

## **Section 0.0 Cover Page**

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## ISO 9001:2000 QUALITY MANUAL

ISSUED TO: TITLE:

COMPANY: Kosmo Machine, Inc.

UNCONTROLLED COPY AUTHORIZED BY:

SERIAL NUMBER TITLE:

N/A DATE ISSUED:

Unless designated as "UNCONTROLLED COPY", this manual, and its contents, are controlled documents. The unique serial number given to each manual is registered and on file with our Quality Assurance Department.

In the event that a controlled copy of this manual is removed from the premises, then it becomes an uncontrolled document. Only those copies that remain on premises will remain designated as a controlled copy.

All information contained within this manual is confidential, and is the property of Kosmo Machine Inc. and may not be distributed to other persons or organizations without the explicit written permission of Kosmo Machine Inc.



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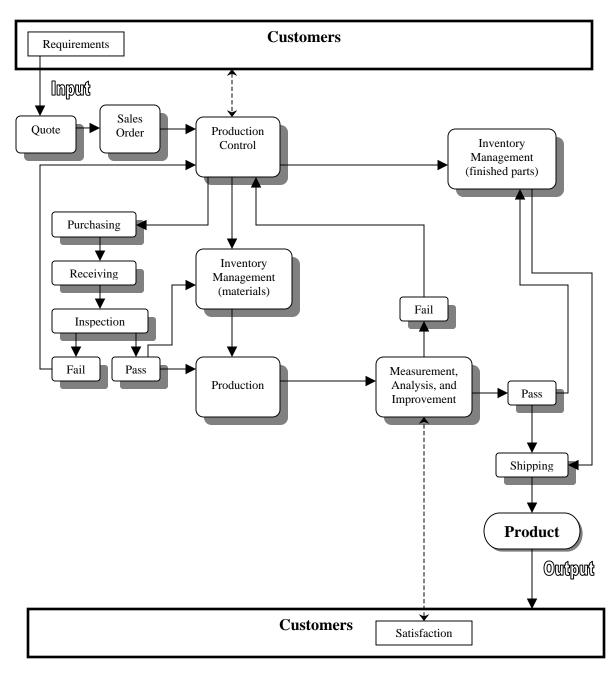
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## **Section 0.2 Process Approach**



Note: At any time during any of these processes corrective and preventive actions, and/or continuous improvement activities may occur.

Value-adding activities←-----> Information flow



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# **Section 0.3 Revision Log**

Revision	Date	Description of Change	Reviewed by:	Approved by:
P1	11/14/03	Preliminary Version 1		
P2	12/17/03	Preliminary Version 2		
P3	1/05/04	Preliminary Version 3		
P4	2/11/04	Preliminary Version 4		
P5	2/16/04	Preliminary Version 5		
P6	9/29/04	Preliminary Version 6		
P7	7/26/05	Added Dean Mallory to the		
		Responsibility and Authority		
		Chart.		
P8	8/3/05	Made changes as suggested by		
		customer.		
P9	9/21/05	Added details of corrective		
		actions to section 8.3		



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Section 0.4 Transfer of Authority Clause					
John T. Smook, President of Kosmo Machine, Inc., hereby grants all authority and responsibility of the implementation and maintenance of the quality management system to Patrick R. Smook, Manager.					
Signed:	Date:				



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### **Section 1.0 Introduction**

#### 1.1 General

Kosmo Machine Inc. was founded as a garage shop in 1976. As the industry evolved, so did our ability to meet customer requirements. With the addition of CNC machinery, our workload became more complex. This commitment to customer satisfaction has led us to the assembly of one of the finest collections of equipment in the region. We now offer a full range of Electrical Discharging Machines (EDM's), as well as multi-axis milling and turning centers.

Our turning department offers Mazak Super Quick Turn lathes with options, like bar feeders, sub-spindle, parts catchers, and milling capability. The milling department includes CNC machining centers ranging in capabilities. There are (3), (4), and (5) axes with spindle speeds up to 10,000 rpm. The EDM section includes 5-axis wire machines, 3 and 4-axis sinkers, and a small diameter hole producing EDM machine. Inspection is the heart of the company. We meet any inspection requirements using our ISO-9001:2000 format. Certificates of Compliance are easily identifiable by their unique serial numbers. These certificates are also stored and logged electronically.

Quality has been, and will continue to be, one of the primary tools that Kosmo Machine Inc. uses to achieve the goals established by our customers. Our concept of quality includes all of the features and characteristics of a product that affect its ability to satisfy the requirements and expectations of the customer.

Technology, transportation, and communications advances are being made everyday, continuously making the world a smaller place. As we look to the future, we must be increasingly prepared to serve our customers in global markets.

Toward this end, we have updated our efforts with this manual covering the wider scope and documentation associated with the ISO-9001:2000 standard.



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## **Section 2.0 Scope**

#### 2.1 General

The purposes of this quality management system are to:

- 1. Ensure that our products meet the quality requirements given by the customer as well as any applicable regulatory requirements.
- 2. Enable the continuous enrichment of customer satisfaction through the effective application of the system, the processes that aid in the consistent improvement of the system, and the assurance of conformity to customer and regulatory requirements.

### 2.2 Application

Kosmo Machine Inc. manufactures parts from drawings supplied to us by the customer. Any drawings that are produced by Kosmo Machine Inc. are done so at the request, and under the direction, of the customer. For this reason, Section 7.3, Design and Development of the ISO 9001:2000 standard does not apply to Kosmo Machine Inc., and is excluded from this quality management system.



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## **Section 3.0 Terms and Definitions**

**Job Traveler** – *a.k.a. router, routing, or job packet.* The set of instructions created by management that describes, in detail, the steps (or operations) to be taken in the manufacturing of a product. Also included in the Job Traveler are lists of tooling and materials, and any special customer requirements.

**Vantage** -a.k.a. system or software. Software used by Kosmo Machine to manage all facets of business. This software also serves as the principle location where documents and records are stored. It is also used to create the Job Travelers, where the production and inspection notes are entered.



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## **Section 4.0 Quality Management System**

### **4.1 General Requirements**

Kosmo Machine Inc. has established a quality management system and documents, implements, and maintains it in order to constantly improve its effectiveness in accordance with the requirements set forth in the ISO 9001:2000 International Standard.

The Internal Auditors are responsible for monitoring and evaluating the quality management system by performing internal audits, reviewing documentation, and reporting the results, along with the status and effectiveness of the system at management review meetings.

In order to execute the quality management system, Kosmo Machine Inc.:

- **A)** identifies the processes, as well as their application, required for the quality management system as outlined in section 7.1, Planning of Product Realization.
- **B**) determines the sequence and interaction of these processes as outlined in section 7.1, Planning of Product Realization.
- C) determines the criteria and methods necessary for ensuring the effective operation and control of these processes as outlined in section 7.5.1, Control of Production and Service Provision.
- **D**) ensures the availability of resources, as well as the necessary information for supporting the operation and monitoring of these processes, as outlined in section 6.1, Provision of Resources.
- **E**) monitors, measures, and analyzes these processes as outlined in section 8.2, Monitoring and Measurement.
- **F)** implements the necessary actions for achieving planned results and continuous improvement as outlined in sections 8.2 Monitoring and Measurement, and 8.5, Improvement.

Where Kosmo Machine Inc. chooses to outsource any process that affects product conformity with requirements, we ensure control over these processes by using only approved vendors, as well as an inspection of the supplied product and/or service.



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## Section 4.0 Quality Management System (continued)

## 4.2 Documentation Requirements

#### 4.2.1 General

The quality management system documentation for Kosmo Machine Inc. includes:

- **A)** The quality policy and objectives.
- **B**) The quality manual.
- C) Documented procedures as required by ISO 9001:2000.
- **D**) The documents required to ensure the effective planning, operation, and control of the processes.
- **E**) Records, as required by the ISO 9001:2000 Standard, that provide evidence of conformity and of the effectiveness of the quality management system.

The extent of the quality management system documentation is dependent on:

- A) The size, and types of activities, of the organization
- **B**) The complexity and interactions of the processes
- **C**) The competence of the personnel.

### 4.2.2 Quality Manual

The quality management system is established, maintained, and documented in this quality manual.

- A) This quality manual is written to satisfy the requirements of the ISO 9001:2000 International Standard. The scope of the quality management system is applicable to all quality related activities within this organization. Kosmo Machine Inc. manufactures parts from drawings supplied to us by the customer. Any drawings that are produced by Kosmo Machine Inc. are done so at the request, and under the direction, of the customer. For this reason, Section 7.3, Design and Development of the ISO 9001:2000 standard does not apply to Kosmo Machine Inc., and is excluded from this quality management system.
- **B)** This manual contains the policies and procedures for the quality management system. These policies and procedures are consistent with ISO 9001:2000 and the policies and procedures of Kosmo Machine Inc. Also referenced in this manual are the Job Travelers, which contain instructions that detail specific operations (procedures), tooling, equipment, checks, and methods that have a direct effect on the quality of professional service and products provided by Kosmo Machine Inc.
- **C**) The interaction of the processes included in the quality management system is documented in section 7.1, Planning of Product Realization.



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## Section 4.0 Quality Management System (continued)

The unique serial number given to each manual and the "CONTROLLED COPY" stamp identify that the manual is a controlled copy. The controlled copies of the manual that have been issued are recorded in the "Quality Manual Distribution Table" which is located in the Quality Assurance Department.

Note: Corrections to typographical or grammatical errors, as well as minor editorial changes, will not be considered as changes for the purposes of issuing a new revision number to this manual.

#### 4.2.3 Control of Documents

All documents required by the quality management system, whether they are supplied to Kosmo Machine Inc. by the customer or generated onsite, are controlled by management as follows:

- **A)** Documents are reviewed before use to ensure that they are adequate and current
- **B)** Documents are examined before each use to determine if an update is needed, and if the document is suitable for re-approval.
- C) Any changes that may be made to a document are marked, initialed, and dated by a member of management. This ensures the legitimacy of the change. The current revision status of documents is always identified on the document. The document is reviewed by management prior to issuance to ensure this.
- **D**) Current versions of applicable documents are available throughout the realization process. They are identified by the job number and revision level to ensure that related documents remain together.
- **E**) Documents are checked prior to issuance for any errors, including legibility issues, and are identified by the job number.
- **F**) Documents of an external origin are identified by any of the following means: the name of the organization to which they belong, part number, job number, purchase order number, or revision level, as applicable.
- **G**) In order to prevent the unintended use of obsolete documents, they are removed from point of use by the individual responsible for original issue. Obsolete documents are adequately identified if retention is necessary.



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## **Section 4.0 Quality Management System** (continued)

#### 4.2.4 Control of Records

Kosmo Machine Inc. establishes and maintains records to provide evidence of conformity to customer requirements, and to show the effective operation of the quality management system. These records are kept legible, identifiable, and retrievable.

All permanent records are stored electronically in the Vantage system and on the server. These records are kept indefinitely, unless otherwise specified by customer requirements. Backups are performed at regular intervals and a copy is kept offsite at all times.

Unless otherwise directed per customer requirements, temporary records are kept for a minimum of two years and a maximum of five years, and are stored in identified cabinets. Obsolete records are destroyed onsite.



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## **Section 5.0 Management Responsibility**

### **5.1 Management Commitment**

The management of Kosmo Machine Inc. provides evidence of its commitment to the implementation, and continual development of the quality management system by the following means:

- **A)** Communicating to each employee the importance of meeting customer as well as statutory and regulatory requirements.
- **B**) Establishing the quality policy and quality objectives.
- **C)** Conducting management reviews.
- **D**) Ensuring that the necessary resources are available.

#### **5.2 Customer Focus**

The management of Kosmo Machine Inc. ensures that the requirements and expectations of the customer are determined and understood throughout the company, and that every effort is put forth to meet or exceed them with the aim of increasing and improving customer satisfaction.

#### **5.3 Quality Policy**

The management of Kosmo Machine Inc. ensures that the quality policy, as stated below, provides a framework for establishing and reviewing quality objectives, is communicated and understood within the company, and is reviewed for continuing suitability.

"The management and employees of Kosmo Machine Inc. are dedicated to meeting or exceeding the expectations of the customer, and to the constant improvement of product quality and of the quality management system."

### 5.4 Planning

## 5.4.1 Quality Objectives

The quality objectives for Kosmo Machine Inc. are established and enable the continual improvement of the quality management system and its processes. The quality objectives are measurable and are discussed at management reviews to determine to what extent they are being met, and the need for changes and improvement. The quality objectives are consistent with the quality policy and are in place to help facilitate the meeting of customer requirements leading to greater customer satisfaction.



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## **Section 5.0 Management Responsibility** (continued)

### 5.4.2 Quality Management System Planning

The management of Kosmo Machine Inc. ensures that:

- **A)** the planning of the quality management system is carried out in order to meet the requirements given in section 4.1 General Requirements, as well as the quality objectives. This planning is conducted during the management review, or whenever necessary.
- **B)** the integrity of the quality management system is maintained whenever changes are made. No changes will be made without first having been discussed and approved at the management review. This review ensures that the company remains in compliance with the quality management system as it is now documented, and that no changes, organizational or otherwise, will affect the system. The records from management reviews are maintained as detailed in section 4.2.4, Control of Records.

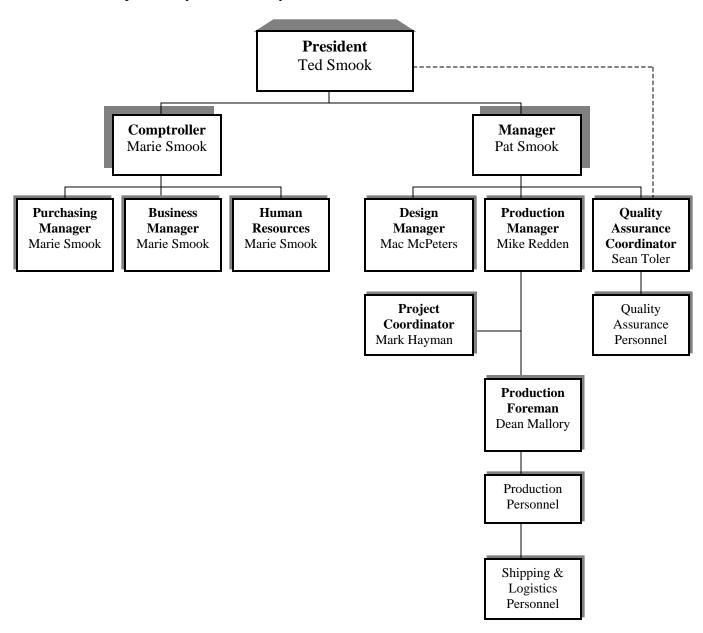


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## Section 5.0 Management Responsibility (continued)

## 5.5 Responsibility, Authority, and Communication

### 5.5.1 Responsibility and Authority





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## **Section 5.0 Management Responsibility** (continued)

### 5.5.2 Management Representative

The management of Kosmo Machine Inc. has appointed the Quality Assurance Coordinator as the Management Representative who, regardless of other responsibilities, has responsibility and authority that includes:

- **A)** Ensuring that the processes needed for the quality management system are established, executed, and maintained,
- **B**) Reporting to management on the performance of the quality management system and any need for improvement,
- **C**) Ensuring that customer requirements are known and understood throughout the company.

#### 5.5.3 Internal Communication

The management of Kosmo Machine Inc. ensures that communication takes place within the company concerning the effectiveness of the quality management system. The following means have been established to accomplish this:

- **A)** Bulletin board notices.
- **B**) Quarterly company newsletters.
- C) Direct communication from management to employee.
- **D)** Yearly reviews of employee performance.
- **E**) Periodic company meetings.

#### **5.6 Management Review**

#### 5.6.1 General

The management of Kosmo Machine Inc. meets on a regular basis to review the suitability, adequacy, and effectiveness of the quality management system. Included in this review are:

- A) the assessment of opportunities for improvement.
- **B**) any need for changes to the quality management system, including the quality policy and objectives.

The records from management reviews are maintained as detailed in section 4.2.4, Control of Records.



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## **Section 5.0 Management Responsibility** (continued)

### 5.6.2 Review Input

The topics discussed at management reviews may include, but are not limited to:

- **A)** Audit results
- **B**) Customer feedback
- C) Process performance and product conformity
- **D**) Current status of preventive and corrective actions
- **E**) Actions to be followed-up on from previous management reviews
- **F**) Any changes that may affect the quality management system
- **G**) Recommendations for improvement

### 5.6.3 Review Output

The output of the management reviews may include any decisions and/or actions related to:

- **A)** ways to improve the quality management system and its processes
- **B**) ways to improve the product in regards to customer specifications
- **C**) resource needs



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## **Section 6.0 Resource Management**

Management has the responsibility of providing the resources required for implementing and improving the quality management system, and meeting the demands and expectations of the customer. Resources may include personnel, time, materials, tooling, equipment, information, facilities, and finances, etc.

#### **6.1 Provision of Resources**

Kosmo Machine Inc. determines and provides the resources necessary to:

- **A)** implement, maintain, and improve the quality management system.
- **B**) enhance customer satisfaction by adhering to the customer's requirements. Resource requirements are examined and determined, as needed, at management reviews.

#### **6.2 Human Resources**

#### 6.2.1 General

All personnel performing work that affects the product quality are competent in education, training, skills and experience.

#### 6.2.2 Competence, Awareness, and Training

#### Kosmo Machine Inc.:

- **A)** determines the necessary competence level for any personnel performing work which would affect the quality of the product,
  - a. competence level is based on a review of résumé and experience upon hire. Experience & competence level are verified during a 90-day probationary period immediately upon hire. Verification is conducted under direct supervision, and through an evaluation of work habits, skills and abilities, and quality of workmanship.
- **B**) provides any training, or takes other actions to satisfy these needs, as necessary,
- C) evaluates the effectiveness of said actions,
- **D**) ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,
- **E**) maintains any appropriate records of education, training, skills, and experience.



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## Section 6.0 Resource Management (continued)

#### **6.3 Infrastructure**

Kosmo Machine Inc. determines, provides, and maintains the infrastructure needed to achieve product conformity. Infrastructure includes, as applicable:

- A) Buildings, workspace, and associated utilities
- **B**) Process equipment (both hardware and software)
- C) Supporting services (such as transport or communication)
- **D)** Work environment

### **6.4 Work Environment**

Kosmo Machine Inc. determines and manages the work environment needed to achieve conformity to product requirements, i.e., temperature and humidity levels.



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### Section 7.0 Product Realization

### 7.1 Planning of Product Realization

Kosmo Machine Inc. plans and develops the processes necessary for product realization. This planning is consistent with the requirements of the quality management system.

In planning the processes for product realization, Kosmo Machine Inc. determines the following, as appropriate:

- **A)** The quality objectives and requirements for the product.
- **B**) The need to establish processes and documents, and to provide resources specific to the product.
- C) The required verification, validation, monitoring, inspection, and test activities exclusive to the product and the specifications for product acceptance.
- **D**) The records necessary to provide the evidence that the realization process and the resulting product meet the specified requirements.

The output of this planning is the Job Traveler.

#### 7.2 Customer-related Processes

### 7.2.1 Determination of Requirements Related to the Product

Kosmo Machine Inc. determines:

- **A)** The requirements specified by the customer, including requirements for delivery.
- **B**) The requirements not stated by the customer, but necessary for specified or intended use, where known.
- C) Statutory and regulatory requirements related to the product.
- **D**) Any additional requirements as determined by Kosmo Machine Inc.

### 7.2.2 Review of Requirements Related to the Product

Kosmo Machine Inc. reviews any requirements related to the product prior to any commitment to supply a product to the customer, and ensures that:

- **A)** The product requirements are defined.
- **B)** Any contract or order requirements that differ from those previously expressed are resolved.
- **C**) Kosmo Machine Inc. has the ability to meet those requirements.



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### **Section 7.0 Product Realization** (continued)

The results of the review and any subsequent follow-up actions are documented. In any such case where no documented requirements are supplied by the customer, Kosmo Machine Inc. confirms the requirements with the customer before acceptance. Where product requirements are changed by the customer, any related documents are amended and relevant personnel are made aware of the changes.

#### 7.2.3 Customer Communication

Kosmo Machine Inc. determines and implements any necessary arrangements for communicating with the customer in regards to:

- **A**) Any product information.
- **B**) Inquiries and contracts, including amendments.
- C) Customer feedback, including any customer complaints.

#### 7.3 Design and Development

Kosmo Machine Inc. manufactures parts from drawings supplied to us by the customer. Any drawings that are produced by Kosmo Machine Inc. are done so at the request, and under the direction, of the customer. For this reason, Section 7.3, Design and Development of the ISO 9001:2000 standard does not apply to Kosmo Machine Inc., and is excluded from this quality management system.

#### 7.4 Purchasing

### 7.4.1 Purchasing Process

Suppliers are evaluated based on their ability to consistently supply products and/or services that meet specified requirements. Kosmo Machine Inc. reserves the right to evaluate suppliers, and/or their products at the supplier's premises, if necessary. If deemed as acceptable, the supplier is placed on the Approved Vendors List. Purchases are made only from those organizations that appear on the list. Approved suppliers are evaluated at regular intervals in accordance with the ISO 9001:2000 standard. Records of these evaluations, as well as necessary actions arising from the evaluation, are maintained as detailed in Section 4.2.4, Control of Records.

### 7.4.2 Purchasing Information

In all such cases of the purchasing of a product/service, Kosmo Machine Inc. ensures that the purchase order adequately describes the product/service to be purchased. This is done prior to communication with the supplier. The purchasing information may include:



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## **Section 7.0 Product Realization** (continued)

- **A)** Requirements for approval of product, procedures, processes, and equipment, i.e.; type of material, quantity, quality specifications, time of delivery, etc.
- **B**) Requirements for qualification of personnel as detailed in section 6.2.2.
- C) Quality management system requirements.

#### 7.4.3 Verification of Purchased Products

When purchased products are received, the packing slip/invoice is entered into the Vantage system. The individual who enters it has the responsibility of ensuring that the product listed on the packing slip/invoice matches both what was ordered, and what was received.

#### 7.5 Production and Service Provision

#### 7.5.1 Control of Production and Service Provision

Kosmo Machine Inc. plans and carries out production and service operations under controlled conditions. Controlled conditions may include:

- **A)** The availability of information that describes the product characteristics, i.e., customer drawings and specifications.
- **B**) The availability of work instructions, i.e., the Job Traveler.
- C) The use of suitable, and properly maintained, equipment and tooling.
- **D)** The availability and use of monitoring and measuring devices.
- **E**) The implementation of monitoring and measurement.
- **F**) The implementation of release, delivery, and related post-delivery activities.
- **G**) The retention and storage of records as detailed in section 4.2.4, Control of Records.

#### 7.5.2 Validation of Processes for Production and Service Provision

Kosmo Machine Inc. validates any processes where the resulting output cannot be verified by subsequent monitoring and measurement. Included in this are any processes where deficiencies become evident only after the product is in use. This validation shows the ability of these processes to achieve the planned results. Kosmo Machine Inc. establishes the arrangements for these processes, as detailed in section 7.1 Planning of Product Realization, and reviews them as necessary at management review. These arrangements may include, but are not limited to:

- A) Any defined criteria necessary for the review and approval of these processes.
- **B**) The approval of required equipment, and the qualification of personnel.



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## **Section 7.0 Product Realization** (continued)

- **C**) The use of specific methods and procedures.
- **D)** Any requirements for records.
- E) Revalidation.

### 7.5.3 Identification and Traceability

Kosmo Machine Inc. identifies each product throughout the manufacturing process. When received, the raw material is marked with the appropriate identification, and stored in the proper bin. Once the material is assigned to a specific job, it is marked with the job number, and remains identified by the job number throughout the realization process.

Evidence of in-process and final inspection is clearly documented. Following inspections, acceptable products are moved on to the next phase in the manufacturing process. Unacceptable products are clearly marked and handled as detailed in section 8.3, Control of Nonconforming Product.

Where traceability is a requirement, Kosmo Machine Inc. marks the product with the appropriate identification, as well as its paperwork, as required by the customer.

#### 7.5.4 Customer Property

In any such case that Kosmo Machine Inc. is supplied with customer property (including intellectual property) provided for use or incorporation into the product, great care is exercised in the handling of it. It is treated the same as purchased material would be treated, i.e., identified, verified, and protected from damage or deterioration. If the circumstance should arise that customer property is lost, damaged, or found to be unfit for use, it is reported to the customer, and records of this are maintained as detailed in section 4.2.4, Control of Records.

### 7.5.5 Preservation of Product

Kosmo Machine Inc. preserves the conformity of products during internal processing and delivery to the intended destination. The methods used in this preservation include:

#### **A)** Identification:

• Materials are identified at receipt and parts identified throughout the manufacturing process as detailed in section 7.5.3, Identification and Traceability.

#### **B**) Handling:

• Throughout the manufacturing process, the product is handled and transported in such a manner as not to cause any damage to it.



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## **Section 7.0 Product Realization** (continued)

#### C) Packaging:

• After the manufacturing process is complete, the product is prepared for shipment to the customer. The product is bagged or wrapped up if needed to prevent parts from touching and becoming damaged during shipment. Labels with any necessary information are applied to the packaged parts if required by the customer. The parts are then loaded into a box, boxes, skid, or crate with sufficient packing material to prevent movement during delivery.

### **D**) Storage:

• During the manufacturing process, the product is either stored on the appropriate in-process shelf, or in the inspection area. As parts are completed and passed at the inspection area, they are moved to the finished parts staging area. Here the parts are stored until the time of delivery.

### **E**) Protection:

• In all cases, from the time the material arrives from the vendor until the time the finished product is shipped to the customer, the product is protected at all times from the elements, extreme temperatures, and any such circumstances that may cause irreparable damage to it.

### 7.6 Control of Monitoring and Measuring Devices

Kosmo Machine Inc. has determined that the Zeiss Eclipse and the LK Evolution Coordinate Measuring Machines are to be identified as the master monitoring and measuring devices, and all other monitoring and measuring tools on premises are designated as "reference only".

Kosmo Machine Inc. identifies the measurements to be performed, and the monitoring and measuring devices required to ensure quality of product, and conformity to specified requirements.

When specified, the technical data concerning monitoring and measuring devices is made available to the customer to confirm that the monitoring and measuring devices are functionally adequate.

The master monitoring and measuring devices are:

**A)** calibrated on a yearly basis by a trained and qualified calibration technician. They are calibrated in accordance with the standards set forth in ASME B89.4.1b-2001.



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## **Section 7.0 Product Realization** (continued)

- **B)** calibrated using equipment that is traceable to the National Institute of Standards and Technology (NIST) or other internationally recognized standards laboratories.
- **C**) identified so that the calibration status may be determined.
- **D**) safeguarded against adjustments or other factors that would invalidate the measurement result.
- **E**) protected from damage and deterioration during use and maintenance.

If, at any time, the master monitoring and measuring devices are found to be out of calibration and/or unsuitable for their intended use, then the validity of the records from the previous use will be assessed and the appropriate action will be taken.



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## Section 8.0 Measurement, Analysis, and Improvement

#### 8.1 General

Kosmo Machine Inc. plans for and implements the monitoring, measurement, analysis and improvement opportunities required in order to ensure product conformity, the effectiveness of the quality management system, and to provide a basis for continual improvement. Included in this is the determination of the need and uses of applicable methodologies including statistical techniques.

## 8.2 Monitoring and Measurement

#### 8.2.1 Customer Satisfaction

Kosmo Machine Inc. monitors the information regarding customer satisfaction and customer perception of product conformity. The methods utilized to obtain this information may include, but are not limited to, telephone calls, e-mails, faxes, surveys, etc.

#### 8.2.2 Internal Audit

Kosmo Machine Inc. conducts internal audits periodically in order to determine if the quality management system:

- **A)** conforms to the planned arrangements as detailed in section 7.1, Planning of Product Realization, and to the requirements of the ISO 9001:2000 standard.
- **B**) is effectively implemented and maintained.

Internal Audits are planned and conducted at regular intervals. The frequency of the audits is based upon the status and importance of the processes and areas to be audited, as well as the results of previous audits. Internal Audits are conducted by qualified Internal Auditors who document the findings of the audits, and report them to management at management review. These auditors do not audit any area, or process, in which they have taken part.

The Internal Audit Checklists (see KMD-0011 – KMD-0021 and KMD-0024 – KMD-0028) are followed when conducting audits. The results of the audits determine whether any nonconformances need to be issued, and the need for corrective and/or preventive actions. This information is entered into the Internal Audit Report (see KMD-0010). Information in this report may include, but is not limited to:

- **A)** A description of the section of the quality management system that is being audited.
- **B**) The date of the audit.



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## Section 8.0 Measurement, Analysis, and Improvement (continued)

- **C**) The name of the auditor.
- **D**) The audit number.
- **E**) A summary of the audit.
- **F)** Corrective/Preventive actions
- **G**) Follow-up actions.

Records that are generated during the Internal Audits, and the subsequent report at management review, are maintained as detailed in section 4.2.4, Control of Records.

### 8.2.3 Monitoring and Measurement of Processes

Kosmo Machine Inc. utilizes appropriate methods for the monitoring and measuring of the quality management system processes, which demonstrate the ability of the processes to achieve the planned results.

When planned results are not achieved, corrective actions are put into place and monitored to ensure effectiveness and product conformity.

#### 8.2.4 Monitoring and Measurement of Product

Kosmo Machine Inc. monitors and measures product characteristics in order to verify that the product requirements have been met. This is carried out at appropriate intervals throughout the product realization process in accordance with quality procedures.

For each manufactured product, the required dimensions and accuracy are indicated on the drawing and/or Job Traveler. It is the responsibility of the employee to utilize the appropriate inspection techniques, and measuring devices, which will provide the necessary precision and accuracy during manufacturing.

Records are maintained that show evidence of conformity to required specifications, and indicate the individual(s) authorizing the release of the product.

Release of product and service delivery will not proceed until all required activities have been completed, unless otherwise approved by the customer or relevant authority.

### 8.3 Control of Nonconforming Product

In such circumstances when a product does not conform to customer requirements, Kosmo Machine Inc. ensures that the nonconforming product is identified and controlled



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to prevent its unintended delivery. The procedures adhered to in these circumstances are detailed below.

Each employee is responsible for reporting any suspected discrepant part(s) at any time during the manufacturing process. If a part(s) is suspected to be discrepant when submitted to the Quality Assurance Department, it is placed in the "Discrepant Part Area" along with any necessary identification, i.e., part number, job number, etc.

The Quality Assurance Department is responsible for verifying that the discrepant part(s) does not conform to specifications. If it is confirmed that the part(s) does not conform to customer specifications, then a unique nonconformance number (NC) is generated and assigned to the part(s), and the actual condition of the part(s) is recorded in the Nonconformance module within Vantage. The part(s) is then identified with its NC number and placed in the designated "Nonconformance Part Area" along with a copy of the Nonconformance Report (see KMD-0006).

Management has the responsibility to obtain a disposition of the nonconformance from the customer or relevant authority.

Once a disposition has been received, the part(s) is processed in one of the following manners:

• If the part(s) is approved "as is", then the name of the individual issuing the approval is recorded along with any other pertinent information. The nonconformance is processed to the Inspection Processing module, where the nonconformance is "passed". The part(s) is then released for further processing. A corrective action may also be issued at this point detailing the nature of the root cause and its correction, if necessary.



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- If the part(s) is conditionally approved, pending correction of the nonconformity, then the name of the individual making this concession is recorded, along with the details of the correction(s) to be made and any other pertinent information. A corrective action is then issued and a unique corrective action (CA) number is assigned to the part(s). The details of the corrective actions to be taken, and any other pertinent information, are recorded on the Rework Instructions form (see KMD-0023). The part(s), Rework Instructions, and the Job Traveler are placed in the rework area. The corrective action remains active until the required corrections have been made, and re-verified by the Quality Assurance Department. If, upon verification, the corrections meet specifications, then the corrective action report is updated with the details of the corrections, the nonconformance is "passed" in the Discrepant Materials Report (DMR) module, and the part is then released for further processing.
- If the part is not approved, then a corrective action is issued stating the root cause and its correction as well as the fact that the part(s) is irreparable and/or rejected by the customer. The nonconformance is then "rejected" within the DMR module, and the name of the individual issuing the rejection is recorded, along with any other pertinent information. The part(s) is then marked with the job, NC, CA, and DMR numbers (as needed) and placed in the appropriate scrap bin.

#### 8.4 Analysis of Data

Kosmo Machine Inc. collects, and analyzes the data and information necessary for determining tendencies in the performance and effectiveness of the quality management system and to identify any opportunities for improvement.

This data is used to provide information on:

- A) Customer satisfaction
- **B**) Product conformity
- **C)** The characteristics and trends of the processes and products including any opportunities for preventive action.
- **D)** The performance of suppliers.



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## Section 8.0 Measurement, Analysis, and Improvement (continued)

#### 8.5 Improvement

### 8.5.1 Continual Improvement

Kosmo Machine Inc. strives to continually improve the effectiveness of the quality management system through the use of the quality policy and objectives, audit results, data analysis, corrective and preventive actions, and management review.

#### 8.5.2 Corrective Action

Kosmo Machine Inc. continually works to define and eliminate the causes of nonconformances in order to prevent their reoccurrence. Corrective actions are appropriate to the effects of each nonconformance.

- **A)** Nonconformances are reviewed by management on an as needed basis. If at any time, a customer complaint is received, it is addressed and resolved at the time of the complaint if possible, and discussed at management review.
- **B**) The cause of nonconformances is determined during the process review. This evaluation results in a corrective action, if necessary.
- C) Management determines the actions necessary to ensure that nonconformances do not recur. The records (Job Traveler, methods of manufacture, etc.) are updated to reflect these improvements.
- **D)** Management determines and implements a corrective action during product and/or process review, if necessary.
- **E**) Records of the results of corrective actions are recorded on the individual jobs and within the Vantage software, and can be accessed at any time for review. These records are maintained as outlined in section 4.2.4, Control of Records.
- **F)** The results of corrective actions are reviewed during in-process inspections. This takes place after any authorized repairs have been performed.

#### 8.5.3 Preventive Action

Kosmo Machine Inc. determines the necessary preventive actions to eliminate the causes of potential nonconformances in order to prevent occurrence. The preventive actions taken are appropriate to the effects of the potential problems.

- **A)** Potential nonconformances and their causes may be predicted before a job is issued and at management review.
- **B**) If a potential nonconformance is predicted, the necessary preventive action is determined, and written into the Job Traveler.



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## Section 8.0 Measurement, Analysis, and Improvement (continued)

- C) Any necessary action that is determined prior to the issuance of a job is implemented using instructions to the employee on the Job Traveler.
- **D**) The records of these actions are stored electronically in Vantage once they are added to the Job Traveler.
- **E**) Potential nonconformances may also be predicted during the manufacturing process. If any such cases do occur, then the person who discovers the potential nonconformance informs management in person, or by completing a Job Traveler Revision Form (see KMD-0029). A preventive action is then planned and implemented, and the current Job Traveler revised.
- **F)** The preventive action taken, if successful, is reviewed at the conclusion of the job. If the preventive action is unsuccessful, it is reviewed at the time of issuance of a nonconformance.