

QW Enterprises, LLP

Quality Manual

ISO 9001:2008

Quality Manual 9001 2008 D1

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1 General

1.1 Purpose and scope

This Quality Manual documents QW Enterprises, LLP's Quality Management System (QMS) to demonstrate the company's ability to consistently provide product that meets customer and regulatory requirements. This manual establishes compliance with those standards and regulations listed in the [Applicable standards and regulations](#) section of this manual. This Quality Manual applies to research and development, production, sales, marketing, installation and servicing activities conducted by QW Enterprises, LLP. This Quality Manual follows the format of ISO 9001:2008.

1.2 Application

Where any requirements of ISO 9001:2008 cannot be applied due to the nature of QW Enterprises, LLP's activities and its products, they will be considered for exclusion. QW EnterprisesLLP's QMS satisfies the full range of requirements of ISO 9001:2008 Standard.

1.3 Applicable standards and regulations

1.3.1 [ISO 9001:2008, Quality management systems - Requirements](#)

2 Company information

QW Enterprises, LLP is located at 123 Innovation Drive, Sun City, AS, 123456, USA. QW Enterprises, LLP designs, manufactures, distributes and services XY products.

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3 Definitions and Conventions

Applicable standards and regulations

- Where the term *Applicable standards and regulations* is used in the Quality Manual, all documents listed in the Applicable standards and regulations section of this document apply.

BPI Matrix - Business Performance Indicator Matrix.

NC-CAPA - Non-conformity and Corrective and Preventive Action.

Management Team

- President and Directors form the Management Team. The Management Team has executive responsibility for performance of the business and quality system.

QMS - Quality Management System.

[XYZ Procedure](#) - Underlined procedures and standards in the body of the Quality Manual identify reference documents supporting a particular element of the manual.

Documented procedure

- Means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

4 Quality management system

4.1 General requirements

QW Enterprises, LLP has established, documented, implemented, and maintains a QMS in accordance with the requirements of [applicable standards](#). QW Enterprises, LLP continually improves the effectiveness of its QMS. QW Enterprises, LLP's QMS:

- a) Determines the processes needed for the QMS and their application throughout the organization per the [Documentation Master List](#),
- b) Determines the sequence and interaction of these processes. This sequence and interaction are documented per the [Process Interaction Matrix](#)
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective per the [Management Review Procedure](#),
- d) Ensures the availability of resources per the [Resource Management Procedure](#) and information necessary to support the operation and monitoring of these processes per the [Infrastructure Procedure](#),
- e) Monitors, measures where applicable, and analyses these processes per the [Management Review Procedure](#), and
- f) Implements actions necessary to achieve planned results and continual improvement of these processes per the [Management Review Procedure](#) and [NC-CAPA Procedure](#).

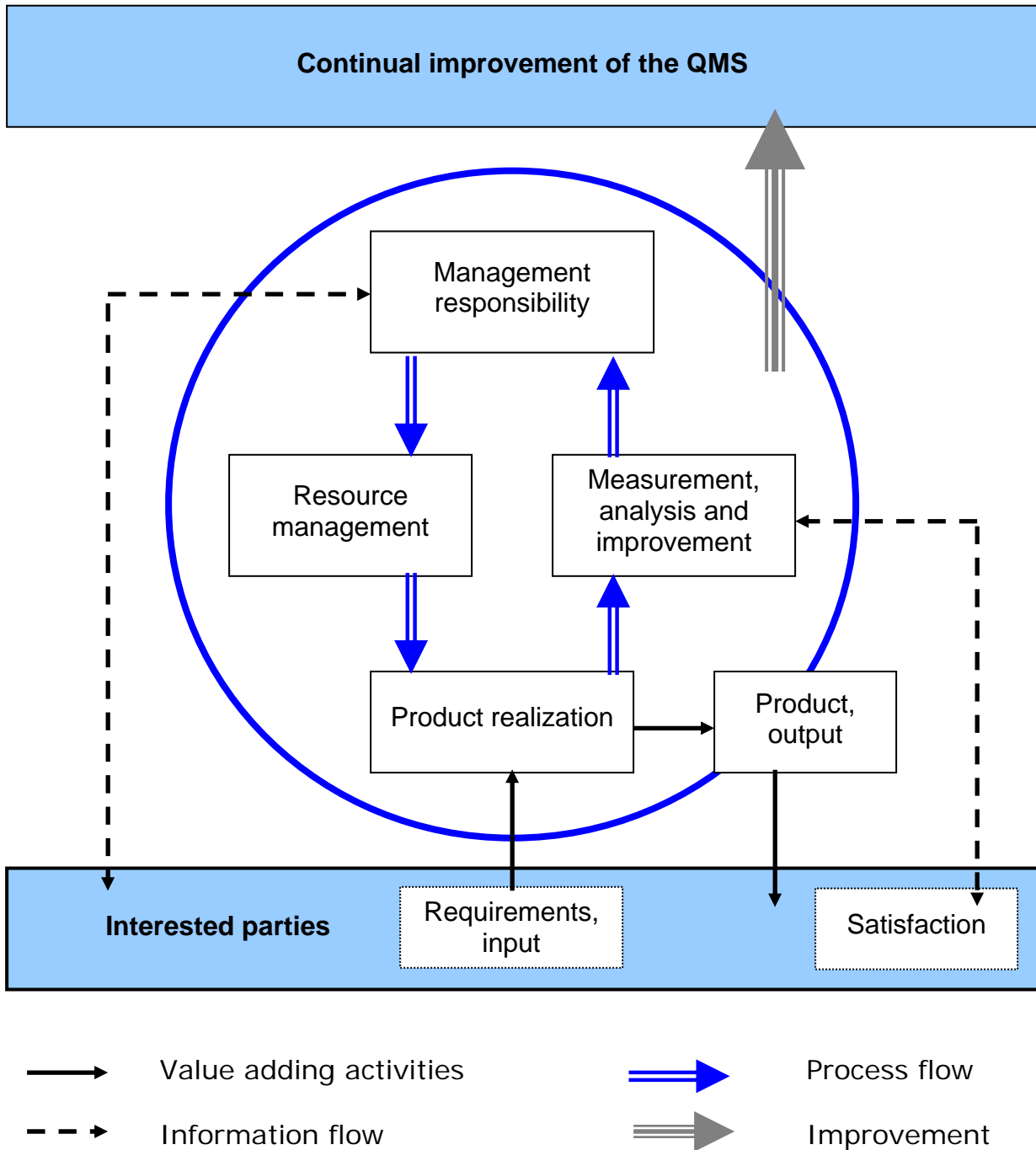
These processes are managed by QW Enterprises, LLP in accordance with [Applicable standards and regulations](#). Where QW Enterprises, LLP outsources any process that affects product conformity to requirements, QW Enterprises, LLP ensures control over such processes per the [Supplier Partnership Program](#). The type and extent of control applied to these outsourced processes are defined within the [Supplier Partnership Program](#).

These processes include management activities, provision of resources, product realization, measurement, analysis and improvement.

Ensuring control over outsourced processes does not absolve QW Enterprises, LLP of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control that QW Enterprises, LLP applies to the outsourced process are influenced by:

- i) The potential impact of the outsourced process on QW Enterprises, LLP's capability to provide product that conforms to requirements,
- ii) The degree to which the control for the process is shared,
- iii) The capability of achieving the necessary control through the [Supplier Partnership Program](#).

4.1.1 Figure 1 - Model of a process-based QMS



4.2 Documentation requirements

4.2.1 General

QW Enterprises, LLP's QMS documentation includes:

- a) Documented statements of the quality policy per the [Quality Policy](#) and quality objectives per the [BPI Matrix](#),
- b) This Quality Manual,
- c) Documented procedures and records required by [Applicable standards and regulations](#),
- d) Documents per the [Documentation Master List](#), including records per the [Records Matrix](#), determined by QW Enterprises, LLP to be necessary to ensure the effective planning, operation and control of its processes.

The extent of the QW Enterprises, LLP's QMS is based on:

- i) The size of the organization and type of activities,
- ii) The complexity of processes and their interactions, and
- iii) The competence of personnel per the [Training Procedure](#).

QW Medial LLP maintains its documents on various media such as paper, electronic, magnetic, optical, etc.

4.2.2 Quality manual

QW Enterprises, LLP has established and maintains this Quality Manual that includes:

- a) The scope of the QMS, including details of and justification for any exclusion per the Application section of this Quality Manual,
- b) The documented procedures established for the QMS, or reference to them, and
- c) A description of the interaction between the processes of the QMS.

8.5 Improvement

8.5.1 Continual improvement

QW Enterprises, LLP has established and maintains documented procedures to continually improve its QMS through the use of the:

- a) [Quality Policy](#),
- b) Quality objectives per the [BPI Matrix](#),
- c) Audit results per the [Audit Procedure](#),
- d) Analysis of data per the [Data Analysis Procedure](#),
- e) Corrective and preventive actions per the [NC-CAPA Procedure](#), and
- f) [Management Review Procedure](#).

8.5.2 Corrective action

QW Enterprises, LLP has established and maintains a documented [NC-CAPA Procedure](#) to eliminate the causes of non-conformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the non-conformities encountered. The [NC-CAPA Procedure](#) defines requirements for:

- a) Reviewing non-conformities, including customer complaints,
- b) Determining the causes of non-conformities,
- c) Evaluating of the need for action to ensure that non-conformities do not recur,
- d) Determining and implementing action needed,
- e) Records of the results of action taken, and
- f) Reviewing the effectiveness of the corrective action taken.

8.5.3 Preventive action

QW Enterprises, LLP has established and maintains documented quality plans, a [Design Management Procedure](#) and a [NC-CAPA Procedure](#) to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions are appropriate

to the effects of the potential problems. Quality plans and the [NC-CAPA Procedure](#) define requirements for:

- a) Determining potential non-conformities and their causes,
- b) Evaluating the need for action to prevent occurrence of non-conformities,
- c) Determining and implementing action needed,
- d) Records of results of action taken, and
- e) Reviewing the effectiveness of the preventive action taken.

9 Revision history and master verification

Rev	DCR	Description of change	Master verified	Date
01	1025	Initial release	<i>Mark Wright</i>	1/20/09