Cambridge Precision Quality Manual

This manual has been written to the
ISO 9001:2000 International Quality Standard

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Revision History

Revision	Date	Description
A	8/9/2010	Initial Issue
B	7/5/2011	Updated Company Name
C		

Introduction

Scope:

This Quality Manual is used by Cambridge Machine Works, Inc. Hereinafter known as Cambridge Precision Machining or Cambridge Precision, as the basis for managing all activities associated with our Quality Management System.

Purpose:

This Quality Manual is intended to describe and provide control over activities that impact customer satisfaction. ISO 9001:2000 is the basis for the creation of this Quality Manual. This document contains all of the requirements of the ISO 9001:2000 standard with the exception of Design Activities.

Application:

Cambridge Precision performs all activities associated with ISO 9001:2000 with the exception of product design, Clause 7.3.

Background:

As a precision machine shop, Cambridge Precision has been a valued partner and supplier to the world markets since 1987. We produce machined parts, components, and assemblies for, among others, industries involved in the Hi-Tech, Medical, Animation, and Automotive fields. Cambridge's niche is in CNC milling and CNC turning operations where we feature a variety of late model equipment supported by the latest version of Autodesk Inventor and GibbsCam and MasterCam programming software. Our staff is dedicated to their craft and takes great pride in their approach to quality and workmanship.

This manual covers the disciplines necessary to manufacture a part from its inception to a production run and successful delivery of the product to the customer.

4.1 General Requirements

Cambridge Precision has established, documented, and implemented a Quality Management System in accordance with the requirements of ISO 9001:2000. This Quality Management System is described in this document. Cambridge Precision strives to continually improve the effectiveness of its Quality Management System.

As part of the Quality Management Systems Cambridge Precision has:

- Identified the processes needed for the Quality Management System and their application throughout the organization. These processes are described in the process maps that are included in Attachment 1 to this Quality Manual.

- Identified the sequence and interaction of processes related to the Quality Management System. These are clearly identified in Attachment 1.

- The criteria and methods needed to ensure that both the operation and control of these processes are effective and clearly described in Attachment 1 and in the body of this Quality Management System.

- Cambridge Precision is committed to supporting its Quality Management System and provides sufficient resources to ensure activities take place as required. Provision of resources and monitoring of these activities are designed to ensure that they take place as planned.

- Critical processes are identified in Attachment 1 and the associated monitoring, measurement and analysis used by Cambridge Precision take place to ensure their continuing suitability.

- Actions are taken whenever necessary to ensure that planned results are achieved and to assure continual improvement.

All of the processes described above are managed by Cambridge Precision in accordance with the requirements listed in ISO 9001:2000.

Cambridge Precision out sources operations within its Quality Management System. Whenever outsourcing occurs, the Cambridge Precision Quality Management System is used to control these processes. Processes outsourced include:

Heat-Treating
Plating/Anodizing
Grinding
Welding
Silk-screening
Tool grinding
Machining operation
Metal Fabrication

We have chosen the companies to provide the services required based on their ability to perform to Cambridge Precision Machine's and Customer requirements.

4.2 Documentation Requirements

4.2.1 General

The Cambridge Precision Quality Management System is based on the following documents:

- Cambridge Precision Quality Policy – (Attachment 2 to this Quality Manual)
- Cambridge Precision Quality Objectives –(Attachment 3 to this Quality Manual)
- This Quality Manual
- Documented Procedures (contained within this Quality Manual)
- Documents used to ensure effective planning, operation and control of processes including the process maps shown in Attachment 1
- Quality Records as described in element 4.2.4 of this Quality Manual

4.2.2 Quality Manual

Cambridge Precision has established this Quality Manual to support its activities.

Documented Procedures that support the Cambridge Precision Quality Manual are referenced within this Manual and include:

- 4.2.3 Control of Documents
- 4.2.4 Control of Quality Records
- 8.2.2 Internal Quality Audits
- 8.3 Control of Nonconforming Product
- 8.5.2 Corrective Action
- 8.5.3 Preventive Action

The description of the interaction between the processes of the Quality Management System is described within this document with a graphical representation included in Attachment 1.

4.2.3 Control of Documents

Documents required by the Cambridge Precision Quality Management System are controlled. Control of these documents are described in Procedure # QP01. This control ensures that:

- Documents are approved for adequacy prior to use
- Documents are reviewed and updated as necessary and re-approved
- Changes and the current revision status of documents are identified
- Relevant versions of applicable documents are available at points of use
- Ensure that documents remain legible and readily identifiable
- Documents of external origin are identified and their distribution controlled
- Obsolete documents are not unintentionally used
- Obsolete documents are suitably identified when they are retained

4.2.4 Control of Quality Records

Cambridge Precision controls all records associated with the maintenance of its Quality Management System. A description of these records and methods used to exercise appropriate control are included in QP02. This control ensures that Quality Records:

- Remain legible
- Are readily identifiable
- Are retrievable

Methods utilized provide for the control of Quality Records including:

- Identification
- Storage
- Protection
- Retrieval,
- Retention time
- Disposition

Management Responsibility

5.1 Management Commitment

The President of Cambridge Precision demonstrates his commitment to the development and implementation of the Quality Management Systems and to continually improving its effectiveness by:

- Communicating to all personnel the importance of meeting customer as well as statutory and regulatory requirements
- Establishing its Quality Policy (see attachment)
- Ensuring Quality Objectives are established (see attachment)
- Conducting Management Reviews
- Ensuring personnel performing tasks are provided with the resources needed

5.2 Customer Focus

The President of Cambridge Precision ensures that all customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction. Methods for accomplishing this are described in this Quality Manual and in the Attachment 1

5.3 Quality Policy

The President of Cambridge Precision has established a Quality Policy that is appropriate to its operations and activities. The Quality Policy includes a commitment to comply with requirements and continually improve the effectiveness of the Quality Management System. This Policy also provides the framework for the establishment and review of Cambridge Precision Quality Objectives.

The Cambridge Precision Quality Policy is published as part of this Quality Manual (see Attachment 2).

5.4 Planning

5.4.1 Quality Objectives

The President of Cambridge Precision has established Quality Objectives to support its Quality Management System (see attachment 3). These objectives include those needed to meet requirements for product. Cambridge Precision Quality Objectives are established at relevant functions within the company and are measurable. The Cambridge Precision Quality Objectives are consistent with the Cambridge Precision Quality Policy.

5.4.2 Quality Management System Planning

The President of Cambridge Precision is responsible for the planning of the Quality Management System. This planning is carried out in order to meet the requirements given in Element 4.1 and the Quality Objectives and is contained in Attachment 1 of this Manual.

The President of Cambridge Precision is responsible for ensuring the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The President of Cambridge Precision ensures that responsibilities, authorities and their interrelation are defined and communicated within the organization. Attachment 1 to this Quality Manual provides additional assignment of responsibility.

5.5.2 Management Representative

The President is the Management Representative. The Management Representative has the responsibility and authority to:

- Ensure that processes needed for the Quality management System are established, implemented and maintained. These processes are described in Attachment 1 of this Quality Manual

- Reporting on the performance of the Quality Management System and any need for improvement. Reports are part of the management review and include customer satisfaction and continuous improvement issues.

- Ensuring the promotion of awareness of customer requirements throughout the organization by face-to-face communication and by setting the standard of performance for day-to-day tasks.

5.5.3 Internal communication:

The President of Cambridge Precision ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the Quality Management System. This communication is typically face-to-face but may consist of written correspondence between employees at any function or level within the organization.

5.6 Management Review

5.6.1 General

The President of Cambridge Precision and designated staff reviews the organization's Quality Management System on a semiannual basis. This review is intended to ensure the continuing suitability, adequacy and effectiveness of the Quality Management System. Included as part of this review is the assessment of opportunities for improvement and the need for changes in the Quality Management System, the Quality Policy, and Quality Objectives.

5.6.2 Management Review Input

Inputs to management reviews at Cambridge Precision consist of:

- Results of internal and external audits of the Quality Management System.
- Feedback provided by customers. This feedback may be formally solicited or initiated by the customer and may be in any format
- Process performance and product conformity
- Status of preventive and corrective action
- Follow-up actions from previous management reviews contained in records of management review
- Planned changes that could affect the Quality Management System including personnel, equipment, product or customer changes.
- Recommendations for improvement to the Quality Management System or any of its related processes

5.6.3 Management Review Outputs

Outputs resulting from management reviews at Cambridge Precision include all decisions and actions related to:

- Improvements to the effectiveness of the Quality Management System and the processes described in Attachment 1
- Improvement of product related to customer requirements. Attachment 1 may be amended based on the results of Management Reviews
- Resource requirements

Resource Management

6.1 Provision of Resources

Cambridge Precision has determined and provides resources necessary for the organization to:

- Implement and maintain the Quality Management system and continually improve its effectiveness
- Enhance customer satisfaction by meeting customer requirements

These resources include but are not limited to:

- Time
- Equipment
- Budget
- Tools
- Supplies

Attachment 1 provides direction for targeting resources to the appropriate time and place within the organization.

6.2 Human Resources

6.2.1 General

Cambridge Precision ensures that personnel performing work that affects product quality are competent. This competence is based on appropriate:

- Education – formal education provided by an educational institution
- Training – provided as OJT or coaching
- Skills – result of previous work activities
- Experience – result of activities performed inside and outside the organization

6.2.2 Competence, Awareness, and Training

Cambridge Precision determines the needs for competence, Awareness and Training of personnel. These requirements are determined by the President with the intent of ensuring customer requirements are met. Steps in this process ensure that:

- Necessary competence for personnel performing work affecting product quality is determined.
- Training is provided or other actions take place to ensure that these skills are acquired. This may be done through OJT, seminars or coaching
- Evaluates the effectiveness of the actions taken to acquire skills. This is done by direct observation of the performance of work or the results of completion of assigned tasks.
- Ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the Cambridge Precision Quality Objectives. This is done by face-to-face communication. This communication includes requirements that may be unique to specific customer jobs.
- Records of education, training skills and experience are maintained in employee files

6.3 Infrastructure

Cambridge Precision has determined and provides the infrastructure needed to achieve conformity of product requirements. The infrastructure provided includes:

- Late-model well-maintained CNC machining centers
- Variety of manual machining equipment
- Multitude of essential tooling and attachments
- Assortment of finishing and cleaning equipment
- Quality control tools consisting of measuring instruments necessary to inspect machined parts
- CAD/CAM Systems
- Networked computer system and software to control shop floor quality data
- This Quality Management System

6.4 Work Environment

Cambridge Precision has determined and provides the work environment needed to achieve conformity of product requirements. The infrastructure provided includes:

- Spacious work areas
- Professionally engineered lighting system
- Clean and dry compressed air supply system
- Clean and organized work environment
- Implemented TPM (Total Preventive Maintenance) program
- Technology driven manufacturing
- Quality Management System

7.1 Planning of Product Realization

The plans describing the processes used to achieve quality are found in Attachment 1 of this Quality Manual. These plans, when applied to a unique customer job take into account the quality objectives associated with that job.

Within each unique job plan, processes and documents are established to support results and customer satisfaction. This includes any required verification, validation; monitoring, inspection and test activities required by the customer or determined to be necessary for customer satisfaction. The Cambridge Precision Job Traveler provides a record of the tasks associated with each job.

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

To ensure customer satisfaction the identification of unique customer requirements is critical. To accomplish this Cambridge Precision ensures:

- Customer requirements are documented for each job. This includes Customer supplied prints; job traveler. These documented requirements form the basis for all Cambridge Precision activities. Whenever there are delivery specifications, these are included in the documented requirements.

- Standards required by generally accepted good practices are engineered into each Cambridge Precision job. These are included to ensure that completed jobs meet requirements.

- Statutory and Regulatory requirements are incorporated as appropriate into each job.

- Additional requirements that are needed are identified and incorporated into each job as appropriate to ensure manufacturability of the completed product.

7.2.2 Review of Requirements Related to the Product

Once Cambridge Precision receives Customer requirements, a review is conducted prior to the commitment to supply the product. This review:

- Ensures customer requirements are adequately defined and documented on Customer supplied documents. These requirements may include specifications, drawings, or written descriptions of the product.

- Any inconsistencies or differences between customer supplied requirements, Cambridge Precision Notes or verbal communications are identified. Resolutions of these differences are undertaken by email, phone or face to face.

- Cambridge Precision does not accept orders that it does not have the capability to fulfill.

Emailed or written records of the results of the review including Cambridge Precision and customer acceptance of the order terms and conditions are kept on file to provide a record of this activity.

When Cambridge Precision develops/creates the documented requirements that represent customer needs, both Cambridge Precision and the customer prior to acceptance confirm these.

The President of Cambridge Precision is responsible for amending and as necessary, re-approving and documenting product changes associated with jobs.

7.2.3 Customer Communication

Cambridge Precision has established methods for effectively communicating with customers:

- Product information is transmitted by mail, fax or email
- Inquiries, contracts or order handling information including amendments to orders are handled as required by the customer
- Open channels of communication are established with each customer to determine their level of satisfaction and/or dissatisfaction. This feedback is provided on a regular basis as the job evolves. As determined by Cambridge Precision Management, additional more formal feedback methods may be used on specified jobs.

7.3 Design and Development

Cambridge Precision is not responsible for design or development activities. Cambridge Precision provides inputs and assistance to design activities as requested by the customer.

7.4 Purchasing

7.41 Purchasing Processes

Cambridge Precision ensures that purchased product conforms to specified purchase requirements. The type and extent of control exercised by Cambridge Precision over suppliers is dependent on the effect of the purchased product on the final product.

Suppliers are evaluated according to their ability to meet Cambridge Precision requirements. The criteria for selection of suppliers and their evaluation criteria are:

Type of Supplier	Type of evaluation
Stocking Vendor	Is it available at the time it is needed History of on time shipments
Subcontractors (Heat-treating, Plating Special tooling, Grinding etc.)	Past performance Ability to correct problems Responsiveness

7.4.2 Purchasing Information

Each order placed by Cambridge Precision provides information necessary for the supplier or subcontractor to successfully fill the order. These requirements vary from order to order and will include as appropriate:

- Requirements for approval of the product ordered, procedures for product fulfillment, processes required for product creation and equipment to be used
- Requirements for the qualification of personnel producing the product
- Quality Management System Requirements

Cambridge Precision reviews each order for accuracy prior to submission to the supplier or subcontractor.

7.4.3 Verification of Purchased Product

Cambridge Precision conducts verification of purchased product as required. These requirements are designated as follows:

- Customer may specify these requirements as part of their documentation
- President of Cambridge Precision may specify these requirements based on the type of product ordered and the risks associated with the product.

7.5.1 Control of Product and Service Provision

Cambridge Precision plans and carries out production activities under controlled conditions. These controlled conditions include:

- Information that describes the characteristics of the product are provided on customer prints and other supporting documents
- Work instructions are provided on Job Travelers
- Suitable equipment is designated on the Traveler
- Measuring devices such as gauge blocks, micrometers etc.
- Implementation of required monitoring and measurement activities as designated in the Traveler
- Release of products is controlled as describe on the Traveler

7.5.2 Validation of Processes for Production and Service Provision

Cambridge Precision does a first article inspection on all jobs. This inspection is designed to ensure that product, tooling and equipment is capable of supplying products that meet customer requirements. This evaluation ensures that:

- Criteria listed on the Job Cost Card are used to perform the evaluation
- Equipment is capable of providing parts that meet customer requirements
- Personnel are capable of producing parts that meet customer requirements
- Specific requirements for validation or verification are listed in the notes section of the Job Cost Card or on customer prints
- Records required by customers or by Cambridge Precision are documented
- When necessary, revalidation activities take place

7.5.3 Identification and Traceability

When a customer requirement for Identification or Traceability is specified, the President of Cambridge Precision
develops the methodology that will be applied to meet the unique customer requirement. This includes as appropriate the identification of:

- Part number
- Tool number
- Lot number
- Customer name

The means to perform the identification is dependent on the item to be identified or traced. This identification then becomes a unique record of the item.

7.5.4 Customer Property

Cambridge Precision exercises care with regard to customer property. Customer property includes, but is not limited to:

- Sample parts
- Computer Diskettes
- Equipment
- Tooling
- Documents including blueprints

The actions taken by Cambridge Precision ensure that customer property is appropriately identified, verified, protected and safeguarded and available for use as required by the job. When customer property is found to be unsuitable for use, the customer is notified and a record of this notification is kept on file.

7.5.5 Preservation of Product

Preservation of product at Cambridge Precision takes place to ensure that parts and customer supplied product takes place to ensure that these items are available for use throughout all phases of jobs. This preservation includes control over three activities:

- Receipt
- Build
- Shipment

Control activities ensure that all necessary actions are taken to assure the proper identification, handling, packaging, storage and protection of materials. Preservation activities include but are not limited to:

- Protection from damage (cosmetic and functional)
- Packaging
- Protection from damage during handling

7.6 Control of Monitoring and Measuring Devices

Cambridge Precision has identified those pieces of equipment that require control and or calibration. For each item identified, the process used for calibration is stipulated on our Inspection Equipment Calibration Schedule. Complete instructions for calibration activities are contained in the calibration file.

Control of this equipment ensures:

- Equipment is calibrated at the appropriate interval to ensure its availability for use.
- Equipment is calibrated against requirements that are traceable to international standards
- Equipment is adjusted/readjusted as necessary to maintain status
- Equipment is identified to include calibration status
- Equipment is safeguarded to prevent adjustments that would invalidate measurements
- Equipment is protected from damage and deterioration during handling maintenance and storage

When equipment is found to be out of calibration an assessment is undertaken to record the validity of previous measuring results. Corrective action is taken to resolve the problem or the customer is notified when they may be affected. Records of calibration are maintained to demonstrate equipment qualification.

Measurement Analysis and Improvement

8.1 General

Cambridge Precision develops plans to implement the monitoring, measurement analysis and improvement processes needed to ensure quality. This plan includes: Demonstration of product conformity by conducting specific defined measurements on products as defined by the customer or determined by Cambridge Precision Management. Records of these measurements are made and used to verify conformance or to take corrective action.

Cambridge Precision conducts Internal Audits as a measure of the effectiveness of its Quality Management System. The results of product and process measurements and measures of the effectiveness of the Quality Management System are used as part of the company's continuous improvement process.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Customer satisfaction data is solicited by the President of Cambridge Precision on each job. This is done by face-to-face conversations or by telephone. Results of this feedback are used to formulate actions that resolve problems and provide for continuous improvement.

8.2.2 Internal Audit

Internal audits are undertaken by Cambridge Precision as a means of determining the effectiveness of their Quality Management System. Specific requirements for the conduct of Internal Audits are defined in a QP03.

Internal Audits take place annually or at any shorter interval that is determined by the President of the company. An internal audit checklist based on this Quality Manual and associated procedures are used as the basis for this audit. Adjustments are made to the planned audit schedule based on:

- Status and importance of the topic to be audited
- Results of customer audits
- Results of previous internal audits
- Results of customer feedback

Personnel performing internal audits are assigned in a way to ensure that they are independent from the subject that is audited. Follow-up activities are taken to ensure that actions are taken and that these results are verified and reported to company management.

8.2.3 Monitoring and Measurement of Process

Monitoring and Measurement of Process takes place as determined by the Customer or by the President of Cambridge Precision. These measurements are unique to each customer job and may include:

- Data analysis (SPC or other)
- Approved process control plan
- FMEA

Measurements are designed to demonstrate the ability of the processes to achieve planned results. Results of measurements are used to provide feedback to the process so that corrective actions can be taken. When requested, results of measurements are also provided to customers as part of the completed job.

8.2.4 Monitoring and Measurement of Product

Monitoring and Measurement of Product takes place as determined by the Customer or by the President of Cambridge Precision. These measurements are unique to each customer product and may include:

- An approved quality plan
- First article inspection data
- Critical characteristic measurement data
- SPC data submitted to customer
- SPC data saved to data base

Measurements are designed to demonstrate the conformance of the product to specified requirements. Results of measurements are used to provide feedback to the process so that corrective actions can be taken. When requested, results of measurements are also provided to customers as part of the completed job. Results of measurements including the responsible authority for the measurement constitute a record of product release to the customer. This release to the customer does not take place until all requirements have been met.

8.3 Control of Nonconforming Product

Cambridge Precision controls all nonconforming products to prevent unintended use or delivery to the customer. This control includes but is not limited to:

- Identification
- Segregation
- Destruction / Disposal

The Production Manager of Cambridge Precision is responsible for the control of Nonconforming Product. QP04 describes specific requirements for the control of Nonconforming Product.

8.4 Analysis of Data

Cambridge Precision uses data analysis as a means for demonstrating the suitability and the effectiveness of its Quality management System. This data is also used to evaluate continual improvement. Data includes:

- Feedback from customers on their level of satisfaction with jobs or products
- Product or process data gathered during the production processes
- Characteristics or trends of processes and products including those that could lead to preventive actions
- Performance of Suppliers and Subcontractors

8.5 Improvement

8.5.1 Continual Improvement

Cambridge Precision is committed to continual improvement in every aspect of its operations. This improvement is accomplished by the use of the most recent technological developments that are appropriate, the use of customer feedback, analysis of data related to product and process and from analysis of the effectiveness of the Quality Management System. The President of Cambridge Precision is responsible for all Continual Improvement Activities.

8.5.2 Corrective Action

Cambridge Precision takes actions to eliminate the causes of nonconformance as a means of preventing their recurrence. The type and extent of corrective actions taken are determined by the President of the company and are appropriate to the effects of the nonconformance encountered. The corrective action system includes:

- Reviewing problems including customer complaints
- Determining the causes of problems
- Evaluating the need for action to ensure the nonconformities do not recur
- Recording the results of actions taken
- Reviewing the corrective action taken

The President of Cambridge Precision is responsible for taking or assigning actions to resolve problems. Once actions have been taken on an identified problem, a record of this action is taken which may be in any form that is determined to be appropriate by the President. A review of corrective actions taken is conducted as part of the company management review process.

8.5.3 Preventive Action

Preventive actions are identified and taken by Cambridge Precision as part of their continuous improvement process and as a means of assuring customer satisfaction. These actions are designed to eliminate the causes of problems before they occur. A documented procedure is used to describe the requirements of this activity. Preventive Action includes:

- Determining the potential for problems and their causes
- Evaluating the need for preventive action
- Determining and implementing action
- Keeping records of actions taken
- Reviewing the actions taken