




Quality System Manual

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Issue: 2
Revision: 4
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	General Introduction	ISS: 2	REV: 4	Page:2 of 53	
	Section 1.1 Control Copy Issued				
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DOCUMENT TITLE: Quality System Manual

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ACKNOWLEDGEMENT OF RECEIPT

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 Recipient's Signature Date

The Quality System Manual shall be distributed to the following:
 Director of Quality Assurance

NOTE: When issued internally to authorized employees, this manual, referenced procedures and documents must be surrendered to the Quality Assurance prior to separation from MO-SCI Corporation or its subsidiaries employment.



Section 1.2 Document Revision Page

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REV LEVEL	REV DATE	DETAILS		DESCRIPTION OF CHANGE
		Page	Para.	
1.0	Nov. 23, 2001	All	All	Original Issue
1.1	10.15-03	All	All	Section 5.5 I1-Rev3
1.2	03/22/04	All	All	Converted from Word to Open Office document and PDF File New Logo Added
2.0	Aug. 30, 2005	All	All	Updated to met AS 9100 requirements and converted to Word
2.1	Sept. 5, 2005	All	All	Clarify process design
2.2	Dec 15, 2006	All 26	All 5.5	Use QM to abbreviated Quality Systems Manual (Ref 11-6,7-06 Audit) New Organizational Chart
2.3	Feb. 15, 2008	23	3.1	Added IT and deleted Sr Processing Engineer
2.4	June 15, 2009	All 2 8 10 14 14 21 27 28 29 30 31 39 40 41 41 41 41 43 43 47 47 49 50 52	All NA NA 3.3 3.3.10 3.4.1 Sec.5.5.1 Sec. 6.2 3.1.5 3.1.2 3.3 3.1.1 7.5 3.2.1 3.3.3 3.3.5 3.4.4 3.4.1.1 3.5.1 7.6 3.5 c 3.2.4 3.2.5 3.4.2.4 3.4 3.3	Replace "ISO 9001:2000" with "ISO 9001:2008" Changed the document status to Uncontrolled unless otherwise stated. Delete "P.O. Box 2" <u>Re-defined "Quality Records"</u> Added "determined by MO-SCI to be necessary for the planning and operation of the QMS" Added "shall be controlled" Updated section and organization chart to include Dir of Mfg. Changed "quality" to "conformity to product requirements" Added "Information Systems" to Section 6.3 Infrastructure Include work environment examples, such as noise, temperature, etc. Added "and" documentation to <i>b</i> & "measurement" to <i>d</i> Changed "related" to "applicable" in <i>e</i> & "determined" to "considered necessary" in <i>f</i> . Monitoring and measuring "devices" changed to "equipment" Replaced "This includes any processes where" with "and, as a consequence" Added "throughout product realization." Added "Records associated with the product traceability shall be maintained." Changed to "or otherwise found to be unsuitable for use, MO-SCI shall report this to the customer and maintain records." Added "or personal data" Added "in order to maintain conformity to requirements." Replaced "Device" with "Equipment" Added "in order to determine its calibration status." Changed to "QMP-020 defines the responsibilities and requirements for planning and conducting audits, establishing records and reporting results." Changed to "The management responsible for the area being audited shall ensure that any necessary corrections and corrective action are taken without undue delay to eliminate detected nonconformities and their causes." Added "Evidence of conformity with the acceptance criteria shall be maintained." (<i>Removed from 3.4.5</i>) Re written per ISO 9001:2008 e.g. add "for delivery to the customer" & Added "d" and remove 3.9



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Section 1.4 Cross Reference of Manual to ISO Requirements

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MO-SCI Corporation and its subsidiaries, **MO-SCI Health Care, L.L.C.**, and **MO-SCI Specialty Products, L.L.C.** located at 4040 HyPoint North, Rolla, Missouri 65401, developed and implemented a Quality Management System, QMS, in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The QMS of MO-SCI meets the requirements of the international standard SAE AS 9001. This system addresses the company's process development and product manufacturing.

The manual is divided into eight sections that correlate to the QMS sections of the ISO 9001:2008 format and AS 9001. Each section begins with a policy statement expressing MO-SCI Corporation's obligation to implement the basic requirements of the referenced QMS section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.


This manual describes the QMS, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for activities comprising the QMS to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the AS 9100 standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our QMS to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the QMS is maintained and focused on customer satisfaction and continuous improvement.

MO-SCI is committed to the policies and procedures described and referenced within this manual while producing products for our customers.

Thomas E. Day
President

	History of Organization		ISS: 2	REV: 4	Page:8 of 53
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MO-SCI Corporation and subsidiaries are manufacturers

of high quality, specialty glass microspheres, fibers, and frit,


as well as a producer of glass products

of unexcelled quality for the health care industry.

The company was created in June 1985.

In 2001, MO-SCI Corporation created two limited liability companies, MO-SCI Health Care, L.L.C. and MO-SCI Specialty Products, L.L.C.

MO-SCI Corporation and subsidiaries is headquartered in Rolla, Missouri.

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1.0 PURPOSE

- 1.1 The objectives of this manual are to provide our company's personnel and customers with a single source of information regarding MO-SCI Corporation and its subsidiaries' policies and procedures for assuring and controlling product quality, and the continual improvement of the Quality Management System (QMS). The system is structured to comply with the conditions set forth in the International Standard SAE AS 9100.

2.0 SCOPE

- 2.1 This manual establishes MO-SCI's management policy concerning quality and refers to QMPs. These procedures have been developed to ensure the quality of deliverables in strict accordance with contractual and jurisdictional requirements. The policies contained within this manual and the methodologies defined within each referenced procedure are applicable to contracts performed by MO-SCI.
- 2.2 This document is divided into twenty-nine (29) sections. From this point forward, each section contains the following blocks of information:
- PURPOSE: Identifies the objective to be achieved by the section.
SCOPE: Describes the extent to which the section applies.
POLICY: Defines company policy regarding the section topic.
REFERENCES: Identifies documents which are referenced or applicable to the section.


3.0 POLICY

3.1 General

- 3.1.1 Nothing within this manual relieves MO-SCI Corporation and subsidiaries of its responsibility for complying with the provisions of awarded contracts including work performed by company suppliers and subcontractors.
- 3.1.2 In the event of an inconsistency between this document and specific contract requirements, the contract requirements shall prevail.
- 3.1.3 Unless otherwise defined, the definition of a specific term used within this document shall be as outlined within International Standard SAE AS 9100.
- 3.1.4 The words "shall", "will" and "must" have been used to indicate a **mandatory** internal requirement. Where the word "should" has been used, it is to be interpreted as meaning a preferred approach.
- 3.1.5 This manual and documents referenced within shall be reviewed at least once a year for suitability.

3.2 Our Quality Management System (QMS)

- 3.2.1 The QMS is documented, implemented, maintained and continuously improved in effectiveness per our stated policies to ensure that products provided to customers conform to contractual and quality requirements and meet or exceed their needs and expectations.
- 3.2.2 The processes that make up the QMS as well as their application, sequence and interaction are identified throughout this manual.
- 3.2.3 The criteria and methods used to ensure the effective operation and control of these processes are defined in Section 7.1 of this manual.
- 3.2.4 Information and resources necessary to support the operation, monitoring, measurement and analysis of these processes are defined within sections 5.5, 6.1, 7.1, 7.5, 8.2 and 8.4.
- 3.2.5 Actions considered necessary to achieve planned results and continual improvement shall be taken by the company as defined within sections 5.4, 7.1 and 8.5.

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- 3.2.6 Purchased products or outsourced processes shall be controlled as defined within Section 7.4.
- 3.2.7 Processes that make up the QMS shall be managed as defined within this manual.
- 3.3 Quality Management System Definitions
 - 3.3.1 Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
 - 3.3.2 Customer supplied product - Any type of material supplied to be utilized in the manufacture, modification or repair of customer-owned property.
 - 3.3.3 Product – The end item result of meeting contract terms and conditions. (e.g: manufactured goods, merchandise etc.)
 - 3.3.4 Quality Records – Documents which furnish objective evidence of activities performed and results achieved. Records to be maintained will be specified in procedures and/or work instruction level documents, as applicable.
 - 3.3.5 Key Characteristics - The features of a material, process, or part whose variation has a significant influence on product fit, performance, or manufacturability.
- 3.4 Exclusions
 - 3.4.1 MO-SCI has determined that product design is not applicable to its operations. MO-SCI manufactures products according to its customer’s requests.

4.0 REFERENCES

- 4.1 Quality Management Procedures
- 4.2 ISO Standard 9001:2008 Quality Management Systems – Requirements
- 4.3 ISO Standard 9000:2005 Quality Management Systems – Fundamentals and Vocabulary.
- 4.4 International Standard SAE AS 9100
- 4.5 American National Standard ANSI/AS 9001/ASQ Q9000-2005, Quality Management Systems - Vocabulary.
- 4.6 American National Standard ANSI/AS 9001/ASQ Q9001-2008, Quality Management Systems – Requirements
- 4.7 American National Standard ANSI/AS 9001/ASQ Q9004-2000, Quality Management Systems – Guidelines for performance Improvements
- 4.8 Society of Automotive Engineers SAE AS 9100B - Quality Management Systems – Requirements



Section 4.1 General Requirements

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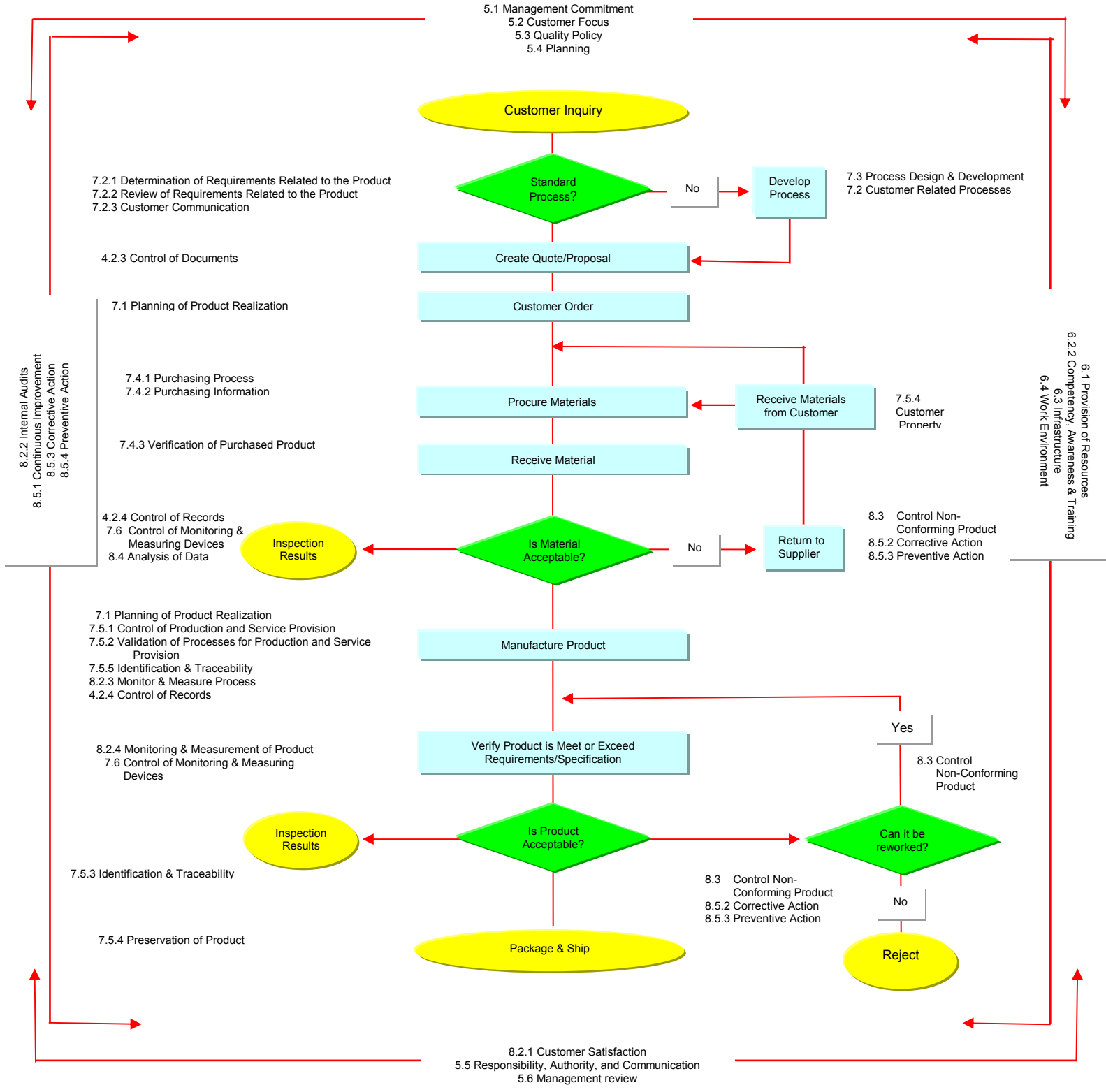
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QMS Diagram



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	Section 4.2 Quality Systems Documentation				
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1.0 PURPOSE

- 1.1 To define the quality system documentation structure and its management and to reference specific procedures and documents that apply to this subject.

2.0 SCOPE

- 2.1 This section describes the QMS documentation used to ensure product compliance to quality and contractual requirements and includes the control, review, approval and storage of these documents and quality records.

3.0 POLICY

3.1 GENERAL

- 3.1.1 The documentation structure of the QMS consists of three tiers or levels of documents with each subsequent tier designed to provide the reader with additional detail, as required, based on the complexity of the function or process being addressed:

Tier 1 Quality System Manual (QM): Single stand-alone controlled document. It defines the quality policy, quality objectives, commitment to customer satisfaction, and continual improvement under sections 5.3, 5.4, 8.2 and 8.4, respectively. It also addresses each of the QMS processes established by the company. The QM references specific Quality Management Procedures, QMP.

Tier 2 Quality Management Procedures (QMP): Consists of twenty-seven (27) stand-alone documents to ensure the effective planning, operation and control of company processes. It defines who is responsible for what, when it would apply and why it is being done. QMPs cross-reference other procedures and make reference to third-tier groups of detailed instructions or related documents and may contain or reference specific forms to aid the reader in establishing required records.

Tier 3 Detailed Instructions, Checklists and Forms: Consists of numerous stand-alone documents including instructions for inspection and testing, calibration, and production as well as quality system forms, audit checklists, workmanship standards and quality plans. It defines details as to how specific tasks must be performed and records to be produced when not covered by QMPs. Instructions cross-reference other third-tier documents and contain specific forms to be used when required.

3.2 QUALITY SYSTEM MANUAL (QM)

- 3.2.1 This QM has been established and shall continue to be maintained in order to provide the reader with:

- The scope of the QMS including details of and justification for any exclusions, as defined within Section 4.1.
- A reference to documented QMPs as defined below under paragraph 3.2.3; and
- A description of the interaction between the processes which make up the QMS.

- 3.2.2 The distribution of this QM shall be controlled as defined under paragraph 3.3 of this section, and, where applicable, shall be submitted to customers and external jurisdictions and agencies for acceptance.

3.2.3 Quality Management Procedures

- 3.2.3.1 The following QMPs have been implemented within the company and form an integral part of the QMS as they are both consistent with the requirements and the policies within this QM:

<u>DOCUMENT</u>	<u>SUBJECT OF PROCEDURE</u>
QMP-001	Quality Planning
QMP-002	Documentation Development



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- QMP-003 Control of Documents
- QMP-004 Control of Quality Records
- QMP-005 Quality Management Review
- QMP-006 Competency, Training and Awareness
- QMP-007 Customer Requirements and Communication
- QMP-008 Process Design and Development
- QMP-009 Purchasing
- QMP-010 Supplier Selection and Evaluation
- QMP-011 Planning of Product Realization
- QMP-012 Preventive Maintenance
- QMP-013 Identification and Traceability
- QMP-014 Inspection and Test Status
- QMP-015 Customer Property
- QMP-016 Preservation of Product
- QMP-017 Validation of Processes
- QMP-018 Control of Monitoring and Measuring Devices
- QMP-019 Measuring Customer Satisfaction
- QMP-020 Internal Quality Audits
- QMP-021 Monitoring and Measurement of Processes
- QMP-022 Monitoring and Measurement of Product
- QMP-023 Control of Nonconforming Product
- QMP-024 Analysis of Data
- QMP-025 Planning for Continual Improvement
- QMP-026 Corrective and Preventive Action
- QMP-027 External Quality Audits

3.2.3.2 The extent of detail contained within each procedure has been based on the complexity of the work processes being used, the interaction of the processes involved, and the prerequisite skills and training needed by personnel to perform each activity defined.

3.2.4 Resulting quality records shall be controlled as defined under paragraph 3.4 of this section.

3.3 CONTROL OF DOCUMENTS


3.3.1 Documents required for the QMS such as this manual, QMPs, instructions, checklists and quality system forms shall be developed per QMP-002 and reviewed, approved and controlled in accordance with QMP-003, including documents of external origin, such as standards, specifications and customer drawings.

3.3.2 Original documents shall be reviewed for adequacy and completeness and approved by the departments and personnel responsible prior to issue.

3.3.3 Each department creating and distributing documents shall maintain a master listing of the documents generated. This master listing shall be made readily available to personnel and shall identify the current revision status of each document and its date of effectiveness.

3.3.4 Documents requiring customer acceptance shall be submitted for review and approval and shall not be distributed or implemented within the company or released to customers or suppliers until such acceptance has been received.

3.3.5 Prior to release, revisions to previously approved documents and data shall require the same authorizations and approvals as the original.

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3.3.6 Changes or additions to approved company documents and data shall be identified as such within the documents or appropriate attachments as they are initiated. Following not more than **five (5) changes**, each document shall be **reissued** in its entirety.

3.3.6.1 Typographical errors and minor editorial changes are not considered changes for the purposes of this procedure.

3.3.7 When changes to customer documents are considered necessary, the proposed changes shall be prepared and formally submitted to the customer in writing.

3.3.8 Approved documents and changes shall be transmitted to functional areas and locations where they apply and shall be made readily accessible to the personnel concerned.

3.3.9 Documents shall be legible, readily identifiable and retrievable.

3.3.10 Documents of external origin determined by MO-SCI to be necessary for the planning and operation of the QMS shall be identified and their distribution controlled.

3.3.11 Invalid and/or obsolete documents shall be promptly removed from points of issue or use.

3.3.12 Obsolete documents retained for the purposes of legal and/or knowledge-preservation shall be identified as "**Archive**" and shall be controlled.

3.3.13 Quality related documentation as required by contract shall be made available to the customer for review and evaluation upon request.

3.3.14 Documents defined as quality records shall be controlled as described under paragraph 3.4 below.

3.4 CONTROL OF RECORDS

3.4.1 The term quality records may include, but are not limited to, records prepared for or required by the QMS. Records providing evidence of conformity to requirements and the effective operation of the QMS shall be controlled.

3.4.2 Quality records shall be legible, readily identifiable and retrievable during the performance of a contract as outlined within the relevant QMP or instruction.

3.4.3 Subsequent to the completion of a contract, documents and quality records shall be assembled and stored.


3.4.4 Periodic verification of stored documentation shall be conducted in accordance with procedure QMP-020 to ensure that environment, access and other contract and QMS requirements are met.

3.4.5 The methodology to be used and the personnel responsible for the identification, storage, protection, retrieval, retention and disposition of quality records shall be in accordance with procedure QMP-004.

3.4.6 When required by contract or at the discretion of the Director of Quality Assurance quality related records and documents shall be made available to the customer for review and analysis upon request.

4.0 REFERENCES

- 4.1 QMP-002 Documentation Development
- 4.2 QMP-003 Control of Documents
- 4.3 QMP-004 Control of Quality Records
- 4.4 QMP-020 Internal Quality Audits
- 4.5 ISO Standard 9001:2008 Quality Management Systems - Requirements
- 4.6 AS9100 Requirements
- 4.7 Quality Management Procedures

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	5.1 Management Commitment				
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1.0 PURPOSE


- 1.1 To define MO-SCI Corporation and subsidiaries' management commitment to the development and improvement of the Quality Management System (QMS).

2.0 SCOPE

- 2.1 This section describes the commitment made by MO-SCI's management to the development, implementation and continuing improvement of the QMS and identifies evidence of this commitment.

3.0 POLICY


- 3.1 Management is committed to the policies and procedures described and referenced within this manual, to the ongoing development and continual improvement of the QMS implemented, and to the following quality management principles:
- 1) Customer Focus: As a customer-focused organization, we must understand our customer's current and future needs and we must meet these needs while striving to exceed our customers' expectations.
 - 2) Leadership: We must establish a unity of purpose, direction and stable environment in order that our employees can become fully involved in achieving our company's objectives.
 - 3) Involvement of People: We must ensure that our employees are fully involved and informed in order to enable them to use their abilities for the maximum benefit of the company.
 - 4) Process Approach: We must ensure that related resources and activities are managed as a process in order to efficiently achieve the desired result.
 - 5) System Approach to Management: We must identify, understand and manage the interrelated processes of our QMS to achieve defined objectives while contributing to the effectiveness and efficiency of our company
 - 6) Continual Improvement: We must ensure that continual improvement is a permanent objective of MO-SCI.
 - 7) Factual Approach to Decision Making: We must ensure that decisions are effective and are based on the logical or intuitive analysis of data and information.
 - 8) Mutually Beneficial Supplier Relationship: We must enhance our ability to create value by fostering mutually beneficial relationships with our suppliers.
- 3.2 To reinforce this commitment, management shall ensure that:
- a) The importance of meeting customer, statutory and regulatory requirements, as defined under section 7.2 of this Quality Manual, is effectively and consistently communicated throughout the organization using any or all of the following means:
Internal and quality indoctrination training sessions;
Postings and bulletin boards; and
E-mail notification.
 - b) The quality policy, defined under section 5.3 of this manual, continues to remain relevant and consistent with the overall organizational policies and provides a suitable framework for setting quality objectives.
 - c) Quality objectives continue to be identified for the relevant functions and levels within the company as defined under section 5.4 of this manual and remain measurable while consistent with the quality policy.
 - d) Quality Management Reviews continue to be conducted, as defined under section 5.6 of this manual, to ensure the continuing suitability, effectiveness and efficiency of the QMS.

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- e) Necessary resources to implement and improve the processes for the QMS and to address customer satisfaction continue to be made available, as defined under section 6.1 of this quality manual.

4.0 REFERENCES

4.1 None.

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	5.2 Customer Focus				
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1.0 PURPOSE

1.1 To define MO-SCI Corporation and subsidiaries' policy concerning customer focus.

2.0 SCOPE

2.1 This section applies to customer contracts and orders.

3.0 POLICY


3.1 MO-SCI strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

3.2 Management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization as defined under section 7.2 of this manual.

3.3 The aim regarding these actions shall be to fulfill customer requirements, comply with statutory and regulatory requirements, and to achieve or enhance customer satisfaction as outlined under section 8.2 of this manual.

4.0 REFERENCES

4.1 None.

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	5.3 Quality Policy				
DOC: QM-I2Rev4	REVIEWED BY:	EShockley	APPROVED BY:	TDay	June 15, 2009

1.0 PURPOSE

- 1.1 To define MO-SCI Corporation and subsidiaries' quality policy and to reference specific procedures that apply to this subject.

2.0 SCOPE


- 2.1 This section covers the overall intentions and direction of MO-SCI as they relate to quality and as expressed by management.

3.0 POLICY – “Make It Right, Reliable, and Cost Effective” or MIRRCE

- 3.1 It is MO-SCI Corporation and subsidiaries' quality policy to provide our customers with products that comply with requirements while meeting or exceeding their needs and expectations for performance, reliability and safety at a competitive cost. In support of this policy, we are committed to continually improving the effectiveness of our quality management system and to ensure an adequate framework for the establishment and review of the quality objectives as defined under section 5.4 is provided.
- 3.2 MO-SCI shall ensure that this policy is communicated and understood by all levels within the organization by providing training sessions as defined within procedure, QMP-006 and by conducting internal quality audits in accordance with procedure QMP-020.
- 3.3 This quality policy is considered appropriate and consistent with MO-SCI's' overall business policies and shall be reviewed on an on-going basis as defined within procedure QMP-005, to ensure its continuing suitability.

4.0 REFERENCES

- | | | |
|-----|---------|------------------------------------|
| 4.1 | QMP-005 | Quality Management Review |
| 4.2 | QMP-006 | Competency, Training and Awareness |
| 4.3 | QMP-020 | Internal Quality Audits |

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	5.4 Planning				
DOC: QM-I2Rev4	REVIEWED BY:	EShockley	APPROVED BY:	TDay	June 15, 2009

1.0 PURPOSE

- 1.1 To define MO-SCI's policy concerning quality objectives and quality planning and to reference specific procedures that apply to this subject.


2.0 SCOPE

- 2.1 This section describes how quality objectives and QMS planning are established to ensure product compliance to both quality and contractual requirements.

3.0 POLICY

3.1 QUALITY OBJECTIVES

- 3.1.1 Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed for suitability
- 3.1.2 Management shall ensure that quality objectives:
- include those needed to meet product requirements, as defined within section 7.1;
 - are established at relevant functions and levels within the company
 - are measurable; and
 - are consistent with MO-SCI's quality policy defined within section 5.3.
- 3.1.2 To this end, MO-SCI's quality objectives shall fall into four main classifications:
- 1) Management Policy Objectives: Management policy is established to identify the overall intentions and direction of the company. Input for establishing management policy objectives shall include:
 - Customer satisfaction surveys;
 - Employee satisfaction surveys;
 - Customer complaints;
 - Health, safety and environmental issues;
 - Productivity, inventory and cost analysis reports;
 - Sales and marketing research; and
 - Quality Management Reviews
 - 2) Process Objectives: Processes are the system of activities which use resources to transform inputs into outputs. Input for establishing process quality objectives shall include:
 - Process capability studies;
 - Process designs and developments;
 - Inspection, testing and examination of process results;
 - Internal nonconformances;
 - New technology and equipment;
 - Health, safety and environmental issues;
 - Productivity analysis reports; and
 - Quality Management Reviews
 - 3) Product Objectives: Products are the result of the system of processes used. Inputs for establishing product quality objectives shall include:
 - Product inspections and tests;
 - Customer satisfaction surveys;
 - Customer complaints; and
 - Product nonconformances and returns.
 - 4) Quality System Objectives: The quality system is a set of interrelated and interactive processes that have been put in place to achieve customer satisfaction by meeting specified product requirement and by continually improving performance. Input for establishing quality system objectives shall

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include:

Internal and external audit results;
 Health, safety and environmental issues;
 Costs of quality analysis;
 Revisions to quality standards;
 Changes to management policy;
 Customer satisfaction surveys;
 Corrective and preventive action; and
 Quality Management Reviews.

3.1.3 The methodology to be used and the personnel responsible for establishing and actioning quality objectives shall be as defined within procedure QMP-001.

3.2 QUALITY MANAGEMENT SYSTEM PLANNING

3.2.1 Management shall ensure that the planning of the QMS, is carried out as explained below in order to achieve the activities outlined in section 4.1 of the AS 9100 standard and 4.1 of this manual and the quality objectives identified in paragraph 3.1 of this section.

3.2.2 Quality planning shall encompass:

- a) The processes of the QMS;
- b) The resources needed to achieve quality objectives; and
- c) The continual improvement of the QMS.

3.2.3 Inputs to quality planning shall include:

- a) The needs and expectations of customers and other parties;
- b) Product and system process performance;
- c) Lessons learned from previous experiences; and
- d) Opportunities for improvements.

3.2.4 The outputs of quality planning shall include:

- a) The responsibility and authority to execute improvement plans;
- b) The identification of skills and knowledge needed;
- c) Improvement approaches, methods and tools;
- d) Resources required;
- e) Indicators for performance achievement, and
- f) The need for documentation and records.

3.2.5 Quality planning shall also ensure that required changes are conducted in a controlled manner and that the integrity of the QMS is maintained during the change.

3.2.6 The methodology to be used and the personnel responsible for quality planning shall be as defined within procedure QMP-001.

4.0 REFERENCES

4.1 QMP-001 Quality Planning

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	5.5 Responsibility, Authority, and Communication				
DOC: QM-I2Rev4	REVIEWED BY:	EShockley	APPROVED BY:	TDay	June 15, 2009

1.0 PURPOSE

- 1.1 To define the responsibilities and authority of MO-SCI Corporation and its subsidiaries' management, the methods used for communication and to reference specific procedures and documents that apply to this subject.

2.0 SCOPE

- 2.1 This section covers the managerial responsibilities, authority and interrelationships within company as well as internal communication.

3.0 POLICY

3.1 RESPONSIBILITY AND AUTHORITY

- 3.1.1 MO-SCI Corporation has established functions in Administration, Information Technology, Quality, Research & Development, Sales, and Manufacturing.
- 3.1.1.1 MO-SCI Health Care, L.L.C., has established functions in Manufacturing.
- 3.1.1.2 MO-SCI Specialty Products, L.L.C. has established functions in Manufacturing.
- 3.1.2 In order to facilitate effective quality management, the following paragraphs define the responsibilities and authorities for each of the above functions with lines of communication and the interrelationship of positions illustrated within the organization chart.

Administration

3.1.2.1 President


- Reports directly to the MO-SCI Corporation Board of Directors.
- Has the responsibility and authority to develop and implement long-term strategic planning and budgeting and to ensure experienced staff are assigned to adequately manage daily operations and contractual commitments, including the policies and procedures included or referenced within this manual.
- Is responsible for compensation and recruitment.
- Is responsible for the Managers' skills development.
- Has the responsibility and authority to represent MO-SCI Corporation and its subsidiaries in the bidding and closing of contracts, preparing annual sales forecasts and budgets, developing marketing strategies and liaison with customer representatives.

3.1.2.2 Vice-President of Administrative Services

- Reports directly to the President and has the responsibility and authority for the financial reporting and analysis, money management, credit and collections, and accounting for MO-SCI Corporation and its subsidiaries.
- Responsible for personnel matters, such as coordination and effective management of aspects of human resources including, employee relations, and benefits.

3.1.2.3 Administrative Assistant

- Reports directly to the Vice-President of Administrative Services
- Responsibility and authority to purchase raw materials, subcontract services and goods required.
- Coordinate warranty and non-warranty repairs.

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3.1.2.4 Materials Management Technician

- Reports directly to the Vice-President of Administrative Services
- Acts as Safety Coordinator
- Manage and coordinate the receiving and shipping and maintain stockrooms.

Information Technology

3.1.2.5 Director of Information Systems

- Reports directly to the President and has the responsibility and authority for operational activities of technology systems for the company and its employees.

Quality

3.1.2.6 Director of Quality Assurance

- Reports directly to the President and is responsible for the implementation of and compliance with the quality policy, quality objectives and procedures defined or referenced within this manual.
- The general scope of the Director of Quality Assurance's responsibility and authority is to:
 - Plan, implement and maintain the QMS Plan, in accordance with ISO Standard 9001:2008;
 - Control and revise as required, this manual and procedures referenced within;
 - Represent MO-SCI in the resolution of matters pertaining to quality with suppliers, customers and representatives from external regulatory and jurisdictional bodies;
 - Ensure that quality related deficiencies are adequately documented, investigated and corrected;
 - Ensure that manufactured items are adequately documented and traceable as required;
 - Ensure that only acceptable material are presented or delivered to the customer.
 - Coordinate calibrations.
 - For additional responsibilities and authority for this function, see paragraph 3.2, Management Representative.

Research & Development

3.1.2.7 Chief Technology Officer

- Reports directly to the President.
- Coordinates with President to implement processes to complete orders, develop required part lists, act as a liaison with vendors and suppliers during development, proposed required tooling and test equipment and maintain control of drawings and specifications for R&D projects.
- Responsibility and authority to represent MO-SCI Corporation in the proposal and closing of contracts and liaison with customer representatives.
- Responsibility and authority to provide internal and external technical training and provide technical services as required.
- Coordinates with President to effectively coordinate MO-SCI R&D manpower and equipment to result in on-time product completion, product quality and cost effective performance for work.

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Sales

3.1.2.8 Director of Sales

- Responsibility and authority to represent effectively coordinate MO-SCI Corporation and its subsidiaries in bidding and closing of contracts, prepare annual sales forecasts and budgets; develop marketing strategies and liaison with customer representatives.
- Responsibility and authority to liaison with vendors, propose required tooling and test equipment and maintain control of drawings and specifications.
- Responsibility and authority to provide internal and external technical training, coordinate standard installations and emergency repairs and provide technical services as required.

Production

3.1.2.9 Director of Manufacturing

- Reports directly to the President and has the responsibility and authority to effectively coordinate MO-SCI Specialty Products, L.L.C. and MO-SCI HealthCare, L.L.C.'s production manpower and equipment to result in on-time product completion, product quality and cost effective performance for work performed.
- Responsibility and authority to prepare MO-SCI Specialty Products, L.L.C. and MO-SCI HealthCare, L.L.C.'s annual budgets and liaison with customer representatives.
- Responsibility and authority to implement processes to complete orders, develop required part lists, liaison with vendors and suppliers during development, propose required tooling and test equipment and maintain control of drawings and specifications.
- Responsibility and authority to provide internal and external technical training, coordinate standard installations and emergency repairs and provide technical services as required.

3.2 MANAGEMENT REPRESENTATIVE

3.2.1 As part of MO-SCI's goal to continuously enhance the effectiveness and efficiency of the QMS, management has appointed the Director of QA to monitor, coordinate, manage and evaluate the QMS processes including responsibility and authority to:

- Ensure the establishment, implementation and maintenance of the processes needed for the QMS;
- Report to management on the performance of the QMS system including needs for improvement;
- Ensure the promotion of awareness of customer requirements throughout the organization, and
- For additional responsibilities of the Director of Quality, see paragraph 3.1.2.2.

3.3 INTERNAL COMMUNICATION

3.3.1 To ensure that the quality policy, QMS requirements and quality objectives are adequately understood, implemented and maintained within the organization:

- A copy of the Quality Manual shall be kept in the QA.
- The quality policy, requirements of the QMS and established quality objectives shall be reviewed with each employee during quality indoctrination training

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sessions as defined within procedure QMP-006.

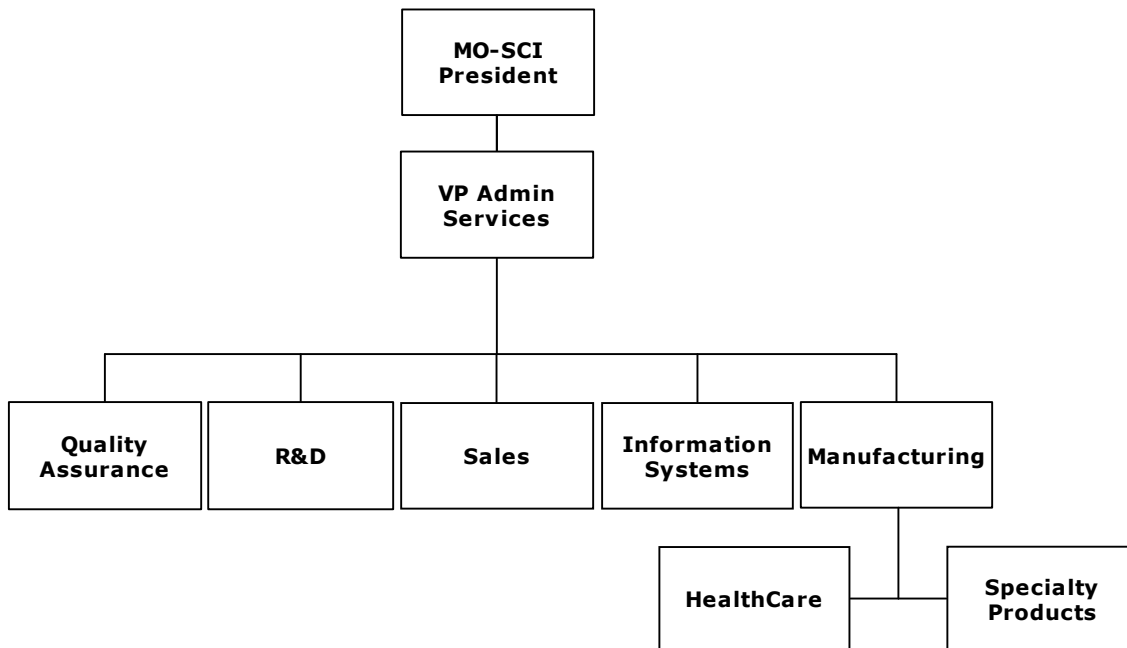
- Managers are to review QM annually.
- 3.3.2 As part of the feedback loop, the Director of QA shall ensure that the effectiveness of the QMS processes and accomplishment towards company quality objectives are properly communicated to the various levels and functions within the organization through:
- Team briefings and departmental meetings;
 - Postings on bulletin boards; and
 - Quality training sessions and presentations.


4.0 REFERENCES

- 4.1 QMP-006 Competency, Training and Awareness
- 4.2 ISO Standard 9001:2008 Quality Management Systems – Requirements
- 4.3 MO-SCI Corporation and subsidiaries' Organization Chart

Note: More than the same person may hold one position

MO-SCI Organizational Chart



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	5.6 Management Review				
DOC: QM-I2Rev4	REVIEWED BY:	EShockley	APPROVED BY:	TDay	June 15, 2009

1.0 PURPOSE

- 1.1 To define MO-SCI's policy concerning the review and continuous improvement of the QMS and to reference specific procedures that apply to this subject.

2.0 SCOPE

- 2.1 This section covers the review and continuous improvement of the QMS through the management review process.

3.0 POLICY

3.1 GENERAL

- 3.1.1 At planned intervals during the year, the Management Review Team (MRT) shall review the QMS to ensure its continuing suitability, adequacy and effectiveness. These reviews shall include assessing opportunities for improvement and the need for change to the current QMS including the quality policy and quality objectives.
- 3.1.2 The methodology to be used to review the QMS and the management personnel who make up the MRT shall be as described within QMP-005.

3.2 REVIEW INPUT

- 3.2.1 Inputs to Quality Management Reviews (QMR) shall include the following sources of information regarding the performance of the QMS as well as improvement opportunities:
- Audit reports (internal, customer and third-party);
 - Feedback from customers;
 - Process performance and product conformance;
 - Company level quality data
 - Performance of suppliers;
 - Status of preventive and corrective actions;
 - Status of action items from previous QMR;
 - Planned changes that could affect the QMS
 - Recommendations for improvement.

3.3 REVIEW OUTPUT

- 3.3.1 Outputs from QMS reviews shall be documented in QMR minutes and shall include decisions made and actions taken related to:
- The improvement of the effectiveness of the QMS and its processes;
 - The improvement of product related to customer requirements
 - Resource needs.
- 3.3.2 QMR minutes shall be maintained in accordance with QMP-004.

4.0 REFERENCES

- 4.1 QMP-004 Control of Quality Records
4.2 QMP-005 Quality Management Review



6.1 Provision of Resources

DOC: QM-I2Rev4

REVIEWED BY:

EShockley

APPROVED BY:

TDay

June 15, 2009

1.0 PURPOSE

1.1 To define MO-SCI's policy concerning the provision of resources for the QMS that complies with the AS9100 standard.

2.0 SCOPE

2.1 This section applies to the determination and provision of resources needed for the QMS, including people, suppliers, information, infrastructure and work environment.

3.0 POLICY

3.1 MO-SCI shall determine and provide, in a timely manner, the resources needed to:


- Implement, maintain and continually improve the QMS.
- To enhance customer satisfaction by meeting customer requirements.

3.2 When determining these resources, consideration shall be given to:

- Current business opportunities and constraints;
- Mechanisms that will encourage innovative continual improvement;
- Methods to enhance existing competency
- Future resource requirements.

4.0 REFERENCES

4.1 None.

	Section 6.0 Resource Management		ISS: 2	REV: 4	Page:27 of 53
	6.2 Human Resources				
DOC: QM-I2Rev4	REVIEWED BY:	EShockley	APPROVED BY:	TDay	June 15, 2009

1.0 PURPOSE

- 1.1 To define MO-SCI Corporation and subsidiaries' policy concerning the management of human resources for the QMS and to reference specific procedures that apply to this subject.

2.0 SCOPE

- 2.1 This section applies to personnel with assigned responsibilities in the QMS and includes their training to ensure competency when performing activities affecting conformity to product requirements during process development, purchasing, and manufacturing.

3.0 POLICY

3.1 GENERAL


- 3.1.1 Job descriptions have been prepared to ensure the competency of personnel whose work affects the affects conformity to product requirements. Job descriptions identifying the qualifications required for each position, including education, skills and experience requirements, along with the training required to provide the competence required for each position.

3.2 COMPETENCE, TRAINING and AWARENESS

- 3.2.1 Employee qualifications are reviewed upon hire, when changing positions or when the requirements for a position change.
- 3.2.1.1 Each manager shall identify the competency needs for personnel within their department performing activities affecting conformity to product requirements.
- 3.2.2 Managers shall evaluate employees under their direction to determine competency gaps.
- 3.2.3 If differences between the employee's qualifications and the job requirements are found, training or other action is taken, where applicable, to provide the employee with the necessary competence for the job.
- 3.2.4 To ensure employees are aware of the relevance and importance of their activities and how they contribute to the achievement of conformity to product requirements, MO-SCI shall develop quality indoctrination course.
- 3.2.4.1 Courses can provide a variety of quality related information including, techniques established for performing verifications, validations and preparing reports.
- 3.2.4.2 Refresher courses to reinforce quality awareness and knowledge of quality policy, objectives and procedures shall be given as the MRT sees necessary.
- 3.2.5 The effectiveness of company-sponsored training, whether by attending internal training sessions or external courses, presentations or seminars should be evaluated.
- 3.2.6 The methodology and the personnel responsible for identifying competency gaps and coordinating training shall be as defined in QMP-006.
- 3.2.7 Training Records
- 3.2.7.1 Records related to employee education, training, skills, qualifications, experience and training assessments shall be retained on file by MO-SCI for a period at least 7 years or unless otherwise specified by contract or applicable jurisdiction.
- 3.2.7.2 Administration maintains employee qualification records.

4.0 REFERENCES

- 4.1 QMP-006 Competency, Training and Awareness

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	6.3 Infrastructure				
DOC: QM-I2Rev4	REVIEWED BY:	EShockley	APPROVED BY:	TDay	June 15, 2009

1.0 PURPOSE

- 1.1 To define MO-SCI's policy on infrastructure to achieve product conformity and to reference specific procedures that apply to this subject.

2.0 SCOPE


- 2.1 This section covers the provision and maintenance of MO-SCI's facilities.

3.0 POLICY

- 3.1 To provide a foundation for operations and to ensure product conformity to requirements, MO-SCI determines, provides and maintains the infrastructure required, including, as applicable:
- 3.1.1 Buildings, workspace and associated utilities and equipment: Process equipment, utilities, office and production buildings and shall be routinely maintained in accordance with QMP-012 to ensure continuous quality output and conformity to product requirements.
 - 3.1.2 Existing infrastructure is maintained to ensure conformity to product requirements. Maintenance requirements are documented in:
 - Preventive maintenance plans
 - Sanitation plans
 - Building maintenance plans
 - 3.1.3 As new infrastructure requirements arise, they will be documented in quality plans.
 - 3.1.4 Hardware and software: To ensure that only acceptable monitoring and measuring hardware and software are used to verify and validate products and processes, such equipment shall be controlled and subject to calibration as defined within QMP-018.
 - 3.1.5 Supporting services: Required support services, such as transport, communication or information systems, processes to ensure the conformity to product requirements, continual system improvement and customer satisfaction shall be provided as identified within this quality manual.
- 3.2 The infrastructure shall be reviewed for continual compliance to operational needs with required corrective and preventive action taken as defined under section 8.5 of this manual.

4.0 REFERENCES

- 4.1 QMP-012 Preventive Maintenance
- 4.2 QMP-018 Control of Monitoring and Measuring Equipment

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	6.4 Work Environment				
DOC: QM-I2Rev4	REVIEWED BY:	EShockley	APPROVED BY:	TDay	June 15, 2009

1.0 PURPOSE

1.1 To define MO-SCI's work environment policy to ensure conformity to product requirements and to reference specific documents that apply.

2.0 SCOPE

2.1 This section covers the work environment including both the human and physical factors which influence it.

3.0 POLICY

3.1 To achieve product requirement conformity, the company shall manage both the human and physical factors which affect the work environment as defined below:

3.1.1 Human Factors

3.1.1.1 Creative Work Methodologies: MO-SCI actively promotes and encourages employee participation, creativity and new ideas from everyone.

3.1.1.2 Opportunities for Personnel: Company policies reflect a genuine concern for employees and a desire to meet their needs and expectations. We expect full measure of value from each individual in their job and in the continual attention to detail and quality that is required. In return, MO-SCI wishes to see employees progress in skill and experience, encouraging education programs and movement to new and challenging assignments as part of a development program. It is the company's practice to send selected employees to fully paid short courses and seminars for professional advancement.


3.1.1.3 Safety Rules and Guidance: Safety rules and guidance are provided in the Safety Manual, including the use of protective equipment and special facilities which have been allocated for personnel.

3.1.2 Physical Factors

3.1.2.1 The temperature, lighting, humidity, noise level, cleanliness and proper air flow within our office and production facilities shall be controlled and continually monitored by managers to ensure the positive enhancement of our personnel's performance.

4.0 REFERENCES

4.1 SM MO-SCI Corporation and subsidiaries' Safety Manual

	Section 7.0 Product Realization		ISS: 2	REV: 4	Page:30 of 53
	7.1 Planning of Product Realization				
DOC: QM-I2Rev4	REVIEWED BY:	EShockley	APPROVED BY:	TDay	June 15, 2009

1.0 PURPOSE

- 1.1 To define MO-SCI's policy concerning the planning of product realization and to reference specific procedures that apply to this subject.

2.0 SCOPE


- 2.1 This section covers how to plan the realization processes to make a product.

3.0 POLICY

- 3.1 Quality planning is required before new products or processes are implemented.
- 3.2 The company shall plan and develop the processes and sub-processes essential to ensure product conformance throughout the manufacturing cycle.
- 3.3 These processes shall be identified and documented within Quality Plans which identify:
 - a) The quality objectives and requirements to be achieved for the product, project or contract involved;
 - b) Where additional processes and documentation need to be established;
 - c) The resources and facilities needed to manufacture the product involved;
 - d) Verification, validation, monitoring, measurement, inspection and test activities specific to the product
 - e) The criteria for product acceptance
 - f) Resources to support operation and maintenance of the product.
 - g) Mandatory hold and witness points established by the customer which requires their verification of selected characteristics of an item or process and beyond which work shall not progress until verification has been completed.
 - h) Records needed to provide evidence of process and product conformity to requirements.
- e) Identify resources to support operation and maintenance of the product.
- 3.4 Quality Plans shall reference procedures and instructions to be followed while performing each activity, as applicable.
- 3.5 Managers should review quality plans to ensure resources, and facilities required can be provided.
- 3.6 Revisions to Quality Plans shall be reviewed and approved in the same manner as originals.
- 3.7 When contractually required, Quality Plans and their revisions shall be submitted for customer acceptance.
- 3.8 Work shall not proceed beyond a verification, hold or witness point established by the customer as a contractual requirement without the activity being performed and accepted by the customer. An exception to this, however, would be a signed release or waiver issued or granted by the customer.
- 3.9 The methodology to be used and the personnel responsible for the planning of product realization shall be as defined within procedure QMP-011.

4.0 REFERENCES

- 4.0 QMP-011 Planning of Product Realization

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	7.2 Customer-Related Process				
DOC: QM-I2Rev4	REVIEWED BY:	EShockley	APPROVED BY:	TDay	June 15, 2009

1.0 PURPOSE

- 1.1 To define MO-SCI policy concerning customer-related processes and to reference specific procedures that apply.

2.0 SCOPE

- 2.1 This section covers how the needs and expectations of customers are defined, implemented and maintained including the review and evaluation of requests for quotation prior to bidding and contracts prior to acceptance.


3.0 POLICY

3.1 DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT

- 3.1.1 Upon receipt of a customer's request for quotation or query, MO-SCI shall determine the customer's requirements including:
- Customer-specific product requirements;
 - Requirements for delivery activities;
 - Product requirements not specified by the customer but considered essential for intended, specified or known use;
 - Statutory and regulatory requirements applicable to the product
 - Additional requirements considered necessary by MO-SCI.

3.2 REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT

- 3.2.1 Requests for quotation, customer requirements and requirements perceived by the company to be relevant to the product, project or contract, shall be reviewed prior to bidding to determine:
- Has the customer defined their product requirements;
 - What product requirements apply;
 - Have the differences between customer defined and product requirements been resolved?
 - What development activities are involved;
 - Which statutory or regulatory entity would apply and what are their requirements;
 - What personnel would be required to perform the work;
 - What materials are required;
 - What facilities would be required to achieve the work;
 - What lead time is necessary to ensure on-time delivery;
 - What costs would be incurred by the company to accomplish the work;
 - Is the company able to meet the defined requirements?
 - Have the risks involved been evaluated.
- 3.2.2 Upon receipt of a contract or order, and prior to acceptance, the company shall review and evaluate it to determine:
- If differences exist between the original quote and the contract received;
 - Relevant issue of codes, standards and specifications applicable;
 - What are the schedules of any data submissions to the customer or jurisdiction;
 - The quality objectives to be attained;
 - What are the formal lines of contractual communication.
- 3.2.3 If differences are detected between the original quote submitted and the contract or order received, the company shall advise the customer of these discrepancies in writing.
- 3.2.4 No contract or order shall be accepted until detected differences have been resolved.

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	7.2 Customer-Related Process				
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3.2.5 In the event that the customer does not provide any documented statement of requirements, the company shall confirm the requirements with the customer before acceptance.

3.2.6 Accepted contracts or orders and any subsequent amendments shall be documented and distributed to the relevant personnel as required.

3.2.7 Contract or Order Amendments

3.2.7.1 Customer-initiated changes to an existing contract or order shall be subject to the same review and approval process as an original. The customer shall be advised of cost or schedule impact resulting from the requested change.

3.2.7.2 Changes initiated by MO-SCI must be submitted to the relevant customer prior to being implemented, including any cost or schedule impacts.

3.2.8 Records

3.2.8.1 Unless otherwise defined by contract or relevant external jurisdiction, records of contract and order reviews performed shall be maintained for seven years.

3.3 CUSTOMER COMMUNICATION

3.3.1 The company shall identify and implement effective arrangements for communication with customers relating to:

- a) Product information;
- b) Enquiries, contracts or order handling, including amendments;
- c) Customer feedback, including customer complaints.

3.4 The methodology to be used and the personnel responsible for conducting and documenting the evaluation of RFQ, contract review, contract amendments and customer communications shall be as defined within procedure, QMP-007.

4.0 REFERENCES

- 4.1 QMP-007 Customer Requirements and Communication

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	7.3 Process Design and Development				
DOC: QM-I2Rev4	REVIEWED BY:	EShockley	APPROVED BY:	TDay	June 15, 2009

1.0 PURPOSE

- 1.1 To define MO-SCI Corporation and subsidiaries' policy concerning process design and development activities and to reference specific procedures that apply to this subject.

2.0 SCOPE

- 2.1 This section covers the activities employed during the process design and development phases of products, processes and custom orders.

3.0 POLICY

3.1 GENERAL

- 3.1.1 The methodology to be used and the personnel responsible for planning, conducting, reviewing, verifying, validating and controlling process design and development activities as defined within QMP-008.

3.2 PROCESS DESIGN AND DEVELOPMENT PLANNING

- 3.2.1 The company shall plan and control the process design and development activities for new products, processes and custom orders.

- 3.2.2 Process design and development planning shall include:

- Process design and development stages including organization, task sequence, mandatory steps, significant stages and method of configuration control.
- Required reviews, verification and validation appropriate to each stage
- Responsibilities and authorities for process design and development.
- Where appropriate, due to complexity, the organization gives consideration to the following activities:
 - Structuring the process design effort into significant elements;
 - For each element, analyzing the tasks and the necessary resources for its development. This analysis considers an identified responsible person, content, input data, planning constraints, and performance conditions. The input data specific to each element is reviewed to ensure consistency with requirements.
- Allowing for amendments during development
- Establishing adequate resources as required

- 3.2.3 Managing technical and organizational interfaces between groups involved to ensure effective communication and clarity of responsibilities

- 3.2.4 Documents shall be updated, as appropriate, as the process development progresses.

- 3.2.5 The different tasks to be carried out shall be defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements.

3.3 PROCESS DESIGN AND DEVELOPMENT INPUTS

- 3.3.1 Inputs relating to product requirements are determined and documented according to QMP-008. Inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. Inputs include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Where applicable, information derived from previous similar processes
- Other requirements essential for the process

- 3.3.2 Inputs determined as incomplete, ambiguous or conflicting shall be resolved between MO-SCI and the originating source.

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3.4 PROCESS DESIGN AND DEVELOPMENT OUTPUTS

3.4.1 Outputs of process design and development are documented according to QMP-008. They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

- Meet the input requirements
- Provide appropriate information for purchasing and production operation.
- Contain or reference product acceptance criteria
- Define the product characteristics that are essential for its safe and proper use
- Identify key characteristics in accordance with process or contract requirements
- encompass the relevant statutory and regulatory requirements

3.4.2 Pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained is defined by the organization. For example:

- Drawings, parts lists, and specifications
- A listing of specifications necessary for the configuration and process to ensure product quality.
- Information on material, processes type of manufacturing and assembly of the product necessary to ensure the conformity of the product.

3.4.3 Output documents shall be reviewed and approved prior to release and updated as needed.

3.5 PROCESS DESIGN AND DEVELOPMENT REVIEW

3.5.1 Systematic reviews shall be planned, performed and documented to

- Evaluate the ability of the process to meet requirements, and
- Identify any problems and propose necessary actions
- To authorize progression to the next stage.

3.5.2 Participants shall include representatives of the functions concerned with the process being reviewed.

3.5.3 Results of these reviews and necessary actions shall be maintained per QMP-004 and retained for seven years from the date of completion of the contract.

3.6 PROCESS DESIGN AND DEVELOPMENT VERIFICATION

3.6.1 Verification is planned and performed to ensure that the process outputs have satisfied the process input requirements. This includes activities such as

- Performing alternative calculations
- Comparing the new process with similar proven processes.
- Undertaking tests and demonstrations
- Reviewing documents before release

3.6.2 Results of process verification and subsequent necessary actions shall be recorded and kept on file in accordance with QMP-004.

3.7 PROCESS DESIGN AND DEVELOPMENT VALIDATION

3.7.1 Process design and development validation is performed according to the process design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use.

3.7.1.1 Validation follows successful verification


3.7.1.2 Validation is normally performed under defined operating conditions.

3.7.1.3 Validation is normally performed on the final product, but may be necessary in earlier stages of production.

3.7.1.4 Multiple validations may be performed if there are different intended uses.

3.7.2 Whenever practicable, validation is completed prior to implementation. When this is impractical, partial validation shall be performed to the extent applicable.

3.7.3 Records of the validation activities are maintained per QMP-004.

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3.7.4 **Documentation of Process Design and Development Verification and Validation**
 At the completion of process design and development, the organization ensures that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for identified operational conditions.

3.7.5 **Process and Development Verification and Validation Testing:**
 Where tests are necessary for verification and validation, these tests are planned, controlled, reviewed, and documented to ensure and prove the following:


- Test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria
- Test procedures describe the method of operation, the performance of the test, and the recording of the results
- The correct configuration standard of the product is submitted for the test
- The requirements of the test plan and the test procedures are observed
- The acceptance criteria are met

3.8 CONTROL OF PROCESS DESIGN AND DEVELOPMENT CHANGES

- 3.8.1 Process design and development changes shall be identified and records maintained. The changes shall be verified, validated and approved before implementation.
- 3.8.2 The review of changes includes an evaluation of the effect of the changes on delivered product.
- 3.8.3 Records are maintained to show the results of the review and necessary actions identified during the review per QMP-004.
- 3.8.4 The change control process allows for customer or regulatory authority approval of changes, when required by contract or regulatory obligation.

4.0 REFERENCES

- 4.1 QMP-003 Control of Documents
- 4.2 QMP-004 Control of Quality Records
- 4.3 QMP-008 Process Design and Development

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	7.4 Purchasing				
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1.0 PURPOSE

- 1.1 To define MO-SCI's policy concerning purchasing and to reference specific procedures and documents that apply to this subject.

2.0 SCOPE

- 2.1 This section applies to the procurement of materials, equipment, parts, assemblies, subcontracts, and services that are used in or form part of the quality of deliverables to production customers.


3.0 POLICY

3.1 PURCHASING PROCESS

- 3.1.1 Purchasing processes are conducted and controlled according to QMP-009 to ensure purchased products conform to quality and contractual requirements.
- 3.1.2 The type and extent of controls exercised over suppliers and purchased products shall be dependent upon the effect of the purchased product on subsequent processes, or on the final deliverable to the customer.
- 3.1.3 Material and products procured shall be subject to verification and testing by authorized personnel as required per QMP-022.
- 3.1.4 Evaluation and Selection of Suppliers
- 3.1.4.1 QMPs-010 and 027 define the methodology and the personnel responsible for evaluating and selecting suppliers. This process is based the suppliers ability to meet the contract/order specifications and quality requirements.
- 3.1.4.2 The criteria for supplier selection, evaluation and re-evaluation shall be based on the criticality and classification of the products or services purchased as defined within QMP-010.
- 3.1.4.3 Quality records containing the results of supplier evaluations and subsequent necessary actions shall be maintained per QMP- 004.
- 3.1.5 MO-SCI is responsible for the quality of products purchased from suppliers, including customer-designated sources.
- 3.1.6 MO-SCI shall:
- Maintain a register of approved suppliers that includes the scope of the approval;
 - Periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented;
 - Define the necessary actions to take when dealing with suppliers that do not meet requirements;
 - Ensure where required that both the organization and suppliers use customer-approved special process sources;
 - Ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use sources;

3.2 PURCHASING INFORMATION

- 3.2.1 Procurement documents shall contain a clear description of the items or services required and include or reference any or all of the following:
- Requirements for approval of product, procedures, processes and equipment
 - Requirements for personnel
 - Quality Management System, QMS, requirements
 - The name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data

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- e) Requirements for design, test, examination, inspection and related instructions for acceptance by MO-SCI.
 - f) Requirements for test specimens such as number, storage conditions for approval, inspection, investigation, or auditing
 - g) Requirements relative to
 - a. Supplier notification to MO-SCI of nonconforming product
 - b. Arrangements for MO-SCI approval of supplier nonconforming material
 - h) Requirements for the supplier to notify MO-SCI of changes in product and/or process definition and, where required obtain approval
 - i) Right of access by MO-SCI, our customer, and regulatory authorities to facilities involved in the order and to applicable records
 - j) Requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required
- 3.2.2 The purchasing documents are reviewed for adequacy of requirements before orders are placed with the supplier.
- 3.3 VERIFICATION OF PURCHASED PRODUCT
- 3.3.1 Inspection and/or other activities necessary for ensuring purchase product meets specified purchase requirements are established and implemented per QMP-022. Verification activities include
- a) Obtaining objective evidence of the quality of the product from the supplier, such as a certificate of analysis.
 - b) Inspection and audit at the supplier
 - c) Review of the required documentation
 - d) Inspection of products upon receipt
 - e) Delegation of verification to the supplier or supplier certification.
- 3.3.2 Purchased product is not used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.
- 3.3.3 If test reports are used to verify purchased product, the data must meet the specifications. Test reports for raw material are periodically validated.
- 3.3.4 When verification activities are delegated to the supplier the requirements are defined, and a register of delegations is maintained.
- 3.3.5 If MO-SCI or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.
- 3.3.5.1 Nonconforming products shall be dispositioned by the supplier.
- 3.3.6 Where specified in the contract, the customer or the customer's representative is given the right to verify at the suppliers and at MO-SCI's premises that product conforms to specified requirements.
- 3.3.7 It is understood that verification of product conformance to customer requirements is not evidence of effective quality control by the supplier, nor does it absolve MO-SCI its responsibility to provide its customers with acceptable product or preclude possible subsequent rejection by the customer.
- 3.3.8 Any nonconforming product detected while verifying purchased product shall be processed in accordance with QMP-023.



7.4 Purchasing

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4.0 REFERENCES

- 4.1 QMP-004 Control of Quality Records
- 4.2 QMP-009 Purchasing
- 4.3 QMP-010 Supplier Selection and Evaluation
- 4.4 QMP-022 Monitoring and Measurement of Product
- 4.5 QMP-023 Control of Nonconforming Product
- 4.6 QMP-027 External Quality Audits

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	7.5 Production Provision				
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1.0 PURPOSE

- 1.1 To define MO-SCI's policy concerning production provision and to reference specific procedures that apply to this subject.


2.0 SCOPE

- 2.1 This section covers the activities employed to control, identify, trace and preserve product, including those provided by our customers and how processes are validated.

3.0 POLICY

3.1 CONTROL OF PRODUCTION PROVISION


- 3.1.1 MO-SCI shall plan and carry out production operations under controlled conditions.
- 3.1.1.1 Planning shall consider, as applicable,
- The establishment of process controls and development of control plans where key characteristics have been identified,
 - The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,
 - The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and
 - Special processes
- 3.1.1.2 Controlled conditions shall include the following, as applicable:
- a) Information pertaining to product characteristics, including the criteria for acceptance shall be identified within the Standard Operating Procedure (SOP) or work order issued for each job.
 - b) Where their absence could adversely affect quality, work instructions, such as SOPs, shall be developed and made available.
 - c) To ensure continuous quality output, only suitable process equipment is used. Process equipment shall be routinely maintained per QMP-012.
 - d) Only valid, calibrated monitoring and measuring equipment shall be used to verify production processes and products per QMP-018.
 - e) Work in-progress shall be monitored to ensure good workmanship standards and specification compliance is being maintained.
 - f) Resulting products shall be subject to inspection and/or testing as defined within QMP-022 prior to product release and delivery shall be performed and monitored per QMP-016.
 - g) Accountability for product during manufacture, such as quantities, split orders, nonconforming product, and disposition of nonconforming material.
 - h) Evidence that manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized.
 - i) Provision for the prevention, detection, and removal of foreign objects.
 - j) Monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality,
 - k) Criteria for workmanship stipulated in the clearest practical manner, such as written standards, representative samples or illustrations.
- 3.1.2 Production Documentation
 Production operations are carried out in accordance with approved data. This data contains as necessary:
- Drawings, parts lists, process flowcharts including inspection operations, production documents and inspection documents

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- A list of specific or non-specific tools and numerical control (NC) machine programs required and specific instructions associated with their use.
- 3.1.3 Control of Production Process Changes
Persons authorized to approve changes to production processes are identified.
 - a) MO-SCI identifies and obtains acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.
 - b) Changes affecting processes, production equipment, tools and programs are documented. Procedures are available to control the implementation.
 - c) The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product quality.
- 3.1.4 Control of Production Equipment, Tools and Numerical Control Machine Programs.
 - a) Production equipment, tools and programs are validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use includes verification of the first unit produced to the specification.
 - b) Storage requirements, including periodic preservation/condition checks, have been established for production equipment or tooling in storage.
- 3.1.5 Control of Work Transferred, on a Temporary Basis, Outside of MO-SCI
 - a) When planning to temporarily transfer work to a location outside the facilities, MO-SCI defines the process to control and validate the quality of the work.
- 3.1.6 Control of Service Operations
Where servicing is a specified requirement, service operation processes provide for:
 - a) A method of collecting and analyzing in-service data,
 - b) Actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements,
 - c) The control and updating of technical documentation,
 - d) The approval, control, and use of repair schemes, and
 - e) The controls required for off-site work

3.2 VALIDATION OF SPECIAL PROCESSES FOR PRODUCTION

- 3.2.1 The company shall validate production processes where resulting output cannot be verified by subsequent monitoring or measurement and, and a consequence, where deficiencies become apparent after the product is in use.
- 3.2.2 Validation shall demonstrate the ability of these processes to achieve planned results.
- 3.2.3 Arrangements for these processes shall be established by the company, as applicable:
 - a) Define criteria for review, qualification, and approval of process prior to use
 - b) Approval of equipment and qualification of personnel
 - c) Use of specific methods and procedures to control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto
 - d) Requirements for records
 - e) Revalidation - to verify that a change made had the desired effect on both the process and resulting product should be re-validated after the changes have been made to a process.
- 3.2.4 The methodology to be used and the personnel involved in qualifying processes, equipment and personnel as well as the records to be maintained shall be in accordance with QMP-017.
- 3.2.5 Process changes which affect the characteristics of a product shall be identified,

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recorded, evaluated, reviewed, authorized and controlled to ensure that the changes made benefit MO-SCI while satisfying the needs and expectations of the relevant customers.

3.3 IDENTIFICATION AND TRACEABILITY

- 3.3.1 MO-SCI identifies the product throughout product realization according to the Identification and Traceability procedure QMP-13.
- 3.3.2 MO-SCI maintains the identification of the configuration of the product in order to identify any differences between the actual and the agreed archetype.
- 3.3.3 Product is identified with respect to monitoring and measurement requirements throughout product realization.
- 3.3.4 When acceptance authority media such as labels, electronic signatures or passwords are used MO-SCI establishes and documents controls for the media.
- 3.3.5 Where the traceability required by a customer exceeds existing methods and scope, the extent of controlling unique product identification shall be established with the customer during the review of product requirements in per QMP-007. Records associated with the product traceability shall be maintained.
- 3.3.6 According to the level of traceability required by contract, regulatory, or other established requirement, MO-SCI's system provides for:
 - a) Identification to be maintained throughout the product life;
 - b) Products manufactured from the same batch of raw material or from the same manufacturing batch are to be traced, as well as the destination (delivery, scrap) of products from the same batch;
 - c) For an assembly, the identity of its components and those of the next higher assembly to be traced;
 - d) For a given product, a sequential record of its production (manufacture, assembly, inspection) is to be retrievable.
- 3.3.7 Unless otherwise defined by contract, product identification and traceability shall be performed, controlled and documented as defined by QMP-013.

3.4 CUSTOMER PROPERTY

- 3.4.1 MO-SCI exercises care with customer property while it is under MO-SCI control or use. QMP-015 outlines the identification, verification, protection and safeguarding of customer property provided for use.
 - 3.4.1.1 Customer property can include intellectual property or personal data, including customer furnished data used for design, production and/or inspection.
- 3.4.2 Unless otherwise defined by contract, upon receipt of customer property, MO-SCI shall examine items for completeness, proper identification and possible transit damage.
 - 3.4.2.1 Items found to be nonconforming shall be identified and recorded as defined within QMP-023 and brought to the immediate attention of the customer.
- 3.4.3 The identification, segregation, handling and protection of customer property from time of receipt, subsequent storage, maintenance, and during the entire realization cycle shall be performed per QMP-015 and applicable contract requirements.
- 3.4.4 In the event that customer property is lost, damaged or otherwise found to be unsuitable for use, MO-SCI shall report this to the customer and maintain records.


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3.5 PRESERVATION OF PRODUCT

- 3.5.1 MO-SCI shall preserve the product during internal processing and delivery to the intended destination per QMP-016 including identification, handling, packaging, storage and protection, in order to maintain conformity to requirements.
- 3.5.2 Product preservation also includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for:
- a) Cleaning;
 - b) Prevention, detection and removal of foreign objects;
 - c) Special handling for sensitive products;
 - d) Marking and labeling including safety warnings;
 - e) Shelf life control and stock rotation;
 - f) Special handling for hazardous materials.
- 3.5.3 MO-SCI ensures that documents required by the contract to accompany the product are present at delivery and are protected against loss and deterioration.

4.0 REFERENCES

- | | | |
|------|---------|---|
| 4.1 | QMP-007 | Customer Requirements and Communication |
| 4.2 | QMP-012 | Preventive Maintenance |
| 4.3 | QMP-013 | Identification and Traceability |
| 4.4 | QMP-014 | Inspection and Test Status |
| 4.5 | QMP-015 | Customer Property |
| 4.6 | QMP-016 | Preservation of Product |
| 4.7 | QMP-017 | Validation of Processes |
| 4.8 | QMP-018 | Control of Monitoring and Measuring Equipment |
| 4.9 | QMP-022 | Monitoring and Measurement of Product |
| 4.10 | QMP-023 | Control of Nonconforming Product |

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	7.6 Control of Monitoring and Measuring Equipment				
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1.0 PURPOSE


- 1.1 To define MO-SCI's policy concerning the control of monitoring and measuring equipment and to reference specific procedures and instructions that apply to this subject.

2.0 SCOPE

- 2.1 This section covers monitoring and measuring equipment used by personnel, including test software, which assist in determining product and process conformance and which can affect end item quality.

3.0 POLICY

- 3.1 MO-SCI has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.
 - 3.1.1 Monitoring and measurements made to provide evidence of product specification conformity shall be identified on drawings, inspection/test forms, SOP/STP or work orders and shall include the monitoring and measuring equipment to be used
 - 3.1.2 QMP-018 describes the methodology to be used and the personnel responsible for conducting, documenting and controlling calibration of monitoring and measuring equipment.
- 3.2 MO-SCI maintains a register of monitoring and measuring equipment.
 - 3.2.1 Equipment such as jigs, fixtures or templates used by production shall be subject to accuracy verification prior to usage.
 - 3.2.2 The use of personally owned tools and gauges for the purpose of product evaluation shall be permitted, provided these tools have been subject to calibration.
- 3.3 The processes established should ensure monitoring and measurement can be and is carried out in a manner consistent with the requirements of QMP-011 and QMP-018.
- 3.4 MO-SCI ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.
- 3.5 Where necessary to ensure valid results, measuring equipment shall be
 - a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
 - Intervals are defined based on stability, purpose and usage of the equipment.
 - The measurements to be made, the accuracy required and the comparator to be used is identified within documented calibration instructions.
 - b) Adjusted or re-adjusted as necessary
 - c) Identified in order to determine its calibration status.
 - The calibration status of equipment shall be indicated by a label affixed to the item or documented on a calibration record.
 - The label or record shall have the equipment identification, the date of calibration, and the individual who performed the calibration.
 - d) Safeguarded from adjustments that would invalidate the measurement result.
 - Certified calibration standards or equipment is used expressly for the purpose of calibrating monitoring and measuring equipment. Under no circumstances shall they be used for testing or manufacturing.
 - e) Protected from damage and deterioration during handling, maintenance and storage.

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- f) Be recalled according to a defined method when requiring calibration.
- Equipment shall be removed from use by the date that calibration is due and shall be protected against damage and deterioration during handling, maintenance and storage.
 - Equipment observed during calibration as beyond the acceptance criteria limits established for that equipment shall be removed from service and processed in accordance with QMP-023.

3.6 In addition, MO-SCI shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements per QMP-023. MO-SCI takes appropriate action on the equipment and affected product.

- These re-evaluations shall be documented and additional corrective action shall be initiated when required and as defined within QMP-026.


3.7 Computer software used for monitoring and measuring of specified requirements shall be validated prior to initial use and reconfirmed as necessary.

3.8 Calibration certificates received from outside laboratories and internal calibration records shall be maintained in accordance with QMP-004.

- Calibration records shall be maintained and updated throughout the life of each monitoring or measuring device. These records shall reflect the dates on which calibrations were performed, the accuracy of results obtained during calibration and adjustments or re-adjustments made.
- These records shall be made available to the customer upon request

4.0 REFERENCES

- 4.1 QMP-004 Control of Quality Records
- 4.2 QMP-011 Planning of Product Realization
- 4.3 QMP-018 Control of Monitoring and Measuring Equipment
- 4.4 QMP-023 Control of Nonconforming Product
- 4.5 QMP-026 Corrective and Preventive Action
- 4.6 Equipment manuals
- 4.7 Common Procedures for Calibration

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	8.1 General				
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1.0 PURPOSE

- 1.1 To define MO-SCI's policy concerning measurement, analysis and improvement activities and to reference specific procedures that apply to this subject.

2.0 SCOPE


- 2.1 This section applies to the planning and implementation of monitoring, measurement, analysis and improvement activities within MO-SCI to assure product and system conformity and continually improve the Quality Management System (QMS) effectiveness.

3.0 POLICY

- 3.1 In sections 8.2, 8.3, 8.4 and 8.5 of this manual, MO-SCI has plans and implementation methods for the monitoring, measurement, analysis and improvement processes, as needed, to:
- a) Demonstrate conformity to product requirements throughout the realization cycle per QMP-022.
 - b) Ensure conformity of the QMS by using internal quality audits per QMP-020.
 - c) Continually improve the effectiveness of the QMS, monitoring and measurement data shall be collected and analyzed per QMP-024. This information supports the planning for continual improvement as defined in QMP-025.
 - d) Ensure process conformity using the monitoring and measurement techniques per QMP-021 and employed during process validation in per QMP-017.
- 3.2 This shall include determination of applicable methods, including statistical techniques, and the extent of their use and shall be routinely evaluated during QMRs per QMP-005 to ensure the information collected remains useful, relevant and supportive of continual improvement.
- 3.2.1 According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:
- Process Design verification (e.g., reliability, maintainability, safety);
 - Process control;
 - Selection and inspection of key characteristics;
 - Process capability measurements;
 - Statistical process control;
 - Experimental design;
 - Inspection - matching sampling rate to the criticality of the product and to the process capability;
 - Failure mode and effect analysis.

4.0 REFERENCES

- | | | |
|-----|---------|---|
| 4.1 | QMP-005 | Quality Management Review |
| 4.2 | QMP-017 | Validation of Processes |
| 4.3 | QMP-020 | Internal Quality Audits |
| 4.4 | QMP-021 | Monitoring and Measurement of Processes |
| 4.5 | QMP-022 | Monitoring and Measurement of Product |
| 4.6 | QMP-024 | Analysis of Data |
| 4.7 | QMP-025 | Planning for Continual Improvement |

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	8.2 Monitoring and Measurement				
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1.0 PURPOSE

- 1.1 To define MO-SCI policy concerning the monitoring and measurement of customer satisfaction, processes, products and the Quality Management System (QMS), and to reference specific procedures and documents that apply to this subject.

2.0 SCOPE

- 2.1 This section covers the activities employed to monitor and measure the overall effectiveness and efficiency of the QMS as well as product characteristics, process adequacy and customer satisfaction.


3.0 POLICY

3.1 CUSTOMER SATISFACTION


- 3.1.1 As one of the measurements to evaluate the performance of the QMS, the company shall monitor the following factors affecting customer perception as to whether requirements have been met:
- a) Factors causing customer dissatisfaction such as:
 - Defective products or service;
 - Late delivery; and
 - Poor response time to queries or complaints.
 - b) Factors causing customer satisfaction, such as:
 - + Expected product quality;
 - + On-time delivery;
 - + Attention to queries or complaints; and
 - + Successful achievement of both stated and implied needs
- 3.1.2 This data can be collected quantitatively using the interviews or questionnaire survey methods defined within QMP-019.
- 3.1.3 Collected data shall be compiled and presented in a Customer Satisfaction Report containing:
- The results of the interviews and questionnaires;
 - A conclusion as to what factors are considered to have contributed to the current level of customer satisfaction; and
 - A comparison to previous results and trends.
- 3.1.4 Customer satisfaction reports shall be distributed, reviewed and analyzed during QMRs per QMP-005.
- 3.1.5 Analysis shall determine opportunities for improvement, such as:
- Correction or prevention of nonconformities; and
 - Continuous improvement.
- 3.1.6 Opportunities for improvement shall be documented, approved, planned, and processed in accordance with QMP-025.
- 3.1.7 The results of improvement implementations shall be reviewed by the MRT to ensure the effectiveness of the actions taken.

3.2 INTERNAL AUDIT

- 3.2.1 Internal Quality Auditing shall be planned and conducted determine whether the QMS
- a) conforms to planned arrangements, AS9100 and ISO 9001:2008 Standard requirements and to the QMS established by MO-SCI.
 - b) is effectively maintained.
- 3.2.2 Audit program planning consider the status and importance of the activities and areas to be audited as well as previous audits results when scheduling criteria, scope and frequency and methods of audits.

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- a) The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.
- b) The methodology to be used and the personnel responsible for planning, conducting, reporting and follow-up on internal quality audits shall be as defined within QMP-020.
- 3.2.3 To ensure objectivity and impartiality of the audit process, internal quality audits shall be performed by personnel who are independent of the activity being evaluated.
- 3.2.4 QMP-020 defines the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.
 - a) Audit findings shall be documented and brought to the attention of the responsible manager.
- 3.2.5 The management responsible for the area being audited shall ensure that any necessary corrections and corrective action are taken without undue delay to eliminate detected nonconformities and their causes.
 - a) Follow-up evaluations of corrective actions taken shall be performed to verify effectiveness and shall be documented.
 - b) Unless otherwise defined by contract, these records shall be retained for the purpose of follow-up and performance improvement comparison for seven years.
- 3.2.6 Detailed tools and techniques such as check sheets, process flowcharts, or similar methods to support audits of the QMS requirements are developed, maintained and used according to the Internal Audit Procedure.
 - a) The acceptability of the selected tools is measured against the effectiveness of the internal audit process and overall organization performance.
- 3.2.7 Internal audits meet contract and/or regulatory requirements.
- 3.2.8 A summary of audit findings shall be forwarded to the members of the MRT, for evaluation to determine possible system improvements.
- 3.3 MONITORING AND MEASUREMENT OF PROCESSES**
- 3.3.1 MO-SCI shall apply suitable methods for monitoring and, where applicable, measurement of the QMS processes.
 - a) These methods shall demonstrate the ability of the processes to achieve planned results.
 - Processes which directly affect quality of contracted work shall be accomplished under controlled conditions as defined by QMP-011.
 - To ensure continuous quality output, process equipment shall be routinely maintained per QMP-012.
 - Where applicable, specifically developed control charts can be used to confirm the continuing ability of processes to achieve planned results.
 - The methodology to be used and the personnel responsible for the monitoring and measurement of processes are defined in QMP-021.
 - b) In the event that planned results are not achieved, correction and corrective action shall be taken, as appropriate per QMP-026.
 - c) Processes whose results cannot be directly verified or examined to establish full conformance to requirements during subsequent verification and testing shall be considered as Special Processes.
 - Conformance verification of special process parameters shall be continuously monitored or achieved per QMP-017.
- 3.3.2 In the event of process nonconformity, the MO-SCI:
 - a) Takes appropriate action to correct the nonconforming process,

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b) Evaluates whether the process nonconformity has resulted in product nonconformity,

c) Nonconforming product is identified and controlled in accordance with QMP-023.

3.4 **MONITORING AND MEASUREMENT OF PRODUCT**

3.4.1 The company shall plan monitoring, measurements, tests and product verification activities required by contract and established internally as essential to ensure product conformance per QMP-022.

3.4.2 Key activities shall be as identified and documented within Quality Plans. They will be monitored and controlled during the following stages of product realization:

3.4.2.1 Receiving

- a) Incoming items received for use in products shall not be allowed to progress into production, inventory or storage until the required verifications and tests have been completed or the necessary test reports have been received and verified as acceptable.
- b) Only valid, calibrated monitoring and measuring equipment shall be used to perform verification or testing per QMP-018.
- c) Objective evidence of the supplier's verification of product quality may be reviewed and evaluated to determine if quality and contract requirements have been met.
- d) Any product observed as nonconforming shall be identified and processed per QMP-023.

3.4.2.2 In-Process

- a) Components produced or procured throughout the manufacturing cycle.
- b) In-process verifications shall be accomplished at identified hold points and in accordance with documented procedures and relevant instructions.
- c) Work in-process shall be monitored via patrol surveillance to ensure good workmanship standards and specification compliance.
- d) Products shall not be allowed to progress to the next operation until the required verifications and tests have been completed.
- e) Items observed as nonconforming shall be identified and processed in accordance with QMP-023.


3.4.2.3 Final

- a) Completed products are subject to final verification and/or identified testing prior to shipping or, when applicable, submission to the customer for evaluation and acceptance.
- b) Contracted work operations and nonconformance corrections shall be verified for completeness and acceptability.
- c) Unless otherwise approved by the customer, only items that fully meet contract requirements shall be shipped or offered to the customer for evaluation and acceptance.

3.4.2.4 Records

- a) Completed product should not be shipped until records resulting from verification and test points have been reviewed and confirmed as acceptable.
- b) Quality records are to identify the personnel responsible for authorizing product release and shall be filed and maintained per QMP- 004.
- c) Evidence of conformity with the acceptance criteria shall be maintained.


3.4.3 When the organization uses sampling inspection as a means of product acceptance, the plan is statistically valid and appropriate for use.

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- The plan precludes the acceptance of lots whose samples have known nonconformities.
 - When required, the plan is submitted for customer approval.
- 3.4.4 Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of required measurement and monitoring activities.
- 3.4.5 Records indicate the person authorizing release of product for delivery to the customer.
- 3.4.6 The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and, where applicable, by the customer.
- 3.4.7 Inspection Documentation
Measurement requirements for product acceptance are documented. This is part of the production documentation, and includes:
- a) Criteria for acceptance and/or rejection,
 - b) Where in the sequence measurement and testing operations are performed,
 - c) A record of the measurement results, and
 - d) Type of measurement instruments required and specific instructions associated with their use.
- 3.4.7.1 Test records shall show actual test results data when required by specification or acceptance test plan.
- 3.4.7.2 Where required to demonstrate product qualification MO-SCI shall ensure records provide evidence that the product meets the defined requirements.
- 3.4.8 First Article Inspection
MO-SCI's system shall provide a process for the inspection, verification, and documentation of a representative sample from production runs, or following subsequent change that invalidates the previous inspection results.

4.0 REFERENCES

- | | | |
|------|------------------------|---|
| 4.1 | QMP-004 | Control of Quality Records |
| 4.2 | QMP-005 | Quality Management Review |
| 4.3 | QMP-011 | Planning of Product Realization |
| 4.4 | QMP-012 | Preventive Maintenance |
| 4.5 | QMP-017 | Validation of Processes |
| 4.6 | QMP-018 | Control of Monitoring and Measuring Equipment |
| 4.7 | QMP-019 | Measuring Customer Satisfaction |
| 4.8 | QMP-020 | Internal Quality Audits |
| 4.9 | QMP-021 | Monitoring and Measurement of Processes |
| 4.10 | QMP-022 | Monitoring and Measurement of Product |
| 4.11 | QMP-023 | Control of Nonconforming Product |
| 4.12 | QMP-025 | Planning for Continual Improvement |
| 4.13 | QMP-026 | Corrective and Preventive Action |
| 4.14 | ISO Standard 9001:2008 | Quality Management Systems – Requirement |

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	8.3 Control of Nonconforming Product				
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1.0 PURPOSE


- 1.1 To define MO-SCI's policy concerning the control of nonconforming product and to reference specific procedures that apply to this subject.

2.0 SCOPE

- 2.1 This section covers the control, documentation and processing of materials or products that have been identified as nonconforming.

3.0 POLICY


- 3.1 Materials or products that do not conform to requirements shall be identified as a nonconformance and shall be controlled to prevent unintended use or delivery.
 - 3.1.1 QMP-023 defines the controls and related responsibilities and authorities for dealing with nonconforming product.
 - 3.1.2 Nonconformances are conditions adverse to quality such as:
 - Failures, malfunctions, deficiencies or deviations in production and installation processes, tooling or facilities;
 - Inadequate or non-compliant procedures and documentation;
 - Inadequate work control
 - The term "nonconforming product" includes nonconforming product returned from a customer.
 - 3.1.3 Nothing contained within this section authorizes the acceptance or use of material, components or information which does not comply with the contract provisions. Authority to utilize materials, components, or information at variance with contract specifications and requirements must be obtained from the customer prior to implementation.
- 3.2 Responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions is defined in the procedure.
 - 3.2.1 Personnel have the authority and responsibility to report a nonconformance during any stage of the realization process.
 - 3.2.2 Nonconforming product shall be labeled and/or physically segregated from conforming items and documented using a Nonconformance Report (NCR).
 - QA shall maintain control of NCRs.
 - NCRs shall identify and include:
 - The nature and extent of the nonconformance detected;
 - The disposition of the nonconformance, including concessions;
 - The objective evidence that re-work and repairs were successfully carried out, re-verified and re-tested in accordance with applicable requirements and found to be acceptable.
 - Date of NCR and Name of person issuing the NCR
 - 3.2.3 No nonconforming material or product shall be released for use or allowed to be further processed until a dispositioned NCR has been received or approval for release is issued by the Director of Quality Assurance.
 - 3.2.4 Nonconforming product may be dispositioned as: rework; scrap; repair; use-as-is; return-to-source or request-for-concession.
- 3.3 Where applicable, nonconforming product can be dealt with in one or more of the following ways:
 - a) by taking action to eliminate the detected nonconformity.
 - b) by authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable

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- c) by taking action to preclude its original intended use or application.
- d) by taking action appropriate to the effects, or potential effects, of nonconformity when nonconforming product is detected after delivery or use has started, such as notifying the customer, end user, and/or regulatory body of the problem as quickly as possible and finding an agreement for the replacement or correction of the items involved or the approval of a Concession as defined within QMP-023.
- 3.4 MO-SCI shall not use dispositions of use-as-is or repair, unless specifically authorization by the customer, if
 - a) the product is manufactured to customer requirements or
 - b) the nonconformity results in a departure from contract requirements.
- 3.5 Unless otherwise restricted by contract, MO-SCI-designed product which is controlled via a customer specification may be dispositioned as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements.
- 3.6 Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, unless physically rendered unusable.
- 3.7 When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.
- 3.8 In addition to contract or regulatory authority reporting requirements, MO-SCI's system shall provide for timely reporting of delivered nonconforming product that may affect reliability or safety.
 - 3.8.1 Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or product numbers, quantity, and dates delivered.
 - 3.8.2 Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.
- 3.9 Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

4.0 REFERENCES

- 4.1 QMP-023 Control of Nonconforming Product

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	8.4 Analysis of Data				
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1.0 PURPOSE

- 1.1 To define MO-SCI's policy concerning the analysis of data and to reference specific procedures that apply to this subject.

2.0 SCOPE


- 2.1 This section covers how data shall be collected, analyzed and used to assess and improve the QMS.

3.0 POLICY

- 3.1 MO-SCI shall collect and analyze appropriate data to determine the suitability and effectiveness of the QMS and to evaluate where continual improvements of it can be made.
- 3.1.1 Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources, such as:
- results from customer surveys;
 - results from employee surveys;
 - customer, supplier and employee feedback;
 - results from internal audits;
 - results from process monitoring and measurements;
 - results from product monitoring and measurements;
 - nonconformance reports; and
 - returned products
- 3.1.2 The purpose of analyzing this data is:
- to assess organizational performance against established quality plans and stated quality objectives;
 - to identify areas for improvement;
 - to help determine the cause of problems; and
 - to provide guidance into the most appropriate and effective corrective or preventive action.
- 3.2 Upon completion, analyzed data shall provide information on:
- a) customer satisfaction and dissatisfaction;
 - b) employee satisfaction and dissatisfaction;
 - c) conformance to product requirements;
 - d) characteristics and trends of processes and products, including opportunities for preventive action and/or improvement;
 - e) suppliers and their contribution; and
 - f) organizational effectiveness and efficiency.
- 3.2.1 The results of data analysis shall be depicted within graphs and charts whenever possible and shall be distributed to members of the MRT.
- 3.2.2 The methodology to be used and the personnel responsible for collecting, analyzing, reporting and distributing QMS data shall be in accordance with QMP-024.

4.0 REFERENCES

- 4.1 QMP-024 Analysis of Data

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1.0 PURPOSE

- 1.1 To define MO-SCI's policy concerning the continual improvement of the QMS and to reference specific procedures that apply to this subject.

2.0 SCOPE

- 2.1 This section covers actions MO-SCI shall take to resolve or prevent nonconformances which have been detected or are perceived as potential problems by the company, its customers, suppliers or applicable jurisdictions.

3.0 POLICY

3.1 CONTINUAL IMPROVEMENT

- 3.1.1 The company shall continually improve the effectiveness of the QMS through the use of the Quality Policy, Quality Objectives, Audit Results, Analysis of Data, QMRs, Corrective and Preventive Actions (C/PA).
- 3.1.2 The methods to be used and the personnel responsible for planning, implementing and reviewing the results of continual improvement activities per QMP-025.

3.2 CORRECTIVE ACTION

- 3.2.1 MO-SCI takes actions to eliminate the causes of nonconformities in order to prevent recurrence.
- 3.2.2 QMP-026 defines requirements for
- a) Reviewing nonconformities, including customer complaints,
 - b) Determining the causes of nonconformities,
 - c) Evaluating the need for action to ensure that nonconformities do not recur,
 - d) Determining and implementing action needed,
 - e) Records of the results of action taken
 - f) Review the effectiveness of corrective action taken to ensure its adequacy to resolve the problem.
 - g) Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause.
 - h) Specific actions where timely and/or effective corrective actions are not achieved.
- 3.2.3 C/PA taken shall be appropriate to the magnitude of the problems and risks involved.
- 3.2.4 The methods to be used and the personnel responsible for determining the steps required to deal with problems of either C/PA, initiation of these actions, and establishing controls to ensure their effective implementation shall be in accordance with QMP-026

3.3 PREVENTIVE ACTION

- 3.3.1 MO-SCI determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence.
- 3.3.2 QMP-026 defines the requirements for:
- a) Determining potential nonconformities and their causes
 - b) Evaluating the need for action to prevent occurrence of nonconformities
 - c) Determining and implementing action needed
 - d) Records of results of action taken
 - e) Reviewing the effectiveness of preventive action taken.

4.0 REFERENCES

- 4.1 QMP-025 Planning for Continual Improvement
- 4.2 QMP-026 Corrective and Preventive Action