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QUALITY MANUAL

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ISO 9001

Quality Management System

Revision History

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Introduction

0.1 General

Dalton Manufacturing Company Inc was originally founded in 1936 by Howard G Dalton in New York City. Mr. Dalton had originally served an eight year apprenticeship with the Henschel Corp.. in Amesbury Ma.. After moving to New York he started his own company machining parts for the mannequin industry. In 1945, with his son Howard A Dalton, he moved his company back to Amesbury and began to do contract machining as well as mannequin parts. In 1947 Mr. Howard G. Dalton died the same year a son was born to Howard A. named H. Griff Dalton.

In 1977 Griff joined Howard and a concerted effort was made to begin to transition the company into production machining using the latest CNC equipment. In 1985 Howard retired and Griff continued to expand the business and obtain customers in core industries of OEM, medical, instrumentation and optics. Dalton Manufacturing has developed a niche of fourth axis machining along with CNC turning and milling.

We also have striven to become a ship to stock manufacturer for many of our customers and we have also participated in KANBAN and Just-in-time inventory programs.

We are a customer centric company focused on customer satisfaction and continuous improvement.

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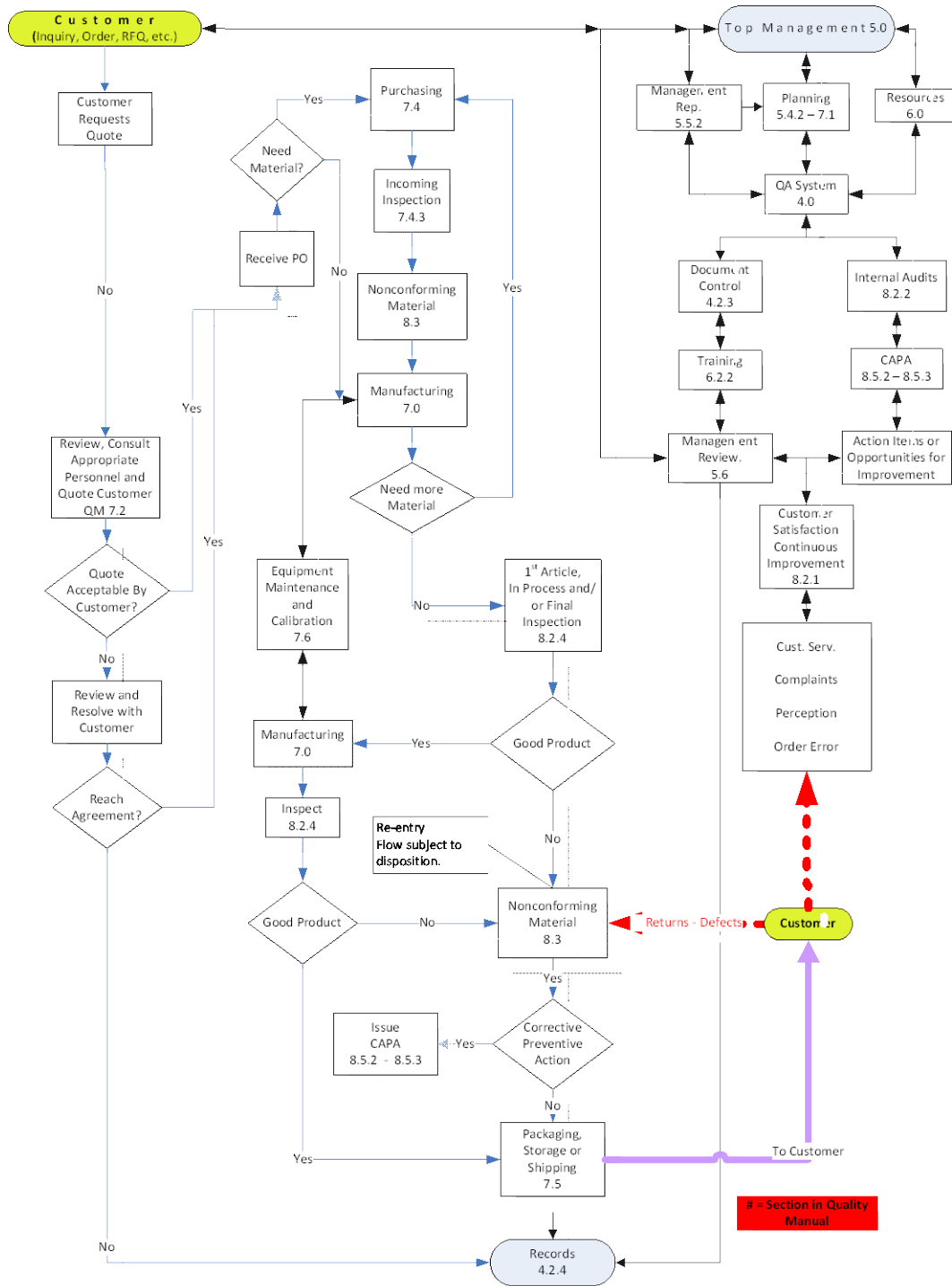
This Quality Policy Manual specifies requirements that Dalton Manufacturing Co. Inc. uses to address customer satisfaction, to meet customer and applicable regulatory and statutory requirements and to meet ISO 9001:2008 requirements, and is supported by additional procedures where necessary. The quality management principles stated in ISO 9000, and ISO 9004, have been taken into consideration during the development of this Quality Policy Manual

This Quality Policy Manual specifies the general requirements for Dalton Manufacturing Co. Inc. competence towards a management system for quality, administrative and technical operations. It covers the machining of customer designed parts and assemblies.

0.2 Process Approach

This Manual has adopted the process approach to quality management. [Figure 1](#), is a conceptual illustration of the process approach of the system aimed towards Continual Improvement and illustrates the process linkages presented in clauses 4 to 8 of ISO 9001.

Figure 1 — Dalton Manufacturing Co. Inc. Processes Interrelationship



1 Scope

1.1 General

This Quality Policy Manual specifies requirements for a quality management system where Dalton Manufacturing Co. Inc.:

- a) Needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements.
- b) Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

Scope of Registration

The Scope associated with Dalton Manufacturing Co. Inc. activities and registration is:

The machining of customer designed parts or assemblies including Medical.

1.2 Application

Dalton Manufacturing Co. Inc. takes exclusion against section 7.3 of ISO 9001 because we do not design.

2 Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

[ISO 9000:2005](#), Quality management systems — Fundamentals and vocabulary

[ISO 9001:2008](#), Quality management systems — Requirements

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000 apply. Throughout the text of this Quality Policy Manual, wherever the term “product” occurs, it can also mean “service.”

“**Product**” is defined as the “result of a process.”

“**Process**” is defined as a “set of interrelated or interacting activities that transforms inputs into outputs.”

If the term “process” is replaced by its definition, the definition of “product” then becomes the “result of a set of interrelated or interacting activities that transforms inputs into outputs.”

4 Quality Management System

4.1 General Requirements

Dalton Manufacturing Co. Inc. establishes, documents, implements, and maintains a quality management system while continually improving its effectiveness in accordance with the requirements of this Quality Policy Manual.

Dalton Manufacturing Co. Inc.:

- a) Determines the processes needed for the quality management system and their application throughout Dalton Manufacturing Co. Inc. ([see 1.2](#)).
- b) Determines the sequence and interaction of these processes, shown in [figure 1](#).
- c) Determines criteria and methods needed to ensure that both the operation and control of these processes are effective.
- d) Ensures the availability of resources and information necessary to support the operation and monitoring of these processes.
- e) Monitors, measures where applicable, and analyzes these processes.
- f) Implements actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed by Dalton Manufacturing Co. Inc. in accordance with the requirements of this Quality Policy Manual.

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

4.2 Documentation Requirements

4.2.1 General

The quality management system documentation includes:

- a) Documented statements of a [quality policy](#) and quality objectives
- b) This Quality Policy Manual
- c) Documented [procedures](#) and [records](#) required by this Quality Policy Manual
- d) [Documents](#), including records determined by Dalton Manufacturing Co. Inc. to be necessary to ensure the effective planning, operation, and control of its processes

4.2.2 Quality Policy Manual

Dalton Manufacturing Co. Inc. established and maintains this Quality Policy 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
- c) A description of the [interaction](#) between the processes of the quality management system.

4.2.3 Control of Documents

Documents required by the quality management system are controlled. Records are controlled according to the requirements given in [4.2.4](#).

A documented procedure ([P-001](#)) has been 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 determined by Dalton Manufacturing Co. Inc. to be necessary for the planning and operation of the quality management system are identified and their distribution controlled
- g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

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 are controlled.

Dalton Manufacturing Co. Inc. has established a documented procedure ([P-002](#)) to define the controls needed for the identification, storage, protection, retrieval, retention, and disposition of records. Records remain legible, readily identifiable, and retrievable.

5 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:

- a) Communicating within Dalton Manufacturing Co. Inc., 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](#)
- e) Ensuring the availability of resources

5.2 Customer Focus

Top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.3 Quality Policy

Top management ensures that the quality policy:

- a) Is appropriate to the purpose of Dalton Manufacturing Co. Inc.
- b) Includes a commitment to comply with requirements and continually improves the effectiveness of the quality management system
- c) Provides a framework for establishing and reviewing quality objectives
- d) Is communicated and understood within Dalton Manufacturing Co. Inc.
- e) Is reviewed for continuing suitability.

Quality Policy:

It is the policy of Dalton Manufacturing Co Inc. to use our Quality Management System to provide a high level of customer satisfaction in all phases of customer interaction.

We are also committed to a program of continuous improvement of the Quality Management System such that the level of customer satisfaction is always improving.

5.4 Planning

5.4.1 Quality Objectives

Top management ensures that [quality objectives](#), including those needed to meet requirements for product, are established at relevant functions and levels within Dalton Manufacturing Co. Inc.. The quality objectives are measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning

Top management ensures 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.
- 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 ensures that responsibilities and authorities are defined and communicated within Dalton Manufacturing Co. Inc. via [job descriptions](#) and an [organizational chart](#).

5.5.2 Management Representative

Top management appointed a member of Dalton Manufacturing Co. Inc.' management (shown in the [organizational chart](#)) who, irrespective of other responsibilities, has 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
- c) Ensuring the promotion of awareness of customer requirements throughout Dalton Manufacturing Co. Inc.

5.5.3 Internal Communication

Top management ensures that appropriate communication processes are established within Dalton Manufacturing Co. Inc. and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 General

Dalton Manufacturing Co. Inc.' management team reviews the quality management system at least annually to ensure its continuing suitability, adequacy, and effectiveness. This review evaluates any need for changes to Dalton Manufacturing Co. Inc. Quality Management System, including its quality policy and quality objectives ([P-007](#)). Records from management reviews are kept ([P-002](#)).

Findings from management reviews and the actions that arise from them are recorded. The management ensures that those actions are carried out within an appropriate and agreed timescale.

5.6.2 Review Input

Input to management review includes current performance and improvement opportunities related to the following:

Issues reviewed at Management Reviews:

- 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.

5.6.3 Review Output

The output from the management review includes any decisions and actions related to:

- a) Improvement of the effectiveness of the QMS and its processes
- b) Improvement of product related to customer requirements
- c) Process, product, service, and/or QMS audits
- d) Resource needs
- e) Suitability of the Quality Policy and Objectives

Results of management reviews are recorded. (Procedure [P-002](#))

Top management will provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

6 Resource Management

6.1 Provision of Resources

Dalton Manufacturing Co. Inc. determines and provides the resources needed:

- a) To implement and maintain the quality management system and continually improve its effectiveness
- b) 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 competent on the basis of appropriate education, training, skills, and experience.

6.2.2 Competence, Training, and Awareness

Dalton Manufacturing Co. Inc. provides training per [P-008](#) and:

- a) Determines the necessary competence for personnel performing work affecting conformity to product requirements

- b) Where applicable, provides training or takes other actions to achieve the necessary competence
- c) Evaluates the effectiveness of the actions taken
- d) Ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives
- e) Maintains appropriate records of education, training, skills, and experience (see [4.2.4.](#))

6.3 Infrastructure

Dalton Manufacturing Co. Inc. determines, provides, and maintains 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)
- c) Supporting services (such as transport, communication, or information systems)

6.4 Work Environment

Dalton Manufacturing Co. Inc. determines and manages the work environment needed to achieve conformity to product requirements.

7 Product Realization

7.1 Planning of Product Realization

Dalton Manufacturing Co. Inc. 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 (see [4.1](#)).

In planning product realization, Dalton Manufacturing Co. Inc. determines the following, as appropriate:

- a) Quality objectives and requirements for the product
- b) The need to establish processes and documents, and to provide resources specific to the product
- c) Required verification, validation, monitoring, measurement, 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.](#))

7.2 Customer-related Processes

7.2.1 Determination of Requirements Related to the Product

Dalton Manufacturing Co. Inc. operates using [P-010](#) and determines:

- 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 applicable to the product
- d) Any additional requirements considered necessary by Dalton Manufacturing Co. Inc..

7.2.2 Review of Requirements Related to the Product

Dalton Manufacturing Co. Inc. reviews the requirements related to the product. This review is conducted prior to Dalton Manufacturing Co. Inc.' 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:

- a) Product requirements are defined
- b) Contract or order requirements differing from those previously expressed are resolved
- c) Dalton Manufacturing Co. Inc. has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained (see [4.2.4](#)).

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by Dalton Manufacturing Co. Inc. before acceptance.

Where product requirements are changed, Dalton Manufacturing Co. Inc. ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication

Dalton Manufacturing Co. Inc. determines and implements 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.

When Dalton Manufacturing Co. Inc. subcontracts work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor.

7.3 *Design and Development*

Dalton Manufacturing takes exclusion to clause 7.3, as we do not design.

7.4 *Purchasing*

7.4.1 Purchasing Process

Dalton Manufacturing Co. Inc. ensures that purchased product conforms to specified purchase requirements via the documented procedure [P-011](#). 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.

Dalton Manufacturing Co. Inc. evaluates and selects suppliers based on their ability to supply product in accordance with Dalton Manufacturing Co. Inc.'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 (see [4.2.4](#)).

7.4.2 Purchasing Information

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

- a) Requirements for approval of product, procedures, processes, and equipment

- b) Requirements for qualification of personnel
- c) Quality management system requirements

Dalton Manufacturing Co. Inc. ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

Dalton Manufacturing Co. Inc. establishes and implements inspection and other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where Dalton Manufacturing Co. Inc. intends to perform verification at the supplier's premises, Dalton Manufacturing Co. Inc. will state the intended verification arrangements and method of product release in the purchasing information.

Where customers intend to perform verification at Dalton Manufacturing Co. Inc., Dalton Manufacturing Co. Inc. will assure the customer 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

Dalton Manufacturing Co. Inc. plans and carries out production and service provision under controlled conditions. ([P-015](#))

Controlled conditions 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 equipment,
- e) the implementation of monitoring and measurement, and
- f) the implementation of product release, delivery, and post-delivery activities.

7.5.2 Validation of processes for production and service provision

Dalton Manufacturing Co. Inc. validates processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation demonstrates the ability of these processes to achieve planned results.

Dalton Manufacturing Co. Inc. establishes 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

7.5.3 Identification and Traceability

Where appropriate, Dalton Manufacturing Co. Inc. identifies the product by suitable means throughout product realization.

Dalton Manufacturing Co. Inc. identifies the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, Dalton Manufacturing Co. Inc. controls the unique identification of the product and maintains records (see [4.2.4](#)).

7.5.4 Customer Property

Dalton Manufacturing Co. Inc. exercises care with customer property while it is under Dalton Manufacturing Co. Inc.'s control or being used by Dalton Manufacturing Co. Inc.. Dalton Manufacturing Co. Inc. 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, Dalton Manufacturing Co. Inc. reports this to the customer and maintains records (see [4.2.4](#)).

7.5.5 Preservation of Product

Dalton Manufacturing Co. Inc. preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, 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**

Dalton Manufacturing Co. Inc. 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 ([P-012](#)).

Dalton Manufacturing Co. Inc. 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.

Where necessary to ensure valid results, measuring equipment is calibrated per [P-012](#) using an outside calibration house, and:

- a) 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 (see [4.2.4](#))
- b) Is adjusted or re-adjusted, as necessary
- c) Are identified in order to determine its calibration status
- d) Are safeguarded from adjustments that would invalidate the measurement result
- e) Are protected from damage and deterioration during handling, maintenance, and storage

In addition, Dalton Manufacturing Co. Inc. assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Dalton Manufacturing Co. Inc. takes appropriate action on the equipment and any product affected.

Records of the results of calibration and verification are 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 is confirmed. This will be undertaken prior to initial use and reconfirmed as necessary.

8 Measurement, Analysis, and Improvement

8.1 General

Dalton Manufacturing Co. Inc. plans and implements the monitoring, measurement, analysis, and improvement processes needed:

- a) To demonstrate conformity to product requirements
- b) To ensure conformity of the quality management system
- c) 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.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Dalton Manufacturing Co. Inc. monitors information relating to customer perception as to whether Dalton Manufacturing Co. Inc. has met customer requirements. The methods ([P-009](#)) for obtaining and using this information are determined and communicated within Dalton Manufacturing Co. Inc..

Dalton Manufacturing Co. Inc. shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system and customer service.

8.2.2 Internal Audit

Dalton Manufacturing Co. Inc. conducts 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 Quality Policy Manual, and to the quality management system requirements established by Dalton Manufacturing Co. Inc.
- b) Is effectively implemented and maintained

An audit program ([P-003](#)) 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. The 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 reporting results. Records of the audits and their results are maintained (see [4.2.4](#)).

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 (see [8.5.2](#)).

8.2.3 Monitoring and Measurement of Processes

Dalton Manufacturing Co. Inc. 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, as appropriate.

8.2.4 Monitoring and Measurement of Product

Dalton Manufacturing Co. Inc. monitors and measures the characteristics of the product to verify that product requirements are met. This is carried out at appropriate stages of the product realization process in accordance with 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 (see [4.2.4](#)).

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**

Dalton Manufacturing Co. Inc. ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure ([P-004](#)) defines the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, Dalton Manufacturing Co. Inc. deals 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 preclude its original intended use or application
- d) 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 (see [4.2.4](#)).

8.4 **Analysis of Data**

Dalton Manufacturing Co. Inc. 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:

- a) Customer satisfaction (see [8.2.1](#))
- b) Conformity to product requirements (see [8.2.4](#))
- c) Characteristics and trends of processes and products, including opportunities for preventive action (see [8.2.3](#) and [8.2.4](#))
- d) Suppliers (see [7.4](#))

8.5 Improvement

8.5.1 Continual Improvement

Dalton Manufacturing Co. Inc. continually improves the effectiveness of the quality management system through the use of:

- a) The [quality policy](#) and [quality objectives](#)
- b) [Audit results](#),
- c) Analysis of data
- d) [Corrective and preventive actions](#)
- e) [Management review](#)

Dalton Manufacturing Co. Inc. shall continually improve the effectiveness of its 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

Dalton Manufacturing Co. Inc. takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure ([P-005](#)) has been 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](#))
- f) Reviewing the effectiveness of the corrective action taken

8.5.3 Preventive Action

Dalton Manufacturing Co. Inc. determines actions needed 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 ([P-005](#)) has been 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](#))
- e) Reviewing the effectiveness of the preventive action taken

Needed improvements and potential sources of nonconformities, either technical or concerning the management system, are identified. When improvement opportunities are identified or if preventive action

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is required, action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.