MAGCAP ENGINEERING, LLC

Quality Manual

Conforms with ISO 9001:2000

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1 Scope

1.1 General

This manual constitutes the policy for MagCap Engineering's quality management system. This manual provides MagCap Engineering personnel and customers with a general description of the quality management system, which has been planned and developed to assure all products and services conform to customer orders and contracts.

This quality system complies with the requirements of the ISO 9001:2000 International Standard. This manual and all other MagCap Engineering quality management documentation are proprietary. All unauthorized use is prohibited.

This Quality Manual applies to all activities and personnel associated with the processes depicted in the Process Interaction Diagram shown in Section 3 of this manual. MagCap Engineering applies this quality management system to supplies, materials and services procured as well as to products produced and/or services rendered for MagCap Engineering's customers.

1.2 Exclusions

All sections of the ISO 9001: 2000 International Standard are applicable to MagCap Engineering's business and therefore are addressed in this Quality Manual.

1.3 Procedures

Written procedures for supplementing the system described herein have been established and are maintained. These Level II documents have not been included in this Quality Manual, but are referenced throughout Section 4 of this manual.

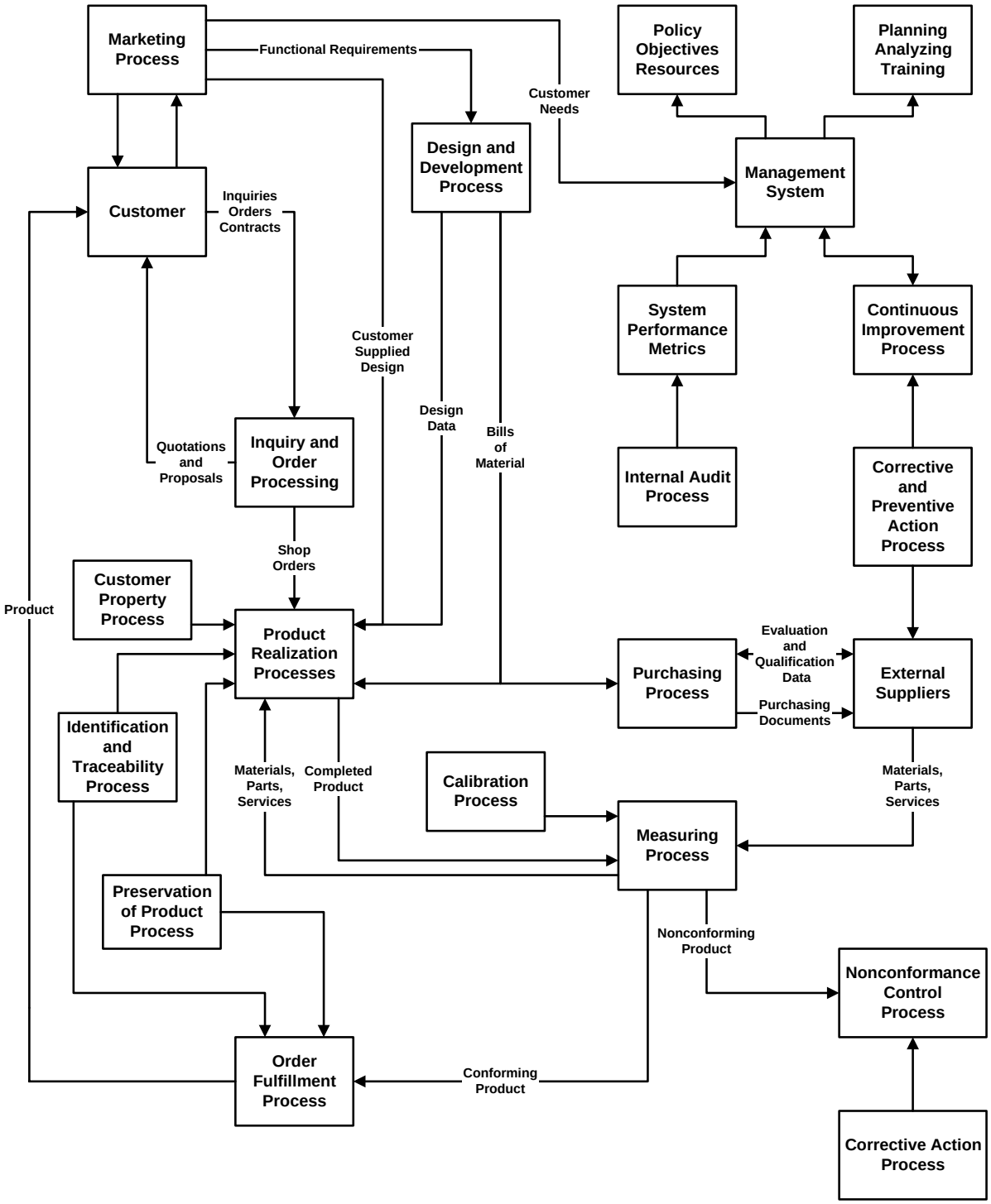
2 MagCap Engineering LLC Profile

Since 1969, MagCap Engineering LLC has been engaged in the design, development, and fabrication of high reliability magnetic components. The company occupies a modern 15,000 square foot facility in Canton, Massachusetts.

In 2000, in an effort to refocus our business strategy and to expand our market share in the high voltage electronics market, MagCap's high voltage business unit was split off from its parent company of 20 employees. This move enables MagCap to focus our marketing, engineering, and production efforts toward the expanding market of high voltage power equipment while our parent company pursues other unrelated ventures.

Our technical group is staffed with experienced design engineers in the development of each type of component for prototype and production quantities to meet the needs of our customers quickly, cost effectively and reliably. Special computer programs developed by our engineers can quickly provide complete, accurate and detailed component information including dynamic response under actual operating conditions

3 MagCap Engineering Process Interactions



4 Quality Management System

4.1 General Requirements

MagCap Engineering has established, documented and implemented a quality management system in accordance with the requirements of the ISO 9001:2000 International Standard. MagCap Engineering is committed to maintaining and continually improving the effectiveness of this quality system.

MagCap Engineering:

a) has identified the processes needed for the quality management system and their application throughout the organization,
b) has determined the sequences and interaction of these processes,
c) has determined the 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 and analyzes these processes, and
f) implements action necessary to achieve planned results and continual improvement of these processes.

MagCap Engineering will manage these processes in accordance with the requirements of the ISO 9001:2000 International Standard.

Where MagCap Engineering chooses to outsource any process that affects product conformity with requirements, these processes will be controlled. This control is identified within the quality management system.

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

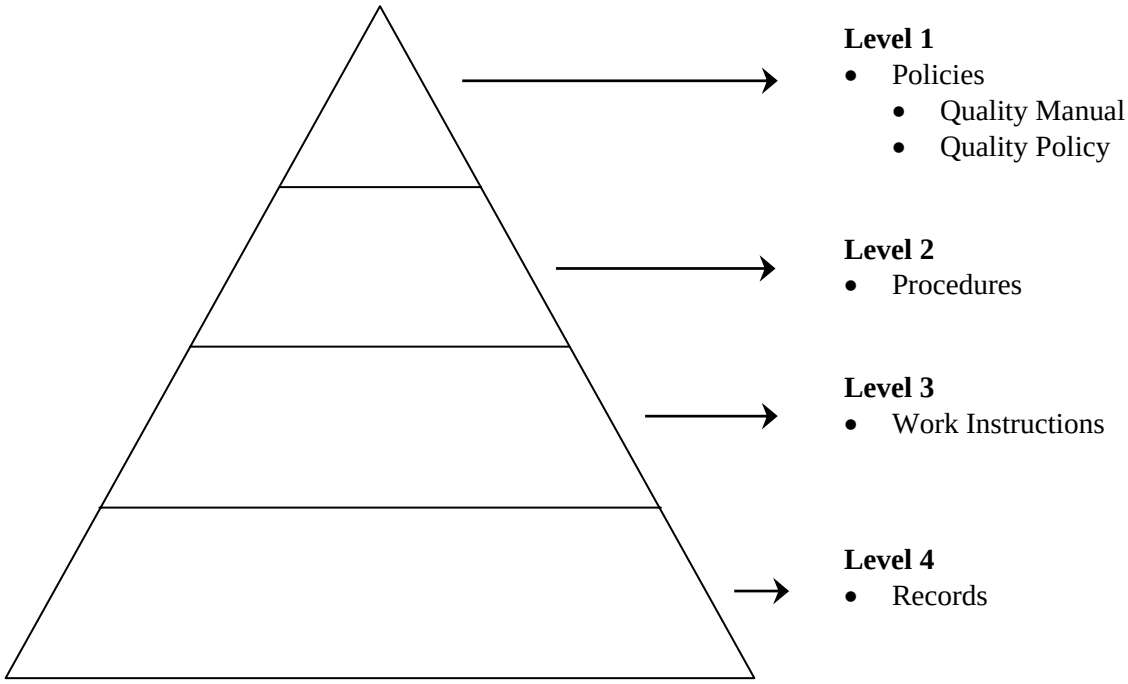
Reference Document
ISO 9001:2000 Quality Management Systems - Requirements

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) a quality manual,
c) documented procedures required by the ISO 9001:2000 International Standard,
d) documents needed to ensure the effective planning, operation and control of its processes, and
e) records required by the ISO 9001:2000 International Standard.

The quality system documentation is structured as follows:



Reference Document
ISO 9001:2000 Quality Management Systems - Requirements

4.2.2 Quality Manual

MagCap Engineering has established and maintains this quality manual that includes
a) the scope of the quality management system, including details of and justification for any exclusions,
b) reference to the documented procedures established for the quality management system, and
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.

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

Reference Document
PR4.2.3 Control of Documents Procedure

4.2.4 Control of Records

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

Reference Document
PR4.2.4 Control of Records Procedure

5 Management Responsibility

Reference Document
PR5 Management Responsibility Procedure

5.1 Management Commitment

Top management provides evidence of its commitment to the development and improvement of the quality management system and to continually improving its effectiveness by

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

5.2 Customer Focus

Top management 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 MagCap Engineering,
b) includes a commitment to comply with requirements and to 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 MagCap Engineering, and
e) is reviewed for continuing suitability.

Reference Document
QP5.3 Quality Policy

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 MagCap Engineering. The quality objectives are measurable and consistent with the quality policy.

Reference Document
QO5.4.1 Quality Objectives

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.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top management ensures that responsibilities and authorities are defined and communicated within MagCap Engineering.

5.5.2 Management Representative

Top Management has appointed a member of management 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 MagCap Engineering, and
d) maintaining liaison with external parties on matters relating to the quality management system.

5.5.3 Internal Communication

Top management ensures that appropriate communication processes are established within MagCap Engineering and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 General

Top management shall review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews 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) 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 quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.

Reference Document
PR5 Management Responsibility Procedure

6 Resource Management

6.1 Provision of Resources

MagCap Engineering 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.

6.2 Human Resources

6.2.1 General

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

6.2.2 Competence, Awareness and Training

MagCap Engineering
a) determines the necessary competence for personnel performing work affecting product quality,
b) provides training or takes other actions to satisfy these needs,
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, and
e) maintains appropriate records of education, training, skills and experience (see 4.2.4).

6.3 Infrastructure

MagCap Engineering 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 or communication).

6.4 Work Environment

MagCap Engineering determines and manages the work environment needed to achieve conformity to product requirements.

Reference Document
PR6 Resource Management Procedure

7 Product Realization

7.1 Planning of Product Realization

MagCap Engineering plans and develops the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, MagCap Engineering 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, 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 will be in a form suitable for MagCap Engineering's method of operation.

Reference Document
PR7.1 Product Realization Procedure

7.2 Customer-related Processes

7.2.1 Determination of Customer Requirements Related to the Product

MagCap Engineering 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 related to the product, and
d) any additional requirements determined by MagCap Engineering.

7.2.2 Review of Requirements Related to the Product

MagCap Engineering reviews the requirements related to the product. This review is conducted prior to the commitment to supply a product to the customer (e.g. submission of a tender, 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) MagCap Engineering 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 MagCap Engineering before acceptance.

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

7.2.3 Customer Communication

MagCap Engineering determines and implements effective arrangements for communicating with customers in relation to

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

Reference Document
PR7.2 Customer Requirements and Communication Procedure

7.3 Design and Development

7.3.1 Design and Development Planning

MagCap Engineering plans and controls design and development of product.

During the design and development planning, MagCap Engineering determines

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

MagCap Engineering 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 (see 4.2.4). These inputs include

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

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

7.3.3 Design and Development Outputs

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

a) meet the design and development input requirements,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential to 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 (see 7.3.1)

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

Participants in such reviews will 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 maintained (see 4.2.4).

7.3.5 Design and Development Verification

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

7.3.6 Design and Development Validation

Design and development validation is performed in accordance with planned arrangements (see 7.3.1) to ensure that 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 (see 4.2.4).

7.3.7 Control of Design and Development Changes

Design and/or 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 maintained (see 4.2.4).

Reference Document
PR7.3 Design and Development Procedure

7.4 Purchasing

7.4.1 Purchasing Process

MagCap Engineering ensures that purchased product conforms to specified purchase 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.

MagCap Engineering evaluates and selects suppliers based on their ability to supply product in accordance with our 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, and
c) quality management system requirements.

MagCap Engineering ensures the adequacy of specified purchase requirements prior to communication to the supplier.

7.4.3 Verification of Purchased Product

MagCap Engineering establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where MagCap Engineering or its customer intends to perform verification at the suppliers' premises, MagCap Engineering states the intended verification arrangements and method of product release in the purchasing information.

Reference Document
PR7.4 Purchasing Procedure

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

MagCap Engineering 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 devices,
e) the implementation of monitoring and measurement, and
f) the implementation of release, delivery and post-delivery activities.

7.5.2 Validation of Processes for Production and Service Provision

MagCap Engineering validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where 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.

MagCap Engineering 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.

Reference Document
PR7.1 Product Realization Procedure

7.5.3 Identification and Traceability

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

MagCap Engineering identifies the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, MagCap Engineering controls and records the unique identification of the product (see 4.2.4).

Reference Document
PR7.5.3 Identification and Traceability Procedure

7.5.4 Customer Property

MagCap Engineering exercises care with customer property while it is under its control or being used. MagCap Engineering 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, this is reported to the customer and records maintained (see 4.2.4).

Reference Document
PR7.5.4 Customer Property Procedure

7.5.5 Preservation of Product

MagCap Engineering preserves conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Reference Document
PR7.5.5 Preservation of Product Procedure

7.6 Control of Monitoring and Measuring Devices

MagCap Engineering identifies the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

MagCap Engineering 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

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

In addition, MagCap Engineering assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. MagCap Engineering 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 is undertaken prior to initial use and reconfirmed as necessary.

Reference Document

PR7.6 Control of Monitoring and Measuring Devices Procedure

8 Measurement, Analysis and Improvement

8.1 General

MagCap Engineering plans and implements the monitoring, measurement, analysis and improvement processes needed to

a) demonstrate conformity of the product,
b) ensure conformity of the quality management system, and
c) 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, MagCap Engineering monitors information relating to customer perception as to whether MagCap Engineering has met customer requirements. The methods for obtaining and using this information are determined by MagCap Engineering.

Reference Document
PR8.1 Measurement, Analysis and Improvement Procedure

8.2.2 Internal Audit

MagCap Engineering 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 9001:2000 International Standard and to the quality management system requirements established by MagCap Engineering, and
b) is effectively implemented and maintained.

An audit program is 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. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

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

The 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.

Reference Document

ISO 9001:2000 Quality Management Systems - Requirements
PR8.2.2 Internal Audit Procedure

8.2.3 Monitoring and Measurement of Processes

MagCap Engineering 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 are taken, as appropriate, to ensure conformity of the product.

Reference Document

PR8.1 Measurement, Analysis and Improvement Procedure

8.2.4 Monitoring and Measurement of Product

MagCap Engineering 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 (see 4.2.4).

Product release and service delivery do not proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Reference Document
PR8.2.4 Monitoring and Measurement of Product Procedure

8.3 Control of Nonconforming Product

MagCap Engineering ensures that product which does not conform to 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 a documented procedure.

MagCap Engineering 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.

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

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

When nonconforming product is detected after delivery or use has started, MagCap Engineering takes action appropriate to the effects, or potential effects, of the nonconformity.

Reference Document
PR8.3 Control of Nonconforming Product Procedure

8.4 Analysis of Data

MagCap Engineering determines, collects and analyzes appropriate data to determine 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) conformance to product requirements (see 7.2.1),
c) characteristics and trends of processes and product including opportunities for preventive action, and
d) suppliers.

8.5 Improvement

8.5.1 Continual Improvement

MagCap Engineering 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.

Reference Document
PR8.1 Measurement, Analysis and Improvement Procedure

8.5.2 Corrective Action

MagCap Engineering takes corrective action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure is established to define requirements for
a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for actions to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) record the results of action taken (see 4.2.4), and
f) reviewing corrective action taken.

Reference Document
PR8.5.2 Corrective and Preventive Action Procedure

8.5.3 Preventive Action

MagCap Engineering determines action to eliminate the causes of potential nonconformities in order to prevent occurrence. Preventive actions are appropriate to the effects of the potential problems.

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

Reference Document
PR8.5.2 Corrective and Preventive Action Procedure

APPROVALS		
President Approval:	**Chris J. Lagadinos**	***Date:*** **5/28/02**
ISO Management Rep. Approval:	**Glenn E. Malin**	***Date:*** **5/28/02**

RELEASE AND REVISION HISTORY		
Rev. Level	***Rev. Date***	***Description***
A	5/28/02	Initial Release