

# **WOLSTENHOLME MACHINE, INC.**

***QUALITY***

***AND***

***PROCEDURES MANUAL***

**ISO 9000 COMPLIANT**

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## **1 About this Manual**

This manual was developed and is maintained by the Quality Manager as part of the Quality Management System (QMS). Requests for changes should be submitted to the Quality Manager. Updates of the manual are issued as required.

It is the responsibility of the department heads to ensure that all employees are familiar with the content of the quality manual and that they are kept informed of any changes and updates.

For each clause, reference is made to the applicable quality management system procedure (QMS), which again makes reference to other pertinent procedures or work instructions. This manual and the quality management system procedures should be used as cross-reference for document review and auditing.

### **1.1 Approvals**

**This edition of the Quality Manual is effective as of March 16, 2007.**

**Quality Manager: Jack Paquette                      Date: \_\_March 16,2007**

**VP/General Manager: Gene Samsi                      Date: \_\_March 16, 2007**

## **2 Introduction**

**Wolstenhome Machine, Inc.**, hereafter called WMI, is located at 3075 Advance Lane, Colmar, PA 18915. WMI's business activities are the design and manufacturing of machined parts to customer specifications.



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This quality manual describes the Quality Management System of WMI and its compliance with the requirements of **ISO 9000**. Its purpose is

- **for internal use**, to communicate to all employees the company's quality policy and quality objectives, to make them familiar with the method of compliance with **ISO 9000** requirements, to facilitate the implementation and maintenance of the Quality Management System and to ensure its continuity and required updates during changing circumstances, to provide effective communication and control of quality related activities and a documented base for quality system audits.
- **for external use**, to inform WMI's customers and other interested external partners about WMI's quality policy, its implemented Quality Management System and measures of compliance with **ISO 9000** requirements.

### 3 General

#### 3.1 Scope

The Quality Management System described hereafter complies with the overall requirements of **ISO 9000** and covers the *manufacturing of custom made parts and products*.

### 4 Quality Management System Requirements

#### 4.1 General Requirements (*QMS 4.1*)

The management of WMI is committed to establish, document, implement, maintain and continually improve the Quality Management System in order to ensure that products meet specified requirements. This Quality Management System shall be in compliance with the requirements of ISO 9000.

To define how the requirements of the Quality Management System shall be met, as applicable and required, documented Quality Management System procedures, operating procedures, work instructions as well as other necessary documents shall be developed and available, in order to identify, define, control, verify, measure, monitor and analyze the various processes of the Quality Management System regarding their effective implementation, operation, compliance with ISO 9000, results in relation to requirements and continual improvement. These documents shall be appropriate for WMI's operation and the effective functioning and administration of the Quality Management System. The availability of required resources shall be ensured.

In the event that processes for the manufacture of product or technical services are outsourced to third party organizations, it shall be ensured that the necessary controls are identified, established and implemented in order to ensure conformity to requirements. Outsourcing of processes shall be identified in the applicable Quality Plan(s).



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### **4.2 Documentation Requirements (*QMS 4.1*)**

#### **4.2.1 General (*QMS 4.1*)**

It is the responsibility of the Quality Manager to ensure that the documentation of the Quality Management System includes: quality policy, quality objectives, this quality manual, quality management system procedures and the necessary documents to ensure the effective planning, operation and control of the Quality Management System processes, and the records as required by ISO 9000.

#### **4.2.2 Quality Manual (*QMS 4.1*)**

The Quality Manager is responsible for the development and maintenance of the Quality Manual. This Quality Manual shall outline the requirements of ISO 9000. The overall responsibilities and brief descriptions of the interaction of processes of the Quality Management System are included in the applicable paragraphs of this manual. More details on responsibilities and Quality Management System processes can be found in the referenced quality system procedure or operating procedure. Each clause in this manual shall be referenced to the applicable Quality Management System procedure (QMS) which again shall make reference to operating procedures and work instructions. These references should be used as cross-reference for document review and quality audits.

#### **4.2.3 Control of Documents (*QMS 4.1*)**

It is the responsibility of the Quality Manager to ensure that Quality Management System (QMS) level procedures are established for the effective control of documents and data needed for the operation of the Quality Management System. Controlled documents shall be identified with the current revision status and changes made. Among other requirements, this procedure shall define: approval of documents and data, review, update and re-approval of documents and data, availability of current revisions, removal and/or invalidation and proper identification of obsolete documents and data which are retained for legal or reference purposes.

#### **4.2.4 Control of Records (*QMS 4.1*)**

It is the responsibility of the Quality Manager to develop, document and implement a procedure for the control of records in order to demonstrate conformance to specified requirements and the effectiveness of the Quality Management System as well as compliance with statutory and regulatory requirements. This procedure shall specify how records shall be identified and stored in a suitable place and

environment in order to ensure their availability and protection against deterioration. Retention time of these records shall be established and their disposal shall be defined and documented.

Master lists with current revision levels of controlled documents and data shall be issued by the responsible department head. These master lists shall be readily available to functions concerned. Documents and data shall be legible, readily identifiable and retrievable. As required, documents and data of external origin shall be identified and controlled. Records shall be controlled.



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### 5 Management Responsibility

#### 5.1 Management Commitment (*QMS 5.1*)

In addition to other activities and issues related to quality, the highest level of management of WMI shall ensure that procedures are implemented in order to make employees aware of the importance of meeting customer requirements, that a quality policy and quality objectives are established, that yearly management reviews of the performance of the Quality Management System are conducted and that required resources for the proper functioning of activities affecting quality and customer satisfaction are available. The proper implementation and functioning of the Quality Management System, as well as the continual improvement of its effectiveness shall be verified through Quality Management System audits. Documented procedures for the identification and compliance of statutory and regulatory requirements concerning the quality and functionality of products shall be established and maintained. Employees affected shall be made aware of the importance of meeting these statutory and regulatory requirements.

#### 5.2 Customer Focus (*QMS 5.1*)

With focus on customer satisfaction, the management of WMI shall ensure that customer requirements are identified, defined and met. To monitor the effectiveness of these activities, customer satisfaction shall be part of management review.

#### 5.3 Quality Policy (*QMS 5.1*)

The management of WMI shall issue and implement a **Corporate Quality Policy** which meets the



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needs of WMI and its customers. The quality policy shall include WMI's commitment for meeting internal requirements and customer requirements as well as the commitment for continual improvement, and shall provide a basis for the establishment and review of quality objectives. The quality policy shall be communicated within the organization and shall be understood and implemented by employees with responsibilities related to the achievement of the quality objectives. During management reviews, the quality policy shall be reviewed for its continuing suitability.

### **5.4 Planning (QMS 5.1)**

#### 5.4.1 Quality Objectives

Yearly quality objectives shall be established by department heads for each department and approved by management. These quality objectives shall be consistent with the quality policy and shall, as appropriate, include that the requirements for products are met.

#### 5.4.2 Quality Management System Planning

The Quality Manager is responsible for the planning of the Quality Management System. Planning shall include the requirements specified in clause 4.1 as well as the achievement of quality objectives. Organizational change resulting from planning activities shall be defined during the planning process and shall be performed in a controlled manner. As required, documents of the Quality Management System shall be updated.

### **5.5 Responsibility, Authority and Communication**

#### 5.5.1 Responsibility and Authority (QMS 5.2)

The overall responsibility for quality rests with the management of WMI, consisting of the President and General Manager. The Quality Manager is responsible for the control and administration of the Quality Management System. Management shall define the responsibility, authority and interrelation of functions within WMI.

#### 5.5.2 Quality Manager (QMS 5.2)

The Quality Manager shall have the responsibility and authority for the implementation and administration of the Quality Management System, its compliance with defined requirements and the achievement of customer satisfaction. The Quality Manager shall advise management on the performance and need for improvement of the Quality Management System, and shall ensure throughout the organization the awareness of meeting customer requirements.

#### 5.5.3 Internal Communication (QMS 5.2)

It is the responsibility of the Quality Manager to ensure the effective communication between departments and functions concerned on quality related matters, and the effectiveness of the Quality Management System.



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## 7 Product Realization

### 7.1 Planning of Product Realization (*QMS 7.1*)

Processes for product development and for the manufacture of products, including changes of these processes and activities, shall be defined during quality planning under the responsibility of the Engineering Department. All planning activities related to manufacturing shall be conducted in close cooperation with Manufacturing, as applicable. The planning for product realization shall be consistent with clause 4.1 of this standard, and shall include as applicable: quality objectives and requirements for the product, as well as manufacturing plans which shall include necessary resources, documents, inspection and acceptance criteria, and records.

### 7.2 Customer-related Processes (*QMS 7.1*)

#### 7.2.1 Determination of Requirements Related to the Product

Customer requirements for product, packaging and delivery, applicable functional and performance requirements, as well as standards, statutory and legal requirements of the product, shall be determined by the responsible department.

#### 7.2.2 Review of Requirements Related to the Product

It is the responsibility of the Quality Manager, in conjunction with the Manufacturing Manager and Sales Manager, to ensure that all required procedures for contract review and related activities are developed, documented, implemented and maintained.

Prior to the acceptance of a contract or purchase order, the contract or purchase order shall be reviewed to ensure that all requirements are adequately determined and documented, that any differences between quotation and contract or purchase order are resolved and that any missing or ambiguous specifications or statements are clarified and documented. Verbal requirements shall be confirmed prior to formal acceptance of the purchase order or contract. Where required, and prior to the acceptance of a contract/purchase order, appropriate reviews and studies are conducted to ensure that WMI has the capability to meet the customer's requirements. Results of reviews and follow-up actions shall be recorded.



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In case that amendments or changes to existing purchase orders/contracts are required, WMI's capability in meeting these new requirements shall be verified and confirmed by the quality planning team or functions concerned. As required, documents are updated and personnel affected shall be informed of the change.

Records of contract reviews, follow-up actions and related activities are maintained per established procedure.

### 7.2.3 Customer Communication

Responsibilities for communication with customers regarding product and service information, general inquiries, ordering and order status, changes to existing orders, customer complaints, nonconforming products and customer feedback shall be defined and included in applicable operating procedures.

### 7.3 Design and Development (*QMS 7.2*)

N/A.

### 7.4 Purchasing (*QMS 7.3*)

#### 7.4.1 Purchasing Process

It is the responsibility of the Purchasing Department to establish procedures to ensure that purchased products conform to specified requirements, including statutory and regulatory requirements. The methods and type of control used for verification of purchased product shall depend on the effect of the purchased product on the final product and applicable production processes and service activities.

Suppliers shall be evaluated and selected according to defined selection criteria and their ability to supply product that meets specified requirements. The selection results and related actions shall be documented.

#### 7.4.2 Purchasing Information

It is the Purchasing Department's responsibility to set-up the purchased-product and supplier database files in the computer system. This data ensures that purchase orders do clearly describe the product, material or service ordered, including as applicable: approval or qualification requirements, Quality



Management System requirements or other special requirements such as certificates of analysis or compliance, inspection reports as well as packaging, marking, labeling and shipping instructions. As appropriate, purchasing documents and/or purchasing data shall be reviewed and approved prior to release.

#### 7.4.3 Verification of Purchased Product

Purchased product shall be inspected and approved or rejected according to documented procedures established by Quality Assurance.

If there is a need for WMI or its customers to verify purchased products at the supplier's premises, these verification arrangements and applicable methods of product release shall be part of the purchasing contract and shall be according to requirements defined by Engineering and/or Quality Assurance and/or Manufacturing.

#### 7.5.3 Identification and Traceability

As appropriate, procedures shall be established and maintained by Manufacturing, Quality Assurance, and Shipping/Receiving for the identification of product at receiving, during all stages of production, storage and delivery. As applicable, this identification shall define the product, the actual acceptance or rejection status at all stages within the process, as well as the required data for traceability. Traceability records shall be maintained per the applicable master list of records



#### 7.5.4 Preservation of Product

It is the responsibility of the Shipping/Receiving department and Manufacturing department to establish and maintain procedures for the identification, handling, storage, packaging for shipping, preservation and delivery of products. This includes the handling of parts and materials during production processes.

#### 7.6 Control of Monitoring and Measuring Devices (*QMS 7.5*)

The Engineering and Manufacturing departments shall identify the measurements to be made and the measuring, testing and monitoring devices needed to assure conformance of product and service to specified requirements. As required, the suitability of computer software for measuring and monitoring activities shall be confirmed prior to use.

Quality Assurance shall establish and maintain procedures for the identification, control and storage, and periodic calibration and maintenance of measuring, monitoring and testing devices that is used to demonstrate conformance of product. Measuring and monitoring devices and software shall be kept in appropriate storage facilities and shall be used by qualified personnel to prevent improper use and damage. Calibration shall be performed according to a recognized standard; where no such standard is used, the method of calibration shall be documented.

Calibration results shall be recorded and records shall be maintained according to the applicable master list of records.

In the event that measuring and monitoring devices are found out of calibration, previous verification results shall be validated and corrective action shall be taken as required, following the applicable established procedure. Records shall be maintained.

### 8 Measurement, Analysis and Improvement

#### 8.1 General (*QMS 8.1*)

It is the responsibility of the Quality Manager and responsible department heads to plan and implement appropriate monitoring and measuring activities in order to demonstrate the conformity of product to specified requirements, the conformity of the Quality Management System to planned objectives and results, and the achievement of continual improvement of the Quality Management System. Appropriate methodologies such as statistical techniques shall be determined and applied.



## 8.2 Monitoring and Measurement

### 8.2.1 Customer Satisfaction (*QMS 8.1*)

At least once every twelve months, management shall conduct a customer satisfaction survey in order to obtain input and feedback directly from the customer regarding WMI's achievement of customer satisfaction. Corrective and preventive actions are taken as required.

### 8.2.2 Internal Audit (*QMS 8.1*)

It is the responsibility of the Quality Manager to establish, maintain and implement documented procedures for planning and conducting internal quality audits. The procedure shall define the auditing process, responsibilities, reporting, necessary actions and records. Internal audits shall verify whether the Quality Management System meets ISO 9000 requirements and the internal requirements of WMI and whether it is effectively implemented and maintained. Internal audits shall verify if the objectives of quality planning are met.

Internal quality audits shall be planned and scheduled. All requirements of the ISO 9000 Quality Management System shall be audited at least once per year. The Quality Manager shall ensure that internal quality audits are conducted by qualified personnel, independent of those having direct responsibility of the area or activity to be audited.

Required corrective action shall be taken, following established procedures. Where applicable, follow-up audits shall be conducted to verify the effectiveness of implemented corrective action. These actions shall be recorded.

Internal audit results shall be reported to management and shall be part of management review.

### 8.2.3 Monitoring and Measurement of Processes (*QMS 8.1*)

As applicable, it is the responsibility of the Quality Manager and department heads to use appropriate methods for the monitoring and verification of the processes of the Quality Management System. Monitoring and verification results shall confirm the ability of the Quality Management System in meeting quality objectives and defined requirements. If results do not meet requirements, corrective action shall be taken as appropriate.

### 8.2.4 Monitoring and Measurement of Product (*QMS 8.2*)

It is the responsibility of Quality Assurance to establish and implement procedures for the monitoring and inspection of product to ensure that products received, products in production and during production, and products to be shipped, meet specified requirements. Verification activities are in accordance with the operating procedures. Records of verification results shall be maintained. These records shall identify the person who authorized the product release.

No product shall be shipped to customers until all acceptance criteria have been met, until final approval for shipping is given by Quality Assurance, or until other necessary approvals for the delivery are available.



### **8.3 Control of Nonconformity (QMS 8.3)**

It is the responsibility of Quality Assurance to establish and maintain documented procedures to ensure that nonconforming product received from suppliers, or in production or in inventory, is identified as nonconforming and is not available for production, sale, service or any other unintended use.

Final disposition is determined by the Material Review Board and consists of rework, acceptance with or without rework or with concession by the customer or applicable regulatory body, to be used for alternative application or to be rejected or scrapped. Reworked or repaired product is re-inspected by Quality Assurance according to the applicable Inspection Report.

In the event that nonconforming product is detected after the product was shipped to the customer or after its use in production or service, the Quality department, in conjunction with the Engineering Department and Sales Department shall analyze the impact of the nonconformity and shall take appropriate action.

### **8.4 Analysis of Data (QMS 8.4)**

Per established documented procedures, statistics on the performance of operational activities and customer satisfaction shall be issued by the Quality Manager and shall be analyzed by department heads. Based on the analysis results, product and service quality trends, the effectiveness and efficiency of operational activities as well as customer satisfaction shall be established. The analysis shall include opportunities for improvement. Timely corrective and preventive actions shall be taken as required.

It is the responsibility of the Quality department, in conjunction with Purchasing, to analyze supplier performance and take necessary action.

### **8.5 Improvement (QMS 8.4)**

#### **8.5.1 Continual Improvement**

Continual improvement is the responsibility of all department heads. It is the responsibility of the Quality Manager to coordinate activities for the continual improvement of the Quality Management System. Continual improvement shall be based on the quality policy, quality objectives, audit results, analysis of performance statistics, results of corrective and preventive actions and management reviews.

#### **8.5.2 Corrective Action**

The purpose of corrective action shall be the prevention of recurrence of nonconformities. The corrective action taken shall be appropriate to the importance of the problem or nonconformity.

The Quality Manager shall establish documented procedures for a corporate approach for corrective action. The corrective action process shall address the identification of nonconformities and their review, including customer complaints. Nonconformities shall be analyzed, root causes shall be determined and necessary action shall be taken to prevent recurrence of the nonconformity. Corrective actions shall be recorded and results shall be monitored and reviewed regarding their implementation and effectiveness. Records of corrective actions shall be maintained.



### 8.5.3 Preventive action

Potential problems or nonconformities shall be identified and preventive action shall be taken to avert their occurrence. Preventive action shall be appropriate to the probability of occurrence and the importance and impact of the potential problems or nonconformities. It is the responsibility of the Quality Manager to establish documented procedures for a corporate approach to preventive action. The procedure(s) shall define the process for the identification of potential problems or nonconformities, the analysis of the impact and probability of occurrence, the need for preventive action, the implementation of actions, and the recording and monitoring of results of these preventive actions.

