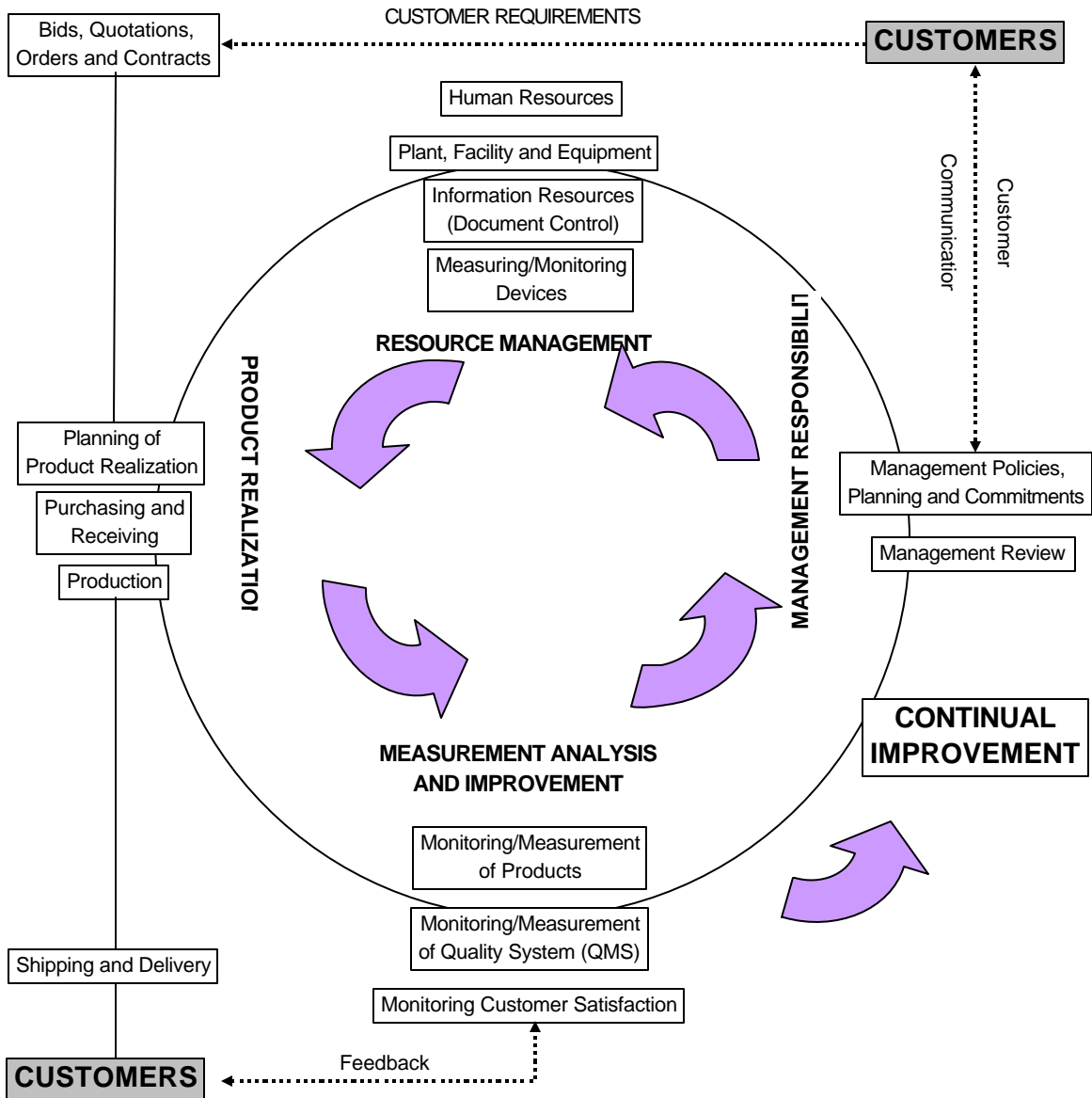


4.0 - QUALITY MANAGEMENT SYSTEMS

Section Description

4.1 Quality System Processes

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1.0 Process Approach

1.1 The quality management system is designed as a system of interrelated processes. All main activities in the company are defined as Quality System Processes (QSPs) and are grouped into the following six categories (refer to the diagram at the top of this section):

Customer Requirements,

Product Realization,

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Measurement, Analysis and Improvement,

Management Responsibility,

Resource Management, and

Continual Improvement,

And are organized into a Plan-Do-Check-Act loop.

1.2 The sequence and interrelation between the six groups and individual QSPs are illustrated in a diagram at the beginning of this section (Quality System Processes Diagram). Every QSP is further defined in process sheets at the end of this section (Quality System Processes Sheets).

1.3 QSPs and their sub-processes are documented in this quality manual and in associated operational procedures and work instructions. The documentation defines these quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.

1.4 Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

1.5 Quality Manual Section 4.2 and the corresponding Operational Procedure QOP-04-01, Quality System Documentation, explain in more detail how quality system processes are defined and documented.

2.0 Resources and Information

Quality Assurance manager is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to the top management. The top management is responsible for ensuring the availability of necessary resources and information. Quality Manual Section 6.1, Provision of Resources, explains in more detail how resource requirements are identified and satisfied.

3.0 Monitoring and Measurement

3.1 Performance of quality system processes is systematically monitored and measured. This is to ensure their effectiveness and identify opportunities for improvement.

3.2 Performance of quality system processes is monitored through internal quality audits (refer to Quality Manual Section 8.2 and Operational Procedure QOP-82-02, Internal Quality Audits). The overall performance of the quality system is monitored by measuring customer satisfaction (refer to Quality Manual Section 8.2 and Operational Procedure QOP-82-01, Customer Satisfaction).

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3.3 Quality system processes are reviewed and analyzed by the management review of the quality system (refer to Quality Manual Section 5.6 and Operational Procedure QOP-56-01, Management Review).

4.0 Continual Improvement

4.1 Quality management system processes are regularly reviewed by the top management to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and through quality objectives.

4.2 Quality Manual Section 8.5 and Operational Procedures QOP-56-01, Management Review, QOP-54-01, Quality Objectives, and QOP-85-03, Corrective and Preventive Actions, define how the quality management system itself ensures its own compliance and continual improvement.

5.0 Sub-Contracted Processes

5.1 When processes that affect product conformity are outsourced, special controls are implemented to ensure that these processes meet specified requirements. Such controls may include, as appropriate:

Evaluation and pre-qualification of suppliers;

Assessment of supplier realization processes and quality system;

Flow-down of customer (contract) requirements,

Monitoring of supplier quality performance;

Requirements for process control, inspection, testing or other records demonstrating product conformity; and

Verification of the supplied product.

Quality Manual Section 7.4 and Operational Procedures QOP 74-01, Supplier Evaluation, QOP-74-02, Purchasing, and QOP-74-03, Verification of Purchased Product, define such purchasing control system.

5.2 Ensuring control over outsourced processes does not absolve AAA Inc. of the responsibility of conformity to all customer requirements.

6.0 Revision History

A --- 01/1/04 --- New

END OF SECTION

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4.2 Documentation and Records

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General Policy

Scope of the quality system documentation is defined. Establishment and revision of documents, and their distribution, are controlled. New documents and revisions are reviewed and approved prior to issue; and are identified with respect to their revision level. Appropriate documents are available at locations where they are used. Obsolete documents are removed from points of use. Documents of external origin are identified and their distribution is controlled.

Quality records are identified and indexed to facilitate their retrieval, and are stored in a suitable environment to minimize deterioration. Quality records are retained for a period of time at least equivalent to the lifetime of the product.

1.0 Scope

1.1 [Company Name]'s quality system documentation comprises the following types of documents:

Quality manual (including a documented quality policy);

Documented statements of quality objectives

Operational procedures;

Work instructions;

Standards and other technical reference materials;

Engineering documents, including drawings, specifications, procedures, and other documents defining products;

Customer engineering documents;

Product realization and control plans.

Purpose, scope, and responsibility for controlling various types of documents are defined in Operational Procedure QOP-42-01, Quality System Documentation.

2.0 Quality Manual

2.1 The top level document defining the overall quality management system is the Quality Manual. It includes:

The scope of the quality system, including details of and justification for any exclusions (refer to Section 0.3);

Description of quality system processes, their sequence, and interrelation; and

References to documented procedures;

3.0 Document Control

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- 3.1 [Company Name] is gradually transitioning from paper to electronic documentation. As this transition progresses, new categories of documents are transferred from paper to electronic document control system. Both systems are currently used, and are defined in Procedure QOP-42-02, Control of Documents.
- 3.2 New documents and document changes may be initiated by anyone in the organization, but may only be issued by an authorized function. The authorized functions and the rules governing the issue of documents are defined in procedures QOP-42-01, Quality System Documentation, and QOP-42-02, Control of Documents. All documents are reviewed and approved prior to issue.
- 3.3 A paper document is officially issued for use when it is approved by authorized function. An electronic document is issued by being placed in a public directory accessible from the network.
- 3.4 Documents are distributed to personnel and locations where they are used. When appropriate and relevant, documents display a distribution list. Electronic documents are available on the network and are accessible at relevant terminals and computers. Document placement is regulated by Procedure QOP-42-02.
- 3.5 Obsolete documents are removed from points of use. Retained masters or copies of obsolete documents are properly marked and are kept separate from active documents. Obsolete electronic documents are removed from the network and, if retained, are stored in directories that are only accessible to authorized personnel.
- 3.6 Document changes are reviewed and authorized by the same function that issued the original document. Revised documents are distributed with a change brief summarizing the changes. Each department issuing paper documents maintains a master list specifying the latest issues and revisions of its documents. For electronic documents such list is not necessary, as only the latest issue and revision of a documents is available on the network.

4.0 Control of quality records

- 4.1 Quality records are established and maintained to provide evidence that:

Product designs satisfy design input requirements;

Materials, components, and production processes meet specified requirements;

Finished products conform to specifications: and

The quality system is operated in accordance with documented procedures and that it is effective.

Where required, quality records also include traceability information.

- 4.2 Records are established by personnel performing the task, operation, or activity the results of which need to be recorded. Records are dated; and identify the product, person, or event to which they pertain.
- 4.3 Records are indexed and grouped to facilitate their retrieval. Cabinets, binders, computer disks, and other storage media containing records are clearly labeled with identification of their content.

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- 4.4 Records are normally stored by the same department that initially established the record. Records are stored in dry and clean areas, and electronic records are regularly backed up. Quality records and documents may not be stored in private desk drawers, unauthorized computer drives, or other obscure locations that are not generally known.
- 4.5 Retention periods for quality records are determined on the basis the lifetime of the product or the event to which the record pertains, and on regulatory and contractual requirements.
- 4.6 All categories of quality records maintained by AAA Inc. are listed in Operational Procedure QOP-42-03, Control of Quality Records. The list identifies specific types of records for each category; their storage location; and retention period.

5.0 Referenced Documents

Operational Procedure QOP-42-01: Quality System Documentation

Operational Procedure QOP-42-02: Control of Documents

Operational Procedure QOP-42-03: Control of Quality Rec

6.0 Revision History

A --- 01/1/04 --- New

END OF SECTION