

Marking Systems Inc.
Quality Manual



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I hereby approve the Quality Management System (QMS) described in this Quality Manual (QM), in support of our Quality Policy and Quality Objectives. I am committed to the ongoing development, implementation and continual improvement of our quality management system.

Mihai Borcoman

07-21-2011

Operations Manager
MSI

QM Revision Date

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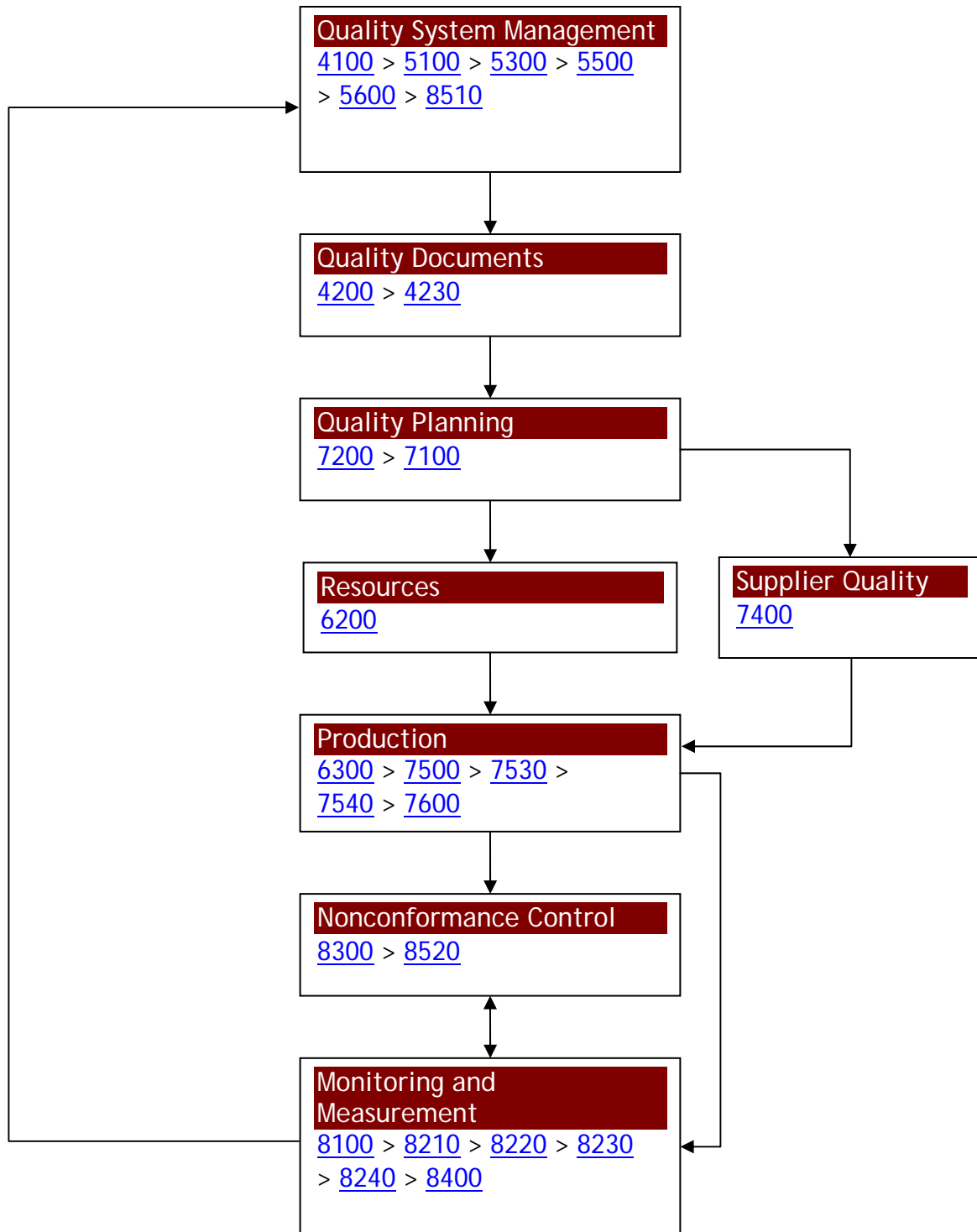
Date of Revision	Section Revised	Nature of Revision	Revision Approved by
6/24/09	all	Original	M. Borcoman
7/27/09	4100F	specific Production Flowcharts listed for clarity	M. Borcoman
	6200D, E, F	Training for hourly personnel clarified	J. Rusmanica
	6300A	Limited preventive maintenance described	R. Datcu
	7400F	Purchase order approval responsibilities and requirements clarified	P. Crain
	7400H	Requirements for control of outsourcing redefined	P. Crain
	8240D, E	Requirements for "final inspection" clearly defined, records of actions taken defined	P. Crain
10/27/09	7500G	Added exclusion for clause 7.5.1, service provision	M. Borcoman
01/28/09	7100E	Production meetings and Production Meetings Log referenced and described	M. Borcoman
02/04/10	5300E	Last quality objective revised	M. Borcoman
02/10/10	Cross Reference, 4100, 4200, 4230, 7200, 8210, 8220, 8510	Changes Cross Reference to identify new roles and responsibilities. Modified each section heading to reflect changes in Cross Reference. Added flowcharts in section 4100.	Joe Sofinowski
4/1/10	Cross Reference and 5500	Change Owner of Customer Product Quality Requirements to Joe until permanent owner found, Change Materials Manager to Operations manager as Management Representative.	Joe Sofinowski
4/13/10	7200 G & H	Revised process for new order review	Joe Sofinowski
5/27/10	7200, 8220	Changed Lead Auditor to Patrick Crain Made Chris Watley owner of section 7200	Joe Sofinowski
1/10/11	4100	Removed Rowlett Facility	Joe Sofinowski
1/12/11	5300	Added quantifiers to Quality Objectives	Joe Sofinowski
7/21/11	Cross Reference	Change Supplier Quality responsibilities to Nancy Clem.	Joe Sofinowski

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QMS Cross-Reference

Section No.	Section Title	Section Owner	Quality Process	ISO 9001:2008 clauses acknowledged in Section
4100	Quality Management System	Joe Sofinowski	QUALITY SYSTEM MANAGEMENT	4.1, 6.1
4200	Quality Manual	Joe Sofinowski	QUALITY DOCUMENTS	4.2, 4.2.1, 4.2.2
4230	Control of Documents and Quality Records	Joe Sofinowski	QUALITY DOCUMENTS	4.2.3, 4.2.4
5100	Management Commitment	Mihai Borcoman	QUALITY SYSTEM MANAGEMENT	5.1, 5.2
5300	Quality Policy, Objectives and Planning	Mihai Borcoman	QUALITY SYSTEM MANAGEMENT	5.3, 5.4, 5.4.1, 5.4.2
5500	Management Responsibility, Authority and Communication	Mihai Borcoman	QUALITY SYSTEM MANAGEMENT	5.5, 5.5.1, 5.5.2, 5.5.3
5600	Management Review	Mihai Borcoman	QUALITY SYSTEM MANAGEMENT	5.6, 5.6.1, 5.6.2, 5.6.3
6200	Personnel Competence, Training and Awareness	Juliana R./ Giani G.	RESOURCES	6.2, 6.2.1, 6.2.2
6300	Infrastructure and Work Environment	Razvan Datcu	RESOURCES	6.3, 6.4
7100	Production Planning	Mihai Borcoman	QUALITY PLANNING	7.1
7200	Customer Product Quality Requirements	Chris Watley	QUALITY PLANNING	7.2, 7.2.1, 7.2.2
7300	Product Design and Development	Exclusion	DESIGN	7.3, 7.3.1, 7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.3.7
7400	Supplier Quality	Nancy Clem	SUPPLIER QUALITY	4.1, 7.4, 7.4.1, 7.4.2, 7.4.3
7500	Control of Production	Razvan Datcu	PRODUCTION	7.5, 7.5.1, 7.5.2, 7.5.5
7530	Product Identification, Status, Traceability	Razvan Datcu	PRODUCTION	7.5.3
7540	Customer Property	Razvan Datcu	PRODUCTION	7.5.4
7600	Control of Monitoring and Measurement Equipment	Michael Bryant	PRODUCTION	7.6
8100	Measurement, Analysis and Improvement	Joe Sofinowski	MONITORING/ MEASUREMENT	8.1
8210	Customer Satisfaction	Jim Clark	MONITORING/ MEASUREMENT	7.2.3, 8.2, 8.2.1
8220	QMS Internal Audits	Patrick Crain	MONITORING/ MEASUREMENT	8.2.2
8230	Quality Process Monitoring and Measurement	Joe Sofinowski	MONITORING/ MEASUREMENT	8.2.3
8240	Product Quality Monitoring and Measurement	Joe Sofinowski	MONITORING/ MEASUREMENT	8.2.4
8300	Control of Nonconformance	Joe Sofinowski	NONCONFORMANCE CONTROL	8.3
8400	Analysis of Data	Joe Sofinowski	MONITORING/ MEASUREMENT	8.4
8510	Continual Improvement	Joe Sofinowski	QUALITY SYSTEM MANAGEMENT	8.5, 8.5.1
8520	Corrective and Preventive Action	Joe Sofinowski	NONCONFORMANCE CONTROL	8.5.2, 8.5.3

Quality Process Interface Flowchart



Section: **4100**

Title: **Quality Management System**

Section Owner: Quality Manager

Quality Process: Quality System Management

A. The registered scope of the MSI QMS is

SCREEN PRINTING, DIGITAL PRINTING, FINISHING AND ASSEMBLY OF DURABLE CUSTOM PRODUCT LABELS, GRAPHIC OVERLAYS, ROLL LABELS, INSULATORS, NAMEPLATES, DOMED LABELS AND MEMBRANE SWITCHES

B. Exclusions within the registration scope include those within ISO 9001:2008

- clause 7.3, as justified in QM Section 7300
- clause 7.5.1 for service provision, as justified in Section 7500
- clause 7.5.2 for process validation, as justified in QM Section 7500

C. MSI has established, implemented and maintains a quality management system (QMS) as described in this Quality Manual (QM). The effectiveness of the QMS is continually improved, acknowledging applicable requirements of ISO 9001:2008.

D. MSI has determined the Quality Processes needed for the QMS and their application throughout MSI. For a Quality Process, MSI

- has determined the activity, or set of activities involved in the process
- determines the criteria and methods to assure effective operation and control of the process
- assures the availability of resources and information necessary to support process operation and monitoring
- monitors, measures (as applicable) and analyzes the Quality Process
- takes action to achieve planned results and continual improvement of the process

E. A Quality Process supporting the QMS is managed by MSI to meet the requirements of ISO 9001:2008. The sequence and interaction of major Quality Processes is shown on the Quality Process Interface Flowchart, page 5.

F. Each Quality Manual Section refers to any supporting Quality Process(s), as applicable. Quality Processes and Quality Process Flowcharts include, but are

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not limited to

- Quality System Management
- Quality Documents
- Quality Planning, per the Production Planning Process Flowchart and the Customer Requirements Process Flowchart
- Resources
- Supplier Quality
- Production, per the Art Department, Screen Printing, Digital Printing, Hot Stamping, Finishing (e. g., die-cutting, laser-cutting, plotter cutting) and Shipping Flowcharts
- Nonconformance Control
- Monitoring and Measurement

G. Quality Processes supporting the QMS include those for management activities, provision of resources, production, measurement, and analysis and improvement.

H. This Quality Manual describes application of Quality Processes throughout MSI, headquartered at

2601 MARKET STREET, GARLAND, TX 75041

including all MSI products.

I. MSI determines and provides the resources necessary to

- implement and maintain the quality management system, including Quality Processes
- continually improve its effectiveness
- enhance customer satisfaction by meeting customer product quality requirements

Section: **4200**

Title: **Quality Manual**

Section Owner: Quality Manager

Quality Process: Quality Documents

- A. This Quality Manual (QM) describes the Quality Management System of MSI, in compliance with ISO 9001:2008, an international quality system standard.
- B. MSI has determined QMS documentation, including quality records necessary to assure the effective planning, operation and control of Quality Processes.
- C. QMS documentation, either included within or referenced from this Quality Manual, includes
- Quality Process Flowcharts supporting the QM, describing process inputs, actions and outputs of Quality Processes
 - MSI Quality Policy and Quality Objectives
 - Procedures required by ISO 9001:2008, including those for
 - document control, as described in Section [4230](#) Control of Documents and Quality Records
 - records control, as described in Section [4230](#) Control of Documents and Quality Records
 - Purchasing (purchase order requirements), as described in Section [7400](#) Supplier Quality
 - process validation, as described in Section [7500](#) Control of Production
 - internal quality audits, as described in Section [8220](#) QMS Internal Audits
 - control of nonconforming products, as described in Section [8300](#) Control of Nonconformance
 - corrective action and preventive action, as described in Section [8520](#) Corrective and Preventive Action
 - QMS Cross-Reference, page 4, showing the relationship of QM Sections, Section Owners, Quality Processes and referenced ISO 9001:2008 clauses
 - Various documentation needed to assure effective planning, operation and control of Quality Processes

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- Quality records required by ISO 9001:2008, as applicable
- D. MSI has established and maintains this Quality Manual (QM). This QM includes
- the registration scope of the QMS, QM page 7
 - details of and justification for any exclusions to the scope, page 7 and within the affected QM Section
 - referenced documented procedures required by ISO 9001:2008
 - appropriate description of the interaction of Quality Processes in the Quality Process Interface Flowchart, page 5
 - Procedures referenced from the QM. Procedures are established, documented, implemented and maintained.
- E. This Quality Manual is organized to describe “what” and, as applicable, “how” MSI meets the requirements of ISO 9001:2008 within its Quality Management System (QMS). This QM is organized to include
- Sections (e. g., Section 4200) and parts within Sections (e. g., part D of Section 4200)
 - Section, Title, and Section Owner as a header for each section
 - where appropriate, procedural requirements within parts of the QM
 - hyperlinks among QM Sections
- F. Revisions to this Quality Manual are described in the Revision Table, page 3.
- G. The extent of QMS documentation is appropriate for the size of MSI, its activities, the complexity and interaction of the Quality Processes, and the competence of MSI personnel.

Section: **4230**

Title: **Control of Documents and Quality Records**

Section Owner: Quality Manager

Quality Process: Quality Documents

- A. Documents and quality records required by the quality management system are controlled.
- B. The origin of a controlled document is either internal to or external to MSI.
- C. The Quality Manager maintains the Controlled Documents Log (CDL) for controlled documents. For each controlled document, the CDL provides
- unique identifier for the document, normally the document name or title
 - document number (optional)
 - the origin of the document (internal or external)
 - document medium (paper, or computer-based)
 - current revision status (revision level, or number, or revision date)
 - name of document owner, or whomever approves the document for adequacy prior to initial use
 - location(s) of controlled document, whether electronic or paper
- D. The document owner reviews, updates as necessary, and approves documents, as applicable. The document owner advises the Quality Manager when the document revision status is changed.
- E. The Quality Manager identifies and controls distribution of external documents (except customer drawings) determined by MSI as necessary for effective planning and operation of the QMS. External controlled documents include, but are not limited to customer Requests for Quotes, the ISO 9001:2008 standard, and customer drawings.
- F. Customer drawings are controlled by the Art Department Manager (Julia Rusmanica) per the MSI Customer Drawing Control procedure.
- G. Revision history for a controlled document is retained, as applicable, normally by retaining the document's archive.
- H. Only the latest revision of a controlled document is accessible where it is used.

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- I. The unintended use of an obsolete document is prevented by disposing of or archiving the obsolete document. An obsolete paper controlled document retained to preserve the knowledge is stamped "Obsolete" and filed with the closed Work Order. Obsolete computer-based controlled documents are deleted.
- J. Quality records supporting the QMS are established and controlled to provide evidence of conformance to quality requirements and effective operation of the QMS.
- K. The Office Manager maintains the Quality Records Log (QRL) for quality records. For each quality record, the QRL provides
- name of the quality record
 - who has access to retrieve the record
 - how long the record is retained before archive/disposal
 - location of the record, in a protected location
 - how a record is archived/disposed of
- L. Quality records remain legible, readily identifiable and easily retrievable.
- M. Most controlled documents and quality records are computer-based. Controlled documents and quality records are saved electronically on the M drive and protected from harm by restricted access, and by backup per the Backup Procedure.

Section: **5100**

Title: **Management Commitment**

Section Owner: Operations Manager

Quality Process: Quality System Management

- A. Top management includes the Operations Manager.
- B. The Operations Manager is committed to the development and implementation of the quality management system and to continually improving its effectiveness.
- C. The Operations Manager
- communicates to MSI the importance of meeting customer and statutory/regulatory requirements, as applicable as described in Section [5500](#) Management Responsibility, Authority and Communication
 - assures customer requirements are determined and are met while enhancing customer satisfaction as described in
 - Section [7200](#) Customer Product Quality Requirements
 - Section [7100](#) Production Planning
 - Section [8210](#) Customer Satisfaction
 - establishes and maintains consistent Quality Policy and Quality Objectives, including those for MSI's product quality, as described in Section [5300](#), Quality Policy, Objectives, and Planning
 - assures that QMS planning meets applicable requirements, including those of the Quality Objectives, as described in Section [5300](#) Quality Policy, Objectives, and Planning
 - defines and communicates responsibilities and authorities for quality as described in Section [5500](#) Management Responsibility, Authority and Communication
 - assures appropriate communication within MSI including communication regarding the effectiveness of the QMS as described in Section [5500](#) Management Responsibility, Authority and Communication
 - assures that the integrity of the QMS is maintained when a change to the QMS is planned and implemented as described in Section [5600](#) Management Review

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- conducts Management Reviews as described in Section [5600](#) Management Review
- assures the availability of resources (i.e., human resources and infrastructure) as described in Section [6200](#) Personnel Competence, Training and Awareness and in Section [6300](#) Infrastructure and Work Environment

Section: **5300**

Title: **Quality Policy, Objectives,
and Planning**

Section Owner: Operations Manager

Quality Process: Quality System Management

A. The Operations Manager has created the following Quality Policy for MSI:

Marking Systems, Inc. meets or exceeds each of our customers' requirements, providing products and customer service of the highest quality at a reduced cost. We will maintain a quality management system and will continually improve its effectiveness to meet the requirements of the ISO 9001:2008 standard.

This Quality Policy is appropriate for the purposes of MSI.

B. The Operations Manager reviews the Quality Policy for continuing suitability in Management Review at least every 90 days.

C. The Quality Policy provides the framework for establishing and reviewing Quality Objectives. MSI Quality Objectives, consistent with the Quality Policy are measurable, and approved by the Operations Manager.

D. The Quality Policy and/or Quality Objectives include commitments to

- comply with ISO 9001:2008 requirements
- comply with customer product quality requirements
- continually improve the effectiveness of the quality management system

E. Quality Objectives include

- To meet or exceed customer delivery expectations on at least 90% of the orders
- To reduce the internal rejects, not to exceed 1% of the orders
- To reduce customers' rejects to a maximum 1% of the orders
- Compliance with statutory and regulatory requirements
 - This objective is measured by zero actions that lead to violations or findings from regulatory inspections.
- To maintain the ISO 9001 Standard requirements through 01/18/2013.
 - This objective is measured by no major non-conformance findings on surveillance audits.

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- F. The Quality Policy and Quality Objectives are communicated and understood within MSI by several means, including:
- posting of the Quality Policy and Quality Objectives throughout the site
 - periodic quality meetings, at which the Quality Policy and Quality Objectives are discussed, and for which attendance is recorded
- G. The Operations Manager assures that Quality Objectives are established and understood throughout MSI, as appropriate, including those that support product quality requirements.
- H. Quality management system (QMS) planning meets the applicable requirements of ISO 9001:2008 and the Quality Policy and Quality Objectives. Planning is recorded in the Management Review Checklist (MRC).

Section: **5500**
Title: **Management Responsibility,
Authority and Communication**
Section Owner: Operations Manager

Quality Process: Quality System Management

- A. The Quality Manager assures that quality-related responsibilities and authorities are defined and communicated per the QMS Cross-Reference, page 4, within this Quality Manual, and within the Training Matrix as applicable.
- B. The Operations Manager, a member of MSI management, is appointed as Management Representative. The Management Representative, regardless of other responsibilities
- assures the quality management system and its supporting processes are established, implemented, and maintained
 - reports to the Quality Manager in Management Review on the performance of the quality management system and any need for improvement as described in Section [5600](#) Management Review
 - supports the Quality Manager in ensuring the promotion of awareness of customer requirements throughout MSI
 - serves as liaison to external parties (e. g., quality management system registrars and customers) regarding quality management system issues
- C. The Operations Manager assures appropriate communication processes are established and maintained. The Operations Manager assures applicable communication regarding quality management system effectiveness in part as described in Section [5600](#) Management Review.

Section: **5600**

Title: **Management Review**

Section Owner: Operations Manager

Quality Process: Quality System Management

- A. By review of MSI's quality management system (QMS) in Management Review at least every 90 days, the Operations Manager assures the continued suitability, adequacy and effectiveness of the QMS.
- B. The Management Review Checklist is the record of management review.
- C. Management Review attendees include Section Owners of this Quality Manual.
- D. As recorded in the Management Review Checklist, Management Review includes assessment of improvement opportunities and the need for change to the QMS, including the Quality Policy and Quality Objectives.
- E. In the Management Review Checklist, inputs to Management Review include data regarding
- any registration audits or surveillance audits
 - internal quality audits as described in Section [8220](#) QMS Internal Audits
 - customer feedback as described into Section [8210](#) Customer Satisfaction.
 - Quality Process performance as described in Section [8230](#) Quality Process Monitoring and Measurement
 - product conformance as described in Section [8240](#) Product Quality Monitoring and Measurement
 - status of corrective/preventive actions, as described in Section [8520](#) Corrective and Preventive Action
 - changes that could affect the QMS
 - continual improvement opportunities as described in Section [8510](#) Continual Improvement
- F. In the Management Review Checklist, outputs from Management Review include decisions and actions related to
- follow-up actions from previous Management Reviews
 - improvement in the effectiveness of the QMS and its processes

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- improvement of product related to customer requirements
- resource needs

Section: **6200**

Title: **Personnel Competence, Training and Awareness**

Section Owner: Office Manager, Art Dept.
Manager, Printing Manager

Quality Process: Resources

- A. MSI personnel performing work affecting conformance to product quality requirements as of June 24, 2009 are considered fully qualified and competent to fulfill those responsibilities, based on their existing education, training, skills and experience as of that date.
- B. MSI personnel performing work affecting conformance to product quality requirements are qualified as competent on the basis of appropriate education, training, skills and experience. Conformance to product quality requirements can be affected directly or indirectly by personnel performing any task within the QMS.
- C. The necessary competence and training needs of personnel performing work affecting product quality requirements is determined, based on the experience of MSI management. Necessary competence and training needs are described in the MSI Training Matrix and Job Descriptions.
- D. On-the-job training is provided by an experienced and qualified Trainer, per the appropriate Work Instructions. Work instructions, including illustrations and photographs, are displayed in clear sleeves by every piece of equipment.
- E. The MSI Training Matrix, including hourly personnel, is maintained by the Art Department Manager and kept by the Office Manager, along with the other personnel records.
- F. The MSI Training Matrix tracks the activities, software, operations or devices for which an employee has received training. The MSI Training Matrix includes personnel in the Art, Printing, Finishing and Shipping Departments.
- G. Skills and experience are evaluated by a qualified Trainer. The Training Matrix is updated at least every six months.
- H. Other training is provided to personnel by equipment manufacturers and in offsite seminars, as applicable.
- I. Training needs are described in the applicable Training Checklists.
- J. As applicable, quality training is provided to new personnel on the job, using the Work Instructions.
- K. Training effectiveness is evaluated by testing, as applicable, and/or evaluation of performance before and after training, as described in the

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Training Checklist.

- L. Personnel are made aware of the relevance and importance of their activities and how they contribute to the achievement of the Quality Objectives in periodic meetings led by the Operations Manager.
- M. Personnel records regarding applicable education, training, skills and experience are kept and maintained by the Office Manager.

Section: **6300**

Title: **Infrastructure and Work Environment**

Section Owner: Production Manager

Quality Process: Resources

- A. MSI determines, provides, and manages the infrastructure and work environment needed to maintain product quality requirements. MSI infrastructure and work environment include, as applicable
- buildings, workspace, and utilities (e. g., compressed air, air conditioning)
 - process equipment (e. g. presses, UV dryers)
 - supporting services (e. g. information technology)
- Some preventive maintenance (i. e., presses, UV driers) is outsourced to a subcontractor.
- B. Consistent with the nature of MSI and its products, MSI site is maintained in a state of appropriate order, cleanliness and repair.

Section: **7100**

Title: **Production Planning**

Section Owner: Operations Manager

Quality Process: Quality Planning

- A. MSI plans and develops processes needed for production, consistent with the requirements of other Quality Processes, as described below and in the Customer Requirements and Production Planning Process Flowchart.
- B. To plan production and to develop a Work Order, MSI determines, as applicable
- product quality objectives and requirements
 - process, document and resource needs specific to the product
 - required inspection and testing specific to the product quality requirements
 - necessary evidence that product quality requirements are met
- C. Production planning is recorded in the Work Order, suitable to MSI operations.
- D. MSI controls and reacts to changes impacting production planning.
- E. [Per the Production Meetings Log and as necessary, a production meeting is held to review special requirements, new procedures, and customer requirements, including quality requirements related to production.](#)
- F. Prior to documenting and implementing changes that impact planning, the effects of the change are assessed to assure compliance with customer product quality requirements determined in Section [7200](#) Customer Product Quality Requirements.
- G. Changes that impact required inspection and testing specific to product quality requirements are recorded in the Work Order.

Section: **7200**
Title: **Customer Product Quality Requirements**
Section Owner: Customer Service Manager

Quality Process: Quality Planning

- A. MSI customer product quality requirements are determined, as described below and in the Customer Requirements and Production Planning Flowchart.
- B. Customer product quality requirements are documented in a customer request for quote, such as an email, EDI, purchase order, or other request for quote, and any referenced documents.
- C. A potential new order is not accepted without a written request for quote.
- D. MSI determines certain customer product quality requirements including those in the customer request for quote and
- lead time
 - requirements on the customer drawing
 - statutory/regulatory requirements related to the product, if any
 - where known, requirements not stated by the customer but necessary for specified or intended use of the product
 - any additional requirements considered necessary by MSI
- E. MSI reviews customer product quality requirements prior to MSI's commitment to supply product to the customer. This review of requirements assures
- product quality requirements are defined
 - customer product requirements different from any previous order requirements are resolved
 - MSI has the ability to meet the customer product quality requirements
- The results of this review and actions arising from this review are recorded by initials and date of the MSI person completing the review (e. g., Customer Service or Sales).
- F. The majority of quote requests received by MSI are typical, repetitive orders. For these orders

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- an extensive product quality requirements review is neither necessary nor practical
 - product quality requirements are normally defined and unchanged from previous orders
 - MSI has proven ability to meet customer requirements
 - the appropriate person from customer service or estimating reviews customer requirements prior to acceptance, and records their Sales number on the Quote Worksheet
- G. For a more complex potential new order requiring a more thorough review of customer quality requirements
- Production Planning will review the requirements with all affected functions (e. g., Quality, Operations, Customer Service, Estimating, Art Department, Materials)
 - personnel from the affected areas investigate and confirm the feasibility and potential risks associated with the order
 - the results of this review, and actions arising from the review are recorded as special instructions in the Work Order
 - If product requirements are changed, the relevant documents are revised (i. e., the quote, or the Work Order) and relevant personnel are made aware of the change.

Section: **7300**

Title: **Product Design and Development**

Section Owner: Artist (Rusmanica)

Quality Process: Design

- A. MSI is not a product design-responsible supplier. Due to the nature of MSI and its product, MSI is excluded from compliance to the product design and development requirements of ISO 9001:2008, clause 7.3.

This exclusion does not affect the ability or responsibility of MSI to provide product that meets customer and applicable statutory/regulatory requirements.

Section: **7400**

Title: **Supplier Quality**

Section Owner: Materials Manager

Quality Process: Supplier Quality

- A. Purchased products and services affecting customer quality requirements include Lexan, polyester, ink, foils, subcontracted printing and membrane production, and calibration services.
- B. MSI purchases products and services from suppliers on the Approved Supplier List (ASL). The scope of approval and date of approval for each approved supplier is in the Approved Supplier List (ASL).
- C. Current MSI suppliers as of June 24, 2009 are considered fully qualified based on their demonstrated ability to supply products and services meeting MSI requirements.
- D. A supplier is evaluated and selected based on its ability to supply products and services meeting MSI requirements. Criteria for selection, evaluation and periodic re-evaluation are established and implemented, as described in the Supplier Quality Survey (SQS).
- E. Supplier quality records are maintained, including the SQS and subsequent follow-up actions.
- F. The Materials Manager, Production Manager, or Operations Manager verify the adequacy of specific purchase information, prior to issue of a Purchase Order to a supplier on the Approved Supplier List. Specific purchasing information in the Purchase Order and referenced documents includes, as applicable
- a complete description of the product or service purchased
 - any requirements for MSI approval of the supplied product or service, including
 - certificates of conformance
 - supplier quality management system requirements
 - specific requirements for approval of product, procedures, processes and equipment
- Supplier personnel qualifications are not required.
- G. Purchased products or services conform to purchase requirements specified in the Purchase Order and referenced documents, as applicable. The controls applied to the supplier and to the purchased product or services vary

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dependent on the effect of the purchased product or service on MSI product quality. Controls applied include

- visual inspection (e. g., verification of piece counts) of supplied product
 - verification, including review and approval of certificates of conformance
- H. As described in the Purchase Order and recorded in the Work Order, MSI maintains control of and responsibility for outsourced processes and products, to maintain product conformance to customer requirements. Outsourced materials or products are inspected before and after outsourcing.
- I. The type and extent of control applied is described within the applicable quality procedure for outsourced processes or products. Outsourcing processes or products does not absolve MSI of its responsibility to conform to customer product quality and statutory/regulatory requirements.
- J. Supplier corrective/preventive action is requested from a supplier, as applicable, when it is determined that the supplier may be responsible for the root cause of the nonconformance.

Section: **7500**

Title: **Control of Production**

Section Owner: Production Manager

Quality Process: Production

- A. Production quality is controlled per the applicable Process Flowchart, including Flowcharts for
- Screen Printing
 - Digital Printing
 - Hot Stamping
 - Finishing (e. g., die-cutting, laser-cutting, plotter cutting).
- B. The Work Order establishes controlled conditions. The Work Order includes or references other items in the Work Order package necessary to assure production quality. In production areas, controlled conditions per the Work Order package include
- use of suitable production equipment (e. g., screen printer, digital printer)
 - readily available data (e. g., customer drawing and/or MSI drawings and Work Order) regarding product quality requirements and specific quality characteristics
 - MSI Production Work Instructions readily available where the work is performed
 - actively implemented monitoring and measurement, including product inspection described in the Work Order
 - available equipment for monitoring and measurement, as applicable
 - effectively implemented finished product release (e. g., sorting at screen printing)
- C. Products, including constituent parts of the product (e. g., printed sheets) are preserved per the Work Order during production, processing and delivery to its intended destination.
- D. Product is identified by the part number printed on the product, and/or by the Work Order accompanying the product.
- E. As described in the Work Order and as applicable, product is handled, packaged, stored and protected to assure the product conforms to product

quality requirements.

- F. MSI has no processes requiring validation. Due to the nature of the organization and its product, MSI is excluded from compliance to the process validation requirements of ISO 9001:2008, clause 7.5.2.

This exclusion does not affect the ability or responsibility of MSI to provide product that meets customer and applicable statutory/regulatory requirements.

- G. MSI does not provide services. Due to the nature of MSI and its product, MSI is excluded from compliance to the service provision requirements of ISO 9001:2008, clause 7.5.1.

This exclusion does not affect the ability or responsibility of MSI to provide product that meets customer and applicable statutory/regulatory requirements.

Section: **7530**

Title: **Product Identification, Status,
Traceability**

Section Owner: Production Manager

Quality Process: Production

A. Product

- identification
- measurement status
- product traceability (i. e., lot control)

are controlled throughout production as described below and in the applicable Production Process Flowchart.

B. Product is identified by printing the part number, and by the accompanying Work Order.

C. Product measurement status is identified on the Work Order by the employee number of the applicable operator and inspector who verified and measured each product.

D. Lot control is controlled by the Work Order number, recorded on the Work Order accompanying the product.

Section: **7540**

Title: **Customer Property**

Section Owner: Production Manager

Quality Process: Production

- A. Customer property includes cutting dies, controlled by the Production Manager, and intellectual property (e. g., customer drawings), controlled by the Customer Drawing Control procedure.
- B. MSI exercises care with customer property under its control and/or being used by MSI.
- C. Cutting dies are identified (e. g., customer name, order number) by and verified, protected and safeguarded while at the MSI site.
- D. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the facts are reported to the customer by the Quality Manager, typically in an email.
- E. Nonconforming cutting dies are handled as described in Section [8300](#) Control of Nonconformance.

Section: **7600**

Title: **Control of Monitoring and Measurement Equipment**

Section Owner: Maintenance Head

Quality Process: Production

- A. MSI has established and maintains ongoing monitoring and measurement of products and production processes, consistent with product quality monitoring and measurement requirements of the Work Order, as applicable.
- B. MSI has determined the equipment required for monitoring and measurement, to provide evidence of product conformance to customer quality requirements, per the Calibration and Control Log.
- C. Monitoring and measurement equipment is controlled, and calibration data recorded per the Calibration and Control Log. Where necessary to assure valid results, monitoring and measurement equipment is
- calibrated or verified or both, at specified intervals or prior to use, against available measurement standards traceable to national measurement standards
 - suitably identified to determine its calibration status
 - adjusted or re-adjusted, as necessary
 - safeguarded from adjustments that would invalidate measurement results
 - protected from damage and deterioration during handling, maintenance and storage

Traceable measurement standards exist as the basis for calibration or verification.

- D. Monitoring and measurement equipment requiring calibration away from the MSI site is calibrated by an approved and accredited supplier (where appropriate), as described in the ASL.
- E. When measurement equipment is found not to conform to calibration requirements, the validity of previous measurement results is assessed and recorded on a CPAR. MSI takes appropriate action on any suspect equipment and/or suspect product.
- F. The ability of spectrophotometer software and HP Indigo used in the monitoring and measurement of color is confirmed at least every eight hours, by comparison to an established color standard. Confirmation is prior to initial use, and reconfirmed as necessary.

Section: **8100**

Title: **Measurement, Analysis, and Improvement**

Section Owner: Quality Manager

Quality Process: Monitoring/Measurement

- A. MSI plans and implements monitoring, measurement, analysis and improvement processes needed to
- demonstrate conformance to product quality requirements as described in Section [8240](#) Product Quality Monitoring and Measurement
 - assure conformance of the quality management system as described in Section [8220](#) QMS Internal Audits
 - continually improve the effectiveness of the quality management system as described in Section [8510](#) Continual Improvement
- B. MSI determines applicable methods for measurement, analysis and improvement, including statistical control limits applied to data analysis per Section [8400](#) Analysis of Data.

Section: **8210**

Title: **Customer Satisfaction**

Section Owner: Sales Manager

Quality Process: Monitoring/Measurement

- A. MSI monitor's data relating to customer perception, to determine if MSI has met customer requirements.
- B. The MSI Customer-Focused Audit, per the Customer Focused Audit Checklist, provides effective data regarding MSI capability to meet customer requirements. Results are reported as described in Section [5600](#) Management Review.
- C. The MSI Customer Quality Survey and customer report cards provide effective data regarding MSI ability to meet customer quality requirements.
- D. A customer complaint, including a customer return, is normally received by Customer Service. A significant complaint is recorded on a Corrective/Preventive Action Request (CPAR).
- E. These data are obtained and used to enhance customer satisfaction per Section [8400](#) Analysis of Data.

Section: **8220**

Title: **QMS Internal Audits**

Section Owner: Lead Auditor

Quality Process: Monitoring/Measurement

- A. MSI defines the responsibilities and requirements for planning and conducting QMS Internal Audits, establishing records and reporting results. A QMS Internal Audit verifies that
- the quality management system conforms to requirements of this Quality Manual and of ISO 9001:2008
 - the quality management system is effectively implemented and maintained
- B. A QMS Internal Audit
- meets contract and/or statutory/regulatory requirements, as applicable
 - provides sufficient records of the internal audit process (e. g., CPARs and supporting objective evidence)
- C. A QMS Internal Audit may include, but not be limited to, an audit of
- the Quality Manual to verify QMS conformance
 - a Quality Process Flowchart listed in Section [4100](#) Quality Management System, to assure conformance of the Quality Processes supporting the QMS
 - a significant area of concern (e. g., a customer complaint), as applicable, deemed necessary by the Shipping Manager to better assure product or process quality
- D. A QMS Internal Audit is scheduled by the Lead Auditor at least every 30 days.
- E. A QMS Internal Auditor is qualified based on a minimum three-day formal training accompanied by a Certificate of Attendance. A list of approved auditors is maintained.
- F. Normally the original QMS Internal Auditor follows-up to verify corrective/preventive action taken, reporting verification results as described in the CPAR.
- G. The Lead Auditor plans and manages QMS Internal Audits. Internal quality audit planning considers the status and importance of the processes and

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areas to be audited, as well as the results of previous internal quality audits, as applicable.

H. The Lead Auditor

- maintains the QMS Internal Audit Schedule, including the criteria, scope and frequency of QMS Internal Audits
- assures auditor selection, the conduct of audits, and the audit process are objective and impartial (e. g., an auditor does not audit his/her own work area)
- maintains audit records, including internal quality audit checklists, as applicable
- maintains various auditor notes with results of the audit, including notes on Quality Process Flowcharts

I. To assure that all clauses of ISO 9001:2008 are audited annually, the QMS Internal Audit Schedule is supported by the QMS Cross-Reference, page 4, a cross-reference of Quality Manual Sections and ISO 9001:2008 standard clauses.

J. The management responsible for the area being audited makes any necessary corrections (without determination of cause) and corrective actions (with elimination of root cause) without undue delay, to eliminate the nonconformance.

K. Follow-up activities are recorded by the QMS internal auditor on a Corrective/Preventive Action Requests (CPAR), as applicable, and include

- verification of the actions taken
- reporting of verification results

Section: **8230**

Title: **Quality Process Monitoring and Measurement**

Section Owner: Quality Manager

Quality Process: Monitoring/Measurement

- A. A Quality Process is monitored and, where applicable, measured to assure the process achieves planned results consistent with Quality Objectives. Results of Quality Process monitoring and measurement are reviewed at Management Review, as recorded in the Management Review Checklist.
- B. Monitoring and/or measurement methods include
- results of QMS Internal Audits
 - periodic QMS registration and surveillance audits
- C. When planned results consistent with Quality Objectives for a Quality Process are not achieved
- correction (i. e., containment), corrective and preventive action are taken, as applicable, as recorded in a CPAR per Section [8520](#) Corrective and Preventive Action, to assure product conformance
 - the process nonconformance is evaluated to determine if it has resulted in product nonconformance
 - nonconforming product is identified and controlled as described in Section [8300](#) Control of Nonconformance
- D. Results of quality process monitoring and measurement are collected and analyzed per Section [8400](#) Analysis of Data.

Section: **8240**

Title: **Product Quality Monitoring and Measurement**

Section Owner: Quality Manager

Quality Process: Monitoring/Measurement

- A. Product quality characteristics are monitored and measured to assure that product requirements have been met, as described and recorded in the Work Order.
- B. Measurement requirements for product acceptance are documented in the Work Order including
 - criteria for acceptance and/or rejection (e. g., product sample)
 - where in the sequence inspection and testing operations are performed
 - a record of the measurement results, as applicable
 - type of measurement equipment required, and reference to any specific instructions associated with their use
- C. Evidence of conformance/nonconformance to acceptance criteria (i. e., product quality requirements), including person(s) authorizing release of product and date released, is recorded and maintained in the Work Order.
- D. Finished product is visually inspected in Shipping. Nonconforming product is reviewed by the Supervisor, and then the Production Manager and Quality Manager, as applicable. Product is not released until requirements of the Work Order have been completed, and the product quality requirements of the Work Order have been found acceptable.
- E. Finished evidence of conformance/nonconformance to acceptance criteria (i. e., product quality requirements), including person(s) authorizing release of product and date released, is recorded and maintained in the paper copy Work Order. If review of nonconforming product by the Supervisor, Production Manager or Quality Manager is required, the person(s) authorizing release of the product and date released is also recorded in the computer Work Order.
- F. The Customer Focused Audit of finished product is also applied to monitor and measure product quality, per Section [8210](#) Customer Satisfaction.
- G. Results of product quality monitoring and measurement are collected and analyzed per Section [8400](#) Analysis of Data.

Section: **8300**

Title: **Control of Nonconformance**

Section Owner: Quality Manager

Quality Process: Nonconformance Control

- A. Nonconformances include quality management system (QMS) nonconformance and nonconformance to product quality requirements.
- B. Potential sources of QMS nonconformance may include
- an internal quality audit
 - a registration/surveillance audit
 - a supplier quality audit, including one from a MSI customer
 - a customer complaint
 - Management Review
- C. For QMS nonconformance, MSI records the
- nonconformance
 - root cause of the nonconformance
 - corrective action taken
 - preventive action taken to prevent recurrence
- using a Corrective/Preventive Action Request (CPAR), as described in Section [8520](#) Corrective and Preventive Action.
- D. Potential sources of product nonconformance may include
- supplied material, product or service
 - in-process material or product
 - finished product
 - product returned from the customer
- E. Nonconforming material or product includes unidentified or suspect material or product.
- F. As applicable, MSI controls nonconforming product by one or more of the following

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- by taking action to eliminate the detected nonconformance
 - by taking action to preclude its original intended use or application
 - by taking appropriate action for the nonconformance, when nonconforming product is detected after delivery or use has started
- G. Nonconforming material or product is identified using a Reject Tag or equivalent record attached to each material/product or container of material/product.
- H. Nonconforming material or product is contained to prevent its unintended use or delivery, and segregated for disposition in the Reject Area.
- I. The Operations Manager determines disposition of nonconforming material or product by signature and date as described in the Reject Tag.
- J. For rework disposition, nonconforming product is corrected and re-verified to demonstrate conformance to applicable product quality requirements.
- K. An MSI customer is promptly informed of the unintended release of nonconforming product by the Quality Manager as reported in an email.
- L. Operations Manager may authorize the release of nonconforming product for use other than its intended use or application, with or without authorization by the customer, as applicable.
- M. For nonconformance to product quality requirements and as applicable, MSI records the
- nonconformance
 - root cause of the nonconformance
 - correction (i. e., containment) action taken, if any
 - corrective action taken
 - preventive action taken to prevent recurrence
- using a Corrective/Preventive Action Request (CPAR), as described in Section [8520](#) Corrective and Preventive Action.

Section: **8400**

Title: **Analysis of Data**

Section Owner: Quality Manager

Quality Process: Monitoring/Measurement

- A. The Quality Manager determines and collects appropriate data to demonstrate the ongoing effectiveness and suitability of the MSI quality management system.
- B. Data are collected and analyzed regarding
- supplier quality. per Section [7400](#) Supplier Quality
 - customer satisfaction and customer complaints, per Section [8210](#) Customer Satisfaction
 - quality management system performance. per Section [8220](#) QMS Internal Audits
 - quality process monitoring and measurement, per Section [8230](#) Quality Process Monitoring and Measurement
 - product quality monitoring and measurement, per Section [8240](#) Product Quality Monitoring and Measurement
 - corrective and preventive action, per Section [8520](#) Corrective and Preventive Action
- C. Data are analyzed and reviewed to
- evaluate opportunities for continual improvement per Section [8510](#) Continual Improvement
 - determine necessary corrective and preventive action per Section [8520](#) Corrective and Preventive Action.
- D. Data are reported and reviewed in Management Review per Section [5600](#) Management Review.

Section: **8510**
Title: **Continual Improvement**
Section Owner: Quality Manager

Quality Process: Quality System Management

- A. The effectiveness of the quality management system is continually improved as described in the Continual Improvement Project Log.
- B. Continual improvement is normally initiated by
- analysis of data reported as described in Section [8400](#) Analysis of Data
 - periodic review and assessment of the MSI Quality Policy and Quality Objectives, as described in Section [5300](#) Quality Policy, Objectives and Planning
 - Management Review as described in Section [5600](#) Management Review
 - contributions from MSI personnel
- C. In addition, the MSI organization is continually improved by training, as well as from experience managing the quality management system.

Section: **8520**

Title: **Corrective and Preventive Action**

Section Owner: Quality Manager

Quality Process: Nonconformance Control

- A. Appropriate and effective action is taken to eliminate the cause of nonconformances, in order to prevent recurrence.
- B. Corrective action is completed and documented for either product-related or process-related nonconformances. Corrective action is taken appropriate for the effects of the nonconformance.
- C. As recorded in the Corrective/Preventive Action Request (CPAR)
- a nonconformance, including a customer complaint, is reviewed to determine the cause(s) of the nonconformance
 - the assignable cause of the nonconformance is determined, and the cause is eliminated
 - the need for corrective action is evaluated
 - effective corrective action is determined and implemented, to assure nonconformances do not recur
 - action taken is verified for effectiveness
- D. To identify and eliminate root cause of a nonconformance, normally Cause and Effect analysis is used for problem-solving, as described in the CPAR.
- E. Similarly, appropriate and effective action is taken to eliminate the cause of potential nonconformances, in order to prevent recurrence. Preventive action is taken for similar processes and products, as applicable, to eliminate the cause of a potential nonconformance. Preventive action is taken appropriate for the effects of the potential problems.
- F. Preventive action is completed and documented for either product-related or process-related nonconformances. As recorded in the Corrective/Preventive Action Request (CPAR)
- the need for preventive action is evaluated
 - effective preventive action is determined and implemented, to assure nonconformances do not recur
 - action taken is verified for effectiveness

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- G. Error-proofing methods are applied to the corrective/preventive action process, as applicable.
- H. CPARs are recorded and tracked until closed out on the CPAR Log.