

QW Enterprises, LLP

Integrated Manual

ISO 9001:2008

ISO 14001:2004

BS OHSAS 18001:2007

Integrated QEHS Manual D1

This document is maintained on the QW Enterprises, LLP's network.
It is the responsibility of the user to verify that this copy is of the latest revision.

0 Table of contents

0	Table of contents	2
1	General	5
1.1	Purpose and scope	5
1.2	Application	5
1.3	Applicable standards and regulations	6
2	Company information	6
1.4	Certification scope.....	6
3	Definitions and Conventions	7
4	Integrated management system	9
4.1	General requirements	9
4.1.1	Figure 1, Model of a process-based IMS	11
4.2	Documentation requirements.....	12
4.2.1	General	12
4.2.2	Integrated Manual	12
4.2.3	Management of documents	13
4.2.4	Management of records	13
5	Management responsibility	14
5.1	Management commitment.....	14
5.2	Customer focus.....	14
5.3	Policies	15
5.3.1	Quality policy	15
5.3.2	Environmental policy	15
5.3.3	OH&S policy.....	16
5.4	Planning	16
5.4.1	Quality objectives	16
5.4.2	EMS objectives, targets and programs	17
5.4.3	OH&S objectives and programs.....	17
5.4.2	IMS planning.....	18
5.5	Responsibility, authority and communication.....	18
5.5.1	Responsibility and authority	18
5.5.2	Management representatives.....	19
5.5.3	Communication	20
5.5.4	Participation and consultation	21
5.6	Management review	22

5.6.1	General	22
5.6.2	Review input	22
5.6.3	Review output	23
6	Resource management	23
6.1	Provision of resources	23
6.2	Human resources	24
6.2.1	General	24
6.2.2	Competence, training and awareness.....	25
6.3	Infrastructure	26
6.4	Work environment.....	27
7	Product realization	27
7.1	Planning of product realization	27
7.2	Customer-related processes.....	28
7.2.1	Determination of requirements related to the product	28
7.2.1.1	Environmental aspects.....	29
7.2.1.2	EMS legal and other requirements.....	29
7.2.1.3	Hazard identification, risk assessment and determination of controls	30
7.2.1.4	OH&S legal and other requirements.....	31
7.2.2	Review of requirements related to the product ..	32
7.2.3	Customer communication.....	33
7.3	Design and development	33
7.3.1	Design and development planning.....	33
7.3.2	Design and development inputs	34
7.3.3	Design and development outputs	34
7.3.4	Design and development review.....	35
7.3.5	Design and development verification	35
7.3.6	Design and development validation	35
7.3.7	Design and development changes	35
7.4	Purchasing	36
7.4.1	Purchasing process	36
7.4.2	Purchasing information	36
7.4.3	Verification of purchased product and/or services.....	38
7.5	Production and service	38
7.5.1	Management of production and service	38

7.5.2	Validation of processes for production and service.....	38
7.5.3	Identification and traceability	39
7.5.4	Customer property.....	39
7.5.5	Preservation of product.....	40
7.6	Management of measuring and monitoring equipment....	40
8	Measurement, analysis and improvement.....	41
8.1	General	41
8.2	Monitoring and measurement.....	42
8.2.1	Customer satisfaction	42
8.2.2	Internal audits.....	42
8.2.2.1	Evaluation of compliance	44
8.2.3	Monitoring and measurement of processes	46
8.2.4	Monitoring and measurement of product	47
8.3	Management of non-conforming product	47
8.3.1	Emergency preparedness and response.....	48
8.3.2	Non-conformity, corrective and preventive action	49
8.3.3	Incident investigation	49
8.4	Analysis of data	50
8.5	Improvement	51
8.5.1	Continual improvement	51
8.5.2	Corrective action	51
8.5.3	Preventive action	51
9	Correspondence between ISO 14001:2004 and this Manual	53
10	Correspondence between BS OHSAS 18001:2007 and this Manual.....	55
11	Revision history and master verification.....	57

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 IMS applies to research and development, production, sales, marketing, installation and servicing activities conducted by QW Enterprises, LLP.



This IMS 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. 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.



This IMS enables QW Enterprises, LLP to control its Occupational Health and Safety (OH&S) risks and improve its OH&S performance. The Manual outlines framework for elimination or minimization of risks to personnel and other interested parties who could be exposed to OH&S hazards associated with QW Enterprises, LLP's activities.

1.2 Application

Where any requirements of ISO 9001:2008 standard 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](#)
- 1.3.3 [BS OHSAS 18001:2007, Occupational Health and Safety management system - 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.

Phone: (123) 123-4567
Fax: (123) 123-4568
Web site: www.qwmedical.com.

1.4 Certification scope

QW Enterprises, LLP's Integrated Management System is certified by QW Registrar to:

- ISO 9001:2008, Quality Management System,
- ISO 14001:2004, Environmental Management System, and
- BS OHSAS 18001:2007, Occupational Health and Safety Management System – Requirements

The scope of all certificates to read:

The design, manufacture, distributes and service of XY products and accessories

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.

[XYZ Procedure](#)

- Underlined document titles in the body of the Manual identify reference documents supporting particular elements 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 green triangle symbol and this green font are used within the text of the Manual to identify specific requirements of the Environmental Management System (EMS).

Where responses to the environmental management system requirements are the same or similar to the responses to the Quality Management System (QMS) requirements, these responses may not be repeated.





- A warning symbol and this dark-red font are used within the text of the Manual to identify specific requirements of the Occupational Health and Safety Management System (OH&S MS).

Where responses to the OH&S MS requirements are the same or similar to the responses to the QMS or EMS requirements, these responses may not be 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 [Applicable standards and regulations](#). QW Enterprises, LLP continually improves the effectiveness of its IMS by:

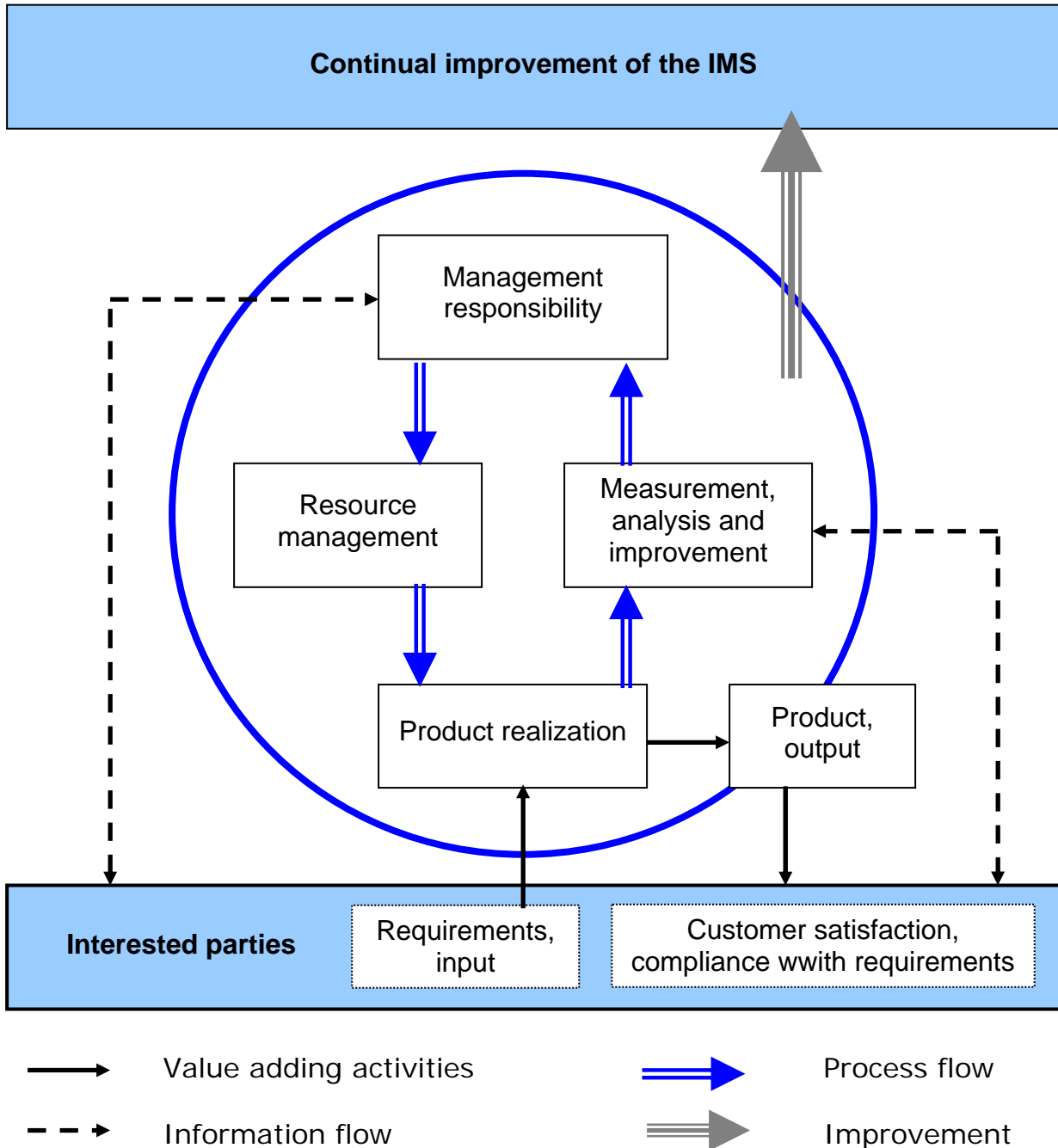
- a) Determining the processes needed for the IMS and their application throughout the organization,
- b) Determining the sequence and interaction of these processes per the structure reflected in this manual and the [Process Interaction Matrix](#),
- c) Determining criteria and methods needed to ensure that both the operation and control of these processes are effective per the [Management Review Procedure](#),
- d) Ensuring the availability of resources and information necessary to support the operation and monitoring of these processes per the [Resource Management Procedure](#),
- e) Monitoring, measuring where applicable, and analyzing applicable processes per the [BPI Matrix](#),
-  f) **Monitoring, measuring where applicable, and analyzing applicable processes per the [EMS Matrix](#),**
-  g) **Monitoring, measuring where applicable, and analyzing these processes per the [OH&S Matrix](#),**
- h) Implementing actions necessary to achieve planned results and continual improvement of these processes per the [Management Review Procedure](#) and the [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 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



4.2 Documentation requirements

4.2.1 General

QW Enterprises, LLP's IMS documentation includes:

- a) Documented statements of the quality policy per the [Quality Policy](#) and quality objectives per the [BPI Matrix](#),
-  b) Documented statements of the environmental policy per the [Environmental Policy](#) and environmental objectives and targets per the [EMS matrix](#),
-  c) The OH&S policy per the [Health and safety Policy](#) and OH&S objectives per the [OH&S Matrix](#).
- d) This Integrated Manual,
- e) Documented procedures and records required by [Applicable standards and regulations](#),
- f) 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 [Training Procedure](#).

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

ISO 14001:2004	This Manual and (ISO 9001:2008)
-----------------------	----------------------------------------

9 Correspondence between ISO 14001:2004 and this Manual

Scope	1	Purpose and scope	1.1
Environmental management system	4	Integrated management system	4
General requirements	4.1	General requirements	4.1
Environmental policy	4.2	Environmental policy	5.3.2
Planning	4.3	Planning	5.4
Environmental aspects	4.3.1	Environmental aspects	7.2.1.1
Legal and other requirements	4.3.2	EMS legal and other requirements	7.2.1.2
Objectives, targets and programs	4.3.3	EMS objectives, targets and programs	5.4.2
Implementation and operation	4.4	Product realization	7
Resources, roles, responsibility and authority	4.4.1	Provision of resources	6.1
Management representative	4.4.1	Management representatives	5.5.2
Competence, training and awareness	4.4.2	Competence, awareness and training	6.2.2
Communication	4.4.3	Communication	5.5.3
Documentation	4.4.4	Documentation requirements	4.2
Control 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	Emergency preparedness and response	8.3.1

This document is maintained on the QW Enterprises, LLP's network.
It is the responsibility of the user to verify that this copy is of the latest revision.

BS OHSAS 18001:2007	This Manual and (ISO 9001:2008)
----------------------------	----------------------------------------

10 Correspondence between BS OHSAS 18001:2007 and this Manual

Scope	1	<u>Purpose and scope</u>	1.1
OH&S MS	4	Integrated management system	4
General requirements	4.1	<u>General requirements</u>	4.1
OH&S policy	4.2	<u>OH&S policy</u>	5.3.3
Planning	4.3	Planning	5.4
Hazard identification, risk assessment and determination of controls	4.3.1	<u>Hazard identification, risk assessment and determination of controls</u>	7.2.1.3
Legal and other requirements	4.3.2	<u>OH&S Legal and other requirements</u>	7.2.1.4
Objectives and programs	4.3.3	<u>OH&S objectives and programs</u>	5.4.3
Implementation and operation	4.4	Product realization	7
Resources, roles, responsibility and authority	4.4.1	<u>Provision of resources</u>	6.1
Management representative	4.4.1	<u>Management representatives</u>	5.5.2
Competence, training and awareness	4.4.2	<u>Competence, awareness and training</u>	6.2.2
Communication, participation and consultation	4.4.3	<u>Communication</u>	5.5.3
Communication control of documents	4.4.3.1	<u>Communication</u>	5.5.3
Participation and consultation	4.4.3.2	<u>Participation and consultation</u>	5.5.4
Documentation	4.4.4	<u>Documentation requirements</u>	4.2

This document is maintained on the QW Enterprises, LLP's network.
It is the responsibility of the user to verify that this copy is of the latest revision.

11 Revision history and master verification

Rev	DCR	Description of change	Master verified	Date
01	1025	Initial release	<i>Mark Wright</i>	1/15/09