

QUALITY MANAGEMENT SYSTEM

Quality Manual

2.1.1 Distribution of Manual

The Quality Manual shall be approved by the General Manager prior to release.

The Personal Assistant General Manager (PA/GM) shall be responsible for publishing a controlled copy of the Manual on the company intranet.

2.1.2 Change Control

The PA/GM shall be responsible for publishing revisions of the Manual as and when changes are approved.

Revisions shall be made by updating the appropriate page(s). Each revised page shall be identified by the date.

All document changes / revisions shall be recorded at the bottom of each procedure to ensure that changes and the current revision status of documents are identified.

It is not permitted to revise the Quality Manual more than once in any one day.

Uncontrolled printed copies of the Manual shall not be maintained or updated by the Company.

Issue or Change Record

Issue or Change date	Owner Controlled by	Reason for Change
1/03/2003	PA / GM	New Manual – ISO 9001:2000 on Intranet

**QUALITY MANAGEMENT SYSTEM
Quality Manual**

2.1 Control Sheet

PROCEDURES MANUAL

CONTROLLED

COPY NUMBER: PM002

MANUAL HOLDER: QMR

DEPT/COMPANY: ABC Pty Ltd

NOTE: After any Quality Manual revisions, please read and insert new pages,
returning superseded pages to QMR for destruction.

Destroyed QMR _____ Date: _____

REV	SECTION	REVISION DESCRIPTION	DATE
0	All	Issue E	1/11/00
1	301	General Changes	11/05/01
1	1401	Complaint Procedure	11/05/01
1	1601 App 1	Additions	11/05/01
1	1801	Minor Changes	11/05/01
1	102	Minor Changes	11/05/01
1	702	Minor Changes	28/11/01
1	601	General Changes	28/11/01
1	602	General Changes	28/11/01
2	301	General Changes	28/06/01
2	602	General Changes	28/06/01
2	1101	General Changes	28/06/01
2	1401	General Changes	28/06/01
1	2001	General Changes	28/06/01
1	1301	General Changes	28/06/01

AUTHORISED BY: _____

ISSUE: E SECTION: C
 REV: 3
 DATE: 28 JUN 2002 PAGE 1 OF 3

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2.2 Distribution List

COPY NO

DOCUMENT HOLDER

PM001

Managing Director

PM002

Manager Quality Assurance

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ISSUE: E

SECTION: D

REV: 0

DATE: 1 November 2000

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QUALITY MANAGEMENT SYSTEM

Quality Manual

3.0 Terms and Definitions

G. MANUAL STATUS AND DEFINITIONS

G1.1 Distribution

- G1.1.1 The Quality Manual/Procedures Manual/Work Instructions Manual shall be approved by the Managing Director prior to release or reissue.
- G1.1.2 Each copy of the Manual shall indicate whether it is a controlled or uncontrolled copy. All controlled copies shall be numbered.
- G1.1.3 The Quality Management Representative shall be responsible for the issuing of controlled copies of the Manual, and shall maintain a distribution list of document holders (Section E).

G1.2 Change Control

- G1.2.1 All revisions of the Quality Manual/Procedures Manual and Work Instructions Manual shall be approved by the Quality Management Representative prior to release.
- G1.2.2 Uncontrolled copies of the Manual shall not be maintained or updated by the Company, but shall be current at the time of issue.
- G1.2.3 The Quality Management Representative shall be responsible for distributing all revisions of the Manual as and when changes are approved.
- G1.2.4 Revisions shall be made by replacement of the appropriate page(s). Each revised page shall be identified by a revision number and the date of the revision. All revisions shall be issued under cover of a Control Sheet (Section C), which shall also contain a description of the revision.
- G1.2.5 Revisions shall be numbered consecutively (Rev:0, 1, 2, etc.), until such time as a new issue incorporates all previous changes.
- G1.2.6 After a practical number of revisions to one issue, the Manual shall be re-issued. All new issues shall be released under cover of a Control Sheet which shall contain the reason for the issue.
- G1.2.7 Issues shall be identified by an alpha notation (Issue; A, B, C, etc.), and each new issue shall cancel and replace all previous issues and revisions.

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G1.2.8 It shall be the responsibility of all holders of controlled copies of the Manual to update, as required, the Manual assigned to them and return obsolete issues or pages to the Quality Management Representative.

G1.2.9 The revision status of individual manuals shall be subject to audit as part of the Company quality audit program.

G1.3 Terms and Definition

Meanings of words used in the Quality Manual are explained as follows:

Audit A documented activity performed to verify by examination or evaluation of objective evidence the adequacy of, and compliance with, the established quality assurance and related quality systems. An audit does not include surveillance or inspection activities performed for the purpose of process control or product acceptance.

Batch A quantity of products identified and related to a customer or supplier's contract or a span of time relevant to dates of manufacture and test.

Certificate of Conformity A document signed by a qualified party affirming that, at the time of signing, the product or service met the stated requirements.

Note: 'Release certificate', 'release note', 'certificate of compliance' and 'certificate of conformance', are considered to be synonymous with 'certificate of conformity'.

Company ABC Pty Ltd.

Contract A verbal or documented statement of agreed requirements, needs and expectations between two parties in customer/supplier relationship.

Concession The authorisation to use or release a limited quantity of products, material, components or stores not complying with the specified requirements.

Customer Supplied Product Any product that is supplied by a customer as free issue or under the terms of a contract.

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<u>Nonconformance</u>	A deficiency in characteristic, documentation or process implementation which renders the quality of a product or activity unacceptable or indeterminate.
<u>Objective Evidence</u>	Any documented statement of fact, information or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements or tests which can be verified.
<u>Plan</u>	A document describing, identifying or scheduling specific practices, procedures or arrangements relevant to particular items, processes, services, project or contracts.
<u>Procedure</u>	A document that specifies or describes how an activity is to be performed.
<u>Product</u>	Equipment, stores, supplies, spares, service, manufacture, process assembly, construction, erection or commission as applicable to the requirements of a contract.
<u>Quality</u>	<p>The totality of features and characteristics of a product or service that bear on its ability to satisfy a given need.</p> <p>Note: In order to be able to assure, control and improve quality, it is necessary to be able to evaluate it. This definition calls for the identification of those characteristics and features bearing upon the 'fitness for purpose' of a product or service. The 'ability to satisfy a given need' includes economics as well as availability, maintainability, reliability, design and all other characteristics that the need for a product or service involve.</p>
<u>Quality Manual</u>	A document setting out the general quality policies and responsibilities of an organisation.
<u>Quality Plan</u>	A document derived from the quality program (extended if necessary) setting out the specific practices, resources and activities relevant to a particular contract or project.

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- Quality Program A documented set of activities, resources and events serving to implement the quality system of an organisation.

- Quality System The organisation structure, responsibilities, activities and events that together provide organised procedures and methods of implementation to ensure the capability of the organisation to meet quality requirements (see ISO 9001).

- Quarantine Status A means of identifying products awaiting Status proof of compliance with specified requirements or a decision on method of disposition.

- Special Process Any process, the results of which cannot be fully verified by subsequent inspection and testing of the product.

- Verification The act of reviewing, inspecting, testing, checking or otherwise confirming and documenting whether items, processes, services or documents conform to specified requirements.

- Work Instruction Sheet A detailed Step-by-Step definition of a particular activity.

Note: All other Quality Related Terms can be found in AS 1057 Quality Assurance and Quality Control - Glossary of Terms.

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QUALITY MANAGEMENT SYSTEM

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3.1.1 Terms and Definitions

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QUALITY MANAGEMENT SYSTEM

Quality Manual

Objective

Evidence

Any documented statement of fact, information or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements or tests which can be verified.

Plan

A document describing, identifying or scheduling specific practices, procedures or arrangements relevant to particular items, processes, services, project or contracts.

Procedure

A document that specifies or describes how an activity is to be performed.

Product

Equipment, stores, supplies, spares, service, manufacture, process assembly, construction, erection or commission as applicable to the requirements of a contract.

Quality

The totality of features and characteristics of a product or service that bear on its ability to satisfy a given need.

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Quality

Manual

A document setting out the general quality policies and responsibilities of an organisation.

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A document derived from the quality program (extended if necessary) setting out the specific practices, resources and activities relevant to a particular contract or project.

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**QUALITY MANAGEMENT SYSTEM
Quality Manual**

Quality System

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**QUALITY MANAGEMENT SYSTEM
Quality Manual**

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**QUALITY MANAGEMENT SYSTEM
4.1 Quality Manual**

4.1.1 General Requirements

This manual describes the Quality Management System in operation at ABC Pty. Ltd. which has been established, documented and implemented by the Company in accordance with its Quality Policy and the International Standard.

The manual is the prime reference document for all quality and business related activities undertaken by the Company. It shall be used for the purposes of maintaining and auditing a quality management system to continually improve its effectiveness and as a training document for the company management.

To achieve our quality vision, the requirements of a documented quality management system based on the standard ISO 9001:2000 will be followed.

The following sections outline the way in which the company addresses each element of the quality management system. Where appropriate, references are made to more detailed operating procedures to:

- Identify the processes needed for the quality management system and their application throughout the company.
- Determine the sequence and interaction of the processes.
- Determine criteria and methods needed to ensure that both the operation and control of the processes are effective.
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
- Monitor and measure and analyse these processes
- Implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the company in accordance with the requirements of this International Standard.

Issue or Change Record

Issue or Change date	Owner Controlled by	Reason for Change
1/03/2003	GM	New Manual – ISO 9001:2000 on Intranet

PRODUCT REALIZATION
7.1 Planning of Product Realization

7.1 Planning of product realization

The Company shall plan and develop processes needed for product realization. Planning of product realization shall consistent with the requirements of the other processes of the quality management system (see 4.1.1).

In planning product realization, the Company shall determine the following as appropriate:

- Quality objectives and requirements for the product.
- The need to establish processes, documents, and provide resources specific to the product.
- Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.
- Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

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QUALITY MANAGEMENT SYSTEM

Control of Documents

4.2.3 Control of Documents

1.0 Purpose

This procedure has been formulated to ensure that the correct version of operating procedures and technical data standards is available and that such documents are properly approved before issue, and that any amendments are properly controlled.

2.0 Scope

This procedure applies to all operating procedures and associated documentation contained in the Quality Management System.

3.0 References

Q.A.P. 5.6.1 Quality System Review
Q.A.P. 7.2.2 Contract Review
Q.A.P. 7.4.2 Sub-Contractor Assessment
Q.A.P. 4.2.4 Quality Records
Work Instructions 501

4.0 Definitions

GM = General Manager
PA/GM = Personal Assistant General Manager
QMR = Quality Management Representative
IF = Internal Form, Printed In-House
EF = External Form, Commercially Printed

5.0 Procedure

5.1 The General Manager (GM) shall ensure that documents and data used in the Quality Management System are properly identified and controlled, as appropriate. The GM shall authorize issue of usernames and passwords, as appropriate, to access electronic data and ensure daily software backup for the AS400 and NT server. The Manufacturing Manager shall ensure adequate periodic backup of manufacturing data not stored on the NT server.

5.1.1 The PA/GM shall ensure that all new company generated documentation and all changes to documents and data are controlled as per 2.1.1 & 2.1.2.

5.2 The PA/GM is authorised to effect revisions or reissues to the Quality Manual, Work Instructions and Forms.

QUALITY MANAGEMENT SYSTEM

Control of Documents

- 5.2.1 The PA/GM shall ensure that the current issue of documents is made available at all locations where they are used.
- 5.2.2 The PA/GM shall ensure that obsolete documents are removed, or identified as OBSOLETE, from all points of issue or use.
- 5.2.3 An archive copy of each document identified as OBSOLETE shall be kept by the PA/GM.
- 5.3 Engineering Drawings (computer stored) and Process Control Plans/Production Orders shall be under the control of the Manufacturing Manager and changes shall be controlled by ECN.
- 5.3.1 Hard copies of engineering drawings shall be destroyed immediately after completion of the Production Order/Process Control Plan, providing that Process Control Plan / Production Order bears a reference to the engineering drawings and their revision status to which part has been made.

5.4 Internal and External Forms.

- 5.4.1 Internal Forms (IF) and External Forms (EF) issued after 22.9.93 shall be issued with the appropriate form number/date of issue, allocated by the PA/GM.
- 5.4.2 Any employee can suggest a new or revised form using IF18.
- 5.4.2.1 All copies of newly initiated documentation to be manually marked "Draft" until finally authorised.
- 5.4.3 Authorities for issuing/reissuing forms shall be in accordance with the IF18 form.
- 5.4.3.1 Issuing/reissuing shall be deemed to have taken place when the IF18 has been completed/updated.
- 5.4.4 The PA/GM shall be responsible for updating the relevant form register and the index.
- 5.4.5 The PA/GM shall be responsible for filing the IF18 authorisation with the new/revised form.
- 5.4.6 When the supplier proofs of external forms are received, they shall be approved by the PA/GM, and if acceptable, printing shall proceed.
- ~~5.4.7 Production printing shall be received into the Office and compared with the external forms register (IF34) by the PA/GM for compliance with the latest issue level.~~

QUALITY MANAGEMENT SYSTEM
Control of Documents

5.4.8 All controlled internal forms, quality related and otherwise, are listed on the Internal Forms Register (IF33).

5.4.9 All controlled external forms, quality related and otherwise, are listed on the External Forms Register (IF34).

5.5 Customer Price Lists/Quotations.

5.5.1 All selling prices are to be obtained by reference to the Itemeyes® computer database. This information is available to all authorized system users.

5.5.2 All pricing should be read in conjunction with the customer discount (if applicable), also stored on Itemeyes® computer database, and communicated in 'net' terms only to customers.

5.5.3 Pricing and discount structures are reviewed by the General Manager in conjunction with the Manager Sales & Technical Support (MS & TS), on an as required basis.

5.5.3.1 If changes are required, these may be authorized by the GM or the MS & TS.

5.5.4 Where written quotations are required, these shall be in accordance with Excel workbook for each month.

5.5.5 A monthly register of quotations, by quotation number, is kept and maintained by the PA-GM.

5.6 Customer/Supplier and General Incoming Correspondence (Mail/Fax).

5.6.1 Incoming faxes excluding junk mail, are photocopied by the Receptionist. The original is filed in the appropriate customer/supplier file, by the Senior Clerk.

5.6.1.1 The copy is distributed to the addressee, by the receptionist, for any necessary review/action.

5.6.2 Incoming mail is opened, reviewed and distributed as deemed appropriate by the PA/GM. Copies of essential documents shall be made and filed at the discretion of the PA/GM.

5.6.3 Customer/supplier documentation and correspondence shall be filed alphabetically within calendar years, i.e.: Jan – Dec basis.

5.6.3.1 The current and superseded year only shall be filed in the General Office Compactus.

QUALITY MANAGEMENT SYSTEM

Control of Documents

- 5.6.3.2 Preceding years' correspondence shall be filed in the Archive room and stored for a minimum of five (5) years.
- 5.7 Current copies of machine and equipment Installation, Operating and Maintenance documentation shall be referenced to each machine and kept by the controlling authority.
- 5.8 Quality Records documentation and data shall be maintained in accordance with QAP 4.2.4.
- 5.9 The Approved Suppliers Master List shall be updated and maintained in accordance with QAP 7.4.2.
- 5.10 Completed Production Orders shall be filed in numerical order by the senior clerk, and kept for a minimum of five (5) years.
- 5.11 Customer Purchase Orders and Quotations shall be filed in accordance with QAP 7.2, and kept for a minimum of one (1) year.
- 5.12 Warranty documentation and correspondence shall be filed and maintained by the Manufacturing Co-ordinator, and kept for a minimum of five (5) years.
- 5.13 Documentation and correspondence relating to quality standards shall be filed and maintained by the QMR.
- 5.14 Documentation relating to Occupational Health and Safety shall be filed and maintained by the Health and Safety Officer.
- 5.15 External quality system auditors reports and documentation shall be filed by the PA/GM and maintained by the Quality Management Representative.
- 5.15.1 The QMR shall ensure the documentation is current by contacting the issuing authority, as appropriate.

5.16 Computer Orientated Documents and Data

- 5.16.1 Levels of access to all information, documents and data is controlled by the use of individual usernames and passwords.
- 5.16.2 The GM has the designated authority to issue and retract usernames and system permissions as necessary.
- 5.16.3 The GM determines the area and scope of access to the system for each authorized user.
- 5.16.4 The GM ensures the correct installation of usernames and passwords and access scope to the appropriate areas of the system for each authorized user.

**QUALITY MANAGEMENT SYSTEM
Control of Documents**

5.16.5 All electronic documentation stored on the company Intranet (accessible by all authorized users) may be assumed to be current and considered to be the latest issue and/or revision by all staff.

5.16.6 All redundant issues and/or revisions of documentation and obsolete documentation will not be accessible to system users.

6.0 Documentation

Internal Forms Register (IF33)

External Forms Register (IF34)

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