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Quality Manual

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# Quality Manual

**Extrusion Technology, Inc.**

**80 Trim Way**

Randolph, MA 02368

Issue 3

Revision 1

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Written By:	Quality Manager	Date: 6/18/03
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## 1.0 Scope and Exclusions

### Scope

This Quality Manual contains policies that have been implemented **at Extrusion Technology, Randolph, MA.**

This manual pertains to processes relating to the quality management system, to include ensuring documenting the company's method for ensuring quality throughout the organization, instructing and guiding employee whose actions affect product quality, providing assurance of conformance to customer and applicable regulatory requirements and continuous improvement.

The manual is written to comply with the requirements of ISO 9001.

### Exclusions

The organization has no permissible exclusions as they apply to ISO 9001 requirements.

## 2.0 Company

Extrusion Technology manufactures and assembles extruded aluminum and sheet metal electronic packaging enclosures to meet the needs of a wide variety of electronic applications.

In many cases, the responsibility for design remains primarily with the customer; however we assist in design creation.

Extrusion Technology also designs its own electronic packaging solutions.

Manufacturing consists of mechanical processes such as extrusion, cutting, bending, drilling, tapping, forming, machining and assembly. Coating processes are provided through subcontract.

## 3.0 Terms and Definitions

Throughout this Quality Manual, the term "organization" refers to **Extrusion Technology.**



## 4.0 Quality Management System

### 4.1 General requirements

The organization has established, documented, implemented and currently maintains a quality management system. We continually improve its effectiveness in accordance with the requirements of ISO 9001.

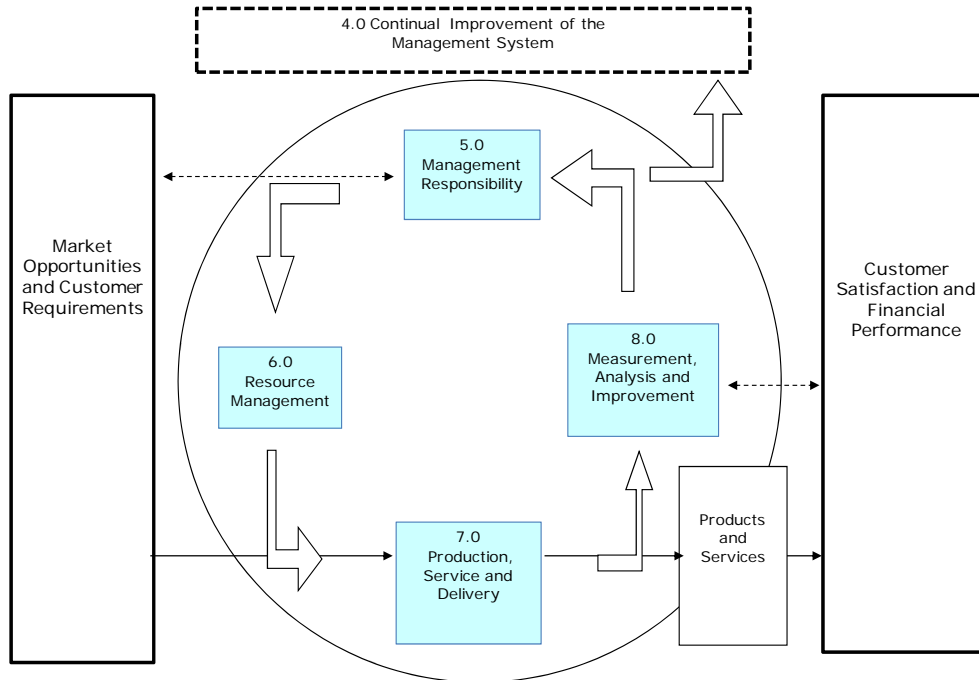
The organization:

- has determined the processes needed for the quality management system and their application throughout the organization,
- determined the sequence and interaction of these processes,
- determined criteria and methods needed to ensure that both the operation and control of these processes are effective,
- ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
- monitors, measures where applicable, and analyzes these processes, and
- implements actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed by the organization in accordance with the requirements of ISO 9001.

Where the organization chooses to outsource any process that affects product conformity to requirements, the organization ensures control over such processes. The type and extent of control to be applied to these outsourced processes are defined within the quality management system.

### Processes and Interactions



#### Key Processes:

Key processes are measured and monitored by the Senior Leadership Team. Key Performance Metrics are established, goals are set on an annual basis and the metrics are monitored on a monthly basis. These metrics include, but are not limited to: Customer Returns, On Time Delivery, Inventory Turns, Cost Reductions, Safety (OSHA Rate), Order to Delivery.

#### 4.2 Documentation Requirements

##### 4.2.1 General

The quality management system documentation includes:

- documented statements of a quality policy and quality objectives,
- a quality manual,
- documented procedures and records required by ISO 9001, including Document Control, Record Control, Internal Audit, Control of Non-conforming Product, Corrective and Preventive Action,
- documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.



#### 4.2.2 Quality Manual

The organization has established and currently maintains a quality manual that includes:

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

The Quality Department is responsible for maintaining the quality manual.

#### 4.2.3 Document Control

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

A documented procedure has been established to define the controls needed:

- to approve documents for adequacy prior to issue,
- to review and update as necessary and re-approve documents,
- to ensure that changes and the current revision status of documents are identified,
- to ensure that relevant versions of applicable documents are available at points of use,
- to ensure that documents remain legible and readily identifiable,
- to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The Quality Manager and Applications Engineering Manager are responsible to maintain the Document Control Procedure, to ensure that relevant versions are available at points of use, to remove obsolete documents, and to control external documents. Documents are reviewed and approved, including re-approval as required, by the appropriate functional manager along with the Quality Manager.

#### 4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

A documented procedure has been established to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records are legible, readily identifiable and retrievable.

The Quality Manager is responsible to maintain the Records Control Procedure.



## 5.0 Management Responsibility

### 5.1 Management Commitment

Top Management provides evidence of its commitment to the development and implementation of the quality management system and continually improves its effectiveness by:

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

Top management is considered to be the Senior Leadership Team that includes the following members: President, Chief Financial Officer, Director of Operations, Director of Product Management and Customer Support, Director of Human Resources, Director of Sales/Marketing, Quality Improvement Leader, and the Quality Manager.

### 5.2 Customer Focus

The Senior Leadership Team ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

### 5.3 Quality Policy

The Senior Leadership Team ensures that the quality policy:

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

The stated quality policy is as follows:

**"Continuous Quality Improvement"  
(CQI)**

through focus on  
Productivity,  
Customer Excellence,  
Business Systems  
and Growth

The Quality Manager is responsible for ensuring the quality policy is reviewed during the Management Review process.



## **5.4 Planning**

### **5.4.1 Quality Objectives**

The Senior Leadership Team ensures that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

The President is responsible for establishing and maintaining the quality objectives.

### **5.4.2 Quality management system planning**

The Senior Leadership Team ensures that:

- the planning of the quality management system is carried out in order to meet the requirements given in section 4.1, as well as the quality objectives, and
- 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 Senior Leadership Team ensures that responsibilities and authorities are defined and communicated within the organization.

### **5.5.2 Management Representative**

The Senior Leadership Team has appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

- ensuring that processes needed for the quality management system are established, implemented and maintained,
- reporting to the Senior Leadership Team on the performance of the quality management system and any need for improvement, and
- ensuring the promotion of awareness of customer requirements throughout the organization.

The appointed management representative is the Quality Manager. They serve as the liaison to external parties on matters relating to the quality system.

### **5.5.3 Internal communication**

The Senior Leadership Team ensures 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

The Senior Leadership Team reviews the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review includes 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 are maintained, as part of the Senior Leadership Team meeting minutes, by the President.

The input to management review includes information on:

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

The output from the management review includes:

- any decisions and actions related to improvement of the effectiveness of the quality management system and its processes,
- improvement of product related to customer requirements, and
- resource needs.

The following individuals attend Management Reviews: President, Chief Financial Officer, Director of Operations, Director of Product Management and Customer Support, Director of Human Resources, Director of Sales/Marketing, Quality Improvement Leader, and the Quality Manager.



## **6.0 Resources Management**

### **6.1 Provision of Resources**

The organization determines and provides the resources needed to implement and maintain the quality management system and continually improve its effectiveness and to enhance customer satisfaction by meeting customer requirements.

### **6.2 Human Resources**

#### **6.2.1 General**

Personnel performing work affecting conformity to product requirements are deemed competent on the basis of appropriate education, training, skills and experience. The Human Resources Department is responsible for assessing competence.

#### **6.2.2 Competence, training and awareness**

The organization:

- determines the necessary competence for personnel performing work affecting conformity to product requirements,
- where applicable, provides training or takes other actions to achieve the necessary competence,
- evaluates the effectiveness of the actions taken,
- ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- maintains appropriate records of education, training, skills and experience.

The Human Resources Department is responsible to determine competency requirements and to oversee the training process. Human Resources also maintains appropriate records of education, training, skills, and experience, with the exception of On the Job Training records (OJT), where are maintained by the individual Managers/Supervisors.

### **6.3 Infrastructure**

The organization determines, provides and maintains the infrastructure needed to achieve conformity to product requirements.

Infrastructure includes, as applicable:

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

### **6.4 Work Environment**

The organization determines and manages the work environment needed to achieve conformity to product requirements. The Operations department is responsible to identify and control work environment requirements.



## 7.0 Product Realization

### 7.1 Planning of Product Realization

The organization plans and develops the processes needed for product realization.

Planning of product realization is consistent with the requirements of the other processes of the quality management system.

In planning product realization, the organization determines the following, as appropriate:

- quality objectives and requirements for the product,
- the need to establish processes and documents, and to provide resources specific to the product,
- required verification, validation, monitoring, measurement, inspection and test activities, specific to the product and the criteria for product acceptance,
- records needed to provide evidence that the realization processes and resulting product meet requirements.

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

The Operations Department is responsible for planning production or service provision and for maintaining associated records.

### 7.2 Customer-related Processes

#### 7.2.1 Determination of requirements related to the product

The organization determines:

- requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- requirements not stated by the customer but necessary for specified or intended use, where known,
- statutory and regulatory requirements applicable to the product, and
- any additional requirements considered necessary by the organization.

The Customer Support/Program Management Department is responsible for determining all customer requirements, whether specified; not stated, but necessary; or statutory and regulatory.

#### 7.2.2 Review of requirements related to the product

The organization reviews the requirements related to the product. This review is 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 ensures that:

- product requirements are defined,
- contract or order requirements differing from those previously expressed are resolved, and



- the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained. The Customer Support/Program Management Department is responsible for the review and for maintaining the records.

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

Where product requirements are changed, the Customer Support/Program Management Department ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

### **7.2.3 Customer communication**

The organization determines and implements effective arrangements for communicating with customers in relation to:

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

## **7.3 Design and Development**

### **7.3.1 Design and development planning**

The organization plans and controls the design and development of product. The Applications Engineering is responsible for controlling all stages of the Xtech design process, and for maintaining the appropriate records.

During the design and development planning, the organization determines:

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

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

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

### **7.3.2 Design and development inputs**

Inputs relating to product requirements are determined and records maintained. These inputs include:

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

The inputs are reviewed for adequacy. Requirements are complete, unambiguous and not in conflict with each other.



### **7.3.3 Design and development outputs**

The outputs of design and development are in a form suitable for verification against the design and development input and are approved prior to release.

Design and development outputs:

- meet the input requirements for design and development,
- provide appropriate information for purchasing, production and service provision,
- contain or reference product acceptance criteria, and
- 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 reviews of design and development are performed in accordance with planned arrangements:

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

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

### **7.3.5 Design and development verification**

Verification is performed in accordance with planned arrangements 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 are maintained.

### **7.3.6 Design and development validation**

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

### **7.3.7 Design and development changes**

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes 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 are be maintained.



## **7.4 Purchasing**

### **7.4.1 Purchasing process**

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

The organization evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

Supply Chain is responsible for controlling the purchasing process and for maintaining appropriate records.

### **7.4.2 Purchasing information**

Purchasing information describes the product to be purchased, including where appropriate:

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

The organization ensures the adequacy of specified purchase requirements prior to communication to the supplier.

### **7.4.3 Verification of purchased product**

The organization establishes and implements 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 states the intended verification arrangements and method of product release in the purchasing information.

## **7.5 Production and service provision**

### **7.5.1 Control of production and service provision**

The organization plans and carries out production and service provision under controlled conditions. Controlled conditions include, as applicable:

- the availability of information that describes the characteristics of the product,
- the availability of work instructions, as necessary,
- the use of suitable equipment,
- the availability and use of monitoring and measuring equipment,
- the implementation of monitoring and measurement, and
- the implementation of product release, delivery and post-delivery activities.



The Production Departments **are** responsible for controlling all phases of product and service provision and for maintaining appropriate records.

#### **7.5.2 Validation of processes for production and service provision**

- There are no special processes where the resulting output cannot be verified. Therefore there is no provision in this QMS for validation.

#### **7.5.3 Identification and traceability**

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

The organization identifies the product status with respect to monitoring and measurement requirements throughout product realization.

Traceability is not a requirement under this QMS. If required, a customized traceability plan would be developed to meet a customer's needs.

#### **7.5.4 Customer property**

The organization exercises care with customer property while it is under the organization's control or being used by the organization. The organization identifies, verifies, protects and safeguards 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, the organization shall report this to the customer and maintain records. Customer property can include intellectual property and personal data.

The Production Department is responsible for controlling and recording customer property. The Customer Support/Program Management Department is responsible for all communication with the customer regarding their property.

#### **7.5.5 Preservation of product**

The Production Department is responsible for preserving the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, this preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

#### **7.6 Control of monitoring and measuring equipment**

The organization determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization establishes 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. The Quality Department is responsible for all aspects related to the system of controlling monitoring and measurement.



Where necessary to ensure valid results, measuring equipment is:

- calibrated or verified, or both, 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 is recorded,
- adjusted or re-adjusted as necessary,
- identified in order to determine its calibration status,
- safeguarded from adjustments that would invalidate the measurement result,
- protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are to be maintained.

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



## **8.0 Measurement, analysis and improvement**

### **8.1 General**

The organization plans and implements the monitoring, measurement, analysis and improvement processes needed:

- to demonstrate conformity to product requirements,
- to ensure conformity of the quality management system, and
- to continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use. The Quality and Operations Departments are responsible for systems related to monitoring, measurement, analysis and improvement.

### **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 monitors information relating to customer perception as to whether the organization has met customer requirements. A formal survey of customer satisfaction shall be performed every two years to determine a customer's satisfaction and perception. The methods for obtaining and using this information are determined by the Sales/Marketing Department.

#### **8.2.2 Internal audit**

The organization conducts internal audits at planned intervals to determine whether the quality management system:

- conforms to the planned arrangements, to the requirements of ISO 9001 and to the quality management system requirements established by the organization, and
- is effectively implemented and maintained.

An audit program has been 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 are defined. This selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

A documented procedure has been established to define the responsibilities and requirements for planning and conducting audits, establishing records and for reporting results. Records of the audits and their results are maintained. The Quality Department is responsible to oversee the internal auditing system and for maintaining appropriate records.

The management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.



### 8.2.3 Monitoring and measurement of processes

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

### 8.2.4 Monitoring and measurement of product

The organization monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product for delivery to the customer.

The release of product and delivery of service to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

## 8.3 Control of nonconforming product

The organization ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure has been established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, the organization deals with nonconforming product by one or more of the following ways:

- by taking action to eliminate the detected nonconformity;
- by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- by taking action to preclude its original intended use or application;
- 
- by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.



## 8.4 Analysis of data

The organization determines, collects and analyzes 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 includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- customer satisfaction,
- conformity to product requirements,
- characteristics and trends of processes and products including opportunities for preventive action, and
- suppliers.

The Quality Department and Operations Departments are responsible for determining the data requirements and for coordinating with other departments to collect and subsequently analyze the data in order to make improvements.

## 8.5 Improvement

### 8.5.1 Continual improvement

The organization continually improves 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 takes action to eliminate the cause of nonconformities in order to prevent their recurrence.

Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure has been established that defines requirements for:

- reviewing nonconformities (including customer complaints),
- determining the causes of nonconformities,
- evaluating the need for action to ensure that nonconformities do not recur,
  
- determining and implementing action needed,
- recording and maintaining records of the results of action taken, and
- reviewing the effectiveness of the corrective action taken.

The Quality Department is responsible for maintaining the procedure and the associated records.



### 8.5.3 Preventive Action

The organization determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

Preventive actions are appropriate to the effects of the potential problems

A documented procedure has been established to define requirements for:

- determining potential nonconformities and their causes,
- evaluating the need for action to prevent occurrence of nonconformities,
- determining and implementing action needed,
- recording and maintaining the results of action taken, and
- reviewing the effectiveness of the preventive action taken.

The Quality Department is responsible for maintaining the procedure and the associated records.

## Reference Documents

- QOP0501 Control of Documents Procedure
- QOP0401 Control of Records Procedure
- QOP1303 Control of Nonconforming Product Procedure
- QOP1401 Corrective Action Procedure
- QOP0001 Preventive Action Procedure
- QOP1701 Internal Audit Procedure

## Change Log

Document Revision Date	Description of Change
8/16/01	Initial Release
12/4/01	Update Rev2
12/27/01	Update Rev 3
2/4/02	Update Rev 4
6/18/03	Update Issue 2 Rev 1
7/20/04	Update Issue 2 Rev 2
10/22/05	Update Issue 2 Rev 3
4/27/07	Update Issue 3 Rev 4
4/21/09	Update to Issue 3 to comply with the ISO9001:2008 standard