

QUALITY MANUAL

for
Carolina Precision Manufacturing, LLC

PAGE	TOPIC	INDEX	ISSUE	DATE
1, 2	Index		1	June 2006
3	Quality Policy		1	June 2006
4	General information		1	June 2006
5	4 Quality management system		1	June 2006
5	4.1 General requirements		1	June 2006
6	4.2 Documentation requirements		1	June 2006
6	4.2.1 General		1	June 2006
6	4.2.2 Quality manual		1	June 2006
7	4.2.3 Control of documents		1	June 2006
7	4.2.4 Control of records		1	June 2006
8	5 Management responsibility		1	June 2006
8	5.1 Management commitment		1	June 2006
8	5.2 Customer focus		1	June 2006
8	5.3 Quality policy		1	June 2006
9	5.4 Planning		1	June 2006
9	5.4.1 Quality objectives		1	June 2006
9	5.4.2 Quality management system planning		1	June 2006
9	5.5 Responsibility, authority and communication		1	June 2006
9	5.5.1 Responsibility and authority		1	June 2006
9	5.5.2 Management representative		1	June 2006
10	5.5.3 Internal communication		1	June 2006
10	5.6 Management review		1	June 2006
10	5.6.1 General		1	June 2006
10	5.6.2 Review input		1	June 2006
11	5.6.3 Review output		1	June 2006
12	6 Resource management		1	June 2006
12	6.1 Provision of resources		1	June 2006
12	6.2 Human resources		1	June 2006
12	6.2.1 General		1	June 2006
12	6.2.2 Competence, awareness and training		1	June 2006
13	6.3 Infrastructure		1	June 2006
13	6.4 Work environment		1	June 2006
14	7 Product realization		1	June 2006
14	7.1 Planning of product realization		1	June 2006

Index(continued)

PAGE	TOPIC	ISSUE	DATE
15	7.2 Customer-related processes	1	June 2006
15	7.2.1 Determination of requirements related to the product	1	June 2006
15	7.2.2 Review of requirements related to the product	1	June 2006
16	7.2.3 Customer communication	1	June 2006
16,17 & 18	7.3 Design and Development (not included in scope of this manual)	1	June 2006
19	7.4 Purchasing	1	June 2006
19	7.4.1 Purchasing process	1	June 2006
19	7.4.2 Purchasing information	1	June 2006
19	7.4.3 Verification of purchased product	1	June 2006
20	7.5 Production and service provision	1	June 2006
20	7.5.1 Control of production and service provision	1	June 2006
20	7.5.2 Validation of processes for production and service provision	1	June 2006
21	7.5.3 Identification and traceability	1	June 2006
21	7.5.4 Customer property	1	June 2006
21	7.5.5 Preservation of product	1	June 2006
22	7.6 Control of monitoring and measuring devices	1	June 2006
23	8 Measurement, analysis and improvement	1	June 2006
23	8.1 General	1	June 2006
23	8.2 Monitoring and measurement	1	June 2006
23	8.2.1 Customer satisfaction	1	June 2006
23	8.2.2 Internal audit	1	June 2006
24	8.2.3 Monitoring and measurement of processes	1	June 2006
24	8.2.4 Monitoring and measurement of product	1	June 2006
25	8.3 Control of nonconforming product	1	June 2006
25	8.4 Analysis of data	1	June 2006
26	8.5 Improvement	1	June 2006
26	8.5.1 Continual Improvement	1	June 2006
26	8.5.2 Corrective action	1	June 2006
27	8.5.3 Preventive action	1	June 2006
Appendices	Process Maps		

Approval:

(President)

Carolina Precision Manufacturing, LLC

Quality Policy

The goal of Carolina Precision is to be the supplier of choice for customers requiring small diameter close-tolerance machined parts. We are committed to on-time delivery of defect-free parts for every order and the continual improvement of our Quality System.

President

General Information

The Quality Manual is designed to provide information on and serve as a basis for the quality system employed at Carolina Precision Manufacturing for safeguarding the quality of our delivered product.

The text of the standard is printed on the left hand side and the application of the requirements by Carolina Precision Manufacturing is printed on the right hand side. Related procedures are shown in the text on the right hand side.

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

- a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure and analyze these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE. Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

4 Quality management system

The company has prepared and published a Quality Manual.

The Quality Manual addresses all areas of the ISO9001: 2000 standard and is a description of the Company's Quality Assurance Policies.

4.1 General requirements

Management has identified the processes to be included in the management system, which is described in the Quality Manual.

Management ensures there are sufficient resources to ensure the satisfactory completion of these processes.

Management sets goal and targets for these processes and monitors and analyzes the results achieved. Actions are taken to achieve the planned results and continually improve the processes.

The company controls the outsourcing of any process that affects the product conformity by specifying purchasing requirements for products and services.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures required by this International Standard
- d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and
- e) records required by this International Standard (see 4.2.4).

NOTE 1 where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

- a) the size or organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

The organizations shall establish and maintain a quality manual that includes

- a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2).
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system.

4.2 Documentation requirements

4.2.1 General

The company has issued a Quality Policy, which includes quality objectives.

The company has issued procedures and work instructions and other quality documents to adequately implement the company’s Quality Manual and policies. (QSP-0424)

4.2.2 Quality manual

The Company’s Quality Manual details the justification of exclusions to the ISO9001:2000 standard and references documented procedures in the quality management system.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable
- f) to ensure that documents of external origin are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identifications to them if they are retained for any purpose.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Record shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

4.2.3 Control of documents

The company has issued procedures for controlling documents that support the quality system.

Preparation, approval, and issue of quality documents are controlled, including regular review status and master document index. (QSP-0423}

4.2.4 Control of records

The company has established firm rules and procedures for retaining quality records. The procedures detail routines for retention, storage, identification, filing, maintenance, access and disposal of quality records.

Adequate facilities are made available to protect the condition and legibility of the records. (QSP-0424)

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1. and 8.2.1).

5.3 Quality policy

Top management shall ensure that the quality policy

- a) is appropriate to the purpose of the organization,
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within the organization, and
- e) is reviewed for continuing suitability

5 Management responsibility

5.1 Management commitment

The company quality policy outlines management commitment to the importance of meeting stipulated requirements. Management review meetings are conducted periodically to monitor and correct the effectiveness of the quality system (QSP-0560).

5.2 Customer focus

The company is focused on the needs and requirements of its customers and top management is responsible to ensure the company meets these needs.

5.3 Quality policy

By issuing the company's quality policy, the management has determined the guidelines for the quality assurance and provided support for the policy by setting targets and goals that implement the policy.

The policy shall be reviewed for adequacy at least once per year. All employees receive training on the policy content.

The training is repeated when the policy is amended.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [(see 7.1a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

- a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- b) 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

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

- a) ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) reporting to top management on the performance of the quality management system and any need for improvement, and
- c) ensuring the promotion of awareness of customer requirements throughout the organization.

5.4 Planning

5.4.1 Quality objectives

Management set targets and goals through the management review meetings/other directives. The objectives are measurable. (See current company quality objectives)

5.4.2 Quality management system planning

The president has the responsibility for ensuring that adequate activities are planned to assure product quality.

The requirements of ISO9001: 2000 clauses 4.1.a) through 4.1.f), are incorporated into the procedures and instructions prepared and issued throughout the quality system.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

The company defines the responsibility and authority for personnel in the employee position descriptions and/or the Organization Chart.

5.5.2 Management representative

The President appoints the management representative, who has been delegated authority and responsibility for maintaining the quality management system.

The reporting to top management on the performance of the quality management system is through the periodic management review meetings (QSP-0560). See Organization Chart for current incumbent.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input

The input to management review shall include information on

- a) results of audits,
- b) customer feedback,
- c) process performance and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) changes that could affect the quality management system, and
- g) recommendations for improvement.

5.5.3 Internal communication

Communication is achieved by posting of informative bulletins/charts and/or meetings with employees, as determined by management

5.6 Management review

5.6.1 General

The management conducts periodic review meetings to monitor, correct and improvement of the quality management system.

5.6.2 Review input

Company management specifies the input to the management review, which includes mandatory elements from the ISO9001:2000 standard. (QSP-0560).

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

- a) improvement of the effectiveness of the quality management system and its processes,
- b) improvement of product related to customer requirements, and
- c) resource needs.

5.6.3 Review output

Company management specifies the output from the management review which includes the mandatory elements specified in ISO9001:2000. (QSP-0560).

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

- a) to implement and maintain the quality management system and continually improve its effectiveness, and
- b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1. General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

The organization shall

- a) determine the necessary competence for personnel performing work affecting product quality,
- b) provide training or take other actions to satisfy these needs,
- c) evaluate the effectiveness of the actions taken,
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

6 Resource management

6.1 Provision of resources

The President is ultimately responsible for the resources needed to implement and maintain the quality management system and continually improve its effectiveness and enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

The company ensures that personnel performing work affecting product quality will be competent by pre-employment interviews and screening.

6.2.2 Competence, awareness and training

The company has determined the required competencies for its personnel and documented these in Job Descriptions.

As needed, training is provided to ensure the competence of all employees to perform the duties assigned to their position, and identification of training needs to develop abilities and skills.

The program evaluates the effectiveness of any training.

Training records are designated as Quality Records and are controlled (QSP-0622).

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements.

Infrastructure includes, as applicable

- a) buildings, workspace and associated utilities,
- b) process equipment (both hardware and software), and
- c) supporting services (such as transport or communication).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

6.3 Infrastructure

The company operates a preventive maintenance system on all major equipment as suggested by the OEM, and its infrastructure is more than adequate to achieve conformity to product requirements.

6.4 Work environment

The company management is responsible to ensure a satisfactory work environment is maintained to achieve conformity to product requirements.

7. Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization.

Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

- a) quality objectives and requirements for the product;
- b) the need to establish processes, documents, and provide resources specific to the product;
- c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4.).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7. Product realization

7.1 Planning of product realization

The Quality Manager has the responsibility for ensuring that adequate activities are planned to assure product quality.

The company prepares a job/part file, from which a shop order is generated, which details quality requirements for the product.

The part file details processing requirements and the company has prepared work instructions detailing inspection requirements and records required.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) requirements not stated by the customer but necessary for specified or intended use, where known,
- c) statutory and regulatory requirements related to the product, and
- d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

- a) product requirements are defined,
- b) contract or order requirements differing from those previously expressed are resolved, and
- c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4.).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The Sales Department is responsible to assure customer and associated requirements are determined (QSP-0710).

7.2.2 Review of requirements related to the products

The Sales Department is responsible for review of initial and changed customer orders. Procedure QSP-0710 outlines these requirements.

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

- a) product information,
- b) enquiries, contracts or order handling, including amendments, and
- c) customer feedback, including customer complaints.

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

- a) the design and development stages,
- b) the review, verification and validation that are appropriate to each design and development stage, and
- c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.2.3 Customer communication

The company assures adequate communication and feedback with customers on product information and inquiries and orders

7.3 Design and development

CLAUSE EXCLUSION

Design and development is not included in the scope of the Quality System, as the customer is responsible for product design in terms of finish machined dimensions, material grade and heat treatment condition.

Consequently this Quality Manual contains no procedures and policies related to this clause.

7.3.2 Design and development inputs

Not applicable

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4.). These inputs shall include

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

- a) meet the input requirements for design and development,
- b) provided appropriate information for purchasing, production and for service provision,
- c) contain or reference product acceptance criteria, and
- d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and development review

At suitable stages, systematic review of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

- a) to evaluate the ability of the results of design and development to meet requirements, and
- b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stages(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

Not applicable

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluation and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

- a) requirements for approval of product, procedures, processes and equipment,
- b) requirements for qualification of personnel, and
- c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.4 Purchasing

7.4.1 Purchasing process

The company has issued procedures and routines for the purchase of product and services determined to affect product quality (QSP-0740)

The criteria for evaluating and approving supplies of product/services that affect product quality are given in QSP-0740. A comprehensive listing of approved suppliers is maintained in the computer system.

7.4.2 Purchasing information

Purchase orders clearly describe product requirements. See QSP-0740

7.4.3 Verification of purchased product

The company has issued procedures and instructions detailing controls for purchased product requiring receiving inspection, including type of product, inspection technique, and level (QSP-0824).

The company reserves the right to verify purchased product at the suppliers' premises or upon receipt of product from the supplier

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring devices,
- e) the implementation of monitoring and measurement, and
- f) the implementation of release, delivery and post-delivery activities.

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where subsequent monitoring or measurement cannot verify the resulting output. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,
- d) requirements for records (see 4.2.4), and
- e) revalidation.

7.5 Production and service provision

7.5.1 Control of production and service provision

The company has issued procedures and routines to control processes that affect quality (QSP-0751)

The company prepares a (shop order/router/work order) that details the characteristics of the product and details the designated equipment to manufacture the product.

The company has issued procedures and routines for the inspection and testing of the product (QSP-0824)

7.5.2 Validation of processes for production and service provision

The company has no special processes and has excluded this clause from its QMS. Should there be a need for special processes in the future, CPM will create validation processes at that time.

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.5.3 Identification and traceability

As appropriate, the company identifies products to ensure that the individual orders are kept separate (QSP-0753)

The company operates using a system that identifies inspection and test status based on location of product, identification of product and documented evidence that product has completed inspection, meeting all acceptance criteria.

Unique identification for traceability purposes is maintained, when required by customers.

7.5.4 Customer property

The company has issued procedures and routines to control and handle products and property supplied by the customer intended for incorporation in the delivery (QSP-0754).

The company notifies the customer of any material, product or property lost, damaged, or scrapped.

7.5.5 Preservation of product

The company has issued procedures detailing the routines and practices necessary to ensure the safe handling, identification, storage, packaging, preservation and delivery of product. (QSP-0755)

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that

is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

- a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
- b) be adjusted or re-adjusted as necessary;
- c) be identified to enable the calibration status to be determined;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

7.6 Control of monitoring and measuring devices

The company has issued procedures and instructions to ensure the accuracy of measurement results are maintained, and equipment calibrated (QSP-0760)

- Measuring and test equipment is maintained traceable to a national standard or other accepted industrial standard.
- Measuring and test equipment is uniquely identified.

The calibration procedure (QSP-0760) and calibration system addresses all the requirements of.

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

- a) to demonstrate conformity of the product,
- b) to ensure conformity of the quality management system, and
- c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

- a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
- b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

8 Measurement, analysis and improvement

8.1 General

The company has issued procedures and instructions detailing inspection and testing methods, techniques and levels for all inspection points. (QSP-0824).

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

The company has methods for determining customer satisfaction as one of the measurements of the performance of the quality management system.

8.2.2 Internal audit

The company has issued a procedure detailing the internal audit system (QSP-0822). There is also a Shop Audit procedure (QSP-0822A).

The system is designed to check the effectiveness of the quality system and conformance with planned activities.

Internal quality audits are carried out in accordance with a program based on status and importance of the activity.

Records of audit results are retained as a quality record (QSP-0424).

Internal quality auditors are trained and authorized to perform audits independent of their area of responsibility.

The audit results are used to test and improve the effectiveness of the system.

Corrective actions implemented to improve the system are followed up to check the effectiveness of the actions taken.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 10011-1, ISO 10011-2 and 10011-3 for guidance.

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person (s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1.) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.2.3 Monitoring and measurement of Processes

The company implements and maintains business performance measures to monitor the various processes.

Management regularly reviews the data and corrective actions are taken, when required, to achieve the desired results. (QSP-0560)

8.2.4 Monitoring and measurement of product

The company has issued a procedure detailing controls for purchased product requiring receiving inspection, including type of products, and inspections required (QSP-0824)

The details of required in-process inspection testing are recorded in procedures, including requirements for segregation, reporting and control of non conforming product.

The company has prepared procedures and instructions detailing the final verification requirements. No order is dispatched until all verifications are completed and conform to specifications (QSP-0824).

All inspection and test records are designated as quality records and retained in accordance with procedure QSP-0424.

The personnel authorized to perform final inspection functions are shown in the relevant procedure.

Inspection/test records clearly state the acceptability/rejections of the inspection/test and the person responsible.

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) by taking action to provide its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

- a) customer satisfaction (see 8.2.1),
- b) conformity to product requirements (see 7.2.1),
- c) characteristics and trends of processes and products including opportunities for preventive action, and
- d) suppliers.

8.3 Control of nonconforming product

A procedure controls the nonconforming material system (QSP-0830). The system provides for identification, segregation, repair/rework, re-inspection, controlled disposition, disposal and reporting.

The procedure defines documentation of customer approval prior to dispatch of product outside of contract requirements (QSP-0830).

The company issues actions to be taken when nonconforming product is detected after delivery, to contain the problem and prevent any future recurrence.

8.4 Analysis of data

The company has identified the collection and analysis of data, which includes

- a) customer satisfaction through the monitoring of complaints and customer satisfaction system (QSP-0821).
- b),c) the collection and analysis of product related-data which includes scrap, non-conforming product and trends in these .
- d) The company has a system to review the performance of key suppliers.

8.5 Improvement

8.5.1 Continual Improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

- a) reviewing nonconformities (including customer complaints),
- b) determining the causes of nonconformities,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) records of the results of action taken (see 4.2.4), and
- f) reviewing corrective action taken.

8.5 Improvement

8.5.1 Continual Improvement

The management conducts periodic review meetings to monitor and improve the effectiveness of the quality management system. (QSP-0560)

8.5.2 Corrective action

A procedure detailing the required actions following customer complaints (QSP-0852) and non conformities is issued to describe the complaint handling methods, investigation for true causes, actions taken to prevent recurrence, and adequate follow up to check effectiveness.

8.5.3. Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

- a) determining potential nonconformities and their causes,
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) determining and implementing action needed,
- d) records of results of action taken (see 4.2.4), and
- e) reviewing preventive action taken.

8.5.3 Preventive action

The company addresses the causes of potential nonconformances and implements appropriate preventive actions to prevent their occurrence (QSP-0853). These preventive actions may also be an output of Management Review Meetings (QSP-0560)