Quality Coils

Policy Manual

Rev. E **6/27/12**

1. Purpose

Quality Coils is committed to meeting the ISO 9001:2008 requirements.

2. Scope

The scope of this quality manual is for the Quality Coils quality management system. Exemptions to the ISO 9001:2008 standard are as follows:

- **7.3 Design Control – Quality Coils does not design or develop new products.**

3. Change History

Rev	Date	Change	Approved by
Draft	8/20/02	Update to ISO 9001:2000	Keith Gibson, President
Rel	2/28/03	Initial Release of New Manual	Keith Gibson, President
A	5/16/03	Modified 5.4.1, Process Flow Chart & Organization Chart Corrected typo on proc.8.2.2	Keith Gibson, President
B	5/15/06	Modified Org Chart	Keith Gibson, Vice President
C	9/19/08	Modified Org Chart	Keith Gibson, Vice President
D	1/26/09	Updated to the ISO 9001:2008 standard. Corrected org chart ref shipping / receiving.	Keith Gibson, Vice President
D	2/11/09 No Rev. Change Required	This manual has been reviewed and found to be compliant with the ISO 9001:2008 Standard.	Michael Orsini V.P. Quality
E	6/27/12	Modified Org. Chart	Kyle Gibson Q.A. Manager

4 Quality management system

4.1 General requirements

Quality Coils has established, documented, implemented and continues to maintain a quality management system, and continually improves its effectiveness in accordance with the requirements of the ISO 9001:2008 standard.

Quality Coils

a) has determined the processes needed for the quality management system and its application throughout Quality Coils (see Process Flow Chart),

b) has determined the sequence and interaction of these processes (see Process Flow Chart),

c) has determined criteria and methods needed to ensure that both the operation and control of these processes are effective (see 5.6 Management Review and 8.2.2 Internal Quality Audit),

d) has ensured the availability of resources and information necessary to support the operation and monitoring of these processes (see 5.6 Management Review and 8.2.2 Internal Quality Audit),
e) monitors, measures (where applicable) and analyzes these processes (see 5.6 Management Review), and
f) implements actions necessary to achieve planned results and continual improvement of these processes (see 5.6 Management Review).

These processes are managed by Quality Coils in accordance with the requirements of the ISO 9001:2008 standard.

Where Quality Coils chooses to outsource any process that affects product conformity to requirements, Quality Coils ensures control over such processes. The type and extent of control applied to these outsourced processes is identified within the Evaluation and Control of Suppliers Procedure (P7.4.1), Purchasing Procedure (P7.4.2), and Receiving Inspection Procedure (P7.4.3).

4.2 Documentation requirements

4.2.1 General

The quality management system documentation includes

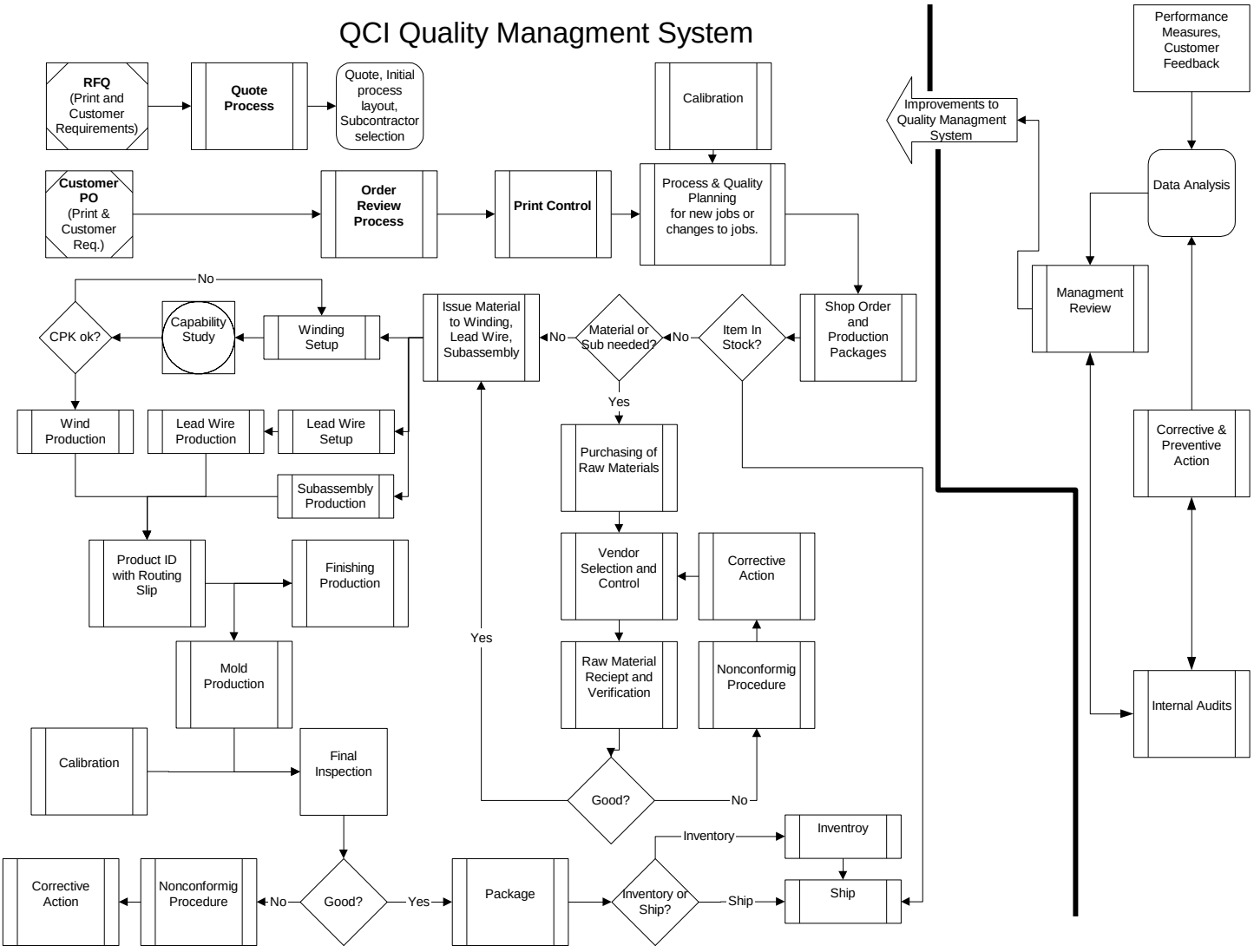
a) documented statements of a quality policy and quality objectives (see 5.3 and 5.4.1),
b) this quality manual,
c) documented procedures and records required by the ISO 9001:2008 standard, (see 4.2.3, 4.2.4, 8.2.2, 8.3, 8.5.2, 8.5.3), and
d) documents, including records determined by Quality Coils to be necessary to ensure the effective planning, operation and control of its processes.

4.2.2 Quality Manual

Quality Coils has established and maintains this document as our quality manual.

a) The scope of Quality Coils' quality management system extends to the quality management processes required by the ISO 9001:2008 standard and includes our Bristol and Pawcatuck Manufacturing sites. Quality Coils has included exclusions to the ISO 9001:2008 standard element 7.3 Design and Development. Quality Coils performs no design or development functions at the facilities.
b) The quality manual references a number of procedures that document important processes in our quality management system. A list of the procedures can be found in the Procedures Master List. The procedures required by the ISO 9001:2008 standard can be found on the list.
c) A description of the interaction between the processes of the quality management system can be found in the Process Flow Chart.

Process Flow Chart



4.2.3 Control of documents

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 4.2.4.

The document and data control procedures have 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 the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The document and data control procedures are as follows:

Print Control P4.2.3-1
SMP Control P4.2.3-2
Quality Manual Control P4.2.3-3
Supplier Quality Manual Control P4.2.3-4
Form Control P4.2.3-5
Standards Control P4.2.3-6
Software Control P4.2.3-7
Work Instruction Control P4.2.3-8

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.

Quality Coils has established the Quality Records Procedure (P4.2.4) to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall 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 improving its effectiveness by

a) the use of one-on-one communications, corrective and preventive actions and quality system performance postings, which serve to continually remind employees of the importance of meeting customer as well as statutory and regulatory requirements,
b) establishing the quality policy (see 5.3),
c) ensuring that quality objectives are established (see 5.4.1),
d) conducting management reviews (see 5.6), and
e) ensuring the availability of resources (see 6.0).

5.2 Customer focus

Top management ensures 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 ensures 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 Quality Coils, and
e) is reviewed for continuing suitability.

QUALITY POLICY

Service our customers by

- ***meeting requirements,***
- ***continually improving the effectiveness of our systems,***
- ***making quality products, and***
- ***being competitive.***

The quality policy is posted throughout our plant and employees are instructed on its intent so that it is clearly understood by them. Management has determined that the quality policy is appropriate to the purpose of the organization and provides a solid framework for establishing quality objectives. This policy is reviewed at Management Review meetings (see 5.6) to ensure its continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management ensures that quality objectives, including those needed to meet requirements for product [see 7.1 a], are established at relevant functions and levels within Quality Coils. The quality objectives are measurable and consistent with the quality policy. These quality objectives are documented in the Management Review Minutes.

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, and
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

The planning of the quality management system is conducted in the management review meetings (see 5.6).

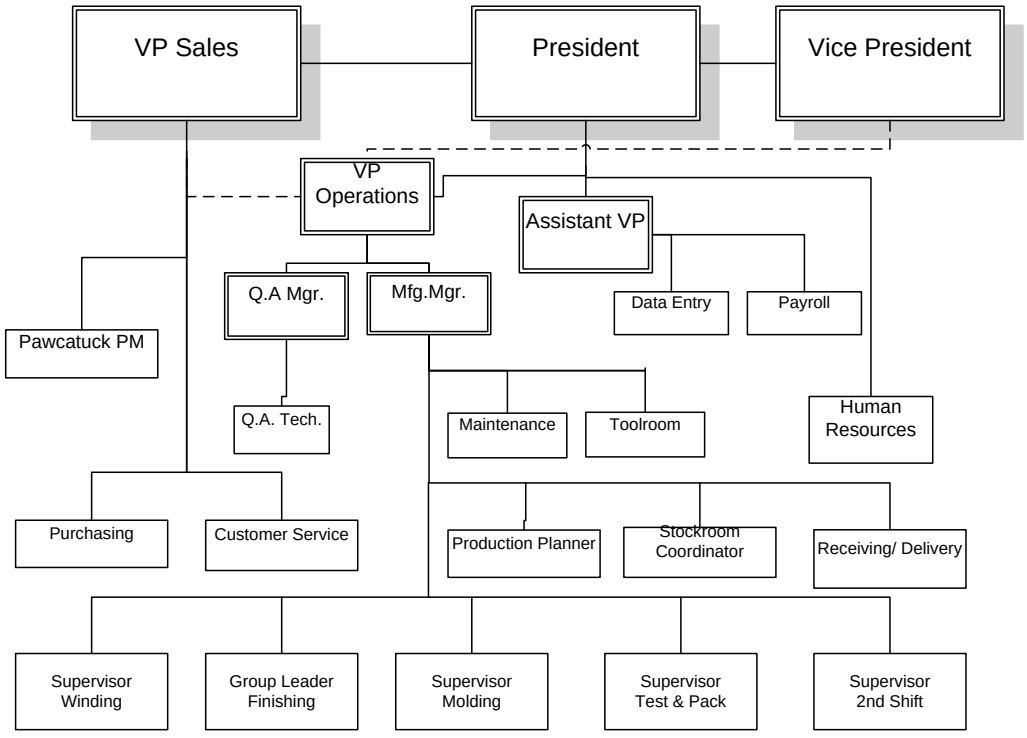
5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management ensures that responsibilities and authorities are defined and communicated within Quality Coils (see Organization Chart below).

Responsibilities and authorities are recorded as part of the employee job description.

ORGANIZATION CHART



5.5.2 Management representative

Top management has appointed the Quality Manager as Quality Management Representative. The Quality Manager 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, and
c) ensuring the promotion of awareness of customer requirements throughout the organization.

5.5.3 Internal communication
Top management ensures that appropriate communication processes are established within Quality Coils and that communication takes place regarding the effectiveness of the quality management system.

Management utilizes employee meetings and quality boards to communicate to employees the effectiveness of the quality management system. Employees are afforded an open door policy to the Quality Management Rep and their Supervisor to report on effectiveness issues.

5.6 Management review

5.6.1 General
Top management reviews their quality management system, a minimum of once per year, 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 review are maintained (see 4.2.4).

5.6.2 Review input
The input to management review includes information on
a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) supplier performance
e) status of preventive and corrective actions,
f) follow-up actions from previous management reviews,
g) current resources.
h) changes that could affect the quality management system (including quality policy and quality objectives), and
i) recommendations for improvement.

See Management Review Procedure (P5.6).

5.6.3 Review output
The output from the management reviews includes 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.

6 Resource management

6.1 Provision of resources

Quality Coils determines and provides 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.

Resources needs are established during management review meetings (see 5.6) and even during the manufacturing planning process. Management provides the resources to meet both the customer requirements and the requirements of the quality management system.

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

Quality Coils

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) ensures that the necessary competence has been achieved,
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, and
e) maintains appropriate records of education, training, skills and experience (see 4.2.4).

See the Training Procedure P6.2 for guidance.

6.3 Infrastructure

Quality Coils 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), and
c) supporting services (such as transport, communication or information systems).

Management has provided the above items, if during planning there is a need to add to or modify infrastructure, it will be addressed.

6.4 Work environment

Quality Coils determines and manages the work environment needed to achieve conformity to product requirements. 100% testing of all products is conducted at final inspection to assure the product meets customer requirements. The current work environment has been proven to meet the product requirements and is maintained in order not to adversely affect the product and maintain a safe an efficient work place.

7 Product realization

7.1 Planning of product realization

Quality Coils 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, Quality Coils determines 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, 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).

The output of this planning shall be in a form suitable for Quality Coils' method of operations.

See Request for Quote Procedure (P7.2-1), Pre-production Samples Procedure (P7.1-1), SMP Control (P4.2.3-2) and UL Requirements (P7.1-2) as required.

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.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Quality Coils determines the

a) requirements specified by the customer, including the requirements for delivery, and for 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, and
d) any additional requirements considered necessary by the organization.

See the Request for Quote Procedure (P7.2-1) and the Contract Review Procedure (P7.2-2).

7.2.2 Review of requirements related to the product

Quality Coils 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

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 are confirmed before acceptance.

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

See the Request for Quote Procedure (P7.2-1) and the Contract Review Procedure (P7.2-2).

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.

7.2.3 Customer communication

Quality Coils 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.

QCI utilizes phone systems, e-mail, web sites and personal contact to ensure that customers can effectively communicate with us. When the customer contacts QCI they are directed to the person(s) who can most effectively handle the customer requests.

7.3 Design and development

Quality Coils does not design or develop new products, this element is considered exempt.

7.4 Purchasing

7.4.1 Purchasing process

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

Quality Coils evaluates and selects suppliers based on their ability to supply product in accordance with Quality Coils' requirements. Criteria for selection, evaluation and re-evaluation are established in the Evaluation and Control of Suppliers Procedure (P7.4.1). 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 qualifications of personnel, and
c) quality management system requirements.

Quality Coils ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

See the Purchasing Procedure (P7.4.2) for guidance.

7.4.3 Verification of purchased product

Quality Coils establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements (see Receiving Inspection Procedure P7.4.3).

Where Quality Coils or its customer intends to perform verification at the supplier's premises, Quality Coils 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

Quality Coils plans and carries out production and service provision under controlled conditions. 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.

The following procedures give guidance:

- Contract Review Procedure (P7.2-2)
- Process Control Procedure (P7.5-1)
- Finishing Dept. Jig & Fixture Control (P7.5-2)
- Mold Control (P7.5-3)
- Inspection Fixture Control (P7.5-4)
- Standard Manufacturing Procedure (SMP) Control (4.P4.2.3-2)

7.5.2 Validation of processes for production and service provision

Quality Coils validates any 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.
Quality Coils 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.

These requirements are recorded in the process's SMPs.

7.5.3 Identification and traceability
Where appropriate, Quality Coils identifies the product by suitable means throughout product realization (see Lot Control & Traceability Procedure (P7.5.3).

Quality Coils identifies the product status with respect to monitoring and measurement requirements throughout product realization. (see Receiving Procedure (P7.4.3), In-process Inspection Procedure (P8.2.4-1), Final Inspection Procedure (P8.2.4-2) and the Process Control Procedure (P7.5-1).

Where traceability is a requirement, Quality Coils controls the unique identification of the product and maintains records (see 4.2.4). Reference the Lot Control & Traceability Procedure (P7.5.3).

7.5.4 Customer property
Quality Coils exercises care with customer property while it is under their control or use. Quality Coils 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, it is reported to the customer and records maintained (see 4.2.4). See Customer Supplied Product Procedure (P7.5.4).

NOTE Customer property can include intellectual property and personal data.

7.5.5 Preservation of product
Quality Coils 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. See the following procedures for guidance:

- Material Handling (P7.5.5-1)
- Storage & Preservation (P7.5.5-2)
- Packaging (P7.5.5-3)
- Delivery (P7.5.5-4)

7.6 Control of monitoring and measuring equipment
Quality Coils determines the monitoring and measurements to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

Quality Coils has defined the calibration process within the Calibration Procedure (P7.6) 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:

a) calibrated and / 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 shall be recorded;
b) adjusted or re-adjusted as necessary;
c) identified in order to determine its calibration status;
d) safeguarded from adjustments that would invalidate the measurement result;

e) protected from damage and deterioration during handling, maintenance and storage.

In addition, Quality Coils assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Appropriate action is taken 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 will be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. Currently Quality Coils does not utilize this type of equipment.

8 Measurement, analysis and improvement

8.1 General

Quality Coils 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, and
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.

These systems are normally determined during the Management Review Process (see 5.6).

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, Quality Coils monitors information relating to customer perception as to whether they have met customer requirements. The methods for obtaining and using this information are documented in the Customer Focus - Satisfaction Procedure (P8.2.1).

8.2.2 Internal audit

Quality Coils 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 the ISO 9001:2008 Standard and to the established Quality Coils quality management system requirements, and
b) is effectively implemented and maintained.

The Internal Audits Procedure (P8.2.2) has been established to define the responsibilities for planning and conducting audits, establishing records and reporting results.

The procedure ensures a planned program, and takes 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. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors shall not audit their own work.

Records of the audit and their results shall be maintained (see 4.2.4).

Management responsible for the area being audited ensures that 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
Quality Coils 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.

Internal audits, in-process inspections, final inspections, and trend analysis of nonconformances and corrective actions are the monitoring methods used to make decisions on whether or not processes are achieving planned results.

8.2.4 Monitoring and measurement of product
Quality Coils 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 (see 7.1). 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 service delivery to the customer does 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.

The following procedures give guidance:

- Process Flow Chart
- Receiving Inspection (P7.4.3)
- In-process Inspection (P8.2.4-1)
- Final Inspection (P8.2.4-2)
- Statistical Process Control (SPC) (4.P8.2.4-4)

8.3 Control of nonconforming product
Quality Coils ensures 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 are defined in the Non-Conforming Product (In-process & Final) (P8.3-1), Non-Conforming Product (Incoming Inspection) (P8.3-2), and the Non-Conforming Product (Customer Returns) (P8.3-3) procedures.

Where practicable, Quality Coils 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

Quality Coils 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 7.2.1),
c) characteristics and trends of processes and products including opportunities for preventive action, and
d) suppliers.

The data collection requirements are determined during Management Review meetings (see 5.6), responsibilities are assigned for the data collection and the analysis takes place throughout the data collection processes and during Management Reviews.

8.5 Improvement

8.5.1 Continual improvement

Quality Coils 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

Quality Coils takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

The Corrective and Preventive Action Procedure (P8.5.2/3-1), Supplier Corrective & Preventative Action (P8.5.2/3-2), Discrepant Material Review (DMR) (P8.5.2/3-3) and Customer Complaints & RGAs for Corrective & Preventive Action (P8.5.2/3-4) were 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 the effectiveness of corrective action taken.

8.5.3 Preventive action

Quality Coils determines 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.

The Corrective and Preventive Action Procedure (P8.5.2/3-1), Supplier Corrective & Preventative Action (P8.5.2/3-2), Discrepant Material Review (DMR) (P8.5.2/3-3) and Customer Complaints & RGAs for Corrective & Preventive Action (P8.5.2/3-4) were 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 the effectiveness of preventive action taken.