

# THE KOCOUR COMPANY

4800 S. St. Louis Avenue, Chicago, IL 60632

*Metal Finishing Instrumentation,  
Equipment and Supplies*

ISO 9001: 2000

## QUALITY MANAGEMENT MANUAL

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APPROVED BY: \_\_\_\_\_

TITLE: PRESIDENT

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## **The Kocour Company**

4800 S. St. Louis Avenue  
Chicago, IL 60632

The Kocour Company is a privately held corporation founded in 1923. The corporate headquarters and manufacturing facility are located in the Central Manufacturing District on the Southwest side of Chicago. The present site has been occupied since 1944. The facility consists of two buildings totaling 70,000 square feet.

The Kocour Company manufactures and distributes innovative products for the plating and related industries. The product line includes microprocessor controlled measuring instruments, analytical equipment, proprietary reagents, reference materials, buffing and polishing compound and wheels, buffing accessories and production equipment. Worldwide sales are conducted through a network of 190 distributors.

Whether produced at the company's own production facility or purchased from other sources, all products are subjected to stringent quality control procedures, and thoroughly tested to insure that Kocour's high standards are met.

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## 1. Scope and Field of Application

This Manual specifies the Quality Management System requirements to demonstrate Kocour Company's capability to manufacture and supply products using a Quality System in accordance with ISO 9001:2000. This manual is focused on the achievement of ongoing improvement as measured through the satisfaction of customers and other interested parties. Additionally, the requirements specified in this Manual are designed to prevent the creation of non-conforming product and to correct such non-conformance should it occur.

This Manual provides specific procedures and requirements to be applied within all departments within the scope of Kocour Company's ISO 9001:2000 Registration (Certification Number C2002-01062). Those production departments are the Laboratory Department (Standards and Liquid Mixtures), Plant (Compound) Department and the Electronics Department (Thickness Test Equipment and Hull Cells). All Administrative departments are included within the scope of this Quality Management System. The Manual does not provide detailed work instructions or test procedures. The operating departments will develop these requirements to meet their needs while conforming to and referring to the Procedures and requirements of this Manual.

A second exclusion is that section referencing "customer supplied components" (a part of § 7.5.4). Kocour Company does not currently use customer supplied and owned components in finished products. If this situation should change, documented procedures will be created and implemented to ensure conformity with ISO 9001:2000 requirements.

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## 2. References

ISO 8402 Quality Management and Quality Assurance Vocabulary

ISO 9000 Quality Management and Quality assurance Standards, Guidelines for selection and use.

ISO 9001:2000 (Third edition, 2000-12-15) Quality Management Systems — Requirements

ANSI/ ISO/ ASQ Q9004-2000 Quality Management Systems — Guidelines for Performance Improvements

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### 3. Quality Management Manual Maintenance and Distribution

#### 3.1 Quality Management Manual Maintenance

##### 3.1.1 Contents

The contents of this Manual are the responsibility of the Company President. The Company President is the Director of Quality Assurance for Kocour Company.

##### 3.1.2 Authorization

The Company President is authorized by the Board of Kocour Company to develop, maintain, authorize and distribute the Kocour Company Quality Management Manual including the Quality Policy.

##### 3.1.3 Revisions and Revision Record

Revisions may be requested by any Employee of the Kocour Company. Requests should be forwarded to their Department Manager, the Management Representative, or President for consideration, review, approval and implementation. The Management Representative will maintain a record of all revisions of this Manual. A summary of Revisions, as Appendix A, is included at the end of this Manual.

#### 3.2 Quality Management Manual Distribution

##### 3.2.1 Controlled Distribution

A list of controlled copy holders is maintained by the President. Only the President, or his designee, is permitted to make and distribute copies of this Manual. Copy holders are personally responsible for the upkeep of their Manual. All controlled copies will be stamped: "CONTROL COPY" in red.

##### 3.2.2 Uncontrolled Distribution

Occasionally, it may be desirable to issue copies of this Manual for informational purposes only. In such cases, it will not be necessary to add the names of the recipients to the distribution list. For this purpose, the President, or his designee, will provide a copy marked as "REFERENCE COPY", or "UNCONTROLLED COPY".

#### 4. Quality Management System

The President is responsible for establishing, documenting, implementing and maintaining the Kocour Company Quality Management System. The President is also responsible for the continual improvement of the System's effectiveness for ensuring that products conform to customer and other specific requirements. This Quality Management Manual is designed to conform to the requirements of ISO 9001:2000. The supporting and related documentation indicated in each section provides the linking requirement. The first of these support documents is considered a level two document and is numbered, for example, Procedure Number 7.3.0, to represent the Design and Development of Product procedure. These documents follow the ISO 9001:2000 standard major paragraph numbering system and address how the requirements of the Standard will be satisfied.

##### 4.1 General Requirements

To implement the requirements of this ISO Standard, Kocour Company will do the following:

- a) identify the processes needed for the quality management system and their application throughout the organization;
- b) determine the sequence and interaction of these processes;
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) monitor, measure and analyze these processes; and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

The above list is not meant to be exclusive. The requirements of Sections 4.1, General Requirements and 4.2, Documentation Requirements are reviewed and discussed within this Manual or, where necessary, in the Kocour Management Review Book (Current).

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## 4.2 Documentation Requirements

### 4.2.1 General

Among other elements, Kocour Quality Management System documentation includes the following:

- a) documented statements of a Quality Policy and quality objectives;
- b) a Quality Management Manual;
- c) documented Procedures required by ISO 9001:2000 and those Procedures necessary for implementation of the Kocour Company Quality System;
- d) documents needed by Kocour Company to ensure effective planning, operation and control of its processes; and
- e) records required by ISO 9001:2000.

Quality Assurance/Control procedures have been prepared and are included by reference in the Quality Management Manual, (a master list is included in Section 9 – Matrix table). These procedures have been issued and are used to implement the Quality Management System. These procedures are consistent with this Manual and ISO 9001:2000 as discussed in the paragraphs above.

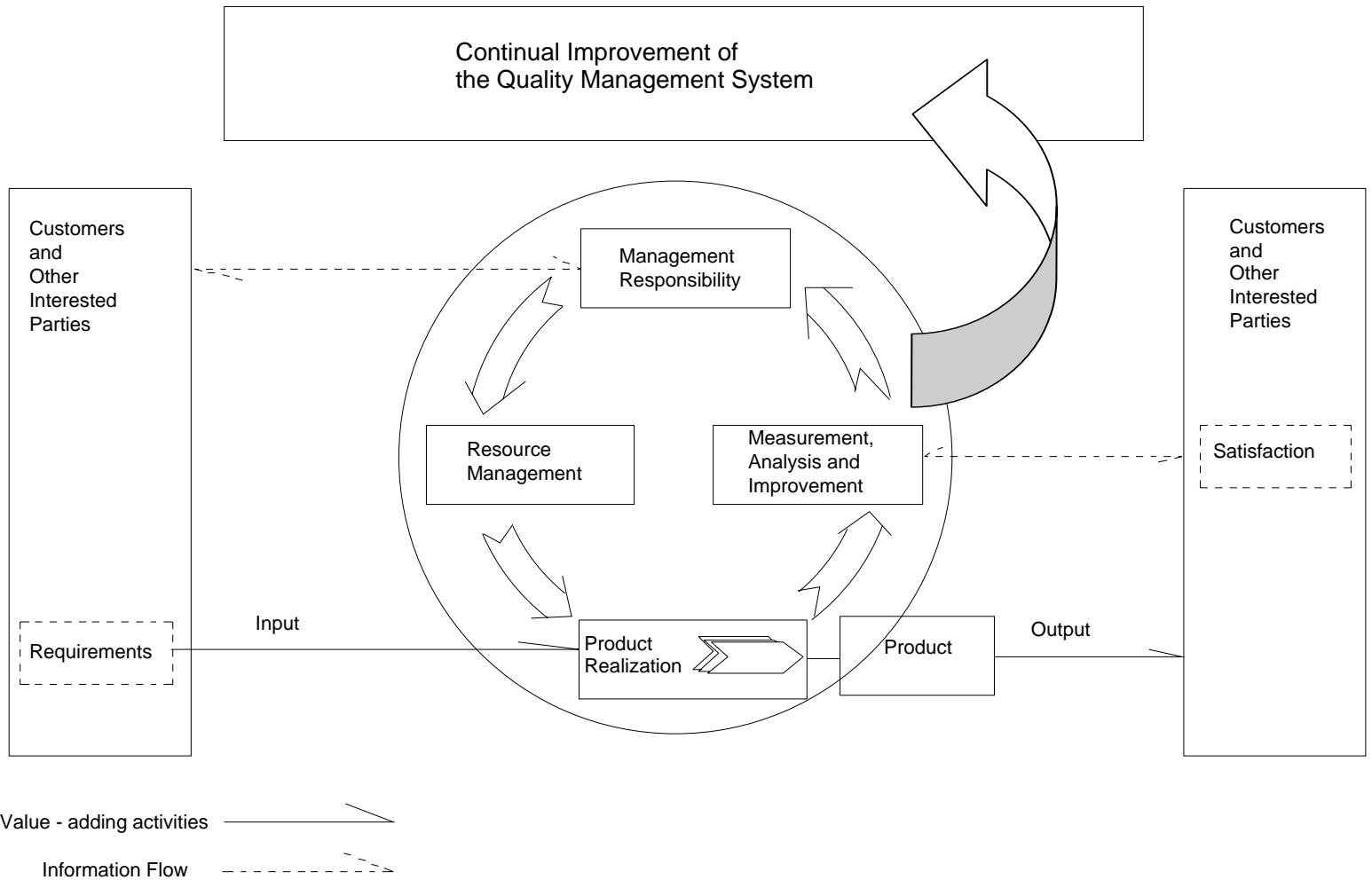
### 4.2.2 Quality Manual

This Quality Manual is established and maintained to include the following:

- a) the scope of the Quality Management System (see Sec. 1), including details of and justification for any exclusions;
- b) inclusion by reference of documented Procedures (see Sec. 9 – Matrix) created for this Quality Management System; and
- c) a description of the interaction between the processes of the Quality Management System. (See Figure 1 next page).

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Figure 1. Kocour Company Process Interaction for Quality Management System



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The above schematic is a visual representation of how the Kocour Company Quality Management System elements interact to achieve the requirements of ISO 9001:2000. Refer to Sec. 9 – *Matrix of ISO 9001:2000 — Quality Management System Requirements and Kocour Company, Inc. Quality Management System Documents* and Sec. 10 – *Quality Assurance Responsibility Matrix* for a more complete characterization of how the ISO elements and Procedures are coordinated to achieve product realization, customer satisfaction and continual process and product improvement.

### 4.2.3 Control of Documents

Procedures for the control of all documents and data that relate to the requirements of this International Standard including, but not limited to, drawings, specifications and work instructions are established, maintained, controlled and documented. Also included are documents of external origins such as industry standards and other specifications supplied by National Standards Organizations. Documents of external origins are under the control of the Technical Director who is responsible for their use, storage and timely updating.

#### Document and Data Approval and Issue

Documents are reviewed and approved for adequacy by authorized personnel before issue. A document control procedure for identifying current revision status of documents has been established to preclude the use of invalid or obsolete documents. (See Procedure 5.5.0, and Form 5.5.0.1 for detail and list of controlled documents; see Related and Support Documents for related list).

Controls include:

- a) The current issue of documents are available at the various designated work stations within the manufacturing system.
- b) Invalid and/or obsolete documents are promptly labeled and removed from points of issue and use.
- c) Obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified and controlled.

#### Document and Data Changes

Changes to documents are reviewed and approved by the same organizational function that performed the original review and approval, unless designated otherwise.

As applicable, the nature of the change is identified in the document or appropriate attachment. To avoid confusion, a “clean” copy of the revised document is preferentially used at the Procedure and Work Instruction level.

### 4.2.4 Control of Records

Documented procedures for identification, collection, indexing, filing, storage, access, maintenance and disposition of quality records have been established and are maintained.

Quality records are maintained to prove conformance to specified requirements and the effective operation of the Quality Management System. Pertinent supplier records will

be an element of this data. Records may be in all types of media, such as hard copy or electronic files.

Quality records are legible and identifiable to the product involved. Quality records are stored and maintained so that they are readily retrievable in facilities that provide a suitable environment to reduce deterioration, damage and to prevent loss.

Retention times for quality records have been established and recorded. When agreed contractually, quality records will be made available for evaluation by the customer or his representative for an agreed period.

#### 4.2.5 Related and Support Documents

- QMP 5.5.0 Document Control
  - 5.5.0.1 Master List – Controlled Documents
- QMP 5.5.1 Solution Formulation, Grandfather/Control
- QMP 5.5.2 Solution Control Sheets (Std. Dept.) – Grandfather/Control
- QMP 5.5.3 Cleaning Standards ( Standards Department); Work Procedures (Electro-Mechanical Department); Production Reports (Electro-Mechanical Department) – Grandfather / Control
- QMP 5.5.4 Control of Quality Records
  - 5.5.4.1 Quality Record Control List
- QMP 5.5.5 Control of Compound Formulation Documentation
- QMP 5.5.6 Control of Plant Production Documentation – Buffing Compounds

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## 5. Management Responsibility

### 5.1 Management Commitment

As proof of Kocour Company management's responsibility and commitment to the development, implementation and continual improvement of the Quality Management System, Kocour Company does the following:

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements;
- b) establishing the quality policy (See Sec. 5.3 below);
- c) ensuring that quality objectives are established;
- d) conducting management reviews; and
- e) ensuring the availability of resources.

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## 5.2 Customer Focus

It has been and is the policy of Kocour Company to serve its customers. In this sense, the broad definition of customer includes marketplace customers, internal customers (employees), company shareholders, the regulatory community and society in general.

To survive and prosper Kocour Company continuously assesses the needs and requirements of the marketplace, that is, current and potential customers. These assessments are manifested by, among other things, sales calls on existing and potential customers, attendance at and participation in trade shows. Within the Kocour organization, industry needs and trends are routinely communicated throughout the organization almost immediately. Those communications are often undocumented, but occur nonetheless. Where the intelligence gathered is of such import as to broadly affect a Kocour product, or product line, management will call together relevant departmental managers and employees to discuss the impact on Kocour products.

It is axiomatic that the elements of Kocour Company product realization efforts are designed to address the needs and expectations of our customers, both existing and potential. The Quality Management System is designed to document prior product realization processes and procedures and address a dynamic marketplace. Customer requirements form the practical basis for all Kocour products — if a Kocour product does not adequately address customer (marketplace) needs, it does not sell, becomes obsolete and will be removed from active production.

Insofar as this ISO Standard establishes product development and marketing requirements, Kocour Company will comply where those requirements coincide with the best interests of Kocour shareholders, management and employees. Where ISO Standard guidance is provided, Kocour will evaluate that guidance in the perspective of Kocour experience in managing its business matters to serve customer needs and shareholder expectations.

Where relevant to product design and specification, statutory and regulatory requirements will be evaluated and made a part of this Quality Management System in appropriate form and suitable documentation.

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### 5.3 Quality Policy

Kocour Company senior management will ensure that the Quality Policy:

- a) is appropriate to the purpose of Kocour Company;
- b) includes the commitment to comply with requirements and continually improve the effectiveness of the Quality Management System;
- c) provides a framework for establishing and reviewing quality objectives; and
- d) is reviewed for continuing suitability.

Kocour Company Quality Policy statement is as follows:

#### **QUALITY POLICY**

*It is the Policy of Kocour Company to supply its customers with product which meets, or exceeds their known specifications or requirements at a fair price.*

*Quality is the Number One operating priority at Kocour Company. Our goal is to give quality the highest priority in every decision we make. To help insure this policy, every Kocour employee must recognize that Quality means total conformance to specifications and procedures. In addition Kocour Company's senior management will be committed to and involved in the organization, development, management and continued improvement of the Quality Management System. Quality objectives are established and reviewed for continued relevancy to the Company's business objectives.*

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President

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## 5.4 Planning

### 5.4.1 Quality Objectives

Senior management, including the President, has responsibility to set specific, measurable, quality objectives. These objectives are to be found within pertinent Procedures, job descriptions, product quality assurance requirements, product design and performance specifications and requirements, purchase specifications and personnel performance requirements. As senior management sets specific measurable quality objectives under this sub-section, they will, upon review and approval, be added to the appropriate location(s) as noted immediately above.

Within this ISO system, Kocour Company senior management has developed a set of objectives based on relevant quality inputs, error experience, reject rates, customer complaint analysis, and other data gathering techniques. It is the goal of senior management to refine its' data gathering and analytical techniques to improve the protocol of quality objective planning and the end result of quality objective development. Various objectives, as found in Procedures and other locations, are meant to be comprehensive but not inclusive of all possible objectives. Individual or departmental objectives are fluid and will be addressed during any given year as required by the needs of Kocour Company management and compliance with ISO requirements.

### 5.4.2 Quality Management System Planning

Quality Planning is consistent with other requirements of the Quality Management System. Consideration is given to the following activities, as appropriate, in meeting the specified requirements for products and processes, as well as maintaining the integrity of the Quality Management System:

- a) preparation of a Quality Plan which includes Quality Assurance procedures, materials, process specifications and work instructions;
- b) identification and acquisition of any controls, processes, inspection equipment, fixtures and skills that are needed to achieve the required quality;
- c) ensuring the capability of the production processes;
- d) updating as necessary of quality control, inspection and testing techniques;
- e) identification of suitable verification at appropriate stages in the manufacturing process;
- f) clarification of standards of acceptability for all product features and requirements, including those that contain a subjective element;
- g) maintenance of the internal consistency of the design, the production process, installation, inspection and test procedures and applicable

- documentation;
- h) identification and preparation of quality records; and
- i) when changes to the Quality Management System are planned and implemented, the integrity of the entire Quality Management System is considered and maintained.

## 5.5 Responsibility, Authority and Communication

### 5.5.1 Responsibility and Authority

The responsibilities and authorities of all personnel who manage, control and verify work affecting Quality are defined and documented, particularly those who need authority to:

- a) initiate actions to prevent the occurrence of any non-conformities relating to product, process and quality systems;
- b) identify and record any Quality problems;
- c) initiate, recommend, or provide solutions through designated channels;
- d) verify the implemented solutions;
- e) suspend further processing, delivery, or installation of non-conforming product until the deficiency has been corrected.

See, also, Sec. 10 – Quality Assurance Responsibility Matrix for responsibility and authority assignment.

### 5.5.2 Management Representative

The President is responsible for appointing a management representative who will have defined authority and responsibility for ensuring that Kocour Company's Quality Management System is established, implemented and maintained in accordance with ISO 9001:2000.

The Management Representative is also responsible for reporting on the performance of the Quality Management System to the President. This communication will serve as a basis for continued Quality Management System improvement.

The Management Representative is the Laboratory Manager.

### 5.5.3 Internal Communication

Senior management is tasked with communicating all aspects of Kocour Company's Quality Management System within the organization. Methods for this communication will be appropriate to the size and complexity of Kocour Company's organization. Notably, Kocour Company is a small, tightly knit organization with supervisory and

managerial personnel tasked with multiple responsibilities. Prescribed communication protocols “suggested” within ISO 9001:2000 generally would be overly formalized for use at Kocour Company.

## 5.6 Management Review

### 5.6.1 General

Senior management reviews the Quality Management System annually in the fourth Quarter. This review uses the results of various Quality Records (primarily, Customer input and product non-conformance input), to assess the effectiveness of the entire Quality Management System. This review includes Kocour Company’s continued compliance with ISO 9001:2000 and efforts to be taken to effectuate continuing improvement of the Company’s Quality Management System.

The Quality Management System, Quality Policy and Records of such reviews (including minutes) are maintained as outlined in the Control of Records section (see sub-section 4.2.4, above). These management reviews include an assessment of the results of internal audits carried out by Quality Assurance and designated management personnel.

### 5.6.2 Review Input

Kocour Company’s Management Review protocol uses the following information (inputs) as the basis for such reviews:

- a) results of both external surveillance and internal audits;
- b) customer feedback, through direct customer contact, call reports, customer complaint reports and marketplace intelligence generally gathered;
- c) process performance and product conformity, through process QA audits and non-conforming product reports;
- d) status of corrective and preventive actions, pending and taken. Cumulative such reports are collected, categorized, summarized and reviewed on a Quarterly basis;
- e) follow-up actions taken from prior Management Reviews;
- f) major organizational changes which could affect Kocour Company’s Quality Management System; and
- g) recommendations made for System improvement.

The above list is not to be considered limiting; senior management will use whatever informational resources are relevant and available for Quality Management System review purposes.

### 5.6.3 Review Output

Review Output includes any Senior management decisions and actions related, but not limited, to:

- a) improvement of the effectiveness of the Kocour Company Quality Management System and its procedures and processes;
- b) improvement of Kocour product and product performance attributes directly related to customer requirements; and
- c) additional resource needs.

The above list is not to be considered limiting; senior management will determine the form and substance of any review output. It will use whatever review output that is relevant and available for Quality Management System continual improvement purposes.

### 5.6.4 Related and Support Documents

- QMP 5.6.0 Management Review  
Kocour Management Review Book (Current)

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## 6. Resource Management

### 6.1 Provision of Resources

Kocour Company Senior management will determine and provide the resources needed to implement, maintain and continually improve the Company's Quality Management System. Additionally, Senior management will determine and provide the resources necessary for the enhancement of customer satisfaction by meeting or exceeding customer requirements.

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## 6.2 Human Resources

### 6.2.1 General

Kocour Company Senior management recognizes that its' human resources are a valuable asset. All Kocour personnel performing work affecting product quality are evaluated upon hiring for competency based on a combination of appropriate training, skills, education and experience required for the position sought.

### 6.2.2 Competence, Awareness and Training

Kocour Company will:

- a) determine the requisite competence for personnel performing work affecting product quality;
- b) provide additional training or take other actions to satisfy these needs, if remediation is deemed necessary for specific job situations;
- c) provide additional training as necessary for personnel if the job skills needed for a particular job change while a particular employee is so assigned;
- d) evaluate the effectiveness of training actions taken;
- e) ensure that Kocour personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives; and
- f) maintain appropriate records of education, training, skills and experience.

A documented procedure has been established and is maintained for identifying the training needs and provide for the training of all Kocour personnel performing activities affecting quality.

Personnel performing specific assigned tasks will be qualified based on appropriate education, training and/or experience as required. Appropriate records of training are maintained.

See related and support documents, specifically, Procedure 6.2.0 – Training, individual Job Descriptions, the Performance Appraisal Form and the Training Schedule Status Sheet.

### 6.2.3 Related and Support Documents

QMP 6.2.0 Training  
Job Descriptions  
Performance Appraisal Form  
Training Schedule Status Sheet

### 6.3 Infrastructure (Facilities)

Management will determine, provide and maintain the infrastructure needed to achieve conformity to product requirements, including:

- a) building, work-space and associated utilities;
- b) process equipment (machinery, tankage, control hardware and software);  
and
- c) supporting services necessary for delivery and communication.

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## 6.4 Work Environment

Kocour Company has identified and planned the production processes which affect quality and will ensure that these processes are carried out under controlled conditions. Senior management takes into consideration work-place environmental factors, such as, ergonomics, heat, humidity, light and airflow which may impact the ability of its personnel to perform their responsibilities in a consistent manner enhancing Kocour Company's Quality objectives. Consideration is given to the providing and maintaining a work environment needed to achieve conformity to product requirements.

Senior management is also tasked with the responsibility to identify information needs, foster business relationships with suppliers, and be aware of any natural resource constraints which may adversely impact the Company's ability to manufacture product to customer's requirements. Senior management, particularly the President, is responsible for management of the financial resources necessary for the Company's continued viability and conformance to the Quality Management System.

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## 7. Product Realization

### 7.1 Planning of Product Realization

Quality Planning is consistent with product realization planning and other requirements of the Quality Management System. Consideration is given to the following activities, as appropriate, in meeting the specified requirements of product realization planning for products and processes:

- a) the preparation of Quality Plan(s) that include quality assurance procedures, selection of materials of construction, purchased raw materials and intermediate component specifications, process specifications and work instructions. This (these) Plan(s) will include, as appropriate, quality objectives and requirements specific to the product;
- b) the identification and acquisition of any controls, processes, inspection equipment, fixtures and skills that are needed to achieve the required quality, specific to the product;
- c) ensuring the capability of the production processes, specific to the product;
- d) the updating as necessary of quality assurance, inspection and testing techniques, specific to the product;
- e) the identification of required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- f) the clarification of standards of acceptability for all features and requirements, including those that contain a subjective element;
- g) the compatibility of the design, the production process, installation, inspection and test procedures and applicable documentation, specific to the product; and
- h) the identification and preparation of quality records necessary to provide evidence that the realization processes and resulting product meet requirements.

Kocour Company has established and maintains documented procedures for inspection and testing activities to verify that quality objectives and requirements for the product are met. Records of the inspection and testing activities have been created and are maintained in compliance with ISO 9001:2000 requirements (see sub-section 4.2.4, above).

## 7.2 Customer Related Processes

### 7.2.1 Determination of Requirements Related to the Product

To confirm that a product meets both the requirements of the customer and a product's intended use, Kocour will determine the following:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities. Each order is reviewed to insure that the requirements are adequately defined and documented on the order entry document;
- b) requirements not stated by the customer but necessary for specified or intended use, where known. These determinations are usually found in Procedures and work instructions, generically, identified as Design and Development documents;
- c) statutory and regulatory requirements related to the product; and
- d) any additional requirements determined by Kocour Company.

### 7.2.2 Review of Requirements Related to the Product

Prior to accepting an order, Kocour sales and management personnel will review the requirements related to the product(s) relevant to a given order to ensure that:

- a) product identification and requirements are adequately defined and documented on the order entry document;
- b) contract or order requirements differing from those previously expressed (for a given customer) are resolved. If any "contract" terms within an order are ambiguous, the ambiguity will be resolved, usually on the face of the document with proper dating and initialing of the disputed (resolved) term;
- c) where product or contract (sales order) requirements are changed, the relevant documents are amended as above and affected personnel are promptly notified; and
- d) the requirements can be met and followed during the order/manufacturing process.

Order entry records, including any document review and modifications to the document are maintained (see sub-section 4.2.4, above).

### 7.2.3 Customer Communication

Kocour Company will determine and implement effective arrangements for customer communication relating to the following:

- a) product information (through such media as advertisements in trade

journals, product specification sheets, maintenance of a web site, direct marketing mailings, participation in trade organizations, and sales calls, both by telephone and in-person);

- b) response to customer enquiries (requests for quotation), contracts or order handling (including amendments); and
- c) customer feedback, including customer complaints.

#### 7.2.4 Related and Support Documents

- QMP 7.2.0 Contract Review  
Customer Order Documents
- QMP 7.2.1 Order Processing
  - 7.2.1.2 Order Processing Flow Charts

#### Work Instructions

- QMP 8.5.0 Corrective and Preventive Action
- QMP 8.5.1 Customer Complaint and Nonconforming Product Forms
  - Customer Complaint Form
  - Non-Conforming Product Form
  - Non-Conforming File
  - Kocour Management Review Book(Current)

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## 7.3 Design and Development

### 7.3.1 Design and Development Planning

Kocour Company plans and controls the design and development of its products. This design and development planning is implemented through one or more Procedures (see QMP 7.3.0) written to address the requirements of this element.

During the design and development planning, Kocour Company determines:

- a) the design and development stages;
- b) the review, verification and validation that are appropriate to each design and development stage, and;
- c) the responsibilities and authorities for design and development.

Kocour Company manages the interfaces among different functions involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output is updated as appropriate, as the design and development progresses.

### 7.3.2 Design and Development Inputs

Inputs relating to product requirements will be determined and records maintained (see sub-section 4.2.4 above). These inputs will include:

- a) functional and performance requirements;
- b) applicable statutory and regulatory requirements;
- c) where applicable, information derived from previous similar designs;
- d) customer specific requirements; and
- e) other requirements essential for design and development.

These inputs are reviewed for adequacy. Requirements will be complete, unambiguous and not in conflict with each other.

### 7.3.3 Design and Development Outputs

The design and development outputs are provided in a form that enables verification against the design and development input and are approved prior to product release.

Design and development outputs will:

- a) meet the input requirements for design and development;
- b) provide appropriate information for purchasing, production and for service

- provision;
- c) contain or reference product acceptance criteria (e.g., blueprints, purchase specifications); and
- d) specify the characteristics of the product that are essential for its proper use.

#### 7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development will be performed in accordance with planned arrangements (see 7.3.1):

- a) to evaluate the ability of the results of design and development to meet requirements; and
- b) to identify any problems and propose necessary actions.

Participants in such reviews will include representatives of functions concerned with the design and development stage(s) being reviewed and any other employees so designated by the President or his designee(s). Records of the results of the reviews and any necessary actions will be maintained, especially in the Kocour Management Review Book (Current) (see 4.2.4).

#### 7.3.5 Design and Development Verification

Verification will be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions will be maintained (see 4.2.4). These typically are found on blueprints as print versions with the print revisions (detail) documented on the face of the blueprint. Notations include authorized signature or initials and date approved.

#### 7.3.6 Design and Development Validation

Design and development validation performed in accordance with planned arrangements (see 7.3.1) ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation will be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions will be maintained, especially in the Kocour Management Review Book (Current) (see 4.2.4).

#### 7.3.7 Control of Design and Development Changes

Design and development changes will be identified and records maintained. The changes will be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes will include evaluation

of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions will be maintained, especially in the Kocour Management Review Book (Current) (see 4.2.4).

#### 7.3.8 Related and Support Documents

- QMP 7.3.0 Design and Development  
Kocour Management Review Book (Current)
- QMP 5.5.0 Document Control
- QMP 5.5.4 Control of Quality Records

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## 7.4 Purchasing

### 7.4.1 Purchasing Process

Kocour Company documented procedures have been established and are maintained to ensure that purchased products, including hardware, raw material, software, processed material and services, conform to specified requirements. Kocour Company evaluates vendors based, in part, on the following criteria:

- a) Suppliers are evaluated and selected based on their ability to meet purchase order contract requirements including system requirements, e.g., material and special process specifications.
- b) Controls exercised over suppliers are dependent on the purchased product and/or the special process being performed, and, the influence upon the manufacturing process and quality of the final product. A supplier's previously proven capability and performance are also considered.
- c) Removal of vendor from Approved Vendor List (AVL) – A vendor is subject to removal from the AVL when Kocour Company experiences four (4) rejects in a given year. A vendor is subject to removal from the AVL at the discretion of a department manager or other designated management personnel. Such grounds for removal will be documented in one or more Non-conforming product reports.

The Approved Vendor (Supplier) List is maintained and is located according to subsection 4.2.4, above and QMP 5.5.4.

### 7.4.2 Purchasing Information

Kocour Company purchase orders contain data clearly describing the item(s) ordered, including, where applicable:

- a) The type, class, style, grade, catalog number, part number or other precise identification;
- b) Positive identification and applicable current version of specifications, drawings, process requirements, inspection instructions, other relevant technical data, and if applicable, qualification of vendor personnel; and
- c) Relevant Quality Management System standards, general terms and conditions are to be a part of the purchase documents including specific requirements listed on the face of the purchase order.

Purchase orders are to be reviewed and approved for adequacy of specified requirements prior to release by the Kocour buyer to the vendor.

### 7.4.3 Verification of Purchased Product

Kocour Company will establish and implement the inspection, or other activities, necessary to ensure that purchased materials meet specified purchase requirements, in the following manner:

- a) Incoming parts are inspected or otherwise verified as conforming to specifications according to documented procedures. Incoming parts are withheld from production pending inspection/verification. Parts that do not meet specification are handled as discussed in Procedure 7.4.0, ¶ 7.4.0.3 h);
- b) In deciding the amount and nature of receiving inspection, consideration is given to the amount of inspection exercised at the vendor level; and
- c) Kocour Company does not currently arrange for customer verification of product at the subcontractor's premises. If this should change in the future, documented procedures will be written to support the requirements of this section.

### 7.4.4 Related and Support Documents

- QMP 7.4.0 Purchasing
- QMP 7.4.1 Purchase Requisition/Purchase Order
- QMP 7.4.2 Supplier Qualification and Re-Evaluation
- QMP 7.4.3 Supplier Corrective Action
- Approved Vendor List
- Purchase Requisitions/Orders
- Receiving Documents

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## 7.5 Production and Service Operations

### 7.5.1 Control of Production and Service Provision

Kocour Company has identified and planned production and service processes that affect quality and will ensure that these processes are carried out under controlled conditions. Controlled conditions include, but are not limited to, the following:

- a) the availability of information (e.g., customer requirements, competitive product knowledge, end use requirements) which describes the characteristics of the product;
- b) documented quality assurance procedures and work instructions describing / defining the manner of production, where the absence of instructions would adversely affect quality;
- c) use of suitable production equipment and a suitable work environment;
- d) compliance with reference standards, specifications, and QA procedures;
- e) monitoring and control of suitable process parameters and product characteristics during production;
- f) the approval of processes and equipment as appropriate;
- g) established criteria for workmanship through documented procedures and instructions, or by means of representative samples;
- h) suitable maintenance of equipment to ensure continuing process capability; and
- i) the implementation of release, delivery and post-delivery activities.

Where “service” (typically, repair and calibration of electronics’ thickness testing products) is requested by a customer through a “repair” purchase order, work instructions have been written and verified. These work instructions are available to Electronics Department personnel and are incorporated by reference in the appropriate Procedure(s) required for production of said equipment.

### 7.5.2 Validation of Processes for Production and Service Provision

Kocour Company utilizes some processes, the results of which cannot be fully verified by inspection and testing of the product during the manufacturing process. These processing deficiencies may become apparent only after the product is in use.

Accordingly, continuous monitoring and/or compliance with documented procedures is required to ensure that they meet the specifications. These processes will be verified and carried out by qualified operators and/or monitored to control process parameters to ensure that they meet the specified requirements.

Records will be maintained for qualified processes, equipment and personnel, as appropriate. Special process operations may be performed by approved suppliers if

required and as designated by Kocour Company personnel.

Kocour Company will demonstrate the ability of these “special” processes to achieve planned results, by establishing the following:

- a) defined criteria for review and approval of the processes;
- b) approval of equipment and qualification of personnel;
- c) use of specific methods and procedures;
- d) requirements for records; and
- e) re-validation.

### 7.5.3 Identification and Traceability

Kocour Company has established and maintains procedures for identifying products from applicable drawings, specifications, or other documents, from receipt and during all stages of production and delivery.

Where traceability to a specified customer order is required, traceability, to the extent possible, will be accomplished by using a unique product serial number or other distinctive product identification.

Documents that provide for product identification will be maintained as described under Quality Management Procedure 5.5.4 – Control of Quality Records.

### 7.5.4 Customer Property

Kocour Company does not currently use customer supplied and owned components in finished products. If this situation should change, documented procedures will be created and implemented to ensure conformity with ISO 9001:2000 requirements.

### 7.5.5 Preservation of Product

Documented preservation of raw materials, components and product procedures have been established and are implemented for handling, storage, packaging, protection and delivery of products (includes customer owned electronics' products returned for “service”). These procedures, work instructions, and work environment include, but are not limited to, the following:

- a) the Quality Management System provides methods (procedures and work instructions) and means (work environment) for handling products that prevent damage or deterioration;
- b) designated secure storage areas are used to prevent damage or deterioration of intermediates or product, pending use or delivery. Appropriate methods for authorizing receipt and dispatch to and from such

areas are defined and communicated to responsible personnel. To detect deterioration, raw materials and finished goods in inventory are inspected at appropriate intervals;

- c) packing, preservation and marking processes (including materials used) are controlled to the extent necessary to ensure conformance to specifications. The pertinent procedure will identify, preserve and segregate all products from the time of receipt until that area's responsibility ceases;
- d) methods for preservation and segregation of product are provided for while under Kocour Company control; and
- e) arrangements are made for the protection of product quality after final inspection, testing and approval. Where contractually specified, this product protection shall be extended to include delivery to destination.

#### 7.5.6 Related and Support Documents

- QMP 7.5.0 Process Control
- QMP 7.5.1 Production of Standardized Stock Solutions
- QMP 7.5.2 Solution Control Procedure-Standards Department
- QMP 7.5.4 Production of Special Standards  
Work Instructions
- QMP 7.5.5 Production of Stock Standards
- QMP 7.5.6 Production of Special Solutions
- QMP 7.5.7 Production of Non-Standardized Stock Solutions
- QMP 7.5.8 Production of Electro-Mechanical Stock  
ASTM Annual Book of Standards, Sec. 2, Vol. 02.05, Current Year  
Revision, upon publication  
Cleaning Procedures File  
Solution Formulation List  
HMIS Label Guide
- QMP 7.5.10 Handling, Storage, Packaging, Preservation and Delivery  
Packing Instructions Document  
UPS (or equivalent) HazMat Software Instructions (*Ship Safe Shipping Paper Program*)
- QMP 7.5.11 Production of Liquid Buffing Compounds
- QMP 7.5.12 Production of Solid, Semi-solid, and Greaseless Buffing  
Compounds

## 7.6 Control of Monitoring and Measuring Devices

Kocour Company has created, uses and maintains documented procedures to control, calibrate and maintain inspection measuring equipment required to prove conformance of product to specifications. As applicable, testing equipment is used so that the measurement uncertainty is known and is consistent with the required measurement capability.

The Quality Management System is, among other things, designed to:

- a) identify the measurements to be made and the accuracy required. The appropriate inspection, measuring, and test equipment capable of the accuracy and precision necessary is then selected;
- b) identify all inspection, measuring and test equipment that can affect product quality. Calibrate and adjust them at prescribed intervals, or before use, with certified equipment having a known valid relationship with nationally recognized standards. Where no such standards exist, the basis used for calibration will be documented;
- c) establish, document and maintain calibration procedures. Provide details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory;
- d) identify inspection, measuring, and test equipment with a suitable indicator or approval identification record to show the calibration status;
- e) maintain calibration records for inspection, measuring, and test equipment (see Quality Management Procedure 5.5.4 – Control of Quality Records);
- f) assess and document the validity of previous inspection and test results when the inspection, measuring, and test equipment used is out of calibration;
- g) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements, and tests being carried out;
- h) ensure that the handling, preservation and storage of inspection, measuring and test equipment are such that the accuracy and fitness for use are maintained and controlled; and
- i) safeguard inspection, measuring, and test equipment, including test hardware from adjustments that would invalidate the calibration setting.

### 7.6.1 Related and Support Documents

- QMP 7.6.0 Control of Inspection, Measuring and Test Equipment
  - 7.6.1 Calibration/Verification Procedure List
  - 7.6.2 Calibration Procedure File (including Work Instructions)

## 8. Measurement, Analysis and Improvement

### 8.1 General

Kocour Company will plan and implement monitoring, measurement, analysis and improvement needed to:

- a) demonstrate conformity of the product;
- b) ensure conformity of the Quality Management System; and
- c) continually improve the effectiveness of the Quality Management System.

Kocour Company has established and maintains documented procedures for inspection and testing activities to demonstrate conformity of its products to customer requirements and internal specifications. Records of inspection and testing activities are maintained and are located variously (see Procedure 5.5.4 – Control of Quality Records for locations).

#### Receiving Inspection and Testing

Incoming parts are inspected or otherwise verified as conforming to specifications according to documented procedures. Incoming parts are withheld from production pending inspection/verification. Parts which do not meet specification are handled as discussed in Procedure 7.4.0, ¶ 7.4.0.3 h).

In determining the quantity and nature of receiving inspection, consideration is given to the quantity and nature of inspection exercised at the vendor level.

#### In-process Inspection and Testing

The manufacturing process at Kocour Company provides for:

- a) inspection, testing, and identification of product as required by documented procedures; and
- b) holding of product until the required inspections and tests have been completed, data reviewed and necessary reports created.

#### Final Inspection and Testing

Documented procedures for final inspection require that all specified inspection, tests, data review and approvals have been carried out and that the data result meets specified requirements. No product will be shipped until all activities specified in the documented procedures have been satisfactorily completed, reviewed and recorded.

## Inspection and Test Records

The Quality Management System provides for the creation and maintenance of records which provide evidence that the product has been inspected, and either meets or does not meet specifications. Records show whether the product has passed or failed the inspection/tests according to defined acceptance criteria. Procedures for the control of non-conforming product apply where product does not meet specified product or performance criteria.

Records identify the inspection authority responsible for product release (see Quality Management Procedure 5.5.4 – Control of Quality Records).

To ensure continued capability of processes Kocour Company has determined that certain specified processes require evaluation and measurement beyond nominal quality assurance in-process inspection.

## Statistical Techniques

Applicable procedures have been established to identify techniques required for verifying the acceptability of process capability and product characteristics, beyond in-process inspection. Documented procedures have been established and are maintained for the implementation and control of statistical techniques.

### 8.1.1 Related and Support Documents

- QMP 6.2.0 Training
  - Job Descriptions
  - Performance Appraisal Form
  - Training Schedule Status Sheet
- QMP 8.2.0 Inspection and Testing
  - Work Instructions
  - 8.2.0.A Vendor Packing List (Receiving Approval)
  - Solutions Formulation Book
  - Purchase Orders
  - Serial Number File
  - Standard Slips
  - Lot Number Log
  - Weight Log
  - Lab Notebook
- QMP 8.2.1 Internal Quality Audits
  - Quality Management Manual, Procedures and Work Instructions
  - Audit Schedule (created annually)
  - Audit Plans (created annually, modified during current year, as

- necessary)
- Noncompliance Reports
- Kocour Management Review Book (Current)
- QMP 8.2.2 Statistical Techniques
- Error in Thickness Determination File (Accuracy Estimate)
- The Gauge Capability Study
- QMP 8.5.0 Corrective Action and Preventive Action
- Departmental Work Instructions
- Blueprints
- Purchasing Specifications

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## 8.2 Monitoring and Measurement

### 8.2.1 Customer Satisfaction

Kocour Company will determine and implement effective methods to determine whether customer requirements have been met and to monitor customer satisfaction. Methods to execute this requirement include, but are not limited, to the following:

- a) customer feedback, including customer complaints;
- b) customer communication, including all indirect media, (e.g., facsimile and e-mail) and direct telephone, trade show meetings and sales calls;
- c) marketing mailings requesting satisfaction feedback; and
- d) internal communication, corrective and preventive actions taken as a result of customer complaint analysis (see Procedure 8.5.0 – Corrective and Preventive Action).

### 8.2.2 Internal Audit

Documented procedures have been established and are maintained for planning and implementing a comprehensive system of scheduled internal quality audits to verify whether quality activities comply with planned arrangements, to determine the effectiveness of the Quality Management System and to identify opportunity for continued System improvement.

Audit frequency will be at least once each calendar year for: Quality Management System, Products, and Processes. The audit plan divides the audit into 2<sup>nd</sup> Quarter and 4<sup>th</sup> Quarter components. The content of any audit (including whether specific System sections are audited once or twice per year) is based on the status and importance of the activity to be audited. These audits are carried out by personnel independent of those having direct responsibility for the activity being audited. The audits and follow up actions are carried out according to documented defined procedures, including the effectiveness of any corrective action taken.

The results of the audits are documented and reported to the personnel having responsibility in the area audited. Management personnel responsible for the area are to take timely corrective action to resolve any deficiencies found by the audit.

### 8.2.3 Monitoring and Measurement of Processes

Kocour Company applies suitable methods for monitoring and, where applicable, measurement of the Quality Management System processes. The methodology demonstrates the ability of the processes to achieve planned results. Further, if planned results are not achieved, corrective action is to be taken, as appropriate to Kocour Company needs, to ensure conformity of its products. This ISO 9001:2000

requirement is essentially included in most, where relevant, Kocour Procedures addressing System processes. No specific Procedure is written to address this Sec. 8.2.3.

#### 8.2.4 Monitoring and Measurement of Product

##### Receiving Inspection and Testing

Incoming parts are inspected or otherwise verified as conforming to specifications according to documented procedures, work instructions or requirements within relevant Procedures or Work Instructions. Incoming parts are withheld from production pending inspection/verification. Parts that do not meet specification are handled as discussed in Procedure 7.4.0, ¶ 7.4.0.3 h).

In deciding the amount and nature of receiving inspection, consideration is given to the amount of inspection exercised at the vendor level.

##### In-process Inspection and Testing

The manufacturing process at Kocour Company provides for the:

- a) inspection, testing, and identification of products as required by documented procedures; and
- b) holding of products until the required inspections and tests have been completed and necessary reports compiled.

##### Final Inspection and Testing

Documented procedures, work instructions or requirements within relevant Procedures or Work Instructions for final inspection require that all specified inspection and tests have been carried out and that the data meets specified requirements. No product will be shipped until all the activities specified in the Quality Plan or documented procedures have been satisfactorily completed and recorded.

##### Inspection and Test Records

The Quality Management System provides for the establishment and maintenance of records which provide evidence that the product has been inspected. Records show whether the product has passed or failed the inspection/tests according to defined acceptance criteria. Procedures for the control of non-conforming product apply.

Records identify the inspection authority responsible for product release (see Procedure 5.5.4 – Control of Quality Records).

## 8.2.5 Related and Support Documents

- QMP 8.2.0 Inspection and Testing
  - Work Instructions
  - 8.2.0.A Vendor Packing List (Receiving Approval)
  - Solutions Formulation Book
  - Purchase Orders
  - Serial Number File
  - Standard Slips
  - Lot Number Log
  - Weight Log
  - Lab Notebook
- QMP 8.2.3 Incoming Inspection of Raw Materials - Compound Production
- QMP 8.2.4 Inspection of Liquid Compounds: In-Process Inspections
- QMP 8.2.5 Inspection of Liquid Compounds: Final Inspections
- QMP 8.5.0 Corrective and Preventive Action
- QMP 8.2.1 Internal Quality Audits
  - Quality Management Manual, Procedures and Work Instructions
  - Audit Schedule (created annually)
  - Audit Plans (created annually, modified during current year, as necessary)
  - Noncompliance Reports (Audit results)
  - Non-Conformance Reports
  - Kocour Management Review Book (Current)

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### 8.3 Control of Nonconforming Product

Documented procedures have been established and are maintained to ensure that products which do not conform to specified requirements are prevented from inadvertent use or installation. Kocour controls (Procedure(s)) provide for identification, documentation, evaluation, segregation (where practical), disposition of non-conforming product, and for notification to the concerned internal functions, as well as customers, if necessary.

#### Non-Conforming Product Review and Disposition

The responsibility for review and authority for the disposition of non-conforming product is defined in relevant quality assurance Procedures. Non-conforming product is to be inspected and evaluated according to documented procedures. Such product may be:

- a) re-worked (nonconformance is corrected) to meet specified requirements;
- b) accepted with or without repair by concession (agreement of customer);
- c) re-graded for alternate applications; or
- d) rejected or scrapped.

Specific procedures and work instructions created pursuant to the requirements of §§ 7.1, 7.5, 8.3, 8.4 and 8.5 provide detailed instructions relevant to the processing of non-conforming product.

Where required by contract, the proposed repair or correction of product which does not conform to specifications is reported to the customer or his representative for concession. The description of non-conformity accepted, and/or nature of repair or correction is recorded on a relevant quality assurance document to indicate the actual product condition.

Repaired or corrected product is re-inspected according to requirements contained within relevant procedures or work instructions.

#### 8.3.1 Related and Support Documents

- QMP 7.5.0 Process Control
- Nonconforming Product reports
- QMP 8.3.0 Control of Non-Conforming Product
- QMP 8.5.0 Corrective and Preventive Action
- Non-conforming Product Report Form

## 8.4 Analysis of Data

Kocour Company will define, collect and analyze appropriate data to demonstrate the suitability and effectiveness and possible areas for continued improvement of the Quality Management System. Kocour Company recognizes that this data may come from many sources. The following, not exhaustive, list identifies some of those sources:

- a) customer satisfaction, through market share maintenance and growth, personal and written communication with individual customers, customer surveys and customer complaint analysis;
- b) conformity to product requirements (analysis of quality assurance inspection and testing data;
- c) characteristics and trends of processes and products including opportunities for preventive action (analysis of product non-conformity data and corrective and preventive measures taken to resolve non-conformities); and
- d) suppliers (continued communication regarding intermediate product purchasing specifications and non-conforming material data).

At Kocour Company some of this data analysis is manifested in certain corrective and preventive action Procedures, as noted in the paragraphs below.

Documented procedures have been established and are maintained for implementing corrective and preventive action.

Corrective action taken to eliminate causes of non-conformities will be appropriate to the importance of the reported problem. Preventive action taken to eliminate potential non-conformities will be proportional to the estimated risk. Documented procedures will be revised to incorporate the changes to accomplish these desired results.

### Corrective Action

Procedures for corrective action include, but are not limited, to:

- a) the effective handling of customer complaints and reports of product non-conformity;
- b) investigation and identification of the root cause of non-conformities relating to product, process or elements of the Quality Management System and recording the results of such investigations;
- c) determination of the corrective action(s) needed to correct the non-conforming product and eliminate the cause of the non-conformity; and
- d) application of controls to ensure that corrective action is taken and is effective.

## Preventive Action

Procedures for preventive action include, but are not limited to, the following:

- a) use and analysis of customer complaints, audit results, quality records and other information sources to detect the potential cause of non-conformities;
- b) reference to and analysis of work instructions, procedures and other instructions to determine the causes of the potential non-conformities;
- c) determination of steps needed to deal with any problems requiring preventive action; and
- d) submission of preventive recommendations and relevant information to management for review and approval. Responsible management authority will document and distribute necessary changes to affected procedures.

### 8.4.1 Related and Support Documents

- QMP 8.5.0 Corrective and Preventive Action
- QMP 8.5.1 Customer Complaint and Nonconforming Product Forms
  - Customer Complaint Form
  - Non-Conforming Product Form
  - Non-Conformance File
  - Kocour Management Review Book (Current)

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## 8.5 Improvement

### 8.5.1 Continual Improvement

Kocour Company strives for continued improvement in its products, processes and Quality Management System through the use of the following:

- a) its Quality Policy;
- b) quality objectives, explicitly stated elsewhere in specific Procedures and departmental work instructions, and implicitly found in product specifications and quality requirements necessary to market its products;
- c) its audit results, and corrective actions taken to remedy any found deficiencies;
- d) analysis of data input from previously specified sources and any source found to be of value by Kocour management;
- e) its corrective and preventive actions, recommended and taken, as a result of actual or perceived product or process non-conformities or deficiencies; and
- f) management review of all stated or unstated data inputs relevant to product, process or System improvement.

### Management Review

Senior management reviews the Quality Management System annually in the fourth Quarter. This review uses the results of various Quality Records to assess the effectiveness of the entire Quality Management System. The ability to comply with ISO 9001:2000 and the Kocour Quality Policy is also reviewed.

The Quality Policy and Records of such reviews is maintained as outlined in the Control of Quality Records section. (see Procedure 5.5.4 – Control of Quality Records). These management reviews include an assessment of the results of internal audits carried out by Quality Assurance and designated management personnel.

### 8.5.2 Corrective Action

Procedures for corrective action include, but are not limited, to:

- a) the effective handling of customer complaints and reports of product non-conformity;
- b) investigation and identification of the root cause of non-conformities relating to product, process or elements of the Quality Management System and recording the results of such investigations;
- c) determination of the corrective action(s) needed to correct the non-conforming product and eliminate the cause of the non-conformity; and

- d) application of controls to ensure that the corrective action is taken and that it is effective.

### 8.5.3 Preventive Action

Procedures for preventive action include, but are not limited to, the following:

- a) use and analysis of customer complaints, audit results, quality records and other information sources to detect the potential cause of non-conformities;
- b) reference to and analysis of work instructions, procedures and other instructions to determine the causes of the potential non-conformities;
- c) determination of steps needed to deal with any problems requiring preventive action; and
- d) submission of preventive recommendations and relevant information to management for review and approval. Responsible management authority will document and distribute necessary changes to affected procedures.

### 8.5.4 Related and Support Documents

- QMP 8.5.0 Corrective and Preventive Action
- QMP 8.5.1 Customer Complaint and Nonconforming Product Forms
  - Customer Complaint Form
  - Non-Conforming Product Form
  - Non-Conformance File
  - Kocour Management Review Book (Current)

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9. Matrix of ISO 9001:2000 — Quality Management System Requirements and Kocour Company, Inc. Quality Management System Documents

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ISO 4.1 GENERAL REQUIREMENTS  
QMM § 4.1

QMP 4.1.0 ISO Quality Management System Management Responsibility

ISO 4.2 DOCUMENTATION REQUIREMENTS  
QMM § 4.2, ¶¶ 4.2.1 to 4.2.5

QMP 5.5.0 Document Control  
5.5.0.1 Master List – Controlled Documents

QMP 5.5.1 Solution Formulation, Grandfather/Control

QMP 5.5.2 Solution Control Sheets (Std. Dept.) – Grandfather / Control

QMP 5.5.3 Cleaning Standards ( Standards Department); Work Procedures (Electro-Mechanical Department); Production Reports (Electro-Mechanical Department) – Grandfather / Control

QMP 5.5.4 Control of Quality Records  
5.5.4.1 Quality Record Control List

QMP 5.5.5 Control of Compound Formulation Documentation

QMP 5.5.6 Control of Plant Production Documentation - Buffing Compounds

ISO 5.1 MANAGEMENT COMMITMENT  
QMM § 5.1

§ 10 Quality Management System Responsibility Matrix

QMP 4.1.0 ISO Quality System Management Responsibility  
Kocour Management Review Book (Current)

ISO 5.2 CUSTOMER FOCUS  
QMM § 5.2

ISO 5.3 QUALITY POLICY  
QMM § 5.3

§ 10 Quality Management System Responsibility Matrix

QMP 4.1.0 ISO Quality System Management Responsibility  
Kocour Management Review Book (Current)

ISO 5.4 PLANNING  
QMM § 5.4, ¶¶ 5.4.1 to 5.4.2

ISO 5.5 RESPONSIBILITY, AUTHORITY and COMMUNICATION  
QMM § 5.5, ¶¶ 5.5.1 to 5.5.3

§ 10 Quality Management System Responsibility Matrix

QMP 4.1.0 ISO Quality System Management Responsibility  
Kocour Management Review Book (Current)

QMP 5.5.0 Document Control  
5.5.0.1 Master List – Controlled Documents

QMP 5.5.1 Solution Formulation, Grandfather/Control

QMP 5.5.2 Solution Control Sheets (Std. Dept.) – Grandfather /  
Control

QMP 5.5.3 Cleaning Standards ( Standards Department); Work  
Procedures (Electro-Mechanical Department);  
Production Reports (Electro-Mechanical Department)  
– Grandfather / Control

QMP 5.5.4 Control of Quality Records  
5.5.4.1 Quality Record Control List

QMP 5.5.5 Control of Compound Formulation Documentation

QMP 5.5.6 Control of Plant Production Documentation - Buffing  
Compounds



- QMP 7.5.2 Solution Control - Standards Department  
Solution Control Sheets
- QMP 7.5.4 Production of Special Standards  
Standard Slips  
Cleaning Procedures File
- QMP 7.5.5 Production of Stock Standards  
Conversion Factor Chart  
Standard Slips File
- QMP 7.5.6 Production of Special Solutions
- QMP 7.5.7 Production of Non-Standardized Stock Solutions
- QMP 7.5.8 Production of Electro-Mechanical Stock  
Electro-mechanical Procedure List/File  
Electro-mechanical Verified List/File
- QMP 8.2.0 Inspection and Testing  
Serial Number File  
Weight Log  
Work Instructions  
Lab Notebook
- QMP 8.2.3 Incoming Inspection of Raw Materials - Compound  
Production
- QMP 8.2.4 Inspection of Liquid Compounds: In-Process  
Inspections
- QMP 8.2.5 Inspection of Liquid Compounds: Final Inspections
- QMP 7.5.10 Handling, Storage, Packaging, Preservation and  
Delivery  
Packing Instructions Document  
UPS (or equivalent) HazMat Software Instructions  
(*Ship Safe Shipping Paper Program*)
- QMP 7.5.11 Production of Liquid Buffing Compounds
- QMP 7.5.12 Production of Solid, Semi-Solid, and Greaseless  
Buffing Compounds

ISO 7.2 CUSTOMER RELATED PROCESSES  
QMM § 7.2, ¶¶ 7.2.1 to 7.2.4

QMP 7.2.0 Contract Review  
Customer Order Documents

QMP 7.2.1 Order Processing  
7.2.1.1 Order Processing Flow Charts  
Purchase Requisition  
Purchase Order  
Shop Copy/Shipping Document  
Work Instructions

ISO 7.3 DESIGN and DEVELOPMENT  
QMM § 7.3, ¶¶ 7.3.1 to 7.3.8

QMP 7.3.0 Design and Development of Product  
Product specific component purchasing specifications  
Product specific production and assembly blueprint(s)  
Kocour Management Review Book (Current)

QMP 5.5.0 Documents Control

QMP 5.5.4 Control of Quality Records

ISO 7.4 PURCHASING  
QMM § 7.4, ¶¶ 7.4.1 to 7.4.4

QMP 7.4.0 Purchasing

QMP 7.4.1 Purchase Requisition/Purchase Order  
Purchase Requisition  
Purchase Order

QMP 7.4.2 Supplier Qualification and Re-Evaluation  
Approved Vendor List  
Vendor Survey Form

QMP 7.4.3 Supplier Corrective Action  
Receiving Documents  
Nonconformance report

ISO 7.5      PRODUCTION and SERVICE OPERATIONS  
QMM § 7.5, ¶¶ 7.5.1 to 7.5.6

- QMP 7.5.3    Product Identification and Traceability
  - Standard Slips
  - Serial Number file
  - Blueprints
  - Lot Number Log
  - Work Order File
  
- QMP 7.5.0    Process Control
  
- QMP 7.5.1    Production of Standardized Stock Solutions
  - ASTM Annual Book of Standards, Sec. 2, Vol. 02.05, Current Year Revision, upon publication
  - Miscellaneous ASTM File
  - Lab Procedure Manual
  - Solution Formulation List
  - HMIS Label Guide
  - Lot Number Log
  
- QMP 7.5.2    Solution Control - Standards Department
  - Solution Control Sheets
  
- QMP 7.5.4    Production of Special Standards
  - Standard Slips
  - Cleaning Procedure File
  
- QMP 7.5.5    Production of Stock Standards
  - Conversion Factor Chart
  - Standard Slips File
  
- QMP 7.5.6    Production of Special Solutions
  
- QMP 7.5.7    Production of Non-Standardized Stock Solutions
  
- QMP 7.5.8    Production of Electro-Mechanical Stock
  - Electro-mechanical Procedure List/File
  - Electro-mechanical Verified List/File
  
- QMP 8.2.0    Inspection and Testing
  - Serial Number File
  - Weight Log
  - Work Instructions

Lab Notebook

QMP 8.2.3 Incoming Inspection of Raw Materials - Compound Production

QMP 8.2.4 Inspection of Liquid Compounds: In-Process Inspections

QMP 8.2.5 Inspection of Liquid Compounds: Final Inspections

QMP 7.5.9 Inspection and Test Status

QMP 7.5.10 Handling, Storage, Packaging, Preservation and Delivery  
Packing Instructions Document  
UPS (or equivalent) HazMat Software Instructions  
(*Ship Safe Shipping Paper Program*)

QMP 7.5.11 Production of Liquid Buffing Compounds

QMP 7.5.12 Production of Solid, Semi-Solid, and Greaseless Buffing Compounds

ISO 7.6 CONTROL of MONITORING and MEASURING DEVICES  
QMM § 7.6, ¶ 7.6.1

QMP 7.6.0 Control of Inspection, Measuring and Test Equipment  
7.6.1 Calibration/Verification Procedure List  
7.6.2 Calibration Procedure File (Work Instructions)

ISO 8.1 GENERAL  
QMM § 8.1, ¶ 8.1.1

QMP 8.2.0 Inspection and Testing  
Standard Slips  
Lot Number Log  
Serial Number File  
Weight Log  
Work Instructions  
Lab Notebook

QMP 8.2.2 Statistical Techniques  
Error in Thickness Determination File (Accuracy)

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Estimate)  
The Gauge Capability Study

QMP 8.2.3 Incoming Inspection of Raw Materials - Compound  
Production

QMP 8.2.4 Inspection of Liquid Compounds: In-Process  
Inspections

QMP 8.2.5 Inspection of Liquid Compounds: Final Inspections

ISO 8.2 MONITORING and MEASUREMENT  
QMM § 8.2, ¶¶ 8.2.1 to 8.2.5

QMP 8.2.0 Inspection and Testing  
Standard Slips  
Lot Number Log  
Serial Number File  
Weight Log  
Work Instructions  
Lab Notebook

QMP 8.2.1 Internal Quality Audits  
Quality Management Manual, Procedures and Work  
Instructions  
Audit Schedule (created annually)  
Audit Plans (created annually, modified during current  
year, as necessary)  
Noncompliance Reports  
Kocour Management Review Book (Current)

QMP 8.2.2 Statistical Techniques  
Error in Thickness Determination File (Accuracy  
Estimate)  
The Gauge Capability Study

QMP 8.2.3 Incoming Inspection of Raw Materials - Compound  
Production

QMP 8.2.4 Inspection of Liquid Compounds: In-Process  
Inspections

QMP 8.2.5 Inspection of Liquid Compounds: Final Inspections

ISO 8.3	<p>CONTROL of NONCONFORMING PRODUCT QMM § 8.3, ¶ 8.3.1</p> <p style="padding-left: 40px;">QMP 7.5.0    Process Control Nonconforming Product Reports Kocour Management Review Book (Current)</p> <p style="padding-left: 40px;">QMP 8.3.0    Control of Non-Conforming Product</p>
ISO 8.4	<p>ANALYSIS of DATA QMM § 8.4, ¶ 8.4.1</p> <p style="padding-left: 40px;">QMP 7.5.0    Process Control</p> <p style="padding-left: 40px;">QMP 8.2.2    Statistical Techniques Error in Thickness Determination File (Accuracy Estimate) The Gauge Capability Study</p> <p style="padding-left: 40px;">QMP 8.5.0    Corrective Action and Preventive Action Departmental Work Instructions Blueprints Purchasing Specifications</p> <p style="padding-left: 40px;">QMP 8.5.1    Customer Complaint and Nonconforming Product Forms Non-Conformance File Nonconforming Product Form Customer Complaint Form</p>
ISO 8.5	<p>IMPROVEMENT QMM § 8.5, ¶¶ 8.5.1 to 8.5.4</p> <p style="padding-left: 40px;">QMP 7.5.0    Process Control Kocour Management Review Book (Current)</p> <p style="padding-left: 40px;">QMP 8.5.0    Corrective Action and Preventive Action Departmental Work Instructions Blueprints Purchasing Specifications</p> <p style="padding-left: 40px;">QMP 8.5.1    Customer Complaint and Nonconforming Product Forms Non-Conformance File Nonconforming Product Form Customer Complaint Form</p>

10. Quality Management System Responsibility Matrix

<b>QMM SECTION</b>	<b>RESPONSIBILITY</b>	<b>CONTRIBUTING</b>
1	President	All Employees
2	President	Department Mgrs.; Technical Director
3.1	President; Technical Director; Department Mgrs.; Salesmen	Clerical Staff; Electronics Assemblers/Technicians; Laboratory Technicians; Department Mgrs.
3.2	President; Technical Director; Department Mgrs.; Salesmen	Clerical Staff; Electronics Assemblers/Technicians; Laboratory Technicians; Department Mgrs.
4.1	Technical Director; Department Mgrs	Clerical Staff; Electronics Assemblers/Technicians; Laboratory Technicians; Department Mgrs.
4.2	Technical Director	Department Mgrs.
5.1	Technical Director	Department Mgrs.
5.2	President	Department Mgrs.; Technical Director
5.3	President	Department Mgrs.; Technical Director
5.4	President	Department Mgrs.; Technical Director
5.5	Technical Director; Department Mgrs.	Department Mgrs. and See 16.1.1 Quality Record Control List
5.6	President	Department Mgrs.; Technical Director
6.1	Department Mgrs.	Clerical Staff; Electronics Assemblers/Technicians; Laboratory Technicians; Department Mgrs.
6.2	President	Employees as assigned by the President
6.3	Technical Director; Department Mgrs.	Electronics Assemblers /Technicians; Laboratory Technicians
6.4	Technical Director; Department Mgrs.	Electronics Assemblers /Technicians; Laboratory Technicians

7.1	Technical Director; Department Mgrs.	Electronics Assemblers /Technicians; Laboratory Technicians; Department Mgrs.; Packing/Shipping Clerk
7.2	President; Technical Director; Department Mgrs.; Salesmen	Clerical Staff; Electronics Assemblers/Technicians; Laboratory Technicians
7.3	President; Technical Director; Sales Manager	Electronics Assemblers /Technicians; Laboratory Technicians; Department Mgrs.
7.4	Department Mgrs.	Clerical Staff; Electronics Assemblers/Technicians; Laboratory Technicians
7.5	Technical Director; Department Mgrs.	Clerical Staff; Packing/Shipping Clerk; Electronics Assemblers /Technicians; Laboratory Technicians
7.6	Technical Director; Department Mgrs.	Electronics Assemblers /Technicians; Laboratory Technicians; Department Mgrs.
8.1	Technical Director; Department Mgrs.	Packing/Shipping Clerk; Electronics Assemblers /Technicians; Laboratory Technicians; Employees as needed and assigned by the Technical Director
8.2	Technical Director; Department Mgrs.	Electronics Assemblers /Technicians; Laboratory Technicians; Employees as assigned by the Technical Director
8.3	Technical Director; Department Mgrs.	All Employees
8.4	Technical Director; Sales Manager	All Employees and employees as needed and assigned by the Technical Director
8.5	Technical Director; Sales Manager	All Employees

## Appendix A. Quality Management Manual Revision Record

Section	Description of Change	Rev. #	Implementation Date	Approval
QMM General — All Sections	All sections of this Manual were revised to conform to ISO 9001:2000 Quality Management Systems – Requirements	0	03/01/02	DRM
QMM General — Various Sections	Several sections of this Manual were revised to reflect the inclusion of Plant (Compound) Production within the ISO Scope. Language inserted was generally document references, e.g., new Procedures.	2	09/30/03	DRM
QMM — 1 Scope	Deleted language excluding Plant Production from ISO Scope. Clarified remainder of this section editorially.	2	09/30/03	DRM
QMM — 1 Scope	Deleted language excluding “Service” of customer owned product from ISO Scope.	3	11/30/04	DRM
QMM — 5.4 Planning, sub§ 5.4.1 Quality Objectives	Added explanatory language regarding development of Quality Objectives. Added list of preliminary Quality Objectives	1	02/08/03	DRM
QMM — 5.4 Planning, sub§ 5.4.1 Quality Objectives	Deleted list of preliminary Quality Objectives. Added clarifying language as to the location of departmental specific objectives.	2	09/30/03	DRM
QMM — 5.5 Responsibility, sub§ 5.5.2 Management Representative	Appointed Laboratory Manager as Management Representative	2	10/31/03	DRM
QMM — 7.5 Production, sub§ 7.5.1 Control of Production and Service Provision	Deleted “exclusion” language and added clarifying language defining “service” as the repair and calibration of Kocour manufactured electronic equipment resulting from a customer “repair” purchase order.	3	11/30/04	DRM
QMM — 7.5 Production, sub§ 7.5.5 Preservation of Product	Added language to include raw materials and components as requiring Preservation.	2	09/30/03	DRM

Section	Description of Change	Rev. #	Implementation Date	Approval
QMM — 7.5 Production, sub§ 7.5.5 Preservation of Product	Added language to include customer owned electronics' products returned for "service".	3	11/30/04	DRM
QMM — 8.4 ANALYSIS OF DATA	Added language to include "customer surveys" as additional measure to determine customer satisfaction	2	09/30/03	DRM
QMM — 8.5 Improvement, sub§ 8.5.1 Continual Improvement	Added language to identify location (various) of quality objectives.	2	09/30/03	DRM
QMM — Section 9. Matrix	Added document references for new Procedures to various locations of this Matrix	2	09/30/03	DRM
QMP — All Procedures	All Procedures revised to conform to ISO 9001:2000. Version, when issued, to be "0"	0	03/01/02	DRM
QMP — All Procedures	All individual Procedure Revisions in effect at the time of Implementation of ISO 9001:2000 are incorporated by reference into each Version "0" identified directly above.  Example of QMP "Header":  Revision #: <u>    0    </u> Implementation Date: <u>03/01/02</u> Replacing Rev. #: <u>4 (11/13/00) QAP X.Y.Z</u> Removal Date: <u>                    </u>	0	Various (last revision # and initial (original) implementation date retained on face of document)) for archival purposes	DRM
QMP 4.1.0	Revised language to ensure consistency with Management Review scheduling date within QMM, § 5.6 and QMP 5.6.0 schedule language	1	02/08/03	DRM
QMP 4.1.0	Named "Laboratory Manager" as ISO Management Representative	2	10/31/03	DRM
QMP 5.5.0	Added language specifying type and location of additional new plant (compound) production controlled documents	1	09/30/03	DRM

Section	Description of Change	Rev. #	Implementation Date	Approval
QMP 5.5.4	Revised Table 5.5.4.1, Master List of Quality Records to add several classes of records and to add location of relevant MAS90 files (MAS90 System files defined as “records”).	1	11/30/04	DRM
QMP 5.5.5	Created new Procedure which describes the control of Plant (compound) formulation documentation	0	09/30/03	DRM
QMP 5.5.6	Created new Procedure which describes the control of Plant (compound) production documentation	0	09/30/03	DRM
QMP 5.6.0	Created Procedure to meet Element 5.6 – Management Review requirement	0	02/08/03	DRM
QMP 6.2.0	Revised language in ¶ 6.2.0.8 to include possible need for training where employee is promoted or job scope or duties substantially change	1	08/31/03	DRM
QMP 6.2.0	Added language to ¶ 6.2.0.9 to require responsible supervisor to evaluate effectiveness of an individual’s training. Added column for said notation to the “Training Schedule Status Sheet”. Added Federal citations to ¶ 6.2.0.4.	2	11/30/04	DRM
QMP 7.3.0	Created Procedure to meet Element 7.3 – Design and Development requirement	0	03/01/02	DRM
QMP 7.3.0	Revised “Policy” language to clarify that design and development procedures are designed to conform to ISO 9001:2000 requirements.	1	07/02/02	DRM
QMP 7.4.0	Revised language to acknowledge use of MAS90 System Purchase Order module	1	08/31/03	DRM
QMP 7.4.0	Added language to include “agreed upon delivery time” as a specification the purchasing departmental manager must consider when entering raw material purchase orders.	2	11/30/04	DRM
QMP 7.4.1	Revised language to acknowledge use of MAS90 System Purchase Order module	1	08/31/03	DRM

Section	Description of Change	Rev. #	Implementation Date	Approval
QMP 7.4.2	Revised and added language to this Procedure to define criteria to be used for the periodic re-evaluation of vendors and the continuing qualification of a given vendor. Added referencing language to use of MAS90 System.	1	11/30/04	DRM
QMP 7.5.3	Added sub ¶ 7.5.3.5 to cover Plant (compound) production product identification and traceability. Added sub ¶ 7.5.3.6 g) to cover buff resale products identification and traceability	1	09/30/03	DRM
QMP 7.5.8	Added language to include "service" (repair and calibration) of Kocour manufactured electronic equipment.	1	11/30/04	DRM
QMP 7.5.10	Revised language of this Procedure to include raw materials, constituent parts and components within the scope of this Procedure	1	09/30/03	DRM
QMP 7.5.11	Created new general Procedure for the manufacture of liquid buffing compounds	0	09/30/03	DRM
QMP 7.5.12	Created new general Procedure for the manufacture of solid, semi-solid and greaseless buffing compounds	0	09/30/03	DRM
QMP 7.6.0	Clarified language at ¶ 7.6.0.2, sub ¶ f) 6) to define allowed steps the Sales Manager may take regarding product found to be non-conforming after receipt by customer(s).	1	11/30/04	DRM
QMP 8.2.1	Revised this Procedure and Internal Audit schedule to include all Quality Elements for audit on at least an annual schedule. Revised audit schedule to 2 <sup>nd</sup> Quarter and 4 <sup>th</sup> Quarter.	1	07/02/02	DRM
QMP 8.2.1	Named "Laboratory Manager" as Lead Auditor and Management Representative. Named Dennis Masarik as Executive responsible for Audit review.	2	08/31/03	DRM
QMP 8.2.3	Created new Procedure to provide a general procedure for the incoming inspection of raw materials - compound production	0	09/30/03	DRM

Section	Description of Change	Rev. #	Implementation Date	Approval
QMP 8.2.4	Created new Procedure to provide a general procedure for the in-process inspection of liquid compound production	0	09/30/03	DRM
QMP 8.2.5	Created new Procedure to provide a general procedure for the final inspection of liquid compound production	0	09/30/03	DRM
QMP 8.3.0	Revised Procedure to include language to control Plant (compound) department non-conforming product. Added language to cover situation where non-conforming raw materials or intermediates are used in a production run. Added language to cover situation where a non-conformance was discovered after the final product shipped.	1	09/30/03	DRM
QMP 8.5.0	Clarified language to specify an Annual Customer Complaint and Non-Conforming Product review meeting	1	07/25/03	DRM
QMP 8.5.1	Clarified language to specify an Annual Customer Complaint and Non-Conforming Product review meeting	1	07/25/03	DRM

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