PLANT QUALITY ASSURANCE MANUAL

FOR DIGITAL DISTRIBUTION

DATE: 07/28/2013

MANUAL SERIAL NUMBER: DIGITAL

APPROVED BY: QA TEAM

PLANT QUALITY ASSURANCE MANUAL
TABLE OF CONTENTS

MBM Packaging Labs, Inc.
Printing Solutions | Graffiti Expressions
Mission Statement

Serve the Customer

We plan to provide the best customer service in our industry. This excellent service will be in the form of on-time delivery of reliable, high quality products, produced at a competitive cost. It will be supported by superior application assistance, inventory availability, and response to special delivery and/or service needs.

Team Environment

We plan to operate in an honest and open environment based on simplicity. Our environment will encourage innovation, self-motivation, and practical risk taking. Management is expected to be listeners, decision-makers, and leaders by example. Team member's mission is to treat employees and customers with respect and honesty and maintain an environment of continuous improvement.

MBM Packaging Labs Vision

To be a principle-centered company dedicated to customer satisfaction and continuous improvement in our field of business.

1.0 PURPOSE:

1.1 To provide an understanding of the operations within MBM Packaging Labs, Inc. and its subsidiaries Printing Solutions and Grafitti Expressions. Throughout this manual all topics addressing MBM Packaging Labs, Inc. will be inclusive of Printing Solutions and Graffiti Expressions.

2.0 SCOPE:

2.1 This procedure applies to all operations within MBM Packaging Labs, Inc and its subsidiaries Printing Solutions and Graffiti Expressions.

3.0 INTRODUCTION TO THE COMPANY:

3.1 Introduction:

In 1997, MBM Packaging Labs, Inc. was founded in Rogersville, Tennessee, USA. Rogersville is located in the northeastern part of Tennessee in the foothills of the beautiful Great Smoky Mountains.

In 2000, Printing Solutions, a subsidiary of MBM Packaging Labs, Inc. was created to cater to the general commercial printing needs of our customers and those of potential clients. The year of 2010 brought the acquisition of Graffiti Expressions, adding the production of large format printing and laminating.

Our company's vision is to be a world leader in the pharmaceutical and medical device packaging industry, providing printed components using offset, flexo, digital, and wide format UV printing.

This manual defines the quality assurance system and establishes the authority for and responsibilities of the quality function as it relates to all other functions in order to achieve optimal quality and service to our customers. It also provides general procedures for all activities comprising the quality assurance system.

This manual is issued and controlled by the QA Team Leader on behalf of the organization.

For more detailed information involving our capabilities, quality, control and systematics contact your representative.

SUBJECT: QUALITY POLICY STATEMENT

1.0 PURPOSE:

1.1 To provide the long term quality policy for MBM Packaging Labs, and its subsidiaries Printing Solutions and Graffiti Expressions for the purpose of: stating philosophy and standards, give direction internally to plant management, and provide an expectation of what is desired from this facility.

2.0 SCOPE:

2.1 This Procedure applies to all operations within MBM Packaging Labs.

3.0 STANDARDS:

3.1 ISO 9002 (ANSI/ASQC Q92-1994) and cGMP compliance are the goals and standards to be followed by MBM Packaging Labs.

4.0 POLICY STATEMENT:

4.1 Goal:

A. MBM Packaging Labs' goal as a company is to be the best supplier of printed packaging material and commercial printing products. A prioritized goal has been developed in: design, manufacturing, and customer service.

4.2 Quality of Design:

A. A quality design is achieved by determining the needs and requirements of each specific customer and incorporating those requirements into the design to achieve the desired product.
B. A quality design must include quality components and raw materials and the parameters of these must be measurable.
C. A cross-functional team of marketing and manufacturing must meet regularly throughout the design phase.

4.3 Quality of Manufacture:

A. Manufacturing quality is determined by the conformance of incoming supplier material and in-plant manufactured product to customer specifications thus creating a total quality product.

B. Internally, this goal may be achieved by capable equipment and processes, which are maintained by capable and well-trained operators.
C. Externally, each supplier of products to this facility must be committed to a similar quality policy of their own. An atmosphere of partnership must be achieved with our suppliers in order that our quality philosophy may be adhered to in their processes.

4.4 Quality of Customer Service:

A. MBM Packaging Labs' goal is to provide the best customer service in the industry through: on time delivery of products, superior application assistance, response to special delivery or service needs and error free business mechanics.
B. This is to be accomplished by: inventory of stock products, trained people, flow charted and streamlined administrative processes, and identified, measured, and controlled critical process parameters.

4.5 Commitment to Continuous Improvement:

A. Producing nominal, reduction of variation, and reduction of defective rates are all attributes of improving quality, which everyone in the organization should strive for in their particular area of responsibility.
B. Actions that can make this occur include: Improvement teams, training in problem solving techniques, design reviews of existing products, and statistical process control.

SUBJECT: PLANT ORGANIZATIONAL CHART

1.0 PURPOSE:

1.1 To define corporate organization and titles of each staff manager, along with a brief description of their responsibilities and authority.

2.0 SCOPE:

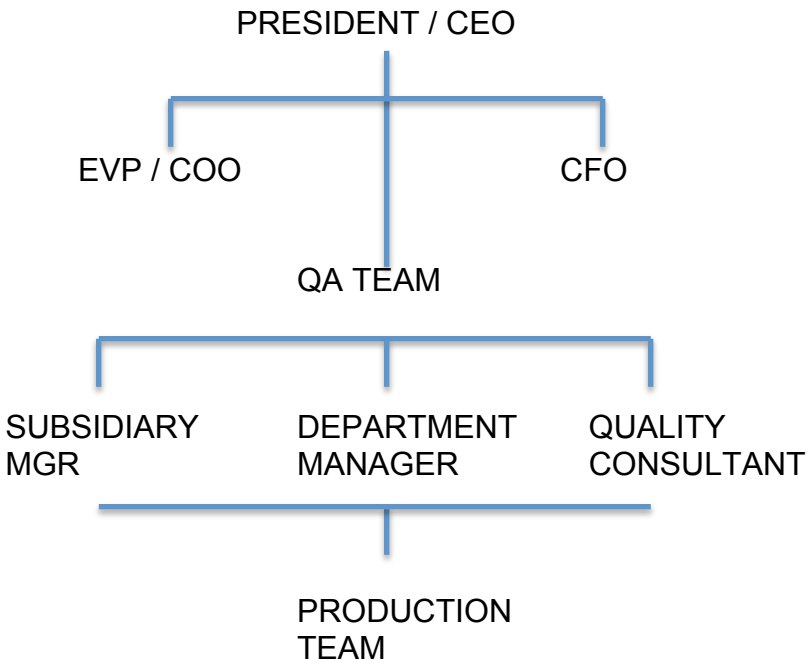
2.1 This procedure applies to the entire MBM Packaging Labs, Printing Solutions and Graffiti Expressions organization.

2.2 See attached organization chart for specifics.

3.0 RESPONSIBILITIES:

3.1 The attached pages are descriptions of each staff manager's job title, department, job summary, and responsibilities and authority.

JULY 2013


PRESIDENT / CEO
EVP / COO
CFO
QA TEAM
SUBSIDIARY MGR
DEPARTMENT MANAGER
QUALITY CONSULTANT
PRODUCTION TEAM

JOB TITLE: **CEO**

JOB SUMMARY:

Provide the vision and leadership necessary for MBM Packaging Labs and subsidiaries to be a leader in the printing industry. Ensure that MBM Packaging Labs' products can compete successfully while selling at prices above the manufactured costs and still provide a product to the marketplace that offers better value than the competition.

The CEO must be an integral part of the Quality Team. Tighter cost saving requirements by our customers will cause a combination of many job functions. Each job function is directly related to quality will require cross-training to ensure all employees have equal knowledge of the final objectives established by the CEO.

RESPONSIBILITIES AND AUTHORITY:

1. To provide leadership for all staff functions in order to meet financial responsibilities of the organization.
2. To provide leadership for all staff functions in order to meet and exceed manufacturing objectives in order to be competitive in a world market.
3. To provide leadership and commitment to cultivating and developing a culture of quality excellence at each level in the organization.
4. To provide leadership for all staff functions in order to meet sales responsibilities of the organization.

JOB TITLE: **EXECUTIVE VICE PRESIDENT/COO**

JOB SUMMARY:

To ensure the manufacturing, engineering, quality and sales departments operate in a manner conducive for a total quality environment. To support each of these departments and make sure all tools are in place to produce and sell the highest quality product.

Tighter cost saving requirements by our customers will cause a combination of job functions. Each job function related to Purchasing Manager, as described on page 9 of 01-101, will now relate to the EVP/COO.

RESPONSIBILITIES AND AUTHORITY:

Manage the manufacturing, engineering, quality and sales departments and coordinate each department so that each department completes their respective tasks so that all customer requirements are met. Provide a culture of teamwork between each department for the betterment of the organization.

JOB TITLE: **VICE PRESIDENT/FINANCE, CFO**

JOB SUMMARY: To advise in the areas of finance, purchasing, and human resource in a manner conducive for a total quality environment. To support each of these areas and make sure all tools are in place to provide fiscal responsibility and that human resource and material requirements of the organization are met.

RESPONSIBILITIES AND AUTHORITY: To manage the finance, purchasing, and human resource to meet organization and customer demands. Provide fiscal responsibility for the organization. Insure that material and human resource requirements are fulfilled in accordance with customer and product demand. Provide for the compliance with all safety and government regulations.

JOB TITLE: **SUBSIDIARY MANAGERS**

DEPARTMENT: MANUFACTURING AND GENERAL OPERATIONS MGMT

JOB SUMMARY: To manage all plant manufacturing processes to meet or exceed production requirements, quality standard, and foster a positive workplace environment where a world-class philosophy can grow.

The Subsidiary Manager is an integral part of the Quality Team. Tighter cost saving requirements by our customers will cause a combination of many job functions. Each job function is directly related to quality will require cross-training to ensure all employees have equal knowledge of the final objectives established by the CEO.

RESPONSIBILITIES AND AUTHORITY: To provide the necessary support relative to operate each manufacturing department efficiently and with a monthly budget. Insure the workplace is safe, tooling and equipment is available to manufacture products and assemblies within specifications, and a positive atmosphere exists on the manufacturing floor. Other responsibilities are: job scheduling, process documentation, and employee supervision.

JOB TITLE: **QUALITY ASSURANCE TEAM**

DEPARTMENT: QUALITY ASSURANCE

JOB SUMMARY: Coordinate Plant Quality Assurance Activities. Strive toward Consistent Improvements in Quality Levels of Activity so that Products may be manufactured with Quality, Efficiency, and Teamwork in order to meet a return on Investment Goals through providing a Quality Product.

RESPONSIBILITIES AND AUTHORITY: To assure each job function has the necessary training and support to produce a quality product. Establish documented Quality System Procedures for communicating the established methods for performing and administering the work relative to assuring and controlling the Quality of MBM Packaging Labs' Products. Decisions toward assuring that the desired Quality is Produced. Establishing Methods that will comply with agreed upon Objectives. Insure that all training requirements by employees have been met. Maintain all quality programs and develop any needed quality systems based on customer or process demands.

Currently all aspects of quality are equally shared by all employees of MBM. The successful completion of each job ensures long-term viability to the organization and satisfaction of the customer.

JOB TITLE: **SPECIAL QUALITY CONSULTANT**

DEPARTMENT: QUALITY ASSURANCE

JOB SUMMARY: Serve as a Quality Advisor to the Quality Team

.

RESPONSIBILITIES AND AUTHORITY: Assure Compliance of the Plant's Quality Program.

JOB TITLE: **PURCHASING MANAGER**

DEPARTMENT: PRODUCTION CONTROL AND PURCHASING

JOB SUMMARY: To Direct the Purchasing Function in providing the Components and Shop Production Schedule required to Support Promised Ship Dates to Customers on all Finished Goods.

RESPONSIBILITIES AND AUTHORITY: Coordinate All Material Planning, Procurement, Receiving, Movement, and Shipping Functions to enable the efficient Scheduling of Production to meet Customer Ship Schedules with a World Class Level of Performance.

This function is currently under the responsible of the EVP/COO. Tighter cost saving requirements by our customers will cause a combination of job functions. Each job function related to quality will require an additional person trained to the same specification to avoid conflicts as they pertain to customer quality.

JOB TITLE: **PRODUCTION TEAM**

DEPARTMENT: ALL DEPARTMENTS RESPONSIBLE FOR PRODUCTION

JOB SUMMARY: To foster a Plant Environment of World Class Values: Quality, Teamwork, Efficiency, Productivity, and Safety for all employees. To verify and validate that each aspect of product is acceptable and capable of producing the highest quality product to the customer.

RESPONSIBILITIES AND AUTHORITY: To communicate openly and freely about all aspects of quality and production. Understand the quality system. Have superior knowledge of the product and the intended use by the customer or end-user.

1.0 PURPOSE:

1.1 This procedure provides direction for the compilation of select procedures into a plant quality assurance manual.

2.0 SCOPE:

2.1 This procedure applies to all employees of MBM Packaging Labs and its subsidiaries involved in the preparation of quality assurance manuals and procedures, as well as those authorized to approve them and those controlling the distribution of approved copies.

3.0 DEFINITIONS:

3.1 Quality Procedures - Directives issued for communicating the established methods for performing and administering the work relative to assuring and controlling the quality of the MBM Packaging Labs' products.

3.2 Terms and their Definitions used in Quality Assurance Procedures will be consistent with those published by the American Standards Association and the American Society for Quality Control, where they exist.

3.3 "Uncontrolled" copy of manual - One in which the holder will receive no additions or updates to the manual. Usually issued with a quotation if customer demands a copy.

3.4 "Controlled" copy of manual - One in which the holder will receive additions and updates to the manual. Usually issued internally to MBM Packaging Labs.

3.5 "Controlled/Limited Update" copy of manual - One in which the holder will receive additions and updates for a limited specified period. Usually issued to a customer with a current order in-house if they demand a copy.

4.0 PROCEDURES - NUMBERING SYSTEM AND CONTENT SUBJECT MATTER:

4.1 General.

A. Procedures will be grouped into twenty subjects numbered 01 through 20. These numbers correspond to the ISO Clauses, for

example any procedure with a subject number of 01 would cover clause 4.1 Management Responsibility.

B. The postfix number provides flexibility for detailed breakdown of the subject matter.

C. A procedure is identified by the separate group of numbers as a whole. For example, this procedures' number is 02-100.

4.2 Department Manual Content:

A. Department Quality Manual, along with Specialty Manuals, will contain procedures in accordance with the requirements of ISO 9002. These requirements are in the Plant Quality Manual.

5.0 RESPONSIBILITIES:

5.1 Procedures and Manual Preparation:

A. The Quality Team is responsible for the preparation of department procedures, which are department-wide in scope, but may at his discretion delegate this to a selected Quality Assurance person.

B. Department Quality Assurance Manuals will cover those requirements of the ISO 9002 Standard pertaining to Quality Assurance Department.

C. The Quality Team is responsible for the preparation of the department's individual unique procedures that define the departments Quality Assurance program in accordance with the Plant's Quality Manual defined in 01-100. At their discretion they may delegate their responsibility to other plant disciplines that have the direct responsibility for a particular function.

D. **(*)** The Quality Team is responsible for the preparation and control of the Quality Forms Master Manual. This manual will house all forms used within the company's operation that are required by ISO 9002.

5.2 Approvals:

A. The President of MBM Packaging Labs must approve the plant's Quality Assurance Policy Statement and the plant's Quality Assurance Policy.

B. The Quality Team and the President must approve all the plant's procedures.

C. **(*)** The Quality Team must approve all changes to the plants forms.

5.3 Publication and Distribution of Plant Quality Assurance Manuals:

A. All manuals will be serialized and issued only by the Quality Assurance Department.
B. A Log as shown in Figure 1 will be completed each time a revision occurs for each manual issued as follows: ***(A)*** The type of manual update to be performed; ***(B)*** The manual serial number; ***(C)*** The date the manual is issued; ***(D)*** The period of limited updating; ***(E)*** The name, address, and phone number of the person to whom the manual is issued; ***(F)*** The date that the latest revised procedure(s) was mailed out; ***(G)*** The procedure numbers, titles, and revision date for all the procedures in the manual; ***(H)*** The date that the revision was received by the issued to; and ***(I)*** Remarks.
C. A Document Transmittal Form, Figure 2, will be sent out with each original or revised procedure and will be completed as follows: ***(A)*** The procedure title; ***(B)*** The issue or reissue date; ***(C)*** The procedure number; ***(D)*** The name of the person sending the transmittal; ***(E)*** Date transmittal is sent out; ***(F)*** The name of the person who receives copies of the transmittal; After transmittal is received, it should be completed as follows and returned to the sender: ***(G)*** Signature of person who received transmittal; and ***(H)*** The date of the receipt.
D. Changes to the procedures shall be reviewed and approved by the same function that performed the original review and approval.

5.4 Procedure Reviews:

A. Quality Team is responsible for establishing a schedule to review all procedures in the ISO Quality System annually.
B. Procedure Review Record Form number MBM-012 (see figure 3) must be completed as follows when a review has been completed.

(A) Manual - Manual housing the procedure that has been reviewed.
(B) MBM Procedure Number - Subject and Postfix number of procedure.
(C) Subject - Procedure involved.

(D) Review Date - Date the procedure review is due to be completed.
(E) Reviewed By - Individual's signature responsible for completion of the review.
(F) Date Completed - Date the procedure review was completed.
(G) Comments - Important information involved in the review.

C. Form number MBM-012 is to be placed in the front of each procedure in the master manuals only. See ***Notice*** on Form MBM-012.

5.5 Manual Maintenance.

A. It is the responsibility of each manual holder to keep their manuals updated by promptly filing new or revised procedures as they are received and by purging the outdated procedures from the manual.
B. Each time a Revision and/or Change is made to a Q. A. Procedure, an asterisk **(*)** is placed in the left hand margin of the procedure beside of the section changed denoting where the change was made.

6.0 FORMAT FOR PROCEDURES:

6.1 Topic Sections:

A. All information will be adaptable to one of the seven topic sections listed below:

1.0 PURPOSE
2.0 SCOPE
3.0 DEFINITIONS
4.0 POLICY OR STANDARDS
5.0 RESPONSIBILITIES
6.0 PROCEDURES
7.0 APPENDIX (Visual aids such as forms, charts, etc., photographed onto the PQM format)

PURPOSE **(1.0)** AND SCOPE **(2.0)** are required in all PQP's. Any other topic section may be omitted, but the

following topic section then moves up to maintain the sequence listed.

B. Topic Section Titles are all caps followed by a colon. Subtitles may be emphasized at the discretion of the writer.

C. Paragraph Identification.

1. Use of the following uniform numbering and indentation system provides instant reference to specific information.

1.0 Topic Section:
1.1
1.2
A.
B.
1.
2.
a)
b)
(1)
(2)

D. General Writing Suggestions.
1. Cover only one subject to each PQP and one idea to a paragraph. Use of postfix numbers will permit breakdown of complex subjects.
2. Write material in third person, present tense.
3. Avoid abbreviations when not defined elsewhere in the PQP.
4. Do not use names and use position titles sparingly because these change frequently.

Figure 1

REVISION LOG

Manual Serial Number _____(B)_____

Date Manual Was Issued _____(C)_____

Type of Manual Issued:

Uncontrolled ☐ (A) Controlled ☐ (D) Controlled / Limited Update _____ to _____ (Period of Update)

Note: _____

Issued To: _____(E)_____
(Name)

_____
(Company/Agency)

_____
(Address)

_____
(City) (State) (Zip)

_____
(Telephone No.)

Record Of Revision Transmittals			
Date Mailed	**Procedure Number / Title / Revision Date**	**Receipt Rec'd**	**Remarks**
(F)	(G)	(H)	(I)

FORM NUMBER: MBM-002

DATE: 3/98

APPROVED BY: MLM

FIGURE 2

DOCUMENT TRANSMITTAL

NOTICE:

These pages are an original. Do not remove from the master manuals without prior approval of the plant ISO Program Manager.

MANUAL: _____ (A)

MBM PROCEDURE NUMBER: _____ (B)

SUBJECT: _____ (C)

PROCEDURE REVIEW RECORD

REVIEW DATE	REVIEWED BY	DATE COMPLETED	COMMENTS
(D)	(E)	(F)	(G)

FORM NUMBER: MBM-012

DATE: 5/98

APPROVED BY: MLM

FIGURE 3

NOTICE:

THESE PAGES ARE AN ORIGINAL. DO NOT REMOVE FROM THE MASTER MANUALS WITHOUT PRIOR APPROVAL OF THE QA TEAM LEADER.

MANUAL: _____(A)_____
MBM PROCEDURE NUMBER: _____(B)_____
SUBJECT: _____(C)_____

PROCEDURE REVIEW RECORD

REVIEW DATE	REVIEWED BY	DATE COMPLETED	COMMENTS
(D)	(E)	(F)	(G)

FORM NUMBER: MBM-012 DATE: 5/98 APPROVED BY: JCM

SUBJECT: QUALITY SYSTEM POLICY

1.0 PURPOSE:

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

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.

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 Team 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 Team Leader.

4. Management Review -

The Quality Team shall have a documented periodic review of the quality system that includes Manufacturing Manager, President, and process leaders to ensure continuing suitability and effectiveness of the quality system. 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 that 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.

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.

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.

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.

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;

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.

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.

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.

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.

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 form preventive action shall be recorded. These should include:

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 that 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.

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

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: AMENDMENT RECORD FORM

1.0 PURPOSE:

1.1 To Keep an Ongoing Record of any Changes made to Quality Assurance Procedures.

2.0 SCOPE:

2.1 This Policy applies to all Employees involved in complying and controlling this procedure within the Plant.

3.0 RESPONSIBILITY OF THE QUALITY ASSURANCE DEPARTMENT:

3.1 When Changes are made to any Quality Assurance Procedure; the Master Manuals such as; Quality Manual, Receiving Inspection Manual, etc., Form Number MBM-004, "Amendment Record Form" is to be filled out by the assigned individual responsible for the Master Manuals. This form is to be filled out as follows: (Figure 1)

A. The Procedure Title should be placed here
B. Subject/Postfix Number
C. Manual Title
D. Date Procedure was issued
E. List Revised Section and/or Page Number
F. Revision Date
G. General Description of Change
H. Revision Control (What was actually done with Revised Copy)
I. Who Copies were Issued to
J. Number of Copies Issued to that Individual

3.2 An Amendment Record Form will be made for each Revised Procedure. The completed Amendment Record Form will then be filed in front of that particular procedure in the Master Manual. Any subsequent changes will be listed on this same Amendment Record Form.

3.3 **(*)** Amendment Record Form (manuals) Form Number MBM-004A is to be used when a revision is made to an operating manual. It is to be filed out by the assigned individual responsible for the master manuals. This form is to be filled out as follows: (Figure 2)

A. Manual Title – Name of the manual (Example – Didde Apollo Operating Manual).

B. Manual Serial Number – Procedure Number assigned to the manual (Example – Didde Apollo Operating Manual Number is 09-129).
C. Date Issued – Date the manual was issued.
D. Revision Date – The date a revision was made to the manual.
E. Revised Section and Page – Identify the section being revised and what page(s) was involved.
F. Description of Change – General description of the change made.
G. **(*)** Procedure Number – The subject and postfix number of the procedure involved in the change.

3.4 **(*)** Form Number MBM-004A should be kept in the front of each master manual that is involved.

3.5 This procedure also encompasses the In-house Controlled Manuals for the registrar with exception of Section "I" and "J" (Copies Issued To and the Number of Copies); these Sections are not applicable. The upkeep of these Manuals is the responsibility of the Plant Quality Assurance Department.

Figure 1

AMENDMENT RECORD FORM

Procedure Title: (A)

Subject/Postfix Number: (B)

Manual Title: (C)

DATE ISSUED	REVISED SECTION AND/OR PAGE #	REVISION DATE	DESCRIPTION OF CHANGE	REVISION CONTROL
(D)	(E)	(F)	(G)	(H)

COPIES ISSUED TO	#	COPIES ISSUED TO	#	COPIES ISSUED TO	#	COPIES ISSUED TO	#
(I)	(J)						

FROM NUMBER: MBM-004
DATE: 3/98
APPROVED BY: MLM

Figure 2 **(*)**

AMENDMENT RECORD FORM (Manuals)

Manual Title: (A)
Manual Serial Number: (B) **Date:** (C)

(Record of Revisions)

DATE	PROCEDURE NUMBER	REVISED SEC. AND PAGE	DESCRIPTION OF CHANGE
(D)	(G) **(*)**	(E)	(F)

FORM NUMBER: MBM-004(A)
APPROVED BY: MLM
DATE: 10/19/98

SUBJECT: AUDITS OF SYSTEMS AND PROCEDURES

1.0 PURPOSE:

1.1 To provide a method for periodically examining systems to determine the effectiveness of the overall Quality Program.

2.0 SCOPE:

2.1 This policy applies to all employees involved in complying and controlling this procedure within the MBM facility.

3.0 REFERENCE DOCUMENTS (Current Revisions):

3.1 Procedure Number 14-100, “Corrective Action Request” **(Figure 3)**
3.2 Form Number MBM-009, “Corrective Action Number Master Form” **(Figure 2)**
3.3 Form Number MBM-006, “Detailed Audit of Systems Plan” **(Figure 1)**
3.4 Procedure Number 16-100, “Quality System Record Retention”
3.5 Procedure Number 01-103, “Management Review”

4.0 QUALITY AUDIT DEFINITION:

4.1 An official examination of our systems, taking place on a periodic, but random, announced basis, to verify the effectiveness of the company’s quality program and processes to determine compliance to systems and procedures. Audit frequency is defined as follows: Audit frequency is to be conducted within an eight-week period during a single calendar year. **(Figure 1)**.

5.0 RESPONSIBILITY:

5.1 Management has the responsibility for planning Systems and Procedures Audits per ISO-9002 Element #17 and MBM Quality System Policy Procedure 02-100, Section 3.16.

A. Time frame for audit scheduling should be one month in advance.
B. The audit schedule dates are flexible. This flexibility will enable us to adjust to customer complaints or any other quality issues we may encounter. The scheduling is addressed on the basis of status and importance.
C. Auditor independence will be exercised at all times.
D. Management will have the authority to modify audit schedules in order to cover priority or trend situations.

5.2 An audit plan is first prepared using the Detailed Audit Plan (MBM-006) see Figure 1. The audit plan is filled out as follows:

A. Plan Number - Enter the assigned number of the audit plan. Detailed Audit Plan Numbers will be assigned per Example 98-8-1.

98 - Year of Audit.
8 - Month of Audits Performed in 1998.
1 - 1st CAR issued for this Audit
(2, 3, etc., when additional CAR's are issued).

B. Planned Audit Date - Enter the Date the Audit is Scheduled to begin and end
C. Enter Element(s) to be Audited (Number and Title)
D. Enter Page of Page Number
E. Plan Prepared By - Name of the QA Team Member
F. Date Prepared
G. Enter System and/or Procedure Name
H. Enter Procedure Number
I. Name of Person assigned to complete Audit
J. Date actual Audit was Completed
K. Approved By - approval of signified by their Name
L. Date of Approval

5.3 The Audit takes place as outlined in the Audit Plan, MBM-006 **(Figure 1).**

A. If discrepancies are found, give detailed account of findings and conclusion on CAR Form, MBM-010.

5.4 The Quality Team will periodically follow-up on corrective actions per the Audit corrective and Preventive Action Procedure 17-101.

5.5 A Corrective Action Number Master Form will be kept in the Corrective Action Log Book MBM-009 **(Figure 2)**. These Corrective Action Numbers will be the Audit Plan Number plus a Detail Number. This Detail Number identifies the "sequential" Corrective Action written against an Audit Plan. An EXAMPLE is a Corrective Action Number 98-1-1, which represents the "1st" CAR logged against Audit Plan 98-1; the "2nd" CAR would be logged as 98-1-2; etc. **(Figure 2)**.

Note: See procedure number 14-100 for details on filling out form number MBM-009.

5.6 The Internal Auditor will audit each Element that applies to the facility once every year.

6.0 RESPONSIBILITY OF THE EMPLOYEES AND MANAGEMENT INVOLVED:

6.1 To provide assistance to the auditor in complying with the Detailed Audit Plan **(Figure 1)**.
6.2 To provide documentation and any necessary records needed to verify compliance with programs or procedures.
6.3 Initiate corrective action if any problems revealed by the auditor involves areas of that department's responsibility.

7.0 MANAGEMENT FOLLOW-UP PROCEDURES:

7.1 When the audit has not been returned by the end of the planned audit date and no request for extension has been made, the QA Team Leader can allow more time or send a copy of the audit plan with a required return date to the immediate manager of the person responsible for performing the audit.
7.2 If the immediate manager is unable to answer in the allotted time, it is his/her responsibility to contact the QA Team Leader and establish a mutually agreed-to date. If an answer is not received at this point, the CAR copy and a note will be sent to the company president requesting his/her assistance.

8.0 DOCUMENTED RECORDS:

8.1 Record of the audit is to be maintained and kept on file by the QA Team.
8.2 All procedures used for the audit must be marked "Uncontrolled Copy" and kept in the Audit Log Book until the next audit. The auditor will then review any changes made to the procedures.
8.3 One Master Copy of MBM-006 (Detailed Audit Plan) will be kept on file by the Quality QA Team. As individuals complete their assigned audits, this copy is to be dated and marked complete.
8.4 The completed copy of their assigned audit (which includes the Detail Audit Plan Form, Trail Notes Form, ISO-9002 Clause Numbers and Areas Assessed Form) will be filed in a Notebook (per the audited department) and kept by the QA Team Leader.

9.0 INTERNAL AUDITOR TRAINING REQUIREMENTS:

9.1 Auditor requirements are limited to a clear understanding of the system and the quality expectations of the customer. The confirming results are proven effective by the limited number of CARs generated within a calendar year.

10.0 INTERNAL AUDIT SCHEDULE:

10.1 Provides a consistent schedule in order to assure adequacy and conformance with the quality system.
10.2 Schedule can be changed on the basis of the status and importance of the activities.

11.0 REPORT TO MANAGEMENT:

11.1 The QA Team Leader shall be responsible to report the audit findings and any discrepancies found during the audits to the Manufacturing Manager and President during the management review process. See Procedure Number 01-103.
11.2 Corrective Actions generated by the auditor should be distributed to all management involved in the audit process.

FIGURE 1

MBM FACILITY DETAILED AUDIT OF SYSTEMS PLAN

PLAN NUMBER: (A) PAGE (D) OF ___

PLAN AUDIT DATE: (B)

ISO ELEMENT(S) SCHEDULED FOR AUDIT: (C)

PLAN PREPARED BY: (E)

DATE PREPARED: (F)

DETAILED AUDIT PLAN

SYSTEM AND/OR PROCEDURE NAME	PROCEDURE NUMBER	ISO-9002 ELEMENT	ASSIGNED RESP.	DATE COMP.
(G)	(H)	(I)	(J)	(K)

PLAN APPROVED BY: (L)

DATE: (M)

DATE: 5/98

APPROVED BY: MLM

FORM NUMBER: MBM-006

FIGURE 2

FORM: MBM-009
DATE: 5/98
APPROVED BY: MLM

CORRECTIVE ACTION NUMBER MASTER FORM

C.A.R. NUMBER	SENT TO	SENT FROM	DATE SENT	DATE DUE	DATE RETD.	RESCHD. DATE DUE	DATE SENT TO MGNT.	DATE DUE	DATE RETD.	RESCHD. DATE	EFFECT OF C.A.R. DATE DUE	RESCHD. DATE	C.A.R. COMP. DATE

FIGURE 3

MBM Packaging Labs Inc

CORRECTIVE ACTION REQUEST

CAR NUMBER: _____

TO: _____ RETURN TO: _____

DEPT.: _____ DEPT.: _____

SUPPLIER /

PART NAME: _____ CUSTOMER: _____

PART NUMBER: _____ ORDER NUMBER: _____

QUANTITY: _____ REJECTION TICKET NUMBER: _____

Reguarding the above subject item, the following discrepancy requires corrective action:

SIGNED: _____ DATED: _____

A reply as to the corrective action taken on the above discrepancy must be submitted by _____. If a corrective action cannot be finalized by this date, advise reason and date action will be completed.

ROOT CAUSE: _____

CORRECTIVE ACTION TAKEN TO PREVENT RECURRENCE: _____

SIGNED: _____ DATED: _____

NOTE: *A copy of this report has been date filed. In the event corrective action is not received by requested or agreed to date, this reoprot will be forwarded to management for follow up.*

For management follow up only:

TO: _____ FROM: _____

RETURN BY: _____ ISSUED DATE: _____

EFFECTIVENESS OF CORRECTIVE ACTION: _____

DATE CLOSED: _____ ISO PROGRAM COORDINATOR: _____ DATE: _____

FORM NUMBER: MBM-010 DATE: 5/98 APPROVED BY: MLM