Nova Magnetics, Inc., MagFlux Corporation
Flujos Magneticos S.A. de C.V.

"THE COMPANIES"

Quality Management Systems Quality Manual

ISO 9001:2008

Leadership

Performance

Customer Satisfaction

The Companies

Corporate Facts

This manual was developed for Nova Magnetics, Inc. (NMI), MagFlux Corporation (MFC), Flujos Magneticos S.A. de C.V. (FM).

The Companies manufacture a wide range of custom wound magnetic components and other electro-mechanical devices. Sales are primarily to OEM accounts. The customer base includes a wide variety of fields including Industrial Equipment, Computers, Communications, Medical, Entertainment and Instrumentation.

Founded by J. Clay Hogan and the late Glynn Davis, Nova Magnetics was incorporated in the State of Texas in 1981, and began operations in April of that year.

The stockholders own a 30,000 square foot facility that houses the office, manufacturing and Warehouse operations. The address is 1101 E. Walnut Street, Garland, Texas (in the Dallas Metropolitan area). A 13,000 square foot building across the street at 1001 E. Walnut St. supplies additional manufacturing needs.

MagFlux Corporation incorporated in 1974, in Texas, has common owners and officers with NMI. MFC elected in 1981 to move Corporate Headquarters to NMI's facility. MFC subcontracts NMI's personnel for sales, design, purchasing and quality system management. MFC maintains a warehouse in Laredo, Texas to receive and ship raw materials and finished goods.

Flujos Magneticos S.A. de C.V. (FM) was incorporated in 1974 in Mexico. It operates as a maquilladora, building wound magnetic components for MFC exclusively. Its manufacturing facility is a 12,000 square foot building at 120 Sur, Lampazos, Mexico.

The combined companies have a seasoned Engineering and Management staff that has functioned to ensure Nova's continued innovation, growth and profitability over the past twenty five years.

Contents

Page Number

Page Number

Page Number

1. Scope

1.1 General

This Quality Manual applies to all products and processes at the companies that affect the quality of goods provided to our customers. These requirements are also applicable to all fabrication sequences at our manufacturing facilities.

Nova Magnetics, Inc. has offices and manufacturing plants at 1101 and 1001 East Walnut Street, Garland, Texas. Its personnel are responsible for all requirements at these facilities, and also perform some functions for MFC, FM.

MagFlux Corporation has a warehouse at 3400 Garfield Street in Laredo, Texas. This facility is a warehouse where raw material is staged and shipped to Lampazos, Mexico.
Also, finished goods are received from Lampazos and shipped to customers. MFC contracts NMI for management, quality system management, sales, contract review, document and data control, purchasing, design and design review, calibration of test and inspection equipment, record retention and some warehousing. MFC contracts with FM for other quality system functions as described below.

Flujos Magneticos S.A. de C.V. operates a warehouse and manufacturing facility in Lampazos, Mexico under the Maquilladora program. It subcontracts exclusively to MFC, performing incoming inspection, warehousing, assembly, test and inspection, maintenance of equipment, training, and internal auditing. It also contracts with NMI for calibration of inspection and test equipment and auditing when required.

This Quality Manual specifies requirements for a quality management system where Nova Magnetics, Inc. and the associated companies

a) need to demonstrate their ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aim to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system.

NOTE: In this quality manual, the term "product" applies only to the product intended for, or required by, a customer.

It is intended that all requirements of this Quality Manual be applied. However, certain requirements may be excluded in particular situations (see 1.2).

1.2 Application

All requirements of this quality manual are generic and are intended to be applicable to the organization, regardless of the product provided.

Where any requirement(s) of this quality manual cannot be applied due to the nature of the organization and its product, exclusion may be considered.

Where exclusions are made, claims of conformity to this quality manual are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

Nova Magnetics, Inc. and the associated companies do not perform servicing activities for customers. Flujos Magneticos does not design product, review customer contracts or purchase materials for the manufacture of product.

2. Normative Reference

The following referenced documents are indispensible 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.

This Quality System is compliant with the guidelines of ANSI/ASQ ISO 9001:2008, Quality Management Systems Requirements. The Quality System is defined in this Quality Manual. The detailed policies and procedures that comprise the Quality System are found in the documents referenced at the end of each section of this manual.

References:

ANSI/ASQ ISO 9000:2005 Quality Management Systems - Fundamentals & Vocabulary
ANSI/ASQ ISO 9001:2008 Quality Management Systems Requirements

COMPARISON BETWEEN ISO 9001:2008 AND ISO 9001:1994

9001:2008 (Elements)	9001:2008 (Clauses)	9001:2008 (Sub-Clauses)	9001:1994 Requirements
Quality Management 4.	**4.1**	**----**	**4.2.1**
	4.2	**4.2.1**	**4.2.1 + 4.5.1**
		4.2.2	**4.2.1**
		4.2.3	**4.5.1 + 4.5.2 + 4.5.3**
		4.2.4	**4.16**
Management Responsibility 5.	**5.1**	**----**	**4.1 + 4.1.2.2 + 4.2.1**
	5.2	**----**	**4.3.2**
	5.3	**----**	**4.1.1**
	5.4	**5.4.1**	**4.1.1 + 4.2.1**
		5.4.2	**4.2.3**
	5.5	**5.5.1**	**4.1.2.1**
		5.5.2	**4.1.2.3**
		5.5.3	**----**
	5.6	**5.6.1**	**4.1.3**
		5.6.2	**4.1.3**
		5.6.3	**4.1.3**
Resource Management 6.	**6.1**	**----**	**4.1.2.2**
	6.2	**6.2.1**	**4.1.2.2 + 4.2.3 + 4.18**
		6.2.2	**4.18**
	6.3	**----**	**4.1.2.2 + 4.9**
	6.4	**----**	**4.9**
Product Realization 7.	**7.1**	**----**	**4.2.3 + 4.9 + 4.10.1**
	7.2	**7.2.1**	**4.3.2 + 4.4.4**
		7.2.2	**4.3.2 + 4.3.3 + 4.3.4**
	7.3	**7.2.3**	**4.3.2**
		7.3.1	**4.4.2 + 4.4.3 + 4.4.6 +**
		----	**4.4.7 + 4.4.8**
		7.3.2	**4.4.4**
		7.3.3	**4.4.5**
		7.3.4	**4.4.6**
		7.3.5	**4.4.7**
		7.3.6	**4.4.8**
		7.3.7	**4.4.9**
	7.4	**7.4.1**	**4.6.2**
		7.4.2	**4.6.3**
		7.4.3	**4.6.4 + 4.10.2 + 4.10.3 +**
		----	**4.10.4**
	7.5	**7.5.1**	**4.9 + 4.10.3 + 4.15.6 + 4.19**
		7.5.2	**4.9**
		7.5.3	**4.8 + 4.10.5 + 4.12**
		7.5.4	**4.7**
		7.5.5	**4.15.2 + 4.15.3 + 4.15.4 +**
		----	**4.15.5 + 4.15.6**
	7.6	**----**	**4.11.1 + 4.11.2**
Measurement, Analysis & Improvement 8.	**8.1**	**----**	**4.10 + 4.17 + 4.20.1**
	8.2	**8.2.1**	**----**
		8.2.2	**4.17**
		8.2.3	**4.9 + 4.17 + 4.20.1**
		8.2.4	**4.10.2 + 4.10.3 + 4.10.4 +**
		----	**4.10.5 + 4.20.1**
	8.3	**----**	**4.13.1 + 4.13.2**
	8.4	**----**	**4.14.2 + 4.14.3 + 4.20**
	8.5	**----**	**----**
		8.5.1	**4.1.3**
		8.5.2	**4.14.1 + 4.14.2**
		8.5.3	**4.14.1 + 4.14.3**

3. Terms and Definitions

For the purposes of this Quality Manual, the terms and definitions given in ISO 9000: 2005 apply.

The following terms used in this Quality Manual to describe the supply-chain are as follows:

supplier ⟶ organization ⟶ customer

The term 'organization' is used to mean the unit to which this Quality Manual applies. The term 'supplier' is used to describe 'subcontractor'. These terms have been introduced to reflect the vocabulary used by the companies.

References:

ANSI/ASQ ISO 9000:2005 Quality Management System - Fundamentals & Vocabulary

4. Quality Management System

4.1 General Requirements

The companies have established, documented, implemented and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this Quality Manual.

The companies have:

a) identified the processes needed for the quality management system and their application throughout the organization (see 1.2),

Processes are identified in the Quality Manual, associated procedures and work instruction that make up this quality system.

b) determined the sequence and interaction of these processes,

The sequence and interaction of processes is defined in the companies process maps.

c) determined criteria and methods needed to ensure that both the operation and control of these processes are effective,

Criteria and methods are defined in the procedures, instructions and job packets as required.

d) ensured the availability of resources and information necessary to support the operation and monitoring of these processes,

Requirements for resources are reviewed and the necessary resources are provided by management. The need for resources is obtained from contract reviews, quotations, production schedules, and other quality reviews.

e) monitored, measured where applicable, and analyzed these processes, and

Company wide data is collected and analyzed and the information is reviewed and evaluated by management for continuing effectiveness.

f) implemented actions necessary to achieve planned results and continual improvement.

Identified problems may be inputs to the Corrective / Preventive action process thereby promoting continuous improvement.

These processes are managed by the companies in accordance with the requirements of this Quality Manual.

When the companies choose to outsource any process that affects product conformity, the organization ensures control over such processes. The type and extent of control applied to these outsourced processes is defined 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, analysis and improvement.

References:

2.4.01.001	Management Practices
2.4.03.001	Contract Review
2.4.04.001	Design Control
2.4.05.001	Document and Data Control
2.4.09.001	Process Control
2.4.14.001	Corrective Action
2.4.14.002	Preventive Action
4.4.01.013	Strategic Quality Plan
4.4.01.023	Process Structure For QMS

Records:

4.4.14.001	Corrective Action Form
Job Packet	

4.2 Documentation Requirements

4.2.1 General

The quality management system documentation includes

a) documented statements of a quality policy and quality objectives,

The quality policy is defined in section 5.3 and the quality objective statements are documented in section 5.4.1 of this manual. The quality policy and objectives are also defined in the Strategic Quality Plan.

b) this quality manual,

c) documented procedures and records required by this quality manual,

The companies have prepared documented procedures consistent with the requirements of ISO 9001: 2008

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of the processes,

The main documents for planning and controlling processes are job packets, procedures, and work instructions. Documents from Nova Magnetics, Inc. are also used by MagFlux Corporation and Flujos Magneticos and may be in either English or Spanish. The MagFlux/Flujos documents have an M prefix, and may or may not be referred to in this document.

e) records required by this quality manual (see 4.2.4).

NOTE 1: Where the term "documented procedure" appears within this Quality Manual, this means that the procedure is established, documented, implemented and maintained. A single document may include requirements for one or more procedures and a requirement for a documented procedure may be covered by more than one document.

NOTE 2 : The extent of the quality management system documentation may differ from one company to another due to:

a) size and type of the organization;

b) complexity and interaction of the processes;

c) competence of personnel

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

References:

2.4.01.001 Management Practices
2.4.05.001 Document and Data Control
4.4.01.013 Strategic Quality Plan

Records:

Job Packet

4.2.2 Quality Manual

The companies have established and maintain this quality manual that includes

a) the scope of the quality management system (see 1.1), including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, and reference to them, and

c) a description of the interaction between the processes of the quality management system.

Interaction between processes are defined in procedures 2.4.09.001 and 4.4.01.023.

References:

2.4.09.001 Process Control
4.4.01.023 Process Structure for QMS

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.

A documented procedure has been established to define the controls needed

a) to approve documents for adequacy prior to issue,

All documents are reviewed as evidenced by a signed approval sheet which is retained by document control.

b) to review and update as necessary and re-approve documents,

A document change request form initiates proposed changes and is retained by document control. The review process and schedule is noted in 2.4.05.001, Document and Data Control.

c) to ensure that changes and the current revision status of documents are identified,

Revision status is identified on the document , and a master list of documents is maintained.

d) to ensure that relevant versions of applicable documents are available at point of use,

This process is defined in the Document Control procedure.

e) to ensure that documents remain legible and readily identifiable,

This process is defined in the Document Control procedure.

f) to ensure that documents of external origin are identified and their distribution controlled,

Documents of external origin are identified, controlled, and lists of these documents are maintained.

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

This process is defined in Document Control procedure.

References:

2.4.05.001	Document and Data Control
2.4.09.001	Process Control

Records:

4.4.05.002	Doc. Change Form
ISO_Log.MDA	Doc. Master List

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 remain legible, readily identifiable and retrievable. A documented procedure has been established to define the controls for the identification, storage, protection, retrieval, retention time and disposition of records. Records created prior to January 1, 1997 are not required to meet the provisions of ISO9001:1995 or later versions of the standard, but are grandfathered in their existing forms.

References:

4.4.16.002	Quality Records Master List

4.3 Use of Quality Management Principles

To lead and operate the companies successfully, it is necessary to manage in a systematic and visible manner. The guidance to management offered in this quality manual is based on eight quality management principles.

These principles have been adopted for use by top management in order to lead the companies toward improved performance. These quality management principles are integrated in the contents of this quality manual and are listed below.

a) Customer focus

The companies focus on their customers and therefore understand current and future customer needs, meet customer requirements and strive to exceed customer expectations.

b) Leadership

Effective leaders establish unity of purpose and direction in the companies. They create and maintain an internal environment in which people can become fully involved in achieving the companies objectives.

c) Involvement of people

People at all levels are the essence of the companies and their full involvement enables their abilities to be used for the companies benefit.

d) Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.

e) System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the companies effectiveness and efficiency on achieving its objectives.

f) Continual improvement

Continual improvement of the companies overall performance is a permanent objective of the companies.

g) Factual approach to decision making

Effective decisions are based on the analysis of data and information.

h) Mutually beneficial supplier relationships

The companies and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

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 to the organization the importance of meeting customer as well as statutory and regulatory requirements,

Top management communicates through a variety of methods, including the company newsletter , employee meetings and posting performance charts.

b) establishing the quality policy,

The Quality Policy has been developed by the quality council and is documented in this manual and the strategic quality plan, and posted throughout the facilities.

c) ensuring that quality objectives are established,

Quality objectives have been developed and referenced in this manual and documented in the strategic quality plan, and are posted throughout the companies.

d) conducting management reviews,

Quarterly management reviews are conducted at each site. Unscheduled reviews are conducted when necessary.

e) ensuring the availability of necessary resources.

Management ensures that once the need for a resource is identified, steps are taken to secure and provide the resource whenever practical.

The management of the companies pledge adequate support and resources to ensure that the Quality System described in this manual is fully implemented and that it will be continuously improved to meet the changing needs of the company and its customers.

References:

2.4.01.001 Management Practices
2.4.05.001 Document & Data Control
4.4.01.013 Strategic Quality Plan

Records:

4.4.01.001 Mgmt. Review Agenda Form
Company Newsletter
Job Packet

5.1.1 Management Commitment

Top management is committed to the ongoing system development and improvement of the effectiveness of the quality management system, which includes providing resources, promoting continual improvement, and communicating to the companies the importance of meeting customer, regulatory, and statutory requirements.

Matthew Davis
President
Nova Magnetics, Inc./MagFlux Corp.

Pat McDermott
Director of Quality
Nova Magnetics Inc./MagFlux Corp.

Carlos Garcia
President
Flujos Magneticos S.A.

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).

Customer requirements are reviewed in the contract review process and documented in the job packet. Customer satisfaction is monitored through the customer complaint process, repeat orders, non-conforming material and direct customer input via meetings, phone calls and other forms of communication.

References:

2.4.01.001	Management Practices
4.4.03.001	Contract Review
2.4.09.001	Process Control

Records:

4.4.01.020	Customer Satisfaction Survey
4.4.03.013	Contract Review Checklist
	Job Packet

5.3 Quality Policy

Top management has defined and documented its policy for quality, including objectives and its commitment to quality.

The companies are committed to perform in accordance with the requirements agreed upon between ourselves and our customers and to promote continual improvement.

This policy has been formulated and approved by the President and the Quality Steering Committee of the companies.

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,

See the Quality Policy and the Management Commitment page, 5.1.1.

c) provides a framework for establishing and reviewing quality objectives,

The framework for establishing quality objectives is defined in the companies Strategic Quality Plan and reviewed quarterly in management reviews.

d) is communicated and understood within in the organization,

The Quality Policy is posted at conspicuous locations throughout the companies. The quality policy is printed in the company newsletter and communicated and reviewed at each employee meeting.

e) is reviewed for continuing suitability.

The Quality Policy is reviewed for suitability on a quarterly basis in management review meetings and during the strategic quality planning process.

References:

2.4.01.001 Management Practices
4.4.01.013 Strategic Quality Plan

Records:

4.4.01.001 Management Review Agenda
4.4.01.019 Employee Survey
4.4.14.001 Corrective Action Form
Quality System Handout
Company Newsletter

5.4 Planning

5.4.1 Quality Objectives

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

Quality objectives are established at all relevant functions and levels as defined in the strategic quality plan. The measures for corporate objectives are documented in the strategic quality plan.

References:

2.4.01.001	Management Practices
4.4.01.013	Strategic Quality Plan

Records:

4.4.01.001	Management Review Agenda Form

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

Product planning is accomplished through design control, contract review, and job packet instructions. Quality system planning is documented in this manual and the strategic quality plan.

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

The proposed changes are studied and approved by the quality council. The approved changes are reviewed and adopted by the quality steering committee.

References:

2.4.01.001	Management Practices
2.4.05.001	Document and Data Control
2.4.09.001	Process Control
4.4.01.013	Strategic Quality Plan

Records:

4.4.01.001	Management Review Agenda
4.4.05.001	Engineering Change Form
4.4.05.002	Document Change Form
	Job Packet

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

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

The companies have defined and documented the responsibility, authority, and the interrelation of all employees who manage, perform, and verify work affecting quality in this manual and the procedures and work instructions that support the quality system.

Responsibilities and authorities are defined in a matrix and communicated throughout the companies. Interrelation of employees is defined in a company organizational chart. These documents are controlled.

References:

2.4.05.001	Document and Data Control
4.4.01.002	Responsibility & Authority Matrix

Records:

4.4.01.002	Responsibility & Authority Matrix
4.4.01.014	Organizational Chart
4.4.01.017	Designee Assigned Responsibility and/or Authority

5.5.2 Management Representative

Top management has appointed member(s) of the organization's management who, irrespective of other responsibilities, have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented, and maintained,

The implementation and maintenance of necessary processes is ensured by performing internal quality audits.

b) reporting to top management on the performance of the quality management system and any need for improvement,

Performance of the quality management system is reported at management review meetings and documented.

c) ensuring the promotion of awareness of customer requirements throughout the companies.

The companies display process performance level charts and communicate performance at employee meetings conducted by management.

The companies have appointed a corporate representative (NMI Director of Quality), along with individual site representatives at each location to monitor the quality management system.

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

References:

2.4.01.001	Management Practices
2.4.17.001	Internal Quality Audits

Records:

4.4.01.001	Management Review Agenda Form
4.4.17.001	Internal Audit Schedule

5.5.3 Internal Communication

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

Examples of internal communication may include

a) team briefings and other meetings,

b) performance level charts,

c) in-house newsletter,

d) daily manufacturing / scheduling meeting,

e) employee meetings conducted by management,

f) management reviews,

g) strategic quality planning process.

References:

2.4.01.001	Management Practices
4.4.01.013	Strategic Quality Plan

Records:

4.401.001	Management Review Agenda Form
	Minutes from Management Review

5.6 Management Review

5.6.1 General

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

The quality management system may be reviewed at any time, but is normally reviewed each quarter of the year. A review may be called by the Director of Quality whenever necessary.

Records from management reviews are maintained (see 4.2.4)

References:

2.4.01.001	Management Practices
4.4.16.001	Quality Records Master List

Records:

4.4.01.001	Management Review Agenda
4.4.01.020	Customer Satisfaction Survey
4.4.13.001	Nonconforming Form
4.4.14.001	Corrective Action Form
4.4.17.001	Audit Schedule
	Minutes of Management Review

5.6.2 Review Input

The input to management review includes information on

a) results of audits,

The reports from internal, customer, and third party audits are presented at management reviews.

b) customer feedback,

Measurements of customer satisfaction, which include customer complaints and customer surveys, are presented at management reviews.

c) process performance and product conformance,

The manufacturing error data collection information is presented at management reviews.

d) status of preventive and corrective actions,

Preventive and corrective actions are reviewed in management review meetings for implementation, follow-up, and final closure.

e) follow-up actions from previous management reviews,

Action items from previous management reviews are reviewed for completion, effectiveness and/or additional actions required.

f) changes that could affect the quality management system,

Sources of information that may affect the quality management system are internal audits, document review and agenda items to management review.

g) recommendations for improvement.

Interested party, customer, supplier recommendations and suggestions by employees may be considered and reviewed for appropriate action and implemented through the corrective/preventive action process.

References:

2.4.01.001	Management Practices
2.4.09.001	Process Control
2.4.14.001	Corrective Action
2.4.14.002	Preventive Action
4.4.17.001	Internal Quality Audits

Records:

4.4.01.001	Management Review Agenda
4.4.01.020	Customer Satisfaction Survey
4.4.13.002	Error Data Collection Form
4.4.14.001	Corrective Action Form
4.4.17.001	Audit Schedule
	Minutes of Management Review

5.6.3 Review Output

The output from 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.

The output includes any decisions or action items related to corrective/preventive actions, resources needed to implement evaluated actions, customer communications and/or revised manufacturing processes, and other opportunities for improvement.

References:

2.4.01.001	Management Practices
4.4.16.001	Quality Records Master List

Records

4.4.01.001	Management Review Agenda
4.4.01.020	Cust. Satisfaction Survey
4.4.14.001	Corrective Action Form
	Minutes of Management Reviews

6. Resource Management

6.1 Provision of Resources

The companies have determined and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness,

The quality management system is maintained and continually improved through verbal requests, internal quality audits, corrective / preventive actions, customer requests, and management reviews.

b) to enhance customer satisfaction by meeting customer requirements.

Customer satisfaction parameters are analyzed so that appropriate resources can be provided to satisfy customer needs.

References:

2.4.01.001	Management Practices
2.4.14.001	Corrective Action
2.4.14.002	Preventive Action
2.4.17.001	Internal Quality Audits

Records:

4.4.01.001	Management Review Agenda
4.4.01.020	Customer Satisfaction Survey
4.4.14.001	Corrective Action Form
4.4.17.001	Internal Audit Schedule

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.

Employee competence is documented in employee training records and personnel files.

References:

2.4.18.001 Training Process
2.4.18.002 Training of Engineers and Engineering Aids

Records:

4.4.18.001 Employee Training Record

6.2.2 Competence, Training and Awareness

The companies have

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

The required skills are defined in job descriptions, employee training records, and process tests, as required.

b) provided training or other actions to achieve the necessary competence,

The companies have analyzed the development needs of the employees and designed training to accomplish those needs.

c) evaluated the effectiveness of the action taken,

Each department director has the responsibility to determine if the training is effective.

d) ensured that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,

Departmental objectives that relate directly to the company objectives and the strategic quality plan are communicated quarterly in the form of performance charts and discussed at employee meetings and/or communicated in the company newsletter.

e) maintained appropriate records of education, experience, training, skills and experience (see 4.2.4).

Training records are maintained per applicable procedures and work instructions.

References:

2.4.18.001	Training Process
2.4.18.002	Training of Engineers and Engineering Aids
4.4.18.003	Job Descriptions

Records:

4.4.18.001	Employee Training Record
4.4.18.003	Job Descriptions

6.3 Infrastructure

The companies determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated facilities,

Facilities and equipment are maintained to ensure that they continue to meet operational needs. The maintenance program considers the type and frequency of maintenance based on the criticality and usage of the equipment.

b) process equipment, (both hardware and software),

Hardware is evaluated and acquired as needed and necessary revisions to software are installed in a timely manner.

c) supporting services (such as transport or communication or information systems)

Outside expert services are contracted whenever internal resources are limited or inadequate.

References:

2.4.09.001 Process Control

Records:

4.4.09.003 Maintenance Log

6.4 Work Environment

The companies have determined and managed the work environment needed to achieve conformity to product requirements.

Safety rules and ergonomics are defined in the companies Occupational Safety and Health Handbook. Periodic inspections and reviews by third party consultants assist in maintaining a safe work environment. The term work environment relates to conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather.)

References:

2.4.09.001 Process Control
Occupational Safety and Health Handbook

7. Product Realization

7.1 Planning of Product Realization

The companies plan and develop 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, the companies determine the following, as appropriate

a) quality objectives and requirements for the product,

Requirement planning for the product is documented in the design file.

b) the need to establish processes, documents, and provide resources specific to the product,

Normally, the establishment of processes, documents, and resources needed specific to the product are determined during the design stage, contract review stage, and the manufacturing prototype stage of product development.

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance,

Planning for verification, validation, monitoring, inspection and test activities are defined and documented.

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

Records of the realization processes are maintained.

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, is referred to as a quality plan.

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

References:

2.4.04.001	Design Control
2.4.04.003	Engineering Change Notice (ECN)
2.4.09.001	Process Control
4.4.01.013	Strategic Quality Plan
4.4.16.001	Quality Records Master List

Records:

4.4.05.001	Engineering Change Notice Form
4.4.03.013	Contract Review Checklist
	Job Packet
	Design File

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

The companies determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

Customer requirements are gathered by the Sales department and reviewed before the acceptance of a contract.

b) requirements not stated by the customer but necessary for specified or intended use, where known,

Unstated requirements are identified in the design stage and documented in the design file.

c) statutory and regulatory requirements applicable to the product,

Statutory and regulatory requirements are determined at the design stage and documented in the design file.

d) any additional requirements determined by the organization.

Additional requirements are identified and referenced in the contract review process.

NOTE: Post delivery activities include, for example, actions under warranty provisions, contracual obligations such as maintenance services and supplementary services such as recycling or final disposal.

References:

2.4.03.001	Contract Review
2.4.04.001	Design Control
2.4.04.004	Quoting Magnetic Components

Records:

4.4.03.013	Contract Review Checklist
4.4.04.002	Index Design Programs
	Job Packet

7.2.2 Review of Requirements Related to the Product

The companies review the requirements related to the product. The 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,

Customer requirements that relate to an order are reviewed by Sales department, with the assistance of various other departments, using the contract review process.

b) contract or order requirements differing from those previously expressed are resolved, and

Changes to an order are implemented with the change order process.

c) the companies have the ability to meet defined requirements.

The design phase and scheduling process evaluates and determines the companies ability to meet customer requirements. This is accomplished through the use of the contract review process.

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 the organization before acceptance.

Normally, undocumented customer requirements are determined by the engineer assigned to the project and communicated to the customer for approval.

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

Changes are amended and documented using a document change request (DCR) for procedures and instructions, a sales order change notice for changes to a sales order, and an engineering change notice (ECN) for product specification changes.

References:

2.4.03.001	Contract Review
2.4.04.001	Design Control
2.4.04.003	Engineering Change Notice (ECN)
2.4.04.004	Quoting Magnetic Components
2.4.04.005	Deviation, Waiver Change

Records:

4.4.03.002	Acknowledgment
4.4.03.005	Order Change Notice
4.4.03.013	Contract Review Checklist
4.4.05.001	Engineering Change Notice Form
4.4.05.002	Document Change Request Form
	Job Packet

7.2.3 Customer Communication

The companies have determined and implemented effective arrangements for communicating with customers in relating to

a) product information,

Communications with the customer relating to product information normally involve Engineering and/or Sales departments via telephone, fax or e-mail. Additional information is provided when requested, or to clarify the offer.

b) inquiries, contracts or order handling, including amendments,

Quotations, sales orders, order acknowledgements, and deviation notices are used in communicating with the customer.

c) customer feedback, including customer complaints.

Customer feedback from multiple sources, including complaints, meetings and e-mail and telephone conversations is documented, analyzed, reviewed and action items generated. The Corrective/Preventive action process may be used to resolve customer issues.

References:

2.4.03.001	Contract Review
2.4.04.001	Design Control
2.4.04.005	Deviation, Waiver or Specification Change Request

Records:

4.4.01.020	Customer Satisfaction Survey
4.4.03.001	Quote Form
4.4.03.002	Acknowledgment
4.4.03.003	Order Form
4.4.03.005	Order Change Notice
4.4.03.008	Customer Complaint Log

7.3 Design and Development

7.3.1 Design and Development Planning

Top management ensures that the companies have defined, implemented, and maintain the necessary design and development processes to respond to the needs and expectations of its customers and other interested parties.

The companies plan and control design and development of the product.

Product design and development is controlled in accordance with the Design Control procedure.

During the design and development planning, the organization determines

a) the design and development stages,

Design and development stages are defined in the Design Review procedure.

b) the review, verification and validation that are appropriate to each design and development stage,

The review of verification and validation of the design is defined in the Design Review procedure.

c) the responsibilities and authorities for design and development.

A design engineer with the necessary training and experience is assigned to a new product. He is given the authority and provided with the resources to complete the design.

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

The interactions and exchanges of information during the design process are defined in the Design Control, Design Review, Engineering Change, and Quoting procedures.

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

NOTE: Design and development review, verification and validation have distinct purposes. They may be conducted and recorded separately or in any combination determined suitable for the product and the companies.

References:

2.4.04.001 Design Control
2.4.04.002 Design Review
2.4.04.003 Engineering Change Notice
2.4.04.004 Quoting Magnetic Components
2.4.09.001 Process Control

Records:

4.4.04.002 Index Design Programs
Job Packet

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 complete, unambiguous and not in conflict with each other.

The design inputs are reviewed and any incomplete, ambiguous or conflicting requirements are resolved with the customer before the completion of the design phase.

References:

2.4.04.001 Design Control
2.4.04.002 Design Review
2.4.04.004 Quoting Magnetic Components

Records:

Job Packet
Design File

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 is approved prior to release.

The outputs of the design are documented in the job packet and design file, and approved prior to release.

Design and development outputs

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing and production operations,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

The design and development output is a complete set of drawings that includes an assembly drawings, bill of materials, fabrication drawings, and purchased part specifications.

References:

2.4.04.001	Design Control
2.4.04.004	Quoting Magnetic Components

Records:

Job Packet
Design File

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 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)

Reviews are conducted at the stages and by the means defined in the Design Review procedure.

References:

2.4.04.001	Design Control
2.4.04.002	Design Review
4.4.16.001	Quality Records Master List

Records:

Job Packet
Design File

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 met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained (see 4.2.4).

The evidence of product verification is documented in the job packet.

References:

2.4.04.001	Design Control
2.4.09.001	Process Control
4.4.16.001	Quality Records Master List

Records:

Job Packet
Design File

7.3.6 Design and Development Validation

Design and/or development validation is performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specific 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).

Designs are validated as described in the Design Review procedure.

References:

2.4.04.001	Design Control
4.4.16.001	Quality Records Master List
2.4.04.002	Design Review

Records:

Job Packet
Design File

7.3.7 Control of Design and Development Changes

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions are maintained (see 4.2.4).

Changes are performed using an (ECN) Engineering Change Notice which requires review and approval before the change is made.

The effective date of change, for products that are not new, is controlled by the Sales department in conjunction with the customer.

References:

2.4.04.001	Design Control
2.4.04.002	Design Review
2.4.04.003	Engineering Change Notice (ECN)
2.4.04.005	Deviation, Waiver Change Notice
2.4.05.002	Design File

Records:

4.4.05.001	Engineering Change Notice Form

7.4 Purchasing

7.4.1 Purchasing Process

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

Computer software is used to aid in the purchasing process and to maintain lists of vendor status. Where the companies choose to outsource any process which affects product conformity to requirements, such controls as necessary are determined on an individual basis and are noted on contracts or otherwise communicated to the supplier of such processes.

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

Supplier selection and evaluation is defined in the referenced procedures.

References:

2.4.06.001 Material Procurement
2.4.10.001 Receiving Inspection

Records:

4.4.10.001 Receiving Inspection Form

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.

Information is defined and documented in the Material Procurement procedure.

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

A review is conducted and approved before release as defined in the referenced procedure.

References:

2.4.06.001 Material Procurement

Records:

4.4.06.003 Purchase Order Form

7.4.3 Verification of Purchased Product

The companies have established and implemented the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Verification and product release are defined in referenced procedures.

Where the companies or its customer intend to perform verification at the supplier's premises, the organization states the intended verification arrangements and method of product release in the purchasing information.

References:

2.4.06.001	Material Procurement
2.4.10.001	Receiving Inspection
2.4.10.002	Final Inspection & Test

Records:

4.4.10.001	Receiving Inspection Form
Job Packet	

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

The companies plan and carry out production provision under controlled conditions.

Controlled conditions include, as applicable

a) the availability of information that describes the characteristics of the product,

Operations performed during the manufacture of parts, sub-assemblies, or end items are specified in the job packet. The job packet lists all production and inspection necessary to manufacture and verify product. Product characteristics are identified in the job packet and may be verified by using statistical techniques to monitor and control product.

b) the availability of work instructions, as necessary,

The job packet is considered a work instruction and additional instructions, if needed, are referred to within the packet.

c) the use of suitable equipment,

Availability of suitable equipment is determined during the design stage, and a preventive maintenance program is established and implemented.

d) the availability and use of monitoring and measuring equipment,

A calibration program for devices is documented and implemented.

e) the implementation of monitoring and measurement,

Inspection and testing activities and results are documented in the job packet.

f) the implementation of product release, delivery and post-delivery activities.

A process for release and delivery of product is defined in the Process Control and In-Process and Final Inspection procedures.

References:

2.4.04.001	Design Control
2.4.09.001	Process Control
2.4.10.001	In-Process & Final Inspection
2.4.11.001	Control of IMTE

Records:

4.4.09.003	Equipment Maint. Record
4.4.11.003	Calibration Record
Job Packet	

7.5.2 Validation of Processes for Production and Service Provision

The companies validate any processes for production 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 has been delivered.

Validation demonstrates the ability of these processes to achieve planned results. The companies establish arrangements for these processes including, as applicable,

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records (see 4,2,4),

e) revalidation.

Items (a) through (e) are covered in referenced procedures.

References:

2.4.04.001 Design Control
2.4.09.001 Process Control
2.4.10.002 In-Process and Final Inspection & Test
4.4.16.001 Quality Records Master List

Records:

Job Packet

7.5.3 Identification and Traceability

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

Product is normally identified by the use of move tickets or other suitable identifiers.

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

Product identification of inspection and/or test status is normally documented on the product and/or in the job packet or any other approved document as defined.

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

Traceability, when required, is defined in referenced procedures.

References:

2.4.08.001 Product Identification & Traceability
2.4.09.001 Process Control
2.4.12.001 Inspection and Test Status
4.4.16.001 Quality Records Master List

Records:

4.4.08.001 Move Tickets
Job Packet

7.5.4 Customer Property

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

NOTE: Customer property may include intellectual property.

Customer IMTE and equipment is handled in the same way the companies IMTE and equipment is handled as defined in procedures.

Customer material/product is handled and controlled in the same way as any other material or product is handled within the companies as defined in procedures.

References:

2.4.06.001 Material Procurement
2.4.08.001 Product Identification & Traceability
2.4.09.001 Process Control
2.4.11.001 Control of IMTE

Records:

4.4.08.001 Move Tickets
4.4.11.003 Calibration Record
Job Packet

7.5.5 Preservation of Product

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

References:

2.4.15.001 Handling, Storage, Packaging, Preservation & Delivery

7.6 Control of Monitoring and Measuring Equipment

The companies have determined the monitoring and measurements to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements (see 7.2.1). Note: For th epurposes of clarity, the terms ***equipment*** and ***devices*** may be used interchangeably in accompanying procedures, work instructions and records.

Requirements are identified in the job packet or left to the experience of the test manager or technicians to determine test equipment requirements when not defined in the job packet.

The companies have established processes to ensure that monitoring and measurement can be carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment

a) is calibrated, 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,

The calibration process is defined in procedures. Calibration records exists for all IMTE.

b) is adjusted or re-adjusted as necessary,

Instrument adjustments are normally accomplished by using an outside calibration service. When equipment is adjusted in-house, procedures define the processes.

c) has identification in order to determine its calibration status,

Calibration labels or other means identify the status of the equipment.

d) is safeguarded from adjustment that would invalidate the measurement result,

When possible, stickers are placed over adjustment areas to prevent movement as defined in procedures.

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

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

Procedures define the process for calibrating out of calibration equipment.

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.

Computer software is verified before use as defined in procedures.

NOTE: Confirmation of the ability of computer software to satisfy the intended application typically includes its verification and configuration management to maintain is suitability for use.

References:

2.4.09.001	Process Control
2.4.10.002	In-Process/Final Inspection & Test
2.4.11.001	Control of IMTE
4.4.16.001	Quality Records Master List

Records:

4.4.11.003	IMTE Records
4.4.11.004	Calibration Label
Job Packet	

8. Measurement, Analysis and Improvement

8.1 General

The companies have planned and implemented the monitoring, measurement, analysis, and improvement processes needed

a) to demonstrate conformity to product requirements,

Demonstrating conformity of product is accomplished through the use of the appropriate sections of the job packet.

b) to ensure conformity of the quality management system,

Ensuring the conformity of the quality management system is accomplished by the internal audit and corrective/preventive action processes and actions of the Quality Steering Committee.

c) to continually improve the effectiveness of the quality management system.

The methods for improving the effectiveness of the quality management system are defined in procedures in the management review process.

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

References:

2.4.01.001	Management Practices
2.4.09.001	Process Control
2.4.14.001	Corrective Action
2.4.14.002	Preventive Action
4.4.01.013	Strategic Quality Plan
4.4.16.001	Quality Records Master List

Records:

4.4.01.001	Management Review Agenda
4.4.13.002	Error/data Form
4.4.14.001	Corrective Action Form
4.4.17.001	Audit Schedule

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

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

Customer satisfaction information is collected by various departments and reviewed by the QSC.

References:

2.4.01.001	Management Practices
4.4.01.013	Strategic Quality Plan

Records:

4.4.01.001	Management Review Agenda
4.4.01.020	Cust. Survey
4.4.03.008	Cust. Complaint Log
	Management Review Minutes

8.2.2 Internal audit

The companies conduct periodic internal audits at planned intervals to determine whether the quality management system

a) conforms to planned arrangements (see 7.1), to the requirements of this Quality Manual, and to the quality management system requirements established by the companies, and

b) is effectively implemented and maintained.

An audit program is implemented, that 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 conducts of audits ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.

Audits are scheduled throughout the year, but the schedule is amended if a situation arises. The schedule takes into consideration the importance of the areas audited and is noted on the schedule form. Auditors are trained and scheduled to audit areas for which they are not directly responsible.

A documented procedure has been established defining the responsibilities and requirements for planning and conducting internal 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 includes the verification of the actions taken and the reporting of verification results (see 8.5.2).

The corrective action process is part of the internal audit process. Corrective actions are defined in the corrective action procedure and in the internal audit procedure. Follow-up activities are part of the corrective action system, and the results are reported to management in

management review meetings.

NOTE: See ISO 19011 for guidance.

References:		Records:	
2.4.01.001	Management Practices 4.4.01.001	Mgmt. Review Agenda	
2.4.14.001	Corrective Action Process	4.4.14.001	Correction Action Form
2.4.14.002	Preventive Action Process	4.4.17.001	Audit Schedule
2.4.17.001	Internal Quality Audits	4.4.17.008	Audit Follow-up Form

8.2.3 Monitoring and Measurement of Processes

The companies apply 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 actions are taken, as appropriate, to ensure conformity of the product.

An error data collection process and internal audits are used as methods for monitoring realization processes.

References:		Records:	
2.4.09.001	Process Control	4.4.01.001	Management. Review Agenda
2.4.14.001	Corrective Action Process	4.4.13.002	Error/data Collection Form
2.4.14.002	Preventive Action Process	4.4.14.001	Corrective Action Form
		4.4.17.001	Audit Schedule

8.2.4 Monitoring and Measurement of Product

The companies monitor and measure 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 the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria is maintained.

In-process inspection and testing is performed as defined in the job packet and deficiencies are recorded on an error data collection form for analysis after job completion.

Records indicate the person(s) authorizing release of product (see 4.2.4).

Evidence of conformity is normally noted by the use of controlled stamps, labels or other identifiers issued to authorized personnel and documented in the appropriate area of the job packet or on the product.

Product release and delivery does not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by an authorized authority and, where applicable, by the customer.

No product is dispatched until final inspection personnel verify that all inspections, tests, and documents have been completed.

References:

2.4.09.001	Process Control
2.4.10.002	In-Process/Final Inspection & Test
2.4.12.001	Inspection and Test Status

Records:

4.4.01.001	Management Review Agenda
4.4.13.001	Error/data Collection
Job Packet	

8.3 Control of Nonconforming Product

The companies ensure that product which does not conform to product requirements is identified and controlled to prevent unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in documented procedures.

The nonconforming process is defined and nonconforming product is identified with a red tag or other suitable identifier and placed in the nonconforming cage or designated area. The responsibilities and authorities for dealing with nonconforming processes are defined in procedures.

Where applicable, the companies deal with nonconforming product by one or more of the following ways

a) by taking action to eliminate the detected nonconformity,

Nonconformities are reviewed and dispositioned as defined in procedures.

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer,

Release, use, or acceptance of nonconforming product is determined by authorized personnel as defined in procedures.

c) by taking action to preclude its original intended use or application.

Actions taken to preclude original use or application are authorized by approval of the engineering department or by personnel trained to make these decisions.

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 the product is subject to re-verification to demonstrate conformity to the requirements.

Product that has been reworked is re-inspected and/or re-tested depending on the manufacturing stage at which the nonconformance was identified.

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

References:

2.4.04.003	Engineering Change Notice Form
2.4.10.002	In-Process/Final Inspection & Test
2.4.13.001	Control of Nonconforming Material

Records:

4.4.01.001	Mgmt. Review Agenda
4.4.13.001	Nonconforming Form
4.4.13.003	Nonconforming "Red" Tag Job Packet

8.4 Analysis of Data

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

The analyses of data provides information relating to

a) customer satisfaction; (see 8.2.1),

b) conformity to product requirements (8.2.4),

c) characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4),

Customer satisfaction data, test data, and error data are analyzed to determine whether preventive or corrective actions are required.

d) suppliers (see 7.4).

Supplier performance and delivery data is analyzed by receiving inspection and purchasing personnel and reviewed by the Quality Steering Committee for possible corrective/preventive action.

References:

2.4.06.001	Material Procurement
2.4.09.001	Process Control
2.4.10.001	Receiving Inspection
2.4.13.001	Control of Nonconforming Material/Processes
4.4.01.013	Strategic Quality Plan

Records:

4.4.01.001	Management Review Agenda.
4.4.10.001	Receiving Inspection Form
4.4.13.002	Error/data Form
4.4.14.001	Preventive Action Form

8.5 Improvement

8.5.1 Continual Improvement

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

Through management reviews, the effectiveness of the quality management system is monitored for continual improvement opportunities.

References:

2.4.01.001	Management Practices
4.4.01.013	Strategic Quality Planning

Records:

4.4.01.001	Mgmt. Review Agenda
4.4.14.001	Corrective Action Form
4.4.17.001	Audit Schedule

8.5.2 Corrective Action

The companies take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective action is appropriate to the effects of the nonconformities encountered.

A documented procedure has been established to define requirements for

a) reviewing nonconformities (including customer complaints),

Nonconformities and customer complaints are collected, analyzed, documented and reviewed by management for appropriate action.

b) determining the causes of nonconformity,

Causes of nonconformities are determined through the corrective action process.

c) evaluating the need for actions to ensure that nonconformities do not recur,

Corrective actions are reviewed by the Director of Quality and the QSC to determine whether or not the action taken is adequate to prevent any chance of recurrence.

d) determining and implementing action needed,

The director of the area where the nonconformity was identified, determines and implements the necessary corrective actions.

e) records of the results of actions taken, and

The records of actions taken are documented on the corrective action form.

f) reviewing the effectiveness of the corrective action taken.

All corrective and follow-up actions are reviewed by the management review process.

References:

2.4.01.001	Management Practices
2.4.13.001	Control of NCMP
2.4.14.001	Corrective Action Process
2.4.14.002	Preventive Action Process
2.4.14.003	8D Corrective Action Process
2.4.14.004	8D Preventive Action Process

Records:

4.4.01.001	Mgmt. Review Agenda
4.4.03.008	Customer Complaints
4.4.13.006	CAR/PAR 8D Report
4.4.14.001	Corrective Action Form
4.4.14.006	Corrective Action Follow-up Form
4.4.16.001	Quality Records Master List

8.5.3 Preventive Action

The companies determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions taken are appropriate to address 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 the 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 the preventive action taken.

The preventive action system is structured and performs similarly to the corrective action process. Investigation, implementation, review and documentation is handled the same as corrective actions.

References:

2.4.01.001	Management Practices
2.4.13.001	Control of Nonconforming Material
2.4.14.001	Corrective Action Process
2.4.14.002	Preventive Action Process
2.4.14.004	8D Preventive Action Process

Records:

4.4.01.001	Mgmt. Review Form
4.4.14.001	Prevent Action Form
4.4.13.006	CAR/PAR 8D Report
4.4.16.001	Quality Records Master List