

SUBJECT: QUALITY SYSTEM POLICY

1.0 PURPOSE:

1.1 To define the MBM Packaging Labs' quality system that conforms to ISO 9002.

2.0 SCOPE:

2.1 Applies to all operations within MBM Packaging Labs' facility. ISO element 4.4, design control, and element 4.19, Servicing, does not apply to the MBM Packaging Labs Quality System.

3.0 MBM PACKAGING LABS QUALITY SYSTEM:

3.1 Management Responsibility:

A. Quality Policy -

Procedures for management to define and document the policy and objectives for, and commitment to, quality. Procedures also address the assurance that policy is understood, implemented, and maintained at all levels of the organization.

B. Organization -

1. Responsibility and Authority -

Procedures which define the responsibility, authority, and interrelation of all personnel who manage, perform, and verify work affecting quality. These may be contained in individual procedures dealing with specialized subjects, in organization charts, and in job descriptions.

2. Resources -

Adequate trained personnel shall be provided for management, performance of work and verification activities including internal audits.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 1	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

3. Management Representative -

The president shall appoint a member of management (usually the Quality Manager) to serve as the authority and facilitator of ensuring that the requirements of the quality system are implemented and maintained. The Quality Manager shall issue reports to the management team on the performance of the quality system and lead in the improvement of the quality system. An alternate is also to be designated to fill this responsibility in the absence of the Quality Manager.

4. Management Review -

The Quality Manager shall have a documented periodic review of the quality system with the Manufacturing Manager, President, and process leaders to ensure continuing suitability and effectiveness of the quality system. Other management personnel may attend the review as deemed necessary. Records of the reviews shall be maintained.

3.2 Quality System:

A. General -

As a means of ensuring that products conform to specified requirements, a quality system shall be established, documented into procedures instructions and records, and maintained in a state of currentness.

B. Quality System and Procedures -

There shall be a quality manual which covers the requirements of the ISO 9002. ISO 9002 is the guideline by which the quality system operates. GMP requirements are co-mingled into the normal ISO 9002 program requirements. The quality manual shall reference all quality system procedures and outline the documentation used in the quality system.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 2	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

C. Quality Planning -

Procedures shall define and document how the requirements for quality will be met and will include, where appropriate, the following elements:

1. Quality Plans;
2. Identification of required controls, processes, equipment, fixtures, resources, and skills needed to achieve the required quality;
3. Ensuring the compatibility of production processes, inspection, testing and documentation;
4. Resolution in a timely manner of measuring requirements;
5. Clarification of standards of acceptability for all features and requirements, including subjective standards;
6. Identification and preparation of required quality records.

3.3 Contract Review:

A. General -

The plant shall establish and maintain documented procedures for contract review and for the coordination of these activities.

B. Review -

Procedures for reviewing contracts and documentation of same to ensure that:

1. The requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance.
2. Any requirements differing from those in the tender are resolved;
3. The plant has the capability to meet contractual requirements.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 3	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

C. Amendment to a contract -

Procedures shall cover how a contract is amended and forwarded to needed personnel.

D. Records -

Records of contract review shall be maintained.

3.4 Design Control -

Design Control is not applicable to the MBM Packaging Labs quality system.

3.5 Document Control:

A. General -

Procedures for establishing and maintaining control of all documents and data that relate to the quality system including, to the extent applicable, documents of external origin such as standards and customer proofs.

B. Document and Data Approval and Issue -

Documents must be reviewed and approved for adequacy by authorized personnel prior to issue. A means for identifying the current revision status of documents shall be established. The control shall ensure that:

1. The pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;
2. Obsolete documents are promptly removed from all points of issue or use.
3. Any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:		APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 4	OF 14

SUBJECT: QUALITY SYSTEM POLICY

C. Document Changes -

Procedures shall be established for changing, reviewing, and approving existing procedures in the quality system. The following guides are to be incorporated:

1. Changes, reviews and approvals are to be made by the same functions/organizations that performed the original tasks;
2. Where applicable, the nature of the change shall be identified in the document or the appropriate attachments.

3.6 Purchasing:

A. Evaluation of Subcontractors -

Procedures for selecting subcontractors on the basis of their ability to meet the plant's requirements, including quality requirements shall be established. Included in this requirement is the documentation of approved subcontractors. Selection is dependent upon the type of product and where appropriate, on record of the subcontractors previously demonstrated capability.

B. Purchasing Data -

Procedures pertaining to the issue of Purchase Orders which stipulate data clearly describing the product ordered, including, where applicable:

1. The type, class, style, grade, or other precise identification;
2. The title or other positive identification, and applicable issue of specifications, drawings, etc.;
3. The title, number, and issue of the quality system standard to be applied to the product.

Requirements state that plant purchasing must review and approve POs prior to release.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 5	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

C. Verification of Purchased Products -

1. If plans are made to verify product at the subcontractor's premises, verification arrangements and the method of product release must be included in the PO.
2. If so specified in the contract, our customer or their representative will be afforded the right to verify purchased product at our plant or at our subcontractor's plant. This is not to take away our responsibility to control the quality of purchased product.

3.7 Control of Customer Supplied Product:

Procedures for the verification, storage, and maintenance of Customer Supplied Product provided for incorporation into the product. Products that are lost, damaged, or are otherwise unsuitable for use must be recorded and reported to the customer.

3.8 Product Identification and Traceability:

Procedures for identifying the product from applicable proofs, specifications, or other documents during all stages of productions, delivery, and installation. Where and to the extent that traceability is a specified requirement, individual product or batches shall have a unique identification, which is to be recorded.

3.9 Process Control:

A. General -

Procedures for identifying and planning the control of processes to ensure that production is "in-control" and "capable". Control shall include the following:

1. Documented work instructions defining the manner of production, use of suitable production equipment, suitable working environment, compliance with reference standards and quality plans;
2. Monitoring and control of suitable process and product characteristics during production;

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 6	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

- 3. The approval of processes and equipment, as appropriate;
- 4. Criteria for workmanship which shall be stipulated, to the greatest practicable extent, in written standards or by means of representative samples;
- 5. Procedures and/or work instructions pertaining to periodic preventative maintenance and to operator daily maintenance and subsequent records of same.

B. Special Processes -

Procedures dealing with the qualification of processes, equipment, and personnel and the maintenance of records for those processes where inspection and testing of the product cannot be fully verified.

Records shall be maintained for qualified processes, equipment, and personnel as appropriate.

3.10 Inspection and Testing:

A. Receiving Inspection and Testing -

- 1. Procedures and quality plans dealing with the verification of incoming product to ensure that it is not used until confirmation that it conforms to specified requirements.
- 2. Procedures dealing with the release of non-verified incoming product for urgent production purposes to ensure proper identification and recording such that immediate recall and replacement can take place if product turns out to be nonconforming.
- 3. Where it becomes necessary to release product for urgent production purposes prior to verification, it shall be positively identified and recorded for the expressed purpose of immediate recall and replacement in the event a nonconformity to specified requirements occurs.

B. In-Process Inspection and Testing -

Procedures or quality plans for holding of product until the required in-process test and inspection of product is done to ensure that it conforms to specified requirements.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 7	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

Product released under positive recall does not preclude the inspection and testing defined above.

C. Final Inspection and Testing -

Procedures or quality plans defining required final inspection and testing, including the verification that in-process inspection and testing has been done. They must ensure that product has been inspected and tested prior to release and that associated documentation is available and authorized.

D. Inspection and Test Records -

Procedures to cover the establishment and maintenance of records which provide evidence that the product has passed inspection and/or test to the defined acceptance criteria.

Records shall identify the inspection authority responsible for the release of product.

3.11 Inspection, Measuring, and Test Equipment:

A. General -

Procedures covering the control, calibration and maintenance of inspection, measuring, and test equipment, whether owned by the plant, on loan, or provided by the customer. Procedures must address the proper use of equipment to ensure that measurement uncertainty is known and is consistent with the required measurement capability. Details of procedures are as follows:

B. Selection -

Procedures defining the selection of appropriate inspection, measuring and test equipment for the particular parameter and its required measurement accuracy.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 8	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

C. Calibration Standard -

All inspection, measuring, and test equipment including maintenance equipment, which can affect product quality, must be calibrated at a known valid relationship to nationally recognized standards; where no such standards exist, the basis used for calibration shall be documented.

D. Calibration Procedures -

Calibration procedures must be established, documented, and maintained and include details of: equipment type, identification numbers, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory.

E. Equipment Capability -

Inspection, measuring, and test equipment is to be ensured to have the accuracy and precision necessary.

F. Calibration Status -

Calibration status is to be indicated on the equipment or on an approved identification record.

G. Calibration Records -

Calibration records must be maintained.

H. Corrective Action -

When inspection, measuring, and test equipment is found to be out of calibration, the validity of previous inspection and test results is to be assessed and documented.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:		APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 9	OF 14

SUBJECT: QUALITY SYSTEM POLICY

I. Environmental Requirements -

Environmental conditions are to be ensured for suitability of the calibrations, inspections, measurements, and tests being carried out.

J. Physical Control -

Handling, preservation, and storage of inspection, measuring, and test equipment are to be such that the accuracy and fitness for use is maintained.

K. Calibration Safeguards -

Inspection, measuring, and test equipment including software is to be protected from adjustments that would invalidate the calibration setting.

L. Indirect Verification Control -

Test software or comparative references, such as test hardware used as forms of inspection, are to be checked periodically and documented to prove their capability for verifying the acceptability of product. Design and calibration records will be maintained.

3.12 Inspection and Test Status:

A. Inspection and Test Status -

Procedures covering the means for identifying the inspection and test status of product to indicate conformance or nonconformance to inspection or tests performed. Status shall be maintained, as to inspection or tests performed. Status shall be maintained, as defined in the quality plan or procedures, throughout production to ensure that only product that has passed the required inspection and test is used or shipped.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 10	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

3.13 Control of Nonconforming Product -

A. General -

Procedures to ensure that product that does not conform to specified requirements is prevented from inadvertent use. Control shall provide for identification, documentation, evaluation, segregation, when practical, disposition of nonconforming product, and for notification to the functions concerned.

B. Nonconformity Review and Disposition -

Procedures defining the responsibility and authority for disposition of nonconforming product and records to denote the disposition whether: rework, accept as is, repaired or scrap. Repair or rework must be re-inspected.

3.14 Corrective Action and Preventive Action:

A. Corrective Action -

Procedures for implementing corrective action. Changes made to the documented procedures resulting from corrective action shall be recorded. They should include:

1. The handling of customer complaints and reports of nonconforming product;
2. Investigating the cause of nonconforming product, process, and quality system and recording the results of the investigation;
3. Determination of the corrective action needed to eliminate the cause of nonconformities;
4. Application of controls to ensure that corrective action is taken and that it is effective.

B. Preventive Action -

Procedures for implementing preventive action. Changes made to the documented procedures resulting from preventive action shall be recorded. These should include:

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 11	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

1. Using information such as processes, work operations, concessions, quality records, service reports, and customer complaints, to detect and eliminate potential causes of nonconforming product;
2. Initiating preventative actions and application of controls to ensure that it is effective;
3. Submitting relevant information on actions taken to management review.

3.15 Receiving, Handling , Storage, Packaging, Preservation, and Delivery:**A. Receiving -**

Procedures for receipt of material to ensure that it was not damaged, that the quantity matched the manifest, that the item descriptions matched and that the material was delivered to the proper area with the proper identification.

B. Handling -

Procedures covering the methods, and means of handling that prevent damage or deterioration.

C. Storage -

Procedures which provide for designated storage areas to prevent damage or deterioration of product, pending use or delivery. Procedures shall cover appropriate methods for authorizing receipt and the dispatch to and from such areas. Procedures should also define the appropriate intervals for assessing the condition of product in stock in order to detect deterioration.

D. Packaging -

Procedures to control packing, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 12	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

E. Preservation -

Procedure for preservation and segregation of product when the product is under the plant's control.

F. Delivery -

Procedures pertaining to the protection of the quality of the product after final inspection and test.

Where contractually specified, this protection shall be extended to include delivery to destination.

3.16 Quality Records:

Procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.

Quality records including subcontractor records should be able to demonstrate conformance to specified requirements and the effective operation of the quality system.

The following is to be included in the procedures:

- A. Records shall be legible and identifiable to the product involved;
- B. Records must be readily retrievable and stored such as to minimize deterioration or damage;
- C. Record retention times must be established and recorded;
- D. Records shall be made available for evaluation by the purchaser where agreed to contractually for the agreed upon period.

3.17 Internal Quality Audits:

Procedures for carrying out internal quality audits to verify whether quality activities comply with planned arrangements and to

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 13	OF 14	

SUBJECT: QUALITY SYSTEM POLICY

determine the effectiveness of the quality system. Procedures should include the following.

- A. Scheduling of the audits on the basis of the status and importance of the activity;
- B. Audit performed by personnel independent of the activity being audited;
- C. Documentation of the results of the audits shall be done;
- D. Results shall be brought to the attention of the personnel having responsibility in the area audited;
- E. Management personnel responsible for the area shall take a timely corrective action on the deficiencies found by the audit;
- F. Follow up audits to verify and record the implementation and effectiveness of the corrective action taken.

3.18 Training:

Procedures for identifying the training needs and providing for the training of all personnel performing activities affecting quality during production. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training, and/or experience, as required. Appropriate records of training shall be maintained.

3.19 Servicing:

Servicing is not applicable to the MBM Packaging Labs quality system.

3.20 Statistical Techniques:

Procedure for identifying adequate statistical techniques required for verifying the acceptability of process capability and product characteristics.

SUBJECT NO. 02	POSTFIX NO. 101	REVISION NO. 1	ISSUED BY QA Manager	ISSUE DATE 02/09/98	
APPROVED BY:	APPROVAL DATE 02/11/98	REVISION DATE 5/21/05	PAGE 14	OF 14	