

Assessment Summary

Company: **Micro Enterprises LLC**
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Date: January 15, 2008
Auditor: Ken Willis, Lead Auditor

Audit Scope:

The audit covered all operations and key processes associated with the Micro Enterprises Management System. The system was audited against the current requirements of ISO 9001:2000, the Micro Enterprises Management System, and customer contract requirements. These included where applicable AS9100, rev. B requirements. The audit covered all applicable operations associated with the machining and fabricating business conducted at this facility.

Purpose of Audit:

The intent of this internal audit was to add value by giving management a better understanding of the performance of its management system. This is accomplished by evaluating the activities and performance of the management system relative to not only the stated requirements but also the organizational needs. During the audit, opportunities for improving the effectiveness and efficiency of the management system were discussed. The actions taken in response to this audit should lead to improved overall performance of the management system.

This is the first non-accredited audit of the management system. It is performed by an independent audit service and will determine if the system meets requirements ISO 9001:2000. The output of this audit will be a report and list of action items that may need to be completed to achieve full compliance. When all open issues are satisfactorily resolved, a certificate of compliance will be awarded as evidence.

Company Status:

Micro Enterprises is a privately owned company that provides precision machined parts to its customers. The company has implemented robust management processes that are intended to be compatible with ISO 9001:2000 and the needs and expectations of its customers. The company currently enjoys a very positive reputation for providing product quality and on-time delivery. They have nurtured long standing partnerships with their key customers. One year ago, after several years of accredited registration, the company decided to pursue self declaration of conformity to ISO 9001 requirements. This has resulted in a cost reduction with no recognized repercussions in the marketplace.

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The company has several management controls in place to support their key objectives. There have been very few personnel changes, and the company benefits from having long-term employees in many key positions. Jeff Eichelberger has taken over all responsibilities of the Management System Administrator. Follow-up audits of findings from the previous assessment were performed and it was determined that corrective actions taken were effective.

Key Processes:

The company has defined five key processes with supporting processes. These activities and their interfaces were the focus of this audit.

1. Administrative Support-

- a. Management Review and Analysis of Data , Planning
- b. Document and Data Control
- c. Records Control
- d. Facilities and Infrastructure
- e. HR Management, Training
- f. Accounting

2. Quality Assurance-

- a. Internal Audits
- b. Control of Nonconforming Material
- c. Corrective and Preventive Action

3. Customer Interfaces-

- a. Sales & Marketing
- b. Quoting
- c. Contract Review & Order Entry
- d. Customer Service
- e. Customer Feedback

4. Material Management-

- a. Supplier Management
- b. Purchasing
- c. Material ID, Traceability, Status
- d. Material Storage & Handling
- e. Packaging & Shipping

5. Production-

- a. Scheduling
- b. Tooling Management
- c. Equipment Maintenance
- d. Machining processes
- e. Gage Calibration
- f. Inspection

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Audit Findings:

The key processes were confirmed in this audit to be appropriate to the business. Within these processes all applicable ISO 9001 requirements, as well as internal and customer expectations are being addressed. The findings listed below are identified as either **NC**, nonconformances, or **OP**, opportunities for improvement. All nonconformances must be resolved before the management system can be considered Compliant to ISO 9001:2000. The opportunities are listed for management consideration, but do not need to be done to satisfy a requirement for compliance to ISO 9001.

1. **Administrative Support**

Top management is actively involved in managing the organization with the tools defined within its management system. Quality assurance activities are integrated into most facets of the business. Customer feedback is effectively monitored and communicated to the organization. Responses to customer concerns are handled quickly and effectively (Cooper)

Sufficient administrative functions are established to address to support product realization and contract completion. To provide additional feedback on organizational performance, PPM metrics have been extended to the administrative functions to monitor their impact on customer satisfaction.

a. Management Review and Analysis of Data, Planning

Management reviews are being conducted bi-annually and cover all standard review requirements. These meeting are providing a strategic look at the business and its performance relative to defined metrics.

- OP-There was some dialog regarding the addition of Cost of Quality (COQ), and Cost of Poor Quality (COPQ) metrics. It was determined at this time that other metrics give sufficient visibility to this data. Specific COQ and COPQ may be considered in the future if it becomes more feasible.

b. Document and Data Control

Controlled internal documents are managed on the server. They are effectively authorized and released to appropriate points of use. CNC programs are backed up in CIMNET.

External documents, i.e. customer drawings, are physically filed as hard documents or stored electronically. Electronic data ids backed up.

- NC- Procedure P-4.2-1, para. 4.7.6 states that the Process Engineer is responsible for securing electronic back-ups. This is actually the responsibility of the IT Manager.

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c. Records Control

All ISO 9001:2000 required records are retained. Currently no records are being destroyed, regardless of the defined minimum retention periods. With one exception, all records were filed appropriately and easily retrieved. The certificate of conformance and NIST traceability to the reference gage blocks used for calibration was accidentally filed with another record.

- OP- Certificates and externally provided records could be scanned and stored electronically to provide easier access.

d. Facilities and Infrastructure

Facilities and infrastructure sufficient for work performed. The Made2Manage ERP system is well utilized for providing performance data and managing information.

e. HR Management, Training

New training database has been established. This process is a significantly improved method of capturing employee qualifications.

- OP- Records regarding the 90-day review of Ewell Leonard Phipps were not current. Make certain that all relevant supervisors and trainers are current with the technology and are regularly making the adjustments to the matrix.

f. Accounting

No accounting concerns were raised in the audit.

2. Quality Assurance

The quality function is customer focused and very responsive to both customer concerns and internal quality issues. The inspection process is addressed in section 5, Production, but it is managed by the quality function.

a. Internal Audits

Internal audits are scheduled by the Quality Manager and performed by qualified auditors. Audits were completed on time. Audit records were thorough with evidence of compliance attached to checklists. Audit findings were addressed in the management review meetings.

b. Control of Nonconforming Material

Micro Enterprises has an effective method of controlling nonconforming material that has worked effectively for years. Material is marked and segregated to a designated hold area on the shop floor. This area was checked on both the 8th and 15th. All NC materials were effectively dispositioned including one involving customer owned castings.

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c. Corrective and Preventive Action

The Corrective and Preventive Action program is effective and CPARs, including those issued to suppliers (Springfield Metal) are resolved and closed quickly.

- OP- You may want to consider a 5-why analysis to dig deeper for root causes.

3. Customer Interfaces

a. Sales & Marketing

The web site is maintained to reflect changes to the organization. Micro Enterprises is continually pursuing new business that suits their strengths and capabilities as a machine job shop.

The Operations Manager demonstrated a thorough knowledge of acquiring necessary customer information and staging quotes. This was reflected downstream in the process when he assumed the responsibility for material purchases.

b. Quoting

No issues or concerns were found in the quoting process. This is a well defined process that is carried out consistently.

c. Contract Review & Order Entry

When orders are received they are processed according to defined procedures. Repeat orders are systematically processed and job packets are reviewed and issued to the production area for scheduling. New products (first time orders) are given special consideration.

- OP- The President and Production Manager have a very nice tool for reviewing and communicating special concerns for new or modified products. This involves the use of color coded routers and added reviews. Presently, this process is not reflected in the documentation and maybe it should be.

d. Customer Service

Customer Service is responsible for the RMA process, which is simple but effective.

- OP-I could not find where the RMA process is documented in the system. The logical place would be the Customer Interfaces procedure, P-7.2-1. Although not required, it may be a good idea to capture in writing how Customer service handles RMAs.

e. Customer Feedback

Micro Enterprises continues to enjoy a positive quality reputation with its customers, many of which are long term. Unsolicited feedback along with supplier scorecards are retained by the quality function. Feedback is positive. No nonconformances found in this area.

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4. Material Management

a. Supplier Management

Qualified suppliers are identified in M2M. New suppliers are used on a probationary status. They are qualified as a result of their performance. Records of supplier corrective actions are retained. Failure of suppliers to effectively resolve quality or delivery problems will typically result in changing their status to “do not use”.

b. Purchasing

Purchase orders are generated in M2M and issued electronically via fax or e-mail. No problems were found.

c. Material ID, Traceability, Status

Material identification appeared to be in order. Certificates are requested and filed. There had been an internal audit finding of not identifying bar stock that was returned to inventory, but this has apparently been resolved.

- OP-I found some finished goods along the south wall of the saw area. Some were marked with green “checked” labels and some were not. I was told that these parts were all determined to be acceptable by virtue of their location. Some signage or a more effective way of defining quality status would reduce all possible doubt.

d. Material Storage & Handling

Bulk materials are moved by authorized and trained lift operators. Material locations are defined in M2M or with the accompanying job packet. No nonconformances were found.

e. Packaging & Shipping

- OP-The scales used in shipping to count parts is currently out of the calibration program. This equipment does not verify quality, but it does verify count. It is randomly checked by the shipper for accuracy, but no record of these checks is made.

Packaging requirements are well understood and communicated through the Shipping Clerk, including NAFTA, customer specific requirements for packaging, etc. Invoicing is processed and monitored in M2M.

5. Production and Verification

Operations on both the first and second shift were audited. I audited two production jobs on the first shift and two on the second shift.

a. Scheduling

Scheduling is reviewed daily and adjusted as needed. On time delivery is measured against the committed ship date. Metrics show very good delivery performance.

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b. Tooling Management

The Safety Manager also has responsibilities for ordering perishable tools and maintaining fixtures. Inventory is checked regularly. Tooling locations are well defined. No problems found here.

c. Equipment Maintenance

Equipment is maintained, but preventive maintenance is not as formal as it could be.

- OP-The Shop Superintendent indicated that he is in the process of setting up an outsourced PM program. This is an area that may be scrutinized more closely in future audits. That said, there is no evidence that machine failure has prevented quality work from being produced or deliveries to be late.

d. Machining processes

CAD programs are written and verified before they become official. Changes to processes are recorded by set-up personnel. If permanent, these changes are incorporated into the M2M documentation. Machine operators are trained and record information correctly on routers.

e. Gage Calibration

New gage control database seems to be working well. No gage calibration issues found.

f. Inspection

The inspection process is very thorough and includes set-up verification, in-process inspections and final inspection and authorization to release products to the customer. The robustness of the inspection program is reflected in the very low PPM metrics.

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Conclusions:

No major nonconformances were found during this assessment. There were fewer nonconformities identified in this assessment, which demonstrates better control of the management system. Management continues to be directly involved in operation of the management system. Jeff Eichelberger, who was new to the role of Quality Manager in the last assessment, has taken full responsibility for administering the system. He works closely with the president and other business functions to sustain the management system and improve its effectiveness.

Since the previous assessment, the system has become more robust. Two examples of continual improvements to the management system include:

1. the control of gage calibration in a database that automatically flags the need to recalibrate and,
2. a step was added to the new product launch process that requires a downstream review of these jobs prior to starting them to recognize and prevent potential oversights.

Upon the successful response to the issues identified in this report, compliance to ISO 9001:2000 will be documented in a certificate.

Q-Squared, Inc.

Assessment Summary

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Mr. Willis is the founder and president of Q-Squared, Inc. Prior to starting his own management system support company in 1995, Mr. Willis was a training program developer for the Edison Community College Business and Industry Center serving the business community with regulatory compliance and technical support. In addition to providing various system support services, he has extensive experience in both the public and private sectors as a quality and environmental management system assessor, program developer and trainer, technology specialist, process engineer, and plant manager. He is currently retained as the Quality System Manager for SICK-STEGMANN, Inc., an international company that designs and manufactures motion control feedback systems.

Mr. Willis holds a degree in Public Administration, and has been recognized by the American Society for Quality as a Certified Auditor (#12642) and by the RABQSA as a certified auditor with emphasis on ISO/TS 16949. (#73181). He was first registered as a Lead Auditor (92/05/5163) by P.E. Batalas in February of 1992. Mr. Willis has participated in and conducted numerous workshops for automotive applications of management system standards including the process approach to organizing and auditing management systems according to ISO/TS 16949 Rules 2 requirements. He has attended several Eagle Registration sponsored workshops in the areas of ISO 9000, ISO 14001, ISO TS 16949, and SAE AS 9100. For the past fifteen years, he has developed and taught numerous quality courses with special emphasis on helping companies achieve compliance and registration to the requirements of ISO 9000 based management system standards.

In addition to creating and teaching courses at Edison and Clark State Colleges, Mr. Willis has performed training and consulting services for such companies as Motorola, Navistar, GM Powertrain, Corning Glass, Robbins and Myers, AMEC/Panasonic, Alcoa, AlliedSignal, Minster Machine, Guide Corp., and numerous other manufacturing companies. He has initiated and facilitated three ISO 9000 users' groups, worked as a contracted auditor in several accredited certification assessments, and developed many of the concepts behind the **qubeIMT** system management software.

Complimenting his quality training and consulting, Mr. Willis has developed programs in international trade, safety and environmental compliance, pollution prevention, and organizational development.