPIC audit team effectively implemented the NUPIC audit process and thoroughly reviewed the areas covered by the audit. Furthermore, the NRC inspectors found the NUPIC audit team's use of immediate user notifications to be an appropriate initial response to significant concerns, and NUPIC's use of "missed opportunities" for process improvement an appropriate post-audit, self-assessment technique.

## **Pending Actions/Planned Next Steps for the NRC**

This NRC assessment was one of at least two planned for FY 2011. Depending on the adequacy of EDSA's responses to the NUPIC findings, the staff may conduct a follow-up inspection. At the next NUPIC general meeting, the NRC staff will discuss its observations related to the performance of this audit with NUPIC leadership.

## **Points for Commission Consideration/Items of Interest**

None.

## **List of Meeting Participants**

			<u>Entrance</u>	<u>Exit</u>
George Lipscomb	Lead Inspector	NRC	X	X
Daniel Pasquale	Inspector	NRC	X	X
Robert Bunz	Lead Auditor (ATL)	OPPD	X	X
Joe Dyer	Auditor	OPPD	X	X
John Sheffield	Auditor	Exelon	X	X
John Larson	Auditor	NPPD	X	X
Korey Wells	Technical Specialist	OPPD	X	X
Kevin Meagher	Chief Technology Officer	EDSA		X
Alexa Cook	QA Manager	EDSA	X	X
Brian Radibratovic	Director of Power Engineering	EDSA		X
Barb Bausch	Internal Auditor	Contractor	X	X