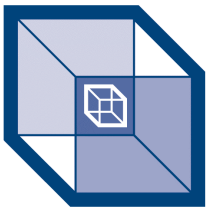

Packwell

D & S Limited

Chettisham Business Park Chettisham,

Ely, Cambs Cb6 1RY

Tel. 01353 666399

Managing Director: Mr G. R. Hartwig

QUALITY ASSURANCE MANUAL

NOTE: This is a CONTROLLED Document. 1ST Jan 2004

1.0 INTRODUCTION

Packwell D&S Ltd was formed in 1985 to satisfy customer requirements for Contract Packing & Fulfilment Services.

This Quality System relates to the full range of company activities.

2.0 POLICY and OBJECTIVES

PACKWELL quality policy is to achieve sustained profitable growth by providing services, which consistently satisfy the needs and expectations of its customers.

This level of quality is achieved through adoption of a system of procedures that reflect the competence of the Company to existing customers, potential customers, and independent auditing authorities.

Achievement of this policy involves all staff, who are individually responsible for the quality of their work, resulting in a continually improving working environment for all. This policy is provided and explained to each employee by the Managing Director or Quality Manager.

To achieve and maintain the required level of assurance the Managing Director retains responsibility for the Quality System with routine operation controlled by the Quality Manager.

The objectives of the Quality Assurance System are:

a) To maintain an effective Quality Assurance System.

b) To achieve and maintain a level of quality which enhances the Company's reputation with customers.

c) To ensure compliance with the relevant statutory and safety requirements.

d) To endeavour, at all times, to maximise customer satisfaction with the services provided by Packwell D&S Ltd

Gary Hartwig - Managing Director

October 1997

3.0 DEFINITIONS

The terms and descriptions used in this Manual are generally defined within Standard Quality Systems.

Additional definitions apply for items not covered by the documents:

Site Any location, other than the Company's established premises, where work is undertaken as part of a formal contract

4.0 QUALITY SYSTEM

The Quality Assurance System applies to all activities of the Company, and has been developed in accordance with Customer requirements. The Quality Assurance System is fully documented

Level 1 : Quality Manual

This document details the corporate quality policy and structure of the Company and references appropriate Operating Procedures.

Level 2 : Operating Procedures

These documents describe the actual process, and controls applied, to all activities concerned with the attainment of a quality assured contracting service. These Documents are either provide by the Customer working within their standard procedures or from our own standard procedures.

Quality Planning

As the Company operates a standard type and range of services, customer satisfaction and quality are achieved by operation in accordance with the documented quality system. Specific customer requirements are identified and documented during the contract review process, allowing these requirements to be communicated and achieved, ensuring satisfaction of all customers declared needs.

5.0 Organisation

G. R. Hartwig	**M.D. QA, Sales & Production**
L. Hartwig	**Finance Director, Personnel,**
A. Follen	**General Manager Factory & Warehouse**
A. Jupp	**Stock Control, Office Administrator**
J. Mayo	**Warehouse Supervisor**
J. Driver	**Administration**
A. Burford	**Packaging Main Line Supervisor**
V. Purton	**Supervisor team A**
L. Turner	**Order Picking**
G. Groom	**Order Picking**
Production	**10 – 15 operatives**
Warehouse	**4 operatives**

6.0 AUTHORITY & RESPONSIBILITIES

6.1 Authority

6.1.1 All staff are allocated with authority to perform their allocated responsibilities. The following provides a summary of the principal responsibilities of each job role, and these are clarified in greater detail within the Operating Procedures.

6.1.2 All staff share the authority and responsibility of identifying non-compliances or possible improvements, and recording these instances such that corrective action can be taken, both to rectify the immediate situation and to prevent recurrence.

6.1.3 The Managing Director continually reviews the company's resources to ensure that adequate staff, equipment and materials are available to meet customer requirements.

6.2 Responsibilities

6.2.1 Managing Director

Approval of the Quality Assurance System

Management Review

Design Control

Supplier Selection & Purchasing

Contract Management & Control

Training

6.2.2 Quality Manager

Internal Audit

Resolution of Quality Assurance System Discrepancies

Control & Maintenance of the Quality Assurance System

Documentation & Change Control (Quality System Documents)

6.2.3 Sales Director

Management & Co-ordination of Sales and Support Functions

Contract Review

Sales Order Processing

Design Control

Estimating

Project Management

Control of Contract Documentation

Planning & organization

Supplier Selection & Purchasing

Definition of Installation, Inspection, Test & Maintenance Requirements

Training

6.2.4 Sales Managers

Quotations

Contract Review and Order Processing

6.2.5 Support Manager

Planning and Co-ordination

Control of Production and Measuring Equipment

Maintenance of Support Stores

Processing of Sales Orders

Purchasing

6.2.6 Support Supervisor

Planning & Performance of Production Line, Technical Assistance, Repairs, Testing and Maintenance Activities

Control of Equipment and Materials Allocated

6.2.7 Financial Director

Control of Finance, Accounts and Warehouse Operations

Training

Supplier Selection and Purchasing

6.2.8 Warehouse

Control of Stock

Replenishment Recommendation

Protection and Preservation of Stock

Receiving Inspection

Packaging and Despatch

6.2.9 Business Development Manager

Sales

Estimating

New Product Identification & Evaluation

Packaging Design

6.2.10 Administration Order Processing Clerk

Sales Database Administration

Checking of Sales Orders

Allocation of Order Reference Numbers

7. COMPLIANCE

This Quality System is structured with policy statements relating to each area of activity being within the relevant Operating Procedure. However, the following items are not addressed within the operating procedures as they are not applicable to this Company:

Statistical Techniques

8. MANAGEMENT REVIEW and INTERNAL AUDIT

Management review of the suitability and effectiveness of the Quality System take place at least twice per year. During the management meetings actions are allocated and minuted to record the development of the Company's management system.

The objectives of Management Review are:

a) To establish that the Quality (Management) System is achieving the expected results and meeting the Company's requirements, continuing to conform to the Standard, continuing to satisfy the customers needs and expectations, and functioning in accordance with the established Operating Procedures.

b) To expose irregularities or defects in the System, identify weaknesses and evaluate possible improvements.

c) To review the effectiveness of previous corrective actions, and to review the adequacy and suitability of the management system for current and future operations of the Company.

d) To review any complaints received, identify the cause and recommend corrective action if required.

e) To review the finding of internal/ external audits and identify any areas of recurring problems or potential improvements.

f) To review the reports of non-conforming items and trend information to identify possible improvements.

Internal audits of the Quality System are undertaken at least once per annum to confirm that the function concerned is adhering to the Company's Procedures. A comprehensive Audit Programme is compiled at least a year in advance however, should particular needs be identified, the frequency of audit may be increased at the discretion of the Quality Manager.

Audits are undertaken by auditors who are trained in auditing and not directly responsible for the functions being audited within that Company. Non-conformance observed is brought to the attention of the person responsible, and is recorded, documented and subject to timely corrective action to ensure full rectification.

9. CONTRACT REVIEW

The Company offers both standard services and specialist services to meet each customer's needs. Standard services are displayed in the Company Brochure and Web site www.packwell.co.uk for customer perusal. Specialist service requirements differ from one customer to another (and from one contract to another), therefore each tends to be quoted for the specific contract.

Once a proposal is accepted by the customer, or an order is placed, it is recorded and reviewed to establish that the requirements of the order are adequately defined and documented, any differences from the proposal are resolved, and the Company is capable of fully satisfying the customers requirements.

In addition to the original order/ contract specification the customer may also request addition/ variation work to be undertaken by the Company. In these circumstances the work content is documented and agreed with the customer prior to execution to ensure that no ambiguity exists.

The Company operates on a computerised database processing system to ensure rapid fulfilment of customer orders.

10. CONTRACT PACKAGING CONTROL

All activities are strictly controlled to ensure that packaging complies with customer/ contract requirements. Production cannot start without a customer approved sample, ongoing Line QC is carried out by Supervisors

All Production are batch controlled for tractability, with batch code/date code on individual products, or if not required on the Transit Packaging. All transit Packaging has the Batch Code, Date Code & Packers Code.

For each and every Production Batch a Production Docket is produced. Each Batch is QC'd and noted. Once passed the Production Batch can be processed through the Computer Stock control system.

Activities are planned and normally executed by experienced staff and are subject to regular management, review and verification by the Sales Director, and where relevant, agreement with the Customer.

The specifications are documented, and where ambiguity exists, will be clarified and documented accordingly. All items of documentation and notes are recorded in a project file. Documentation is produced and reviewed to ensure that it:

Meets the Customer requirements

References the Customer Rrequirements

And Identifies all of the characteristics which are critical to the final product/service

Packaging is reviewed and approved by the Sales Director, and is also provided to the Customer for approval prior to bulk production. Samples are made in accordance with the Customer specification to confirm compliance to the customer's requirements.

The designer is required to specify any inspections or tests (Transit tests etc.) which may verify the design, by practical means, at the earliest possible stage of development.

All changes to the packaging design criteria, input or output are subject to strict review and documentation control procedures.

11. DOCUMENTATION & CHANGE CONTROL

All documentation utilised within the Company related to the management system itself, or to the execution of individual customer contracts is controlled to ensure that it is issued to the appropriate personnel, under the correct level of authority, is revised and reissued as necessary, and all obsolete versions are removed from the point of use.

Such documentation typically includes:

Specifications, Customer Orders, Drawings,
Quality Assurance Manual/ Operating Procedures,
Customer Standards and Codes of Practice.

The Quality Assurance Manual, Procedures and Quality Plans are maintained by the Quality Manager who ensures that the appropriate items, at the correct revision levels, are issued to all who need them within the Company.

Customer Standards, Codes of Practice are maintained by the Support Engineers who ensure that appropriate documents are available within the Company, and are issued at the correct revision levels. External suppliers of documentation are contacted regularly to ascertain that the documents held remain current.

The distribution of standard documents is controlled and recorded on Distribution Lists, which also show the current issue status. The Distribution Lists are reviewed and updated as changes occur.

All changes to documents are reviewed and approved by the person responsible for the original issue and, where appropriate, the nature of the change is indicated on the document. Master copies of the revised documents are retained as records of the changes and renewed as necessary to ensure clarity.

Each contract has a File, which contains all relevant information. Information is also held on the company's computer system for ease of access and manipulation.

12. PURCHASING

Suppliers of products, materials and services, where unspecified by a customer contract, are selected on their ability to meet the company's requirements given due consideration to the quality, statutory obligations, timescale and cost. A list

of approved suppliers and sub-contractors is maintained which is compiled on the following criteria:-

a) Previous performance in supplying to similar specifications and requirements.

b) Stocking of high volume standard items conforming to a relevant British Standard, or supplied with a statement of conformity.

c) Compliance with an approved third party product/ quality registration scheme.

d) Recommendation by other similar purchasers, or manufacturers of equipment.

e) A trial order and evaluation of performance.

All supplies and sub-contracts are subject to an authorised Purchase Order providing full clarification of the type and extent of supply.

Should a supplier, not appearing on the Approved Suppliers List be proposed, they will be analysed by capability and subject to acceptance on the authority of a Director.

13. CUSTOMER SUPPLIED ITEMS

Goods received from customers (i.e. free issue items or equipment being serviced) are always visually inspected at the receipt stage, with any un-declared non-conformance being immediately reported to the customer.

14. PROCESS CONTROL

All productive work is planned and undertaken in accordance with the company's procedures, and any specific documents agreed for individual contracts (e.g. contract specifications).

Work instructions are provided by the agreed contract specification and any documents referenced therein, alternatively work is performed in accordance with the Customers codes of practice.

15. RECEIVING INSPECTION

All stores areas are maintained as secure as practical. All items received by the Company are identified and verified in accordance with the requirements of the Delivery Note and Purchase Order, and are inspected for correct identity, quantity and any signs of damage.

All goods received are documented and, in the event of non-conformance, the items are placed in a reject area or labelled to ensure identification. The extent of the non-conformance is noted and subject to disposition review by nominated personnel.

16. INSPECTION

Inspection is carried out continuously during production, with results being documented on the production Dockets. Should items not be acceptable against the agreed contract criteria they will be repaired, replaced or identified for a subsequent evaluation and decision. All repaired items are subject to a re-inspection to ensure acceptability.

On completion or during production, the customer is also invited to check the work performed to ensure full acceptability.

17. PRODUCTION & MEASURING EQUIPMENT

Production and measuring equipment held is maintained in good condition, and capable of safe and effective operation within a specified tolerance of accuracy. Test and measuring equipment is regularly inspected or calibrated to ensure that it is capable of accurate operation, by comparison with external sources traceable back to National Standards.

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18. INDICATION OF INSPECTION STATUS

As goods are inspected, the status is defined by location in stores, with all non-conforming items being placed in a reject area or marked as reject for review. The status of work in progress is established by markings or associated documentation recording the inspections undertaken and their acceptability.

19. NON-CONFORMING ITEMS, PREVENTIVE & CORRECTIVE ACTION

Once non-conforming items have been noticed they are identified by location, associated documents, or specific markings to prevent their inadvertent use. All non-conforming items and customer complaints are subject to review and rectification by nominated personnel. The type and extent of non-conformity is documented in order to establish trends and identify possible areas for improvement.

The corrective action required to prevent recurrence is evaluated, documented, and its effective implementation is monitored. All rectification is subsequently re-inspected to ensure complete customer satisfaction.

All employees are encouraged to suggest improvements in methods, materials, suppliers,

and sub-contractors. The Company has established procedures for review of all activities in order to identify and evaluate all possible improvements in methods/ materials and its procedures.

20. HANDLING, STORAGE, PACKAGING, PRESERVATION & DELIVERY

The identification of materials/ equipment, where it is not obvious, is confirmed by the presence of a manufacturers/ suppliers part number or description label, or other marking for each item. The identification of the item may be on the packaging or on the item itself, and this identification remains in place for as long as possible, provided it does not hamper effective use of the item. Materials and consumables are not identified by the company where they are obvious to a trained/ experienced employee, however, should a risk of misinterpretation exist between two or more types of material these will be marked in a suitable manner to ensure that no ambiguity exists.

All items with serial numbers are recorded individually.

Materials and goods received, whether the property of the company or others, will, as far as practicable, be protected and their quality preserved until such time as they are transferred to a customer, or disposed of to a third party. The objective is to prevent deterioration and damage whilst in storage, or in the process of transportation, installation, commissioning or maintenance.

21. RECORDS

Storage facilities are allocated which ensure that all stored records are identifiable and retrievable, and the storage areas are free from damp and other agents which could cause premature deterioration.

Where records are maintained on computer magnetic media, and these are subject to "back-up" at regular intervals, with the "back-up" information being stored in a protected location to ensure security from loss/ damage of active data.

All records are retained for a minimum of 2 years.

22. TRAINING

The policy of the company is to ensure that all personnel are trained and experienced to the extent necessary to undertake their assigned activities and responsibilities effectively. The company generally procures and recruits

employees capable of meeting the technical, skill, experience and educational requirements of the company's activities.

All staff and senior employees are responsible for recommending the training needs of others, and for ensuring that all employees allocated specific tasks are suitably qualified and experienced to execute those tasks. Once training needs are identified these are provided under the responsibility of the Directors.

Full records are maintained of all training undertaken by employees.

23. SERVICING

Service and maintenance contracts are offered to all customers, and these activities are controlled in the same manner as Process Control.

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