QW Enterprises, LLP

Integrated Manual

ISO 9001:2008

ISO 14001:2004

Integrated QE Manual D1

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1 General

1.1 Purpose and scope

This Integrated Manual documents QW Enterprises, LLP's Integrated Management System (IMS) to demonstrate the company's ability to consistently provide product that meets customer and regulatory requirements. This Manual establishes compliance with the standards and regulations listed in the Applicable standards and regulations section of this Manual. This Manual applies to research and development, production, sales, marketing, installation and servicing activities conducted by QW Enterprises, LLP.



This Manual also specifies requirements for an environmental management system. This system enables QW Enterprises, LLP to develop and implement environmental policy and objectives which take into account legal and other requirements to which QW Enterprises, LLP subscribes. These requirements are shown in the Applicable standards and regulations section of this Manual. The Manual outlines a framework for establishment and management of significant environmental aspects that QW Enterprises, LLP identified as those it can control and those which it can influence.

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 Enterprises LLP's IMS 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

1.3.2 ISO 14001: 2004, Environmental management systems -

Requirements with guidance for use

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 Manual and other management system documents, standards and regulations listed in the Applicable standards and regulations section of the Manual 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 Integrated Management System.

IMS - Integrated Management System.

<u>XYZ Procedure</u> - Underlined document titles in the body of the 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 processes. A requirement for a documented procedure may be covered by more than one document.



- A globe in the flower symbol is used within the text of the Manual to identify specific requirements of the environmental management system.

Where responses to the environmental management system requirements are the same or similar to the responses to the quality management system requirements, these responses are not repeated.

4 Integrated management system

4.1 General requirements

QW Enterprises, LLP has established, documented, implemented, and maintains an IMS in accordance with the requirements of <u>Applicable standards and regulations</u>. QW Enterprises, LLP continually improves the effectiveness of its IMS. QW Enterprises, LLP's IMS:

- a) Determines the processes needed for the IMS and their application throughout the organization,
- b) Determines the sequence and interaction of these processes.

 This sequence and interaction are documented within the

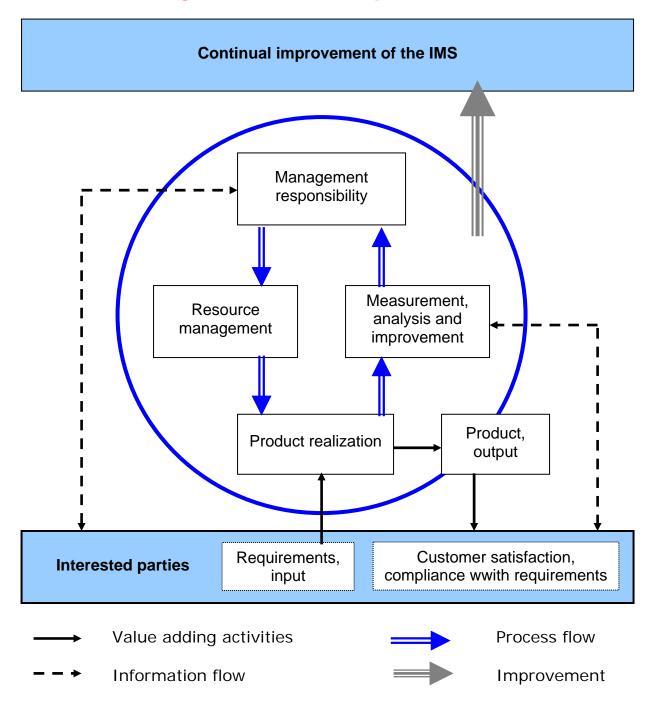
 Process Interaction Matrix
- Determine criteria and methods needed to ensure that both the operation and control of these processes are effective per the <u>Management Review Procedure</u>,
- Ensures the availability of resources and information necessary to support the operation and monitoring of these processes per the <u>Resource Management Procedure</u>,
- e) Monitors, measures where applicable, and analyses these processes per the <u>BPI Matrix</u>, and
- f) Implements actions necessary to achieve planned results and continual improvement of these processes per the <u>Management Review Procedure</u> and the <u>NC-CAPA Procedure</u>.

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

These processes may 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 outsourced process are documented in the Supplier Partnership Program.

4.1.1 Figure 1, Model of a process-based IMS



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4.2 Documentation requirements

4.2.1 General

QW Enterprises, LLP's IMS documentation includes:

 Documented statements of the quality policy per the <u>Quality</u> <u>Policy</u> and quality objectives per the <u>BPI Matrix</u>,



- b) Documented statements of the environmental policy per the Environmental Policy and environmental objectives and targets per the EMS matrix,
- c) This Integrated Manual,
- d) Documented procedures and records required by <u>Applicable</u> standards and regulations,
- e) Documents, including records, 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 IMS is based on:

- a) The size of the organization and type of activities,
- b) The complexity of processes and their interactions, and
- c) The competence of personnel per the <u>Training Procedure</u>.

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

4.2.2 Integrated Manual

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

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

IMS.

4.2.3 Management of documents

Documents required by the IMS are managed per the <u>Documentation</u> <u>Management Procedure</u>. Records are a special type of document and are managed per the <u>Records Procedure</u>.

The <u>Documentation Management Procedure</u> is established to define the means needed to:

- a) Approve documents for adequacy prior to issue,
- b) Review and update as necessary and re-approve documents,
- Ensure that changes and the current revision status of documents are identified,
- d) Ensure that relevant versions of applicable documents are available at points of use,
- e) Ensure that documents remain legible and readily identifiable,
- f) Ensure that documents of external origin are identified and their distribution managed using the <u>Documentation Master List</u>, and
- g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Management of records

Records are established to provide evidence of conformity to requirements and of the effective operation of the IMS. A documented Records Procedure is established to define the means needed for the identification, storage, protection, retrieval, retention time and disposition of records. QW Enterprises, LLP ensures that records remain legible, readily identifiable and retrievable.

5 Management responsibility

5.1 Management commitment

QW Enterprises, LLP's Management Team provides its commitment to the development and implementation of the IMS and continually improving its effectiveness by:

- a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements per the <u>Communication Procedure</u>,
- b) Establishing the quality policy documented in the Quality Policy,



- c) Establishing the environmental policy documented in the Environmental Policy,
- d) Ensuring that quality objectives are established per the BPI
 Matrix.



- e) Ensuring that environmental objectives and targets are established per the EMS Matrix.
- f) Conducting management reviews per the <u>Management Review</u> <u>Procedure</u>, and
- g) Ensuring the availability of resources per the <u>Resource</u> <u>Management Procedure</u>.

5.2 Customer focus

QW Enterprises, LLP's Management Team ensures that customer requirements are determined and met with the objective of enhancing customer satisfaction per the Design Management Procedure and the Contract Review Procedure.

5.3 Policies

5.3.1 Quality policy

QW Enterprises, LLP's Management Team ensures that QW Enterprises, LLP's quality policy is documented in the <u>Quality Policy</u> and It:

- a) Is appropriate to the purpose of QW Enterprises, LLP's activities,
- b) Includes commitments to comply with requirements of <u>Applicable standards and regulations</u> and continually improve the effectiveness of the IMS,
- c) Provides a framework for establishing and reviewing quality objectives,
- d) Is communicated and understood within the organization per the <u>Training Procedure</u> and <u>Communication Procedure</u>, and
- e) Is reviewed for continuing suitability per the <u>Management</u> Review Procedure.



5.3.2 Environmental policy

QW Enterprises, LLP's Management Team defined company's environmental policy in the <u>Environmental Policy</u> and It:

- a) Is appropriate to the nature, scale and environmental impacts of its activities, products and services,
- b) Includes a commitment to continual improvement and prevention of pollution,
- c) Includes a commitment to comply with applicable legal requirements and with other requirements to which QW Enterprises, LLP subscribes which relate to its environmental aspects,
- d) Provides the framework for setting and reviewing environmental objectives and targets,
- e) Is documented, implemented and maintained,
- f) Is communicated to all personnel working for or on behalf of the organization per the <u>Training Procedure</u> and <u>Communication</u> Procedure, and

g) Is available to the public through QW Enterprises, LLP's Website.

5.4 Planning

5.4.1 Quality objectives

QW Enterprises, LLP's Management Team ensures that quality objectives, including those needed to meet requirements for product, are established for relevant functions and levels within the organization per the Management Review Procedure and the BPI Matrix. The quality objectives are measurable and consistent with the quality policy.



5.4.2 Environmental objectives, targets and programs

QW Enterprises, LLP's Management Team has established, implemented and maintains documented environmental objectives and targets at relevant functions and levels within the organization per the EMS Matrix. The EMS Matrix format insures that the objectives and targets are measurable and consistent with the environmental policy.

When establishing and reviewing its environmental objectives and targets, QW Enterprises, LLP takes into account the legal and other requirements to which it subscribes. Environmental objectives and targets also take into account organization's significant environmental aspects, technological options, financial, operational and business requirements, and the views of interested parties.

QW Enterprises, LLP has established, implemented and maintains programs for achieving environmental objectives and targets per the <u>EMS Matrix</u>. Programs include:

- a) Designation of responsibility for achieving objectives and targets at relevant functions and levels of the organization per the EMS Matrix, and
- b) The means and time-frame by which they are to be achieved per

ISO 14001:2004	This Manual and (ISO 9001:2008)
130 14001.2004	11113 Maridar and (130 7001:2000)

10 Correspondence between ISO 14001 and this Manual

Scope	1	Scope	1
EMS - title	4	IMS (QMS) - title	4
General requirements	4.1	General requirements	4.1
Environmental policy	4.2	Quality policy	5.3
Planning	4.3	Planning - title	5.4
Environmental aspects	4.3.1	Determination of requirements related	7.2.1
		to the product	
Legal and other requirements	4.3.2	Determination of requirements related	7.2.1
		to the product	
Objectives, targets and programs	4.3.3	Quality objectives	5.4.1
Implementation and operation		Product realization - title	7
Management representative	4.4.1	Management representative	5.5.2
Resources, roles, responsibility and	4.4.1	Provision of resources	6.1
authority			
Competence, training and awareness	4.4.2	Competence, awareness and training	6.2.2
Communication	4.4.3	Internal communication	5.5.3
Documentation	4.4.4	General	4.2.1

ISO 14001:2004		This Manual and (ISO 9001:2008)	
Management of documents	4.4.5	Management of documents	4.2.3
Operational control	4.4.6	Planning of product realization	7.1
Emergency preparedness and response	4.4.7	Management of non-conforming	8.3
		product	
Checking - title	4.5	Measurement, analysis and	8
		improvement - title	
Monitoring and measurement	4.5.1	Monitoring and measuring devices	7.6
Evaluation of compliance	4.5.2	Monitoring and measurement of	8.2.3
·		processes	
Non-conformity, corrective and preventive	4.5.3	Management of non-conforming	8.3
action		product	
Management of records	4.5.4	Management of records	4.2.4
Internal audit	4.5.5	Internal audit	8.2.2
Management review	4.6	General	5.6.1

11 Revision history and master verification

Rev	DCR	Description of change	Master verified	Date
01	1025	Initial release	Mark Wright	11/15/08