

**AmerenUE**  
**AUDIT REPORT VA09-004**

**SUPPLIER**

Graftel, Inc.  
Elk Grove Village, IL

**AUDIT DATE**

May 5-7, 2009

**AUDIT TEAM**

Earl Mayhorn, Audit Team Leader, AmerenUE  
Ted Homard, Audit Team Member, Florida Power & Light  
Kevin Schoolcraft, Audit Team Member, AmerenUE  
Vijay Behl, Audit Team Member, Energy Northwest

**PRODUCTS/SERVICES**

Graftel provides calibration services and field services related to heat exchanger performance testing including data acquisition and analysis using an approved subcontractor.

**AUDIT PURPOSE/SCOPE**

Verify the adequacy and effectiveness of the Graftel quality assurance program used to supply safety related field services related to heat exchanger testing, data analysis; and calibration of temperature, humidity, flow rate, and air velocity M&TE in the field and at Graftel's Elk Grove Village facility.

**AUDIT SUMMARY**

The audit found that Graftel is implementing an effective quality assurance program in accordance with 10CFR50, Appendix B for supplying the services identified in the audit scope. Graftel was found to have the necessary personnel, procedures, and equipment to perform these services. In regard to heat exchanger testing, the analysis of the heat exchanger performance data is required to be subcontracted to Proto-Power Corporation by Graftel. Final test reports are required to be prepared jointly by Proto-Power and Graftel with Graftel taking overall responsibility for the project, report, and 10CFR21 reporting as applicable.

The audit also resulted in the initiation of three (3) Requests for Corrective Action (RCA) to address areas for which the program was not adequately implemented. The issues identified in RCA's VA09-004-02, 03 & 04 were found to be minor and administrative in nature with no impact on services previously provided to nuclear utilities. All three RCA's were issued closed due to completion of the required corrective action. In addition, Recommendation VA09-004-01 was issued during the audit to address potential program enhancements. Graftel elected to implement the recommendations and VA09-004-01 was subsequently closed.

Based on the favorable results of the audit, Graftel will remain on the AmerenUE Qualified Suppliers List (QSL) for providing safety related calibration services in the field and at the Graftel facility and field services including heat exchanger performance testing services (data acquisition and analysis) using an approved subcontractor. It should be noted that the scope of this approval does not include commercial grade dedication. AmerenUE will require additional assessment activities prior to accepting commercial grade dedication activities performed by Graftel. Also, it should be note that Graftel performs Integrated Leak Rate Testing (ILRT) at nuclear utilities. However, to date, these services have been performed under non-safety related contracts.

The conclusions of the audit team were based on walk-downs of the facility, observations of work activities, discussions with Graftel personnel, and reviews of program controls & representative documents/records.

**PROGRAM EFFECTIVENESS**

Graftel's quality program was found to be effectively implemented except where noted.

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**AUDIT DEFICIENCIES AND IMPACT**

There were three Requests for Corrective Actions (RCA's) issued during the audit. All of the RCA's addressed concerns that were minor and administrative in nature.

**VA09-004-02** was issued to address instances for which a nuclear unique requirement was invoked on commercial suppliers. Five (5) instances were identified where 10CFR Part 21 was imposed on commercial suppliers. This concern was found to be minor and administrative in nature with no adverse impact on items or services previously supplied to nuclear utilities. RCA VA09-004-02 was issued closed due to completion of all required corrective action.

**VA09-004-03** was issued to address concerns in the area of internal audits. In one instance the checklist associated with an internal audit was not included with the report as required by Graftel procedures. Also, the 2008 internal audit was performed a few months past the scheduled date. In both instances, it was determined that the concern did not have an adverse impact on items provided to nuclear utilities. Graftel took actions to implement the appropriate procedure revision. RCA VA09-004-03 has been closed based on completion of all required corrective actions.

**VA09-004-04** was issued to address an instance for which the required certification documentation was not completed for a person contracted to lead internal audits of the Graftel quality program. The individual was determined to be well qualified to perform this function but Graftel had not certified the individual under the Graftel quality program. This concern was found to be minor and administrative in nature with no adverse impact on services provided to nuclear utilities.

**REVIEW OF ITEMS/AREAS AS REQUESTED (INPUT) BY OTHER LICENSEES**

Energy Northwest and Florida Power & Light served on the audit team and provided input on the audit scope.

**REVIEW OF PREVIOUSLY IDENTIFIED INDUSTRY AND AUDIT CONCERNS**

AmerenUE led a 2006 Audit of Graftel and no adverse concerns were identified. American Electric Power (AEP) led a NUPIC Joint Utilities Commercial Grade Calibration Survey of Graftel in August 2008. There were no adverse findings identified during the survey.

There was no information concerning Graftel listed in the Industry Issues section of the NUPIC Database. The Nuclear Regulatory Commission has not performed any inspections of Graftel since the 2006 AmerenUE Audit. Graftel has not issued any 10CFR Part 21 reports since the 2006 AmerenUE Audit.

**UNIQUE ORDER ENTRY REQUIREMENTS/RECOMMENDATIONS TO USERS/APPROVED SHIPPING LOCATION**

The scope of approval of Graftel is limited to that specified in the audit scope. The scope of approval does not include commercial grade dedication.

This assessment only included Graftel's Elk Grove Village, IL facility.

**AUDIT DETAILS**

A summary of each audit area is provided for below.

**Section 1 – Order Entry**

Graftel has established and implements an acceptable program for reviewing customer contract/purchase order requirements and translating them into Graftel internal documents. Records of the contract review process are also maintained. Exceptions and/or clarifications are required to be resolved in writing. If any portion of the requested services is to be subcontracted, Graftel is required to notify the customer in writing. During the course of the audit, contract review/order entry records were reviewed for several

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utility contracts associated with calibration services, heat exchanger performance testing and analysis, and ILRT services. All of the records reviewed met Graftel program requirements.

A few enhancements relative to documenting the contract review process were identified as described in **Recommendation VA09-004-01**. Graftel elected to implement the recommendation. As a result, VA09-004-01 has been closed.

**Section 2– Design Control**

It was determined that design control is not applicable to the services listed under the scope of qualification. Analysis of data and calculations are performed by an approved subcontractor as discussed in Section 5-Procurement.

**Section 3 – Commercial Grade Dedication**

This area is not applicable.

Currently, Graftel does not perform commercial grade dedication activities. However, Graftel has revised their QA Manual to include provisions for dedication. Next, Graftel plans to develop a commercial grade dedication procedure. This process would be required to be assessed by customers prior to acceptance of any dedicated item or service from Graftel.

**Section 4- Software Quality Assurance**

Graftel has developed procedures to control software under their Appendix B program and these procedures implement controls for software developed for clients and those developed for use in Graftel's internal calibration process. These controls included provisions of configuration control, validation and verification testing, and other key life cycle management requirements.

This area was found to be satisfactory.

**Section 5 – Procurement**

Graftel has established and implements an acceptable program for the procurement of items and services. Written procurement documents which include the appropriate technical and quality requirements are required for items and services. Safety related procurement activity performed by Graftel includes calibration services and subcontracted data analysis services. Procedures have been developed to control the selection, evaluation and approval of suppliers. Graftel has revised their QA program to take credit for NRC SER ML05710224 for commercial grade calibration services. Calibration suppliers that are accredited to IEC/ISO Guide 17025 for calibration services by NVLAP, A2LA, ACLASS, LAB, and IAS are not required to be surveyed. Graftel is required to maintain a copy of the supplier's accreditation documentation and verify the scope of the accreditation includes the services being procured by Graftel.

Graftel contracts safety related data analysis services to Proto-Power Corporation. This service includes the use of safety related computer software. Proto-Power is listed on Graftel's Approved Vendor List based on an audit performed by Graftel. Contracts to Proto-Power impose 10CFR50, Appendix B, 10CFR21, and other applicable requirements such as right of access, record requirements, and the applicable QA program.

One minor concern was identified relative to purchase orders issued to commercial suppliers. Five (5) examples were identified for which 10CFR Part 21 was invoked in purchase orders. Request for Corrective Action (RCA) **VA09-004-02** was issued since this practice is contrary to 10CFR Part 21 and the Graftel procurement process. Graftel took immediate action by agreeing to revise the procurement procedure to disallow this practice. As a result, VA09-004-02 was issued closed.

**Section 6 – Fabrication/Assembly Activities, Material Control and Handling, Storage & Shipping**

Graftel provides calibration and field testing services. This area was found to be not applicable.

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**Section 7 - Special Processes**

Graftel provides calibration services and field services unrelated to special processes. This area was found to be not applicable.

**Section 8 – Tests/Inspections/Calibration**

Graftel has established and implements measures to govern and control field testing activities. Graftel has the capability to dispatch personnel to a customer's site to perform heat exchanger performance testing (data collection) and Integrated Leakage Rate Testing using Graftel Measuring & Test Equipment. Heat exchanger performance testing can include computation of fouling factors with the support of Proto-Power Corp. as a subcontractor. Completed work packages were reviewed and found to have been completed using approved personnel, procedures, and M&TE.

Graftel implements a calibration program which is based on ISO/IEC 17025 and ANSI/NCSL Z540. Graftel is accredited to ISO/IEC 17025 by the Laboratory Accreditation Bureau (LAB) for temperature, gas flow rate, relative humidity, dew point temperature, liquid flow rate, and air velocity. Calibrations are performed using NIST traceable standards of the appropriate accuracies and ranges using written procedures. All Graftel M&TE were found to be uniquely identified with labels that identified the calibration and calibration due dates. All M&TE has been assigned a calibration interval. As found/as left calibration data is documented and history files are maintained for each item. Calibration activities are performed in laboratory areas with acceptable environmental controls. Out of tolerance conditions are documented and resolved using the nonconformance process.

The equipment used to provide Heat Exchanger Testing consists of ultrasonic flow meters with transducers, temperature sensors, and a laptop PC with HX data acquisition software. The data acquisition software is validated and verified as part of the system calibration process. Field service M&TE requires both pre-job and post-job calibrations.

This area was found to be satisfactory.

**Section 9 - Document Control**

Graftel has established and implements a program to control the identification, preparation, review, approval, and distribution of quality documents. Documents controlled under Graftel's document control program include the Quality Manual, test and calibration procedures, product drawings and specifications, software, and calculations. All controlled documents reviewed during the audit were found to have been reviewed and approved for adequacy. Documents were found to include the appropriate acceptance criteria and were distributed to the appropriate work locations.

This area was found to be satisfactory.

**Section 10 Organization/Program**

Graftel has established an acceptable organization and quality program in accordance with the Quality Manual and implementing procedures. The Graftel quality assurance program is based on 10CFR50, Appendix B and ISO/IEC 17025. The Quality Manager is designated as the person responsible for maintenance of the Graftel quality program. The Quality Manager reports directly to the company president and was found to be sufficiently independent of production pressures. The Graftel QA program requires an annual management review to determine the suitability and effectiveness of the program and to introduce changes or improvements. Records of these reviews were found to be acceptable.

This area was found to be satisfactory.

**Section 11 Nonconforming Items**

Graftel has established measures for the identification, documentation, tracking, controlling, and disposition of nonconforming items. Nonconformances are documented on a Nonconformance and Corrective Action Report (NCR). The NCR's reviewed during the audit were found to have been acceptably processed and in accordance with Graftel QA program requirements. Each NCR identified

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the disposition, evaluated the significance of the nonconformance, evaluated whether the nonconformance was reportable under 10CFR21, and whether customer notification was required.

It was verified that 10CFR21 was posted at Graftel. Also, Section 206 of the Energy Reorganization Act was posted along with the Graftel's Part 21 evaluation process. Graftel Part 21 procedure describes the requirements for identifying, evaluating, and reporting potential safety-related defects or noncompliance per 10CFR Part 21. All NCR's and correction action reports require screening for 10CFR21 reporting applicability. To date, Graftel has not issued any Part 21 notifications.

This area was found to be satisfactory.

**Section 12 Internal Audits**

Graftel has established an internal audit program which requires periodic audits to be conducted to evaluate the effectiveness and implementation of the Graftel quality assurance program. Procedures govern the planning, conduct, and reporting of internal audits. The Graftel QA Program is required to be audited every 12 months and when significant changes have been made in the program, or when deficiencies are suspected. Audits are required to be scheduled, planned, performed and reported in accordance with written procedures.

Two concerns were identified in this area. In one instance the checklist associated with an internal audit was not included with the report as required by Graftel procedures. Also, the 2008 internal audit was performed a few months past the scheduled date. In both instances, it was determined that the concern did not have an adverse impact on items provided to nuclear utilities. Graftel took actions to implement the appropriate procedure revision. These concerns are addressed in Request of for Corrective Action (RCA) VA09-004-03 which was issued closed.

**Section 13 Corrective Action**

Graftel has established and implements an adequate program for the identification, documentation, and corrective action for conditions adverse to quality. Conditions adverse to quality are typically documented on a Nonconformance and Corrective Action Report (NCR). An Action Item Record (AIR) is required for long term, large or complex corrective actions with multiple phases of completion. AIR's issued since the 2006 audit were reviewed and found to be acceptably processed.

This area was found to be satisfactory.

**Section 14 Training/Certification**

Graftel has established and implements the appropriate measures for the indoctrination, training, and qualification of personnel performing activities affecting quality. Personnel performing contract review, procurement, test/inspection, calibration, field services, and oversight functions were found to be adequately indoctrinated and trained for their assigned functions.

One concern was identified relative to certification documentation for an individual contracted to perform internal audits of the Graftel quality assurance program. The individual was determined to be well qualified to perform this function but Graftel had not certified the individual under the Graftel quality program. RCA VA09-004-03 was issued to address this concern.

**Section 15 Field Services**

The field services provided by Graftel include providing qualified personnel and M&TE to perform Integrated Leak Rate Testing (ILRT) of nuclear reactor buildings and performance testing of safety related heat exchangers. Testing is accomplished in accordance with plant procedures as applicable. Also as part of Graftel's heat exchanger testing program, Graftel has the capability to provide analysis of data acquired through field testing using an approved subcontractor (Proto Power, Groton, CT). M&TE used to support Heat Exchanger testing includes ultrasonic flow meters with transducers, temperature sensors, and a Laptop PC with data acquisition software. Field service M&TE requires both pre-job and post-job

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calibrations. The data is analyzed and calculations are performed to determine fouling factors using Proto-Power's safety related computer software. Graftel also has the capability to calibrate customer own M&TE at the customer's facility.

The areas of the audit checklist related to field services include contract review, procurement, testing/inspection, calibration, document control, nonconformance control, corrective action, training/qualifications, and records.

This area was found to be satisfactory.

**Section 16 Records**

Graftel has established the appropriate measures for the identification, generation, control, storage and maintenance of quality records. Record storage locations and minimum retention times are specified in the appropriate departmental procedures. All records reviewed during the audit were found to be legible, readily identifiable and retrievable. Also records were stored in a manner to prevent damage and deterioration.

This area was found to be satisfactory.

**PERSONNEL CONTACTED DURING THE AUDIT**

<u>NAME/TITLE</u>	<u>PRE-AUDIT MEETING</u>	<u>DURING AUDIT</u>	<u>POST-AUDIT MEETING</u>
<b><u>Graftel, Inc.</u></b>			
Jim Glover, Engineer Manager & President	X	X	X
Roger Anderson, Quality Assurance Manager	X		
Vaibhav Gogte, Design Engineer		X	X
Mike Rodriguez, Technician		X	
Esther Reilly, Office Manager		X	
Scott Pickett, Technician		X	

The results of the audit were discussed during the post audit conference on May 7, 2009.

Earl R. Mayhorn (Signature on File) 6/5/09

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Audit Team Leader Date

Mark Hillstrom (Signature on File) 6/5/09

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Supervising Engineer, QA Date