Quality Management System Manual

Revision Record

Date	Description	Change Request Reference
8/7/01	Initial release	----------

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1. Introduction

This Quality Management System Manual (QMSM) defines the policies, objectives, responsibilities, and requirements for the organization's quality management system. The QMSM defines the quality management system (QMS) which:

- Establishes the framework for providing outstanding value to customer through process improvement, increasing quality, and productivity
- Authorizes and governs the creation and implementation of subsidiary quality-related documentation
- Provides direction to personnel in defining and implementing effective, flexible, and compliant quality plans and procedures
- Provides evidence to customers, suppliers, and employees commitment to establishing and maintaining practices that maximize product and process quality
- Establishes the benchmark/criteria for measuring progress and improvement
- Emphasizes prevention over detection.

Figure 1 shows the quality management system organization including top management responsibilities for the specific sections of this QMSM. All personnel within the organization are responsible for implementing QMSM policies and requirements as they pertain to them. The QMSM includes the quality system process policies, requirements, and procedure references. The QMSM is divided into the following sections:

- **Section 1** (*Introduction*) provides an introduction to the QMSM including its purpose and section overview
- **Section 2** (*References*) identifies external and organizational documents used to develop and support implementation of the QMSM
- **Section 3** (*Quality Policy and Objectives*) defines the organization's quality policy and specific, measurable quality objectives
- **Sections 4 through 8** include specific quality management system policies, responsibilities, requirements, and implementation procedure references
- **Annex A** (*Traceability Matrix*) includes an ISO 9001 to QMSM traceability table.

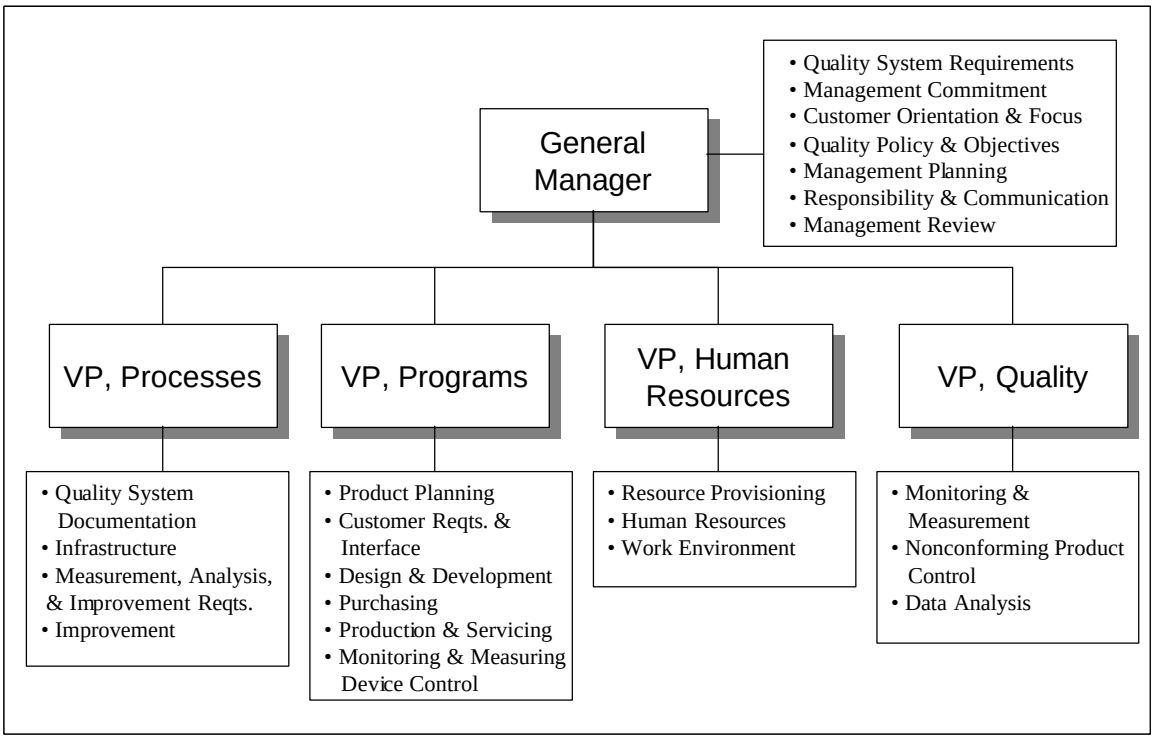

Figure 1. Quality Management System Organization

The Vice President, Processes, has overall responsibility for establishing and maintaining the QMSM.

Figure 2 shows the interrelationships (interfaces) between the quality management system process components.

Quality Management System	Management policies, requirements, and procedures	Resource management policies, requirements, and procedures	Product realization policies, requirements, and procedures	Measurement, analysis, & improvement policies, reqts., procedures
Management responsibility process performance Improvement opportunities	Management Responsibility	Budget Management review & oversight	Budget Management review & oversight Customer surveys	Customer survey data Management review & progress data
Resource mgmt. process performance Improvement opportunities	Staffing status Training status Work environment status	Resource Management	Work conditions Assets and tools Capable staff	Training performance data Staffing data
Product realization process performance Improvement opportunities	Quality products Product lifecycle status	Training feedback Staffing needs Resource needs Best practices	Product Realization	Product lifecycle implementation data Product defect data
Quality system process performance Corrective actions Improvement opportunities	Customer satisfaction levels Management effectiveness Corrective actions Improvement opportunities	Training program effectiveness Staff trends Corrective actions Improvement opportunities	Product & process performance Corrective actions Improvement opportunities	Measurement, Analysis, & Improvement

Figure 2. Quality Management System Interrelationships

2. References

The following references were used to support the development of the Quality Management System Manual. These references support the establishment, maintenance, and implementation of the quality management system.

External References:

ANSI/ISO/ASQ Q9001-2000 Quality Management Systems - Requirements	December 2000

Company References:

<Identify specific company references>	*<Date>*

3. Quality Policy and Objectives

Quality Policy

Quality is integral to everything we do. We continuously seek ways to improve our processes and products. Quality is everyone's responsibility. We meet customer requirements and provide both employee and customer satisfaction in the performance of our work while offering the best value, quality, and service.

Quality Objectives

Quality objectives are defined and measured continuously in the improvement of the quality management system. Quality objectives for the organization include continuous improvement in:

- Process cycle time
- Productivity
- Product defect rate
- Customer satisfaction
- Estimating schedule and effort.

The General Manager is responsible for defining and maintaining quality policy and objectives.

4. Quality Management System

The quality management system (QMS) defines the processes needed to ensure the quality of products and to continuously improve. QMS overall and documentation requirements are specified in the following sections.

Section	QMS Requirement
4.1	Quality System Requirements
4.2	Quality System Documentation

4.1 Quality System Requirements

Policy:

Quality management system processes are defined including their interfaces, controls, and monitoring, measurement, and analysis methods.

Responsibility:

The General Manager is responsible for defining and maintaining quality system requirements policy, requirements, and procedure.

Requirements:

The organization establishes, documents, implements, and maintains a quality management system and continually improves its effectiveness.

The organization:

a. Identifies the processes needed for the quality management system and their application throughout the organization
b. Determines the sequence and interaction of these processes
c. Determines criteria and methods needed to ensure that both the operation and control of these processes are effective
d. Ensures the availability of resources and information necessary to support the operation and monitoring of these processes
e. Monitors, measures, and analyses these processes
f. Implements actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed by the organization in accordance with the requirements defined in this manual.

When any process is outsourced that affects product conformity to requirements, the organization ensures control over such processes. The control of such outsourced processes is identified within the quality management system.

Procedure References:

- Quality Management System

4.2 Quality System Documentation

Policy:

Quality system documentation provides the direction and instructions for implementing, controlling, and improving quality management system processes and recording results.

Responsibility:

The Vice President, Processes, is responsible for defining and maintaining quality system documentation policy, requirements, and procedures.

Requirements:

4.2.1 General Requirements

The quality management system includes:

a. Documented statements of a quality policy and quality objectives
b. A quality manual
c. Documented procedures as identified in this manual
d. Documents needed by the organization to ensure the effective planning, operation and control of its processes
e. Records defined in this manual and referenced procedures.

4.2.2 Quality Manual

The organization establishes and maintains a quality manual that includes:

a. The scope of the quality management system
b. Reference to the documented procedures established for the quality management system
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.

A documented procedure is established to define the controls needed:

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

4.2.4 Control of Records

Records 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 records.

Procedure References:

- Quality Management System Manual
- Quality Management System Procedures
- Document Control
- Quality Records

5. Management Responsibility

The quality management system (QMS) defines the mechanisms and methods for management involvement, review, and direction. Specific QMS requirements for management responsibility are specified in the following sections.

Section	QMS Requirement
5.1	Management Commitment
5.2	Customer Orientation and Focus
5.3	Quality Policy and Objectives
5.4	Management Planning
5.5	Responsibility and Communication
5.6	Management Review

5.1 Management Commitment

Policy:

Senior management ensures quality management system establishment, implementation, and improvement.

Responsibility:

The General Manager is responsible for defining and maintaining management commitment policy, requirements, and procedure.

Requirements:

Senior management provides evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

a. Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements

b. Establishing the quality policy

c. Ensuring that quality objectives are established

d. Conducting management reviews

e. Ensuring the availability of resources.

Procedure References:

- Management Commitment

5.2 Customer Orientation and Focus

Policy:

Customer requirements are determined and met.

Responsibility:

The General Manager is responsible for defining and maintaining customer orientation and focus policy, requirements, and procedure.

Requirements:

Senior management ensures customer requirements are defined, understood, and are met with the purpose of enhancing customer satisfaction.

Procedure References:

- Customer Orientation and Focus

5.3 Quality Policy and Objectives

Policy:

Quality policy and objectives provide the overall intentions and direction for the quality management system.

Responsibility:

The General Manager is responsible for defining and maintaining the quality policy and objectives.

Requirements:

Senior management ensures that the quality policy:

a. Is appropriate to the business needs of the organization

b. Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system

c. Provides a framework for establishing and reviewing quality objectives

d. Is communicated and understood within the organization

e. Is reviewed for continued suitability.

Procedure References:

No specific procedure. Quality policy and objectives are included in section 3 of this manual.

5.4 Management Planning

Policy:

Management planning provides the roadmap for implementing, controlling, directing, and improving the quality management system.

Responsibility:

The General Manager is responsible for defining and maintaining management planning policy, requirements, and procedure.

Requirements:

5.4.1 Quality Objectives

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

5.4.2 Quality management system planning

Senior management ensures that:

a. The planning of the quality management system is carried out in order to meet quality system requirements as well as the quality objectives

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

Procedure References:

- Quality Management System Planning

5.5 Responsibility and Communication

Policy:

Quality management system roles are defined and status communicated.

Responsibility:

The General Manager is responsible for defining and maintaining responsibility and communication policy, requirements, and procedure.

Requirements:

5.5.1 Responsibility and Authority

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

5.5.2 Management Representative

Senior management appoints a member of management who, irrespective of other responsibilities, has responsibility and authority to:

a. Ensure that processes needed for the quality management system are established, implemented, and maintained
b. Report to senior management on the performance of the quality management system and any need for improvement
c. Ensure the promotion of awareness of customer requirements throughout the organization.

5.5.3 Internal Communication

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

Procedure References:

- Responsibility and Communication

5.6 Management Review

Policy:

Senior management provides quality management system oversight and direction.

Responsibility:

The General Manager is responsible for defining and maintaining management review policy, requirements, and procedure.

Requirements:

5.6.1 General Requirements

Senior management reviews the organization's quality management system, at planned intervals, to ensure continuing suitability, adequacy, and effectiveness. Management review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and objectives.

Records from management reviews are maintained.

5.6.2 Review Input

Input to the management review include the following information:

a. Audit results
b. Customer feedback
c. Process performance and product conformity
d. Corrective and preventive action status
e. Previous management review follow-up actions
f. Changes that could impact the quality management system
g. Recommendations for improvement.

5.6.3 Review Output

Output from the management review include any decisions and actions relating to:

a. Improvement of the effectiveness of the quality management system and its processes
b. Improvement of product related to customer requirements

c. Resource needs.

Procedure References:

- Management Review

6. Resource Management

The quality management system (QMS) defines the mechanisms and methods for managing its resources, environment, and infrastructure. Specific QMS requirements for resource management are specified in the following sections.

Section	QMS Requirement
6.1	Resource Provisioning
6.2	Human Resources
6.3	Infrastructure
6.4	Work Environment

6.1 Resource Provisioning

Policy:

Personnel have the resources to effectively implement, maintain, and improve the quality management system and to satisfy customer needs and requirements.

Responsibility:

The Vice President, Human Resources, is responsible for defining and maintaining resource provisioning policy and requirements.

Requirements:

The organization determines and provides the resources needed:

a. To implement and maintain the quality management system and continually improve its effectiveness
b. To enhance customer satisfaction by meeting customer requirements.

Procedure References:

No specific procedure.

6.2 Human Resources

Policy:

Personnel performing work that affects product quality are competent.

Responsibility:

The Vice President, Human Resources, is responsible for defining and maintaining human resources policy, requirements, and procedures.

Requirements:

6.2.1 General Requirements

Personnel performing work that affects the quality of products are competent based on the appropriate education, training, skills, and experience.

6.2.2 Competence, Awareness, and Training

The organization:

a. Determines the necessary competence requirements for personnel performing work affecting product quality
b. Provides training or takes other actions to satisfy these needs
c. Evaluates the effectiveness of training and other actions taken
d. Ensures that its personnel are aware of the relevance and importance of their activities and their contribution to achieving the quality objectives
e. Maintains appropriate records of education, training, skills, and experience.

Procedure References:

- Human Resource Management
- Training

6.3 Infrastructure

Policy:

The infrastructure provides the facilities, equipment, and services needed to operate the quality management system.

Responsibility:

The Vice President, Processes, is responsible for defining and maintaining infrastructure policy, requirements, and procedure.

Requirements:

The organization determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements including, as applicable:

a. Building, workspace, and associated utilities
b. Process equipment (both hardware and software) and assets
c. Supporting services (intranet, e-mail).

Procedure References:

- Infrastructure

6.4 Work Environment

Policy:

The work environment provides the working conditions conducive to achieving conformity to product requirements.

Responsibility:

The Vice President, Human Resources, is responsible for defining and maintaining work environment policy, requirements, and implementation procedure.

Requirements:

The organization determines and manages the working conditions needed to achieve conformity to product requirements considering physical, social, psychological, and environmental factors, as applicable.

Procedure References:

- Work Environment

7. Product Realization

The quality management system (QMS) defines the mechanisms and methods for controlling product realization processes throughout the product lifecycle. Specific QMS requirements for product realization are specified in the following sections.

Section	QMS Requirement
7.1	Product Planning
7.2	Customer Requirements and Interface
7.3	Design and Development
7.4	Purchasing
7.5	Production and Servicing
7.6	Monitoring and Measuring Device Control

7.1 Product Planning

Policy:

Product planning provides the roadmap for realizing the product consistent with customer requirements.

Responsibility:

The Vice President, Programs, is responsible for defining and maintaining product planning policy, requirements, and implementation procedure.

Requirements:

The organization plans and establishes the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system and is agreed to by affected functions including QA.

Product planning determines the following, as appropriate:

a. Quality objectives and requirements for the product
b. The need to establish processes, develop documents, and provide resources specific to the product to support its total lifecycle
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.

Planning output is in a form suitable for the organization's method of operations and consistent with customer requirements, as applicable. Planning output includes a product schedule, estimates, implementation procedures, product acceptance criteria, and required resources/documentation.

Procedure References:

- Product Planning

7.2 Customer Requirements and Interface

Policy:

Customer-related processes provide requirements determination and review and communication.

Responsibility:

The Vice President, Programs, is responsible for defining and maintaining customer requirements and interface policy, requirements, and procedure.

Requirements:

7.2.1 Determination of Requirements Related to the Product

The organization determines:

a. Requirements specified by the customer, including 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
d. Any additional requirements determined by the organization.

7.2.2 Review of Requirements Related to the Product

The organization reviews the requirements related to the product. This review is conducted prior to the organization's commitment to supply a product to the customer (e.g., submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) to ensure that:

a. Product requirements are defined
b. Contract or order requirements differing from those previously expressed are resolved
c. The organization has the ability to meet the defined requirements.

Records of the results of the review actions arising from the review are maintained.

Where the customer does not provide a documented statement of requirements, the customer requirements are confirmed by the organization before acceptance.

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

7.2.3 Customer Communication

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

a. Product information
b. Enquiries, contracts or order handling, including amendments
c. Customer feedback, including customer complaints.

Procedure References:

- Customer Requirements and Interface

7.3 Design and Development

Policy:

Design and development defines how the product is built, integrated, tested, reviewed, and updated.

Responsibility:

The Vice President, Programs, is responsible for defining and maintaining design and development policy, requirements, and procedures.

Requirements:

7.3.1 Design and Development Planning

The organization plans and controls the design and development of product.

During the design and development planning, the organization determines:

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

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

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

7.3.2 Design and Development Inputs

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

a. Functional and performance requirements
b. Applicable statutory and regulatory requirements
c. Information derived from previous similar designs, where applicable
d. Other requirements essential for design and development.

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

7.3.3 Design and Development Outputs

The outputs of design and development are 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 input requirements for design and development
b. Provide appropriate information for purchasing, production, and for service provision
c. Contain or reference product acceptance criteria
d. Specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and Development Review

Systematic reviews of design and development are performed in accordance with planned arrangements at suitable stages to:

a. Evaluate the ability of the results of design and development to meet requirements
b. 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.

7.3.5 Design and Development Verification

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

7.3.6 Design and Development Validation

Design and development validation is performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specific application or intended use, where known. Where practicable, validation

is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

7.3.7 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.

Procedure References:

- Product Planning
- Design
- Implementation
- Integration
- Acceptance
- Peer Review
- Technical Review
- Design and Development Changes

7.4 Purchasing

Policy:

Suppliers are managed through selection, communication, monitoring, and product verification.

Responsibility:

The Vice President, Programs, is responsible for defining and maintaining purchasing policy, requirements, and procedure.

Requirements:

7.4.1 Purchasing Process

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

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

7.4.2 Purchasing Information

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

a. Requirements for approval of product, procedures, processes, and equipment
b. Requirements for qualification of personnel
c. Quality management system requirements.

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

7.4.3 Verification of Purchased Product

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

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

Procedure References:

- Supplier Management

7.5 Production and Servicing

Policy:

Production and servicing include controls for product identification, handling, storage, delivery, operations, maintenance, and customer property.

Responsibility:

The Vice President, Programs, is responsible for defining and maintaining production and servicing policy, requirements, and procedures.

Requirements:

7.5.1 Control of Production and Service Provision

The organization plans and carries out production and service provision under controlled conditions that 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
f. The implementation of release, delivery, and post delivery activities.

7.5.2 Validation of Processes for Production and Service Provision

The organization validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring and 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.

The organization 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

e. Revalidation.

7.5.3 Identification and Traceability

The organization identifies the product by suitable means throughout product realization, where applicable.

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

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

7.5.4 Customer Property

The organization exercises care with customer property while it is under the organization's control or being used by the organization. The organization identifies, verifies, protects, and safeguards customer property provided for use or incorporation into the product. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, it is reported to the customer and records maintained.

7.5.5 Preservation of Product

The organization preserves the 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.

Procedure References:

- Production
- Servicing
- Product Identification and Traceability
- Customer Property
- Handling and Delivery

7.6 Monitoring & Measuring Device Control

Policy:

Monitoring and measuring devices used to demonstrate product conformity are controlled.

Responsibility:

The Vice President, Programs, is responsible for defining and maintaining monitoring and measuring device control policy, requirements, and procedure.

Requirements:

The organization determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

The organization establishes processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

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 is recorded
b. Adjusted or readjusted as necessary
c. Identified to enable the calibration status to be determined
d. Safeguarded from adjustment that would invalidate the measurement result
e. Protected from damage and deterioration during handling, maintenance, and storage.

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

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

Procedure References:

- Monitoring & Measuring Device Control

8. Measurement, Analysis, and Improvement

The quality management system (QMS) defines the mechanism and methods for measuring its processes and products, analyzing performance, and continuously improving its effectiveness. Specific QMS requirements for measurement, analysis, and improvement are specified in the following sections.

Section	QMS Requirement
8.1	Measurement, Analysis, & Improvement Requirements
8.2	Monitoring and Measurement
8.3	Nonconforming Product Control
8.4	Data Analysis
8.5	Improvement

8.1 Measurement, Analysis, & Improvement Requirements

Policy:

Measurement, analysis, and improvement processes ensure product conformity and process effectiveness and improvement.

Responsibility:

The Vice President, Processes, is responsible for defining and maintaining overall measurement, analysis, and improvement policy and requirements.

Requirements:

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

a. To demonstrate conformity of the product
b. To ensure conformity of the quality management system
c. To continually improve the effectiveness of the quality management system.

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

Procedure References:

No specific procedure.

8.2 Monitoring and Measurement

Policy:

Monitoring and measurement ensure product conformity to requirements and process compliance to plans and effectiveness.

Responsibility:

The Vice President, Quality, is responsible for defining and maintaining monitoring and measurement policy, requirements, and procedures.

Requirements:

8.2.1 Customer Satisfaction

The organization monitors information relating to customer perception as to whether the organization has met customer requirements as one of the measurements of the performance of the quality management system. Methods for obtaining and using this information are defined.

8.2.2 Internal Audit

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

a. Conforms to the planned arrangement and to the quality management system requirements established by the organization
b. Is effectively implemented and maintained.

The audit program is planned and takes into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods are defined. Selection of auditors and conduct of audits ensure 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 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.

8.2.3 Monitoring and Measurement of Processes

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

8.2.4 Monitoring and Measurement of Product

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

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

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

Procedure References:

- Customer Satisfaction
- Internal Quality Audits
- Monitoring and Measurement

8.3 Nonconforming Product Control

Policy:

Nonconforming product is prevented from unintended use and integration.

Responsibility:

The Vice President, Quality, is responsible for defining and maintaining nonconforming product control policy, requirements, and procedure.

Requirements:

The organization ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming products are defined in a documented procedure.

The organization 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.

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 begun, the organization takes action appropriate to the effects, or potential effects, of the nonconformity.

Procedure References:

- Nonconforming Product Control

8.4 Data Analysis

Policy:

Data analysis identifies quality system status, trends, and improvement opportunities.

Responsibility:

The Vice President, Quality, is responsible for defining and maintaining data analysis policy, requirements, and procedure.

Requirements:

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

The analysis of data provides information relating to:

a. Customer satisfaction
b. Conformity to product requirements
c. Characteristics and trends of processes and products including opportunities for preventive action
d. Suppliers.

Procedure References:

- Quality Data Analysis

8.5 Improvement

Policy:

Improvement ensures effective corrective action and the implementation of preventive action to continuously improve the quality management system.

Responsibility:

The Vice President, Processes, is responsible for defining and maintaining improvement policy, requirements, and procedures.

Requirements:

8.5.1 Continual Improvement

The organization continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective Action

The organization takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective action is 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 action to ensure that nonconformities do not recur
d. Determining and implementing action needed
e. Recording the results of action taken
f. Reviewing corrective action taken.

8.5.3 Preventive Action

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

A documented procedure 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. Recording the results of action taken
e. Reviewing preventive action taken.

Procedure References:

- Corrective and Preventive Action
- Improvement

Annex A: Traceability Matrix

ISO 9001:2000		Quality Management System Manual	
Section	**Requirement**	**Section**	**Requirement**
4.	Quality Management System	4.	Quality Management System
4.1	General Requirements	4.1	Quality System Requirements
4.2	Documentation Requirements	4.2	Quality System Documentation
5.	Management Responsibility	5.	Management Responsibility
5.1	Management Commitment	5.1	Management Commitment
5.2	Customer Focus	5.2	Customer Orientation & Focus
5.3	Quality Policy	5.3	Quality Policy & Objectives
5.4	Planning	5.4	Management Planning
5.5	Responsibility, Authority, and Communication	5.5	Responsibility and Communication
5.6	Management Review	5.6	Management Review
6.	Resource Management	6.	Resource Management
6.1	Provision of Resources	6.1	Resource Provisioning
6.2	Human Resources	6.2	Human Resources
6.3	Infrastructure	6.3	Infrastructure
6.4	Work Environment	6.4	Work Environment
7.	Product Realization	7.	Product Realization
7.1	Planning of Product Realization	7.1	Product Planning
7.2	Customer-Related Processes	7.2	Customer Requirements & Interface
7.3	Design and Development	7.3	Design and Development
7.4	Purchasing	7.4	Purchasing
7.5	Production and Service Provision	7.5	Production and Servicing
7.6	Control of Monitoring and Measuring Devices	7.6	Monitoring and Measuring Device Control
8.	Measurement, Analysis, and Improvement	8.	Measurement, Analysis, and Improvement
8.1	General	8.1	Measurement, Analysis, & Improvement Requirements
8.2	Monitoring and Measurement	8.2	Monitoring and Measurement
8.3	Control of Nonconforming Product	8.3	Nonconforming Product Control
8.4	Analysis of Data	8.4	Data Analysis
8.5	Improvement	8.5	Improvement