AS 9100	ISO 13485	AS 9100:2016 and ISO 13485:2016 Cross Reference Table
CONTEXT OF THE ORGANIZATION		
4.0	4.0	Corporate History
4.1	4.1	Understanding the Organization and Its Context
4.2	4.1	Understanding the Needs and Expectations of Interested Parties
4.3	4.1, 4.2.2	Determining the Scope of the Quality Management System
4.4	4.1	Quality Management System and Its Processes
LEADERSHIP		
5.1	5.1	Leadership and Commitment
5.1.1	5.1	General
5.1.2	5.2	Customer Focus
5.2	5.3	Policy
5.2.1	5.3	Establishing the Quality Policy
5.2.2	5.3	Communicating the Quality Policy
5.3	5.4.2, 5.5.1, 5.5.2	Organizational Roles, Responsibilities, and Authorities
PLANNING		
6.1	5.4.2, 8.5.3	Actions to Address Risks and Opportunities
6.2	5.4.1	Quality Objectives and Planning to Achieve Them
6.3	5.4.2	Planning of Changes
SUPPORT		
7.1	6	Resources
7.1.1	6.1	General
7.1.2	6.2	People
7.1.3	6.3	Infrastructure
7.1.4	6.4.1	Environment for the Operation of Processes
7.1.5	7.6	Monitoring and Measuring Resources
7.1.6	6.2	Organizational Knowledge
7.2	6.2	Competence
7.3	6.2	Awareness
7.4	5.5.3	Communication
7.5	4.2	Documented Information
7.5.1	4.2.1	General
7.5.2	4.2.4, 4.2.5	Creating and Updating
7.5.3	4.2.3, 4.2.4, 4.2.5, 7.3.10	Control of Documented Information
OPERATION		
8.1	7.1	Operational Planning and Control
8.1.1	7.1	Operational Risk Management
8.1.2	7.1	Configuration Management
8.1.3	7.1	Product Safety
8.1.4	7.1	Prevention of Counterfeit Parts
8.2	7.2	Requirements for Products and Services
8.2.1	7.2.3	Customer Communication
8.2.2	7.2.1	Determining the Requirements for Products and Services

8.2.3	7.2.2	Review of the Requirements for Products and Services
8.2.4	7.2.2	Changes to Requirements for Products and Services
8.3	7.3	Design and Development of Products and Services
8.3.1	7.3.1	General
8.3.2	7.3.2	Design and Development Planning
8.3.3	7.3.3.	Design and Development Inputs
8.3.4	7.3.5, 7.3.6, 7.3.7, 7.3.8	Design and Development Controls
8.3.5	7.3.4	Design and Development Outputs
8.3.6	7.3.9	Design and Development Changes
8.4	4.1, 7.4.1	Control of Externally Provided Processes, Products, and Services
8.4.1	7.4.1	General
8.4.2	4.1, 7.4.1, 7.4.3	Type and Extent of Control
8.4.3	7.4.2, 7.4.3	Information for External Providers
8.5	7.5	Production and Service Provision
8.5.1	7.5.1, 7.5.6	Control of Production and Service Provision
8.5.2	7.5.8, 7.5.9	Identification and Traceability
8.5.3	7.5.10	Property Belonging to Customers or External Providers
8.5.4	7.5.11	Preservation
8.5.5	7.5.1,7.5.3, 7.5.4, 8.2.2, 8.2.3, 8.3.3	Post-Delivery Activities
8.5.6	7.3.9	Control of Changes
8.6	7.4.3,8.2.6	Release of Products and Services
8.7	8.3	Control of Nonconforming Outputs
PERFORMANCE EVALUATION		
9.1	8	Monitoring, Measurement, Analysis, and Evaluation
9.1.1	8.1, 8.2.5, 8.2.6	General
9.1.2	7.2.3, 8.2.1, 8.2.2	Customer Satisfaction
9.1.3	8.4	Analysis and Evaluation
9.2	8.2.4	Internal Audit
9.3	5.6	Management Review
9.3.1	5.6.1	General
9.3.2	5.6.2	Management Review Inputs
9.3.3	5.6.3	Management Review Outputs
IMPROVEMENT		
10.1	8.5, 8.5.1	General
10.2	8.3, 8.5.2	Nonconformity and Corrective Action
10.3	5.6.1, 8.5	Continual Improvement

ISO 13485	AS 9100	ISO 13485:2016 and AS 9100:2016 Cross Reference Table
QUALITY MANAGEMENT SYSTEM		
4.0	4.0	Corporate History
4.1	4.1, 4.2, 4.3, 4.4, 8.4, 8.4.2	General Requirements
4.2	7.5	Documentation requirements
4.2.1	7.5.1	General
4.2.2	4.3	Quality Manual
4.2.3	7.5.	Medical Device File
4.2.4	7.5.2, 7.5.3	Control of Documents
4.2.5	7.5.2, 7.5.3	Control of Records
MANAGEMENT RESPONSIBILITIES		
5.1	5.1, 5.1.1	Management Commitment
5.2	5.1.2	Customer Focus
5.3	5.2, 5.2.1, 5.2.2	Quality Policy
5.4	6	Planning
5.4.1	6.2	Quality Objectives
5.4.2	6, 6.1, 6.3	Quality Management System Planning
5.5	5	Responsibility, Authority, and Communication
5.5.1	5.3	Responsibility and Authority
5.5.2	5.3	Management Representative
5.5.3	7.4	Internal Communication
5.6	9.3	Management Review
5.6.1	9.3.1	General
5.6.2	9.3.2	Review Input
5.6.3	9.3.3	Review Output
RESOURCE MANAGEMENT		
6.1	7.1.1, 7.1.2	Provision of Resources
6.2	7.2, 7.3	Human Resources
6.3	7.1.3	Infrastructure
6.4	7.1.4	Work Environment and Contamination Control
PRODUCT REALIZATION		
7.1	8.1	Planning of Product Realization
7.2	8.2	Customer-Related Processes
7.2.1	8.2.2	Determination of Requirements Related to Product
7.2.2	8.2.3, 8.2.4	Review of Requirements Related to Products
7.2.3	8.2.1	Communication
7.3	Not Applicable	Design and Development
7.3.1	Not Applicable	General
7.3.2	Not Applicable	Design and Development Planning
7.3.3	Not Applicable	Design and Development Inputs
7.3.4	Not Applicable	Design and Development Outputs
7.3.5	Not Applicable	Design and Development Review
7.3.6	Not Applicable	Design and Development Verification

7.3.7	Not Applicable	Design and Development Validation
7.3.8	Not Applicable	Design and Development Transfer
7.3.9	Not Applicable	Control of Design and Development Changes
7.3.10	Not Applicable	Design and Development Files
7.4	8.4	Purchasing
7.4.1	8.4, 8.4.1, 8.4.2	Purchasing Process
7.4.2	8.4.3	Purchasing Information
7.4.3	8.4.2, 8.4.3, 8.6	Verification of Purchased Product
7.5	8.5	Production and Service Provision
7.5.1	8.5.1	Control of Production and Service Provision
7.5.2	7.2	Cleanliness of Product
7.5.3	NE/Not Applicable	Installation Activities
7.5.4	NE/Not Applicable	Servicing Activities
7.5.5	NE/Not Applicable	Particular Requirements for Sterile Medical Devices
7.5.6	8.5.1	Validation of Processes for Production and Service Provisions
7.5.7	NE/Not Applicable	Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
7.5.8	8.5.2	Identification
7.5.9	8.5.2	Traceability
7.5.10	8.5.3	Customer Property
7.5.11	8.5.4	Preservation of Product
7.6	7.1.5	Control of Monitoring and Measuring Equipment
MEASUREMENT, ANALYSIS, AND IMPROVEMENT		
8.1	9, 9.1, 9.1.1	General
8.2	9.1	Monitoring and Measurement
8.2.1	9.1.2	Feedback
8.2.2	9.1.2	Complaint Handling
8.2.3	8.5.5	Reporting to Regulatory Authorities
8.2.4	9.2	Internal Audit
8.2.5	9.1.1	Monitoring and Measurement of Processes
8.2.6	8.6	Monitoring and Measurement of Product
8.3	8.7	Control of Nonconforming Product
8.3.1	10.2	General
8.3.2	8.7	Actions in Response to Nonconforming Product Detected Before
8.3.3	8.7	Action in Response to Nonconforming Product Detected After Delivery
8.3.4	8.7, 10.2	Rework
8.4	9.1.3	Analysis of Data
8.5	10	Improvement
8.5.1	10.1, 10.3	General
8.5.2	10.2	Corrective Action
8.5.3	0.3.3, 6.1, 10.1, 10.3	Preventive Action

***NE = No Equivalent**

MO SCI, LLC innovates and manufactures specialty glass materials of exceptional quality. The company was created in June 1985. Heraeus Incorporated acquired MO SCI in 2021. MO SCI is headquartered at 4040 HyPoint North, Rolla, Missouri 65401 and 4030 HyPoint North, Rolla, Missouri 65401

MO SCI, LLC developed and implemented a Quality Management System (QMS) 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. MO SCI's QMS meets the requirements of the AS 9100:2016 International Standard, also referred to as AS9100, and ISO 13485:2016 (+AC:2018+A11:2021 – Not Applicable), also referred to as ISO 13485, for glass materials products for use in medical devices, excluding AS 9100:2016 clause 8.3 Design and Development of Products and Services and ISO 13485:2016 clause 7.3 Design and Development. The justification of exclusions and non-applicabilities is detailed in Section 4.3 of this manual. This system addresses the company's process development and product manufacturing. MO SCI products are used as raw materials in Aerospace and Medical Device applications and several other industries.

The Quality Manual (QM) describes the QMS, delineates authorities, inter-relationships, and responsibilities of the personnel responsible for performing within the system. The QM provides procedures or references for activities comprising the QMS to ensure compliance to the necessary requirements of the standard.

The QM is divided into sections that correlate to the sections of AS 9100 and are cross referenced to ISO 13485. Each section begins with a policy statement expressing MO SCI, LLC's obligation to implement the requirements of the referenced section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

The QM is used internally to guide employees through the various requirements of the AS 9100 and ISO 13485 standards that must be met and maintained in order to consistently provide product that meets customer and applicable statutory and regulatory requirements and enhance customer satisfaction through the effective application of the QMS, including processes for continual improvement of the system and the assurance of conformity to customer and provide the necessary instructions that create an empowered work force.

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

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

Joe Bales
President

1.0 PURPOSE

1.1. MO SCI, LLC exists to provide the highest quality custom glass products through innovation, customer service, and collaboration with industrial partners.

2.0 SCOPE

2.1. This section describes the external and internal issues relevant to MO SCI's purpose and that affect our ability to achieve the intended outcomes of the Quality Management System (QMS).

3.0 POLICY

3.1. The QMS considers relevant external and internal issues and determines the risks and opportunities related to product conformity and customer satisfaction that need to be addressed to assure the QMS can achieve its intended outcomes, prevent, or reduce undesired effects, and achieve continual improvement.

3.1.1 It is designed to consistently provide products that meets customer requirements, enhances customer satisfaction, and ensures company growth.

3.2. The following issues were accounted for when planning the QMS:

3.2.1. External context issues, such as:

a) Relevant Social, Cultural, Legal, Regulatory, Financial, Technological, Economic, Natural and Competitive Environment, whether International, National, Regional or Local issues.
b) Key drivers and trends impacting the objectives of MO SCI, such as customers changing needs.
c) Relationships with, and the perceptions, values, and expectations of external interested parties.
d) Climate change impact.

3.2.2. Internal context issues, such as:

a) Governance, Organizational Structure, Roles, and Accountabilities.
b) Strategies in place to achieve the Policies and Objectives.
c) Capabilities in terms of resources and knowledge, including capital, time, people, processes, systems, and technologies.
d) Information Systems, Information flows and Decision-Making processes, both formal and informal.
e) Relationships with, and the perceptions and values of internal stakeholders as well as MO SCI's culture and core values of Quality, Value, Relationships, and Innovation.
f) Standards, guidelines, and models adopted by MO SCI.
g) The form and extent of contractual relationships.

4.0 REFERENCES

4.1. AS 9100:2016 - Quality Management Systems – Requirements.
4.2. ISO 13485:2016 – Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes.
4.3. ISO Standard 9001 Quality Management Systems – Requirements
4.4. Quality Management Procedures

1.0 PURPOSE

1.1 The purpose of this section is to define the interested parties relevant to the QMS and related requirements of these interested parties.

2.0 SCOPE

2.1 MO SCI has identified interested parties, their needs, and expectations relevant to the QMS due to their effect or potential effect on our ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

3.0 POLICY

3.1 The relevant interested parties for MO SCI's QMS are:

a) Owners.
b) Employees.
c) Direct Customers and End Users.
d) Suppliers, Distributers, Partners, and Competitors.
e) Society, including Regulators.

3.2 Customer and other interested parties' needs and expectations include:

a) Innovation, Technological and Intellectual Property Opportunities.
b) Product Value and Cost.
c) Timely Delivery.
d) Specifications.
e) Functionality.
f) Risk.
g) Financial and Environmental Sustainability – International, National, Regional and Local.
h) Social issues – Conflict Metals, Youth Employment, Pollution, Cultural.
i) International, National, Regional and Local Legal, Statutory and Regulatory Environments.

4.0 REFERENCES

4.1 AS 9100:2016 - Quality Management Systems – Requirements.
4.2 ISO 13485:2016 – Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes
4.3 ISO Standard 9001 Quality Management Systems – Requirements
4.4 Quality Management Procedures listed in the document management system.

1.0 PURPOSE

1.1 The Quality Manual objectives are to provide our relevant interested parties with a single source of information regarding MO SCI's policies and procedures for assuring and controlling product quality and QMS continual improvement. The QMS is based on AS 9100 and ISO 13485.

2.0 SCOPE

2.1 The scope of MO SCI's QMS is the manufacture of specialty glass microspheres, fibers, and frit, as well as producers of glass products for Healthcare, Aerospace, and other industries.

3.0 POLICY

QUALITY MANUAL (QM)

3.1 MO SCI manufacturers and provides glass raw material to customers who further process the material for use in finished devices.

3.1.1 MO SCI does not manufacture finished aerospace or medical devices. The regulatory requirements for such devices are the responsibility of the legal manufacturers of finished devices, not MO SCI.

3.1.2 The role and scope of MO SCI's QMS applicable to AS9100 and ISO 13485 is limited to the raw materials produced for customer's using them in their products, such as medical devices.

3.1.3 MO SCI manufactures products according to its customer's requested specifications.

3.1.4 MO SCI is not a legal manufacturer, authorized representative, importer, or distributor as defined by ISO 13485.

3.1.5 MO SCI has determined that design and development is excluded from the QMS because MO SCI is a raw material provider for Aerospace and Healthcare customers and is not the legal manufacturer of any finished medical device.

3.1.6 The exclusions, non-applicabilities, and the justifications are list in the tables below.

AS 9100	ISO 13485	Exclusions and Justifications
		The following clauses are excluded from MO SCI's QMS because MO SCI does not design or develop finished goods or devices.
8.3	7.3	Design and Development
8.3.1	7.3.1	Documenting design and development procedures.
8.3.2	7.3.2	Planning or controlling design of develop products.
8.3.3	7.3.3	Design and development inputs.
8.3.4	7.3.5	Performing systematic reviews of design and development.
	7.3.6	Verifying the design and development outputs.
	7.3.7	Design and development validations (Process Validations are not exempt.)
	7.3.8	The transfer of design and development outputs to manufacturing.
8.3.5	7.3.4	Design and development outputs.
8.3.6	7.3.9	Documentation or review of design and development changes.
-	7.3.10	Maintaining design and development files.

AS 9100	ISO 13485	Exclusions and Justifications
		The following clauses are not applicable MO SCI's QMS.
NA	7.5.3	Not Applicable. MO SCI products do not require installation.
NA	7.5.4	MO SCI materials do not require servicing.
NA	7.5.5	MO SCI does not provide sterilization services.
NA	7.5.7	MO SCI does not provide sterilization services.
NA	7.5.9.2	MO SCI does not manufacturer implantable devices.
-	8.2.3	MO SCI is not responsible for Reporting to Regulatory Authorities because it know not what products of devices have incorporated its raw materials.

3.1.7 The exclusion shall not affect MO SCI's ability or responsibility to provide conforming product or to meet other QMS requirements.

3.2 This QM establishes Top Management's policy concerning quality and refers to Quality Management Procedures (QMPs).

3.2.1 These QMPs have been developed to ensure the quality of deliverables in strict accordance with contractual and jurisdictional requirements.

3.2.2 The policies in this QM and the methodologies defined within each referenced procedure are applicable to customer, statutory, and regulatory QMS requirements.

3.3 This QM has been established and shall continue to be maintained and controlled to provide the reader with:

- The QMS scope, including details of and justification for exemptions.
- A reference to documented QMPs.
- A description of the interaction between the processes which make up the QMS.

3.4 The QMS documented information structure consists of three tiers. Each subsequent tier is designed to provide the reader with additional detail based on the complexity of the function or process being addressed.

3.5 The QM is a Tier 1 document. It is a single stand-alone controlled document that defines the Quality Policy, setting annual Quality Objectives, Commitment to Customer Satisfaction, and Continual Improvement.

3.6 The QM establishes Management's policy concerning Quality and refers to QMPs.

3.6.1 QMPs have been developed to ensure the quality of deliverables in strict accordance with contractual and jurisdictional requirements.

3.6.2 The policies in the QM and the methodologies defined in the referenced procedures are applicable to customer, statutory, and regulatory QMS requirements.

3.7 Nothing within this manual relieves MO SCI of its responsibility for complying with the provisions of awarded contracts including work performed by company suppliers and subcontractors.

3.8 In the event of an inconsistency between this document and specific contract requirements, the contract requirements shall prevail.

3.9 In the event of a conflict between the requirements of this standard and the applicable or regulatory requirements, the latter shall take precedence.

3.10 The definition of specific terms shall be used as outlined in AS 9100 and ISO 13485, unless otherwise defined.

3.11 The QM and documented information referenced within shall be reviewed for suitability.

4.0 REFERENCES

4.1 AS 9100:2016 - Quality Management Systems – Requirements.

4.2 ISO 13485:2016 – Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes

4.3 ISO Standard 9001 Quality Management Systems – Requirements

1.0 PURPOSE

1.1 The purpose of this section is to describe the Quality Management System (QMS) and its processes.

2.0 SCOPE

2.1 This section explains the QMS established, implemented, maintained, and continually improved by MO SCI in accordance with AS 9100 and ISO 13485 requirements, including the processes needed and their interactions.

3.0 POLICY

MO SCI's Quality Management System (QMS)

3.1 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, statutory, regulatory, and MO SCI's quality requirements and that the products meet or exceed the customer's needs and expectations.

3.2 The design of the QMS is influenced by MO SCI's:

a) Organizational environment, changes in the environment, and the risks associated with that environment.
b) Varying needs.
c) Objectives.
d) Products.
e) Processes.
f) Size and Organizational structure.

3.3 The Process Approach methodology known as "Plan-Do-Check-Act" should be applied to MO SCI processes.

- **Plan** – Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policy.
- **Do** – Implement the processes.
- **Check** – Monitor and measure processes and product against policies, objectives, and requirements for the product and report the results.
- **Act** – Take actions to continually improve process performance.

3.4 MO SCI's processes are used to develop, implement, and improve the effectiveness of the QMS. The processes, as well as their application, sequence and interaction are identified throughout this QM.

3.5 The QMS processes and applications are used throughout MO SCI to:

3.5.1 Document information and resources necessary to support the operation, applicable monitoring, measurement, and analysis of these processes.

3.5.1.1 E.g. Define the inputs required and the outputs expected from each process.

3.5.2 Define the actions and interactions considered necessary to achieve planned results and continual improvement.

3.5.3 Determine the criteria, methods and measurements used to ensure that both the operation and control of these processes are effective.

3.5.4 Determine and ensure the availability of resources to support the required processes.

3.5.5 Understand the allocation of responsibilities and authorities for processes or sets of processes.

3.5.6 Determine and address the risks and opportunities.

3.5.7 Outline the method for determining the risks to quality performance if unintended outputs are produced or process interaction is ineffective.

3.5.8 Guide the monitoring, analysis, and review of processes to ensure that new or revised processes continue to deliver the intended outcomes.

3.5.9 Determine the type and extent of control on purchased products or outsourced processes that affect product conformity to requirements.

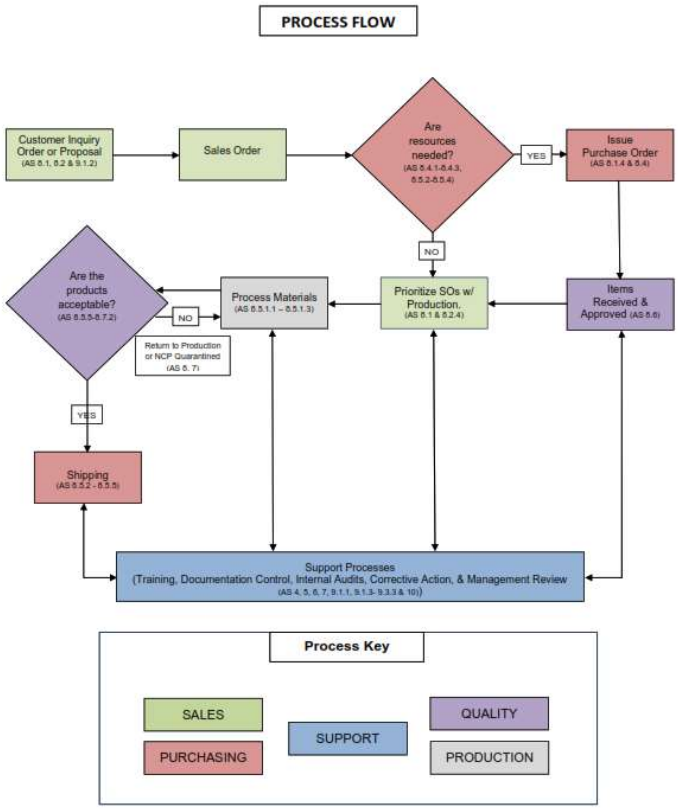
3.5.10 Determine the criteria and methods used to ensure the effective operation and control of processes.

3.5.11 Maintain documented information to support the operation of MO SCI processes and retain this information to show the processes are being carried out as planned.

3.6 The QMS addresses customer and applicable statutory and regulatory QMS requirements.

3.7 Processes that make up the QMS shall be managed as defined within this QM.

3.8 The sequence and interaction of these processes shown in the following chart.



4.0 REFERENCES

4.1 AS 9100:2016 - Quality Management Systems – Requirements.

4.2 ISO 13485:2016 – Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes

4.3 ISO Standard 9001 Quality Management Systems – Requirements

1.0 PURPOSE

1.1 To define MO SCI Top Management's leadership and commitment to the Quality Management System (QMS) and customer focus policy.

2.0 SCOPE

2.1 This section describes the leadership and commitment made by Top Management to the development, implementation, and continuing improvement of the QMS and identifies evidence of this commitment.

3.0 POLICY

3.1 Top Management (TM) is committed to the policies and procedures described and referenced within the QM, to the ongoing development and continual improvement of the QMS implemented, and to the following quality management principles:

a) Accountability – TM must take responsibility and accountability for the effectiveness of the QMS.

b) Quality Policy – TM must ensure the Quality Policy continues to remain relevant and consistent with the overall organizational policies and provides a suitable framework for setting quality objectives.

c) System Approach to Management - TM must identify, understand, and manage the interrelated processes of our QMS to achieve defined objectives while contributing to the effectiveness and efficiency of MO SCI. The QMS is to be compatible with MO SCI's context and strategic goals.

d) Process Approach - TM must ensure that related resources and activities are managed as a process to efficiently achieve the desired result and promote the use of risk-based thinking.

e) Resource Management – TM must ensure the necessary resources to implement and improve the processes for the QMS and to address customer satisfaction continue to be made available.

f) Communication – TM must convey the importance of effective Quality Management and conformance to QMS requirements.

g) Factual Approach to Decision Making - TM must ensure that decisions are effective and are based on the logical or intuitive analysis of data and information so that the QMS achieves its intended results.

h) Involvement of People - TM must ensure that our employees are fully involved and informed to enable them to use their abilities for the maximum benefit of MO SCI. We strive to enhance our ability to create value by fostering mutually beneficial relationships with our interested parties.

i) Improvement - TM ensure that continual improvement is a permanent MO SCI objective.

j) Leadership - TM must establish a unity of purpose, direction, and stable environment in order that our employees can demonstrate leadership in their area of responsibility and become fully involved in achieving MO SCI's objectives and QMS' effectiveness.

3.2 MO SCI products are used as raw materials in Aerospace and Medical Device applications and several other industries.

3.3 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. To reinforce this commitment, Top Management shall ensure that:

a) The importance of meeting customer, statutory and regulatory requirements is understood and met, by requiring compliance with customer communication. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people. This information can be communicated throughout MO SCI using any or all the following means:
   - Internal and quality indoctrination training sessions.
   - Postings and bulletin boards.
   - Documented information, including E-mail notifications.

b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed.

c) The goal of these actions is to fulfill customer requirements, comply with statutory and regulatory requirements, and to achieve or enhance customer satisfaction.

d) Product and service conformity and delivery performance are measured, and that appropriate action is taken if planned results are not or will not be achieved.

4.0 REFERENCES

4.1 None.

1.0 PURPOSE

1.1 To define MO SCI, LLC's Quality Policy and to reference specific applicable procedures.

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 Top Management.

3.0 POLICY

3.1 The QUALITY POLICY is **"Make It Right, Reliable, and Cost Effective" or MIRRCE.**

3.2 This Quality Policy is considered appropriate and consistent with MO SCI's overall business policies and Quality Management Principles. It shall be reviewed on an on-going basis as defined within 1-QA-QMP-24 Quality Management Review, to ensure its relevance and continuing suitability to AS9100 and ISO 13485.

3.3 It is MO SCI, LLC's Quality Policy to provide our customers with safe and effective 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 the QMS and to ensure an adequate framework for the establishment and review of the quality objectives is provided.

3.4 MO SCI shall ensure that this policy is documented, communicated, and understood by all levels within the organization by providing training sessions as defined by 1-ADM-QMP-5 Competency, Training and Awareness and by conducting Internal Quality Audits in accordance with 1-QA-QMP-14 Internal Quality Audit.

4.0 REFERENCES

4.1 1-QA-QMP-24 Quality Management Review

4.2 1-ADM-QMP-5 Competency, Training and Awareness

4.3 1-QA-QMP-14 Internal Quality Audit

1.0 PURPOSE

1.1 To define the responsibilities and authorities of relevant roles within MO SCI, the methods used for communication and to reference specific procedures and documents that apply to this subject.

2.0 SCOPE

2.1 This section is to communicate the responsibilities, authorities and inter-relationships created by Top Management and show the internal communication structure.

3.0 POLICY

3.1 ROLES, RESPONSIBILITY AND AUTHORITY

3.1.1 MO SCI has established functions in Administration, Human Resources, Quality Assurance, Research and Development (R&D), Sales, and Manufacturing.

3.1.2 To facilitate effective quality management, MO SCI establishes an Organizational Chart and Job Descriptions to define the roles, responsibilities, and authorities for each function with lines of communication and the interrelationship of positions illustrated within the organization chart, 1-ADM-FORM-400.

3.1.2.1 Management Representative

- 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:
  - Plan, implement and maintain a QMS that conforms to ISO Standard 9001 and AS 9100 AND ISO 13485.
  - Ensure that the processes are delivering the required outputs and that the process interactions are producing the required QMS outcomes.
  - Report to Top Management on the QMS performance, including needs for improvement.
  - Promote of awareness of customer focus throughout the organization.
  - Ensure the integrity of the QMS is maintained when changes to the system are planned and implemented.
  - Has the organizational freedom and unrestricted access to Top Management to resolve quality management issues.

3.1 QMS COMMUNICATION

3.1.2 To ensure the Quality Policy, QMS requirements and Quality Objectives are adequately understood, implemented, and maintained within the organization:

- The QM shall be kept in QT9.
- The Quality Policy, QMS requirements shall be reviewed with each employee during quality indoctrination training sessions as defined in 1-ADM-QMP-5 Competency, Training and Awareness.
- Managers are to periodically review QM.

3.1.3 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.

- Electronic communication.

4 REFERENCES

4.1 1-ADM-QMP-5 Competency, Training, and Awareness
4.2 ISO Standard 9001:2015 Quality Management Systems – Requirements
4.3 1-ADM-FORM-400 MO SCI, LLC Organization Chart
Note: The same person may hold more than one position

1.0 PURPOSE

1.1 To define MO SCI's policy concerning QMS Planning to ensure product compliance to both quality and contractual requirements and determine risks and opportunities.

2.0 SCOPE

2.1 This section describes how QMS planning is established to achieve the activities outlined in the AS 9100 Standard Section 4.1, meet the requirements in 4.2, and determine the risks and opportunities to be addressed and ISO 13485 Standard Section 4.1 and 7.1

3.0 POLICY

3.1 QUALITY MANAGEMENT SYSTEM PLANNING

3.1.1 Management shall ensure the QMS planning encompasses:

a) Assurance that the QMS processes can achieve its intended results.

b) Enhance desirable effects by identifying risk per 1-ADM-COM-86 Risk Analysis, 1-PUR-COM-92 Supply Chain Risk Management and 1-IT-ISMP-5 Data Risk Management Policy.

c) Prevent, or reduce, undesirable effects by identifying opportunities.

d) The continual improvement of the QMS.

3.1.2 Inputs to quality planning shall include:

a) The needs and expectations of customers and other interested parties.

b) Product and system process performance.

c) Resources.

d) Identified Risks per 1-ADM-COM-86, 1-PUR-COM-92 and/or 1-IT-ISMP-5

e) Identified Opportunities.

f) Lessons learned from previous experiences.

g) Opportunities for improvements.

3.1.3 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) Determine the Risk Actions:

- Avoid risk.
- Engage a risk to pursue opportunity.
- Eliminate the risk source.
- Mitigate risk.
- Share the risk.
- Retain risk by informed decision.

f) Determine Opportunity Action:

- Adopt new practices.
- Launch new products.
- Open new markets.
- Address new customers.
- Build partnerships.
- Use new technology and other desirable and viable possibilities to address MO SCI's or its customers' needs.

g) Action to eliminate the causes of potential nonconformities to prevent their occurrence. 1-QA-QMP-10 Corrective and Preventive Action defines the requirements for:
- Determining potential nonconformities and their causes,
- Evaluating the need for action to prevent occurrence of nonconformities,
- Determining and implementing action needed,
- Records of results of action taken,
- Reviewing the effectiveness of the action taken.
- Examples include risk management, error proofing, Failure Mode and Effect Analysis (FMEA), and information on product problems reported by external sources.

h) Indicators for performance achievement, and

i) The need for documentation and records.

3.1.4 The actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

3.1.5 The methodology to be used and the personnel responsible for quality planning shall be as defined within procedure 1-QA-QMP-25 Quality Planning.

4.0 REFERENCES

4.1 1-QA-QMP-25 Quality Planning
4.2 1-QA-QMP-18 Planning for Continual Improvement
4.3 1-QA-QMP-10 Corrective and Preventive Action
4.4 1-ADM-COM-86 Risk Analysis
4.5 1-PUR-COM-92 Supply Chain Risk Management
4.6 1-IT-ISMP-5 Data Risk Management Policy

1.0 PURPOSE

1.1 To define MO SCI's policy concerning Quality Objectives and reference applicable procedures.

2.0 SCOPE

2.1 This section describes how Quality Objectives are established to ensure product compliance to both quality and contractual requirements and determine risks and opportunities.

3.0 POLICY

3.1 QUALITY OBJECTIVES

3.1.1 Quality objectives are established at relevant functions, levels, and processes within MO SCI's QMS annually, or as needed.

3.1.2 Management shall ensure that quality objectives:

a) are consistent with MO SCI's quality policy.
b) are measurable.
c) include applicable requirements from regulatory groups and other interested parties.
d) are relevant to conformity of products and services and to enhancement of customer satisfaction.
e) are monitored.
f) are communicated.
g) are reviewed for suitability and revised as appropriate.

3.1.3 MO SCI shall maintain documented information on its quality objectives.

3.1.4 To this end, MO SCI's quality objectives shall fall into four main classifications:

a) 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.
- Quality Management Reviews.

b) 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 developments.
- Inspection, testing and examination of process results.
- Internal nonconformances.
- New technology and equipment.
- Health, safety, and environmental issues.
- Productivity analysis reports.
- Quality Management Reviews.

c) 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.
- Product nonconformances and returns.

d) 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 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 Actions.
- Quality Management Reviews.

3.1.5 1-QA-QMP-25 Quality Planning defines the methodology to be used and the personnel responsible for establishing and actioning quality objectives.

4.0 REFERENCES

4.1	1-QA-QMP-25	Quality Planning
4.2	1-QA-QMP-18	Planning for Continual Improvement
4.3	1-QA-QMP-10	Corrective and Preventive Action

1.0 PURPOSE

1.1 To define MO SCI's policy concerning changes to the QMS.

2.0 SCOPE

2.1 This section describes how changes to the QMS are planned.

3.0 POLICY

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

3.2 When designing a plan to change the QMS, MO SCI shall consider:

- 3.2.1 The purpose of the change and the potential consequences of the change.
- 3.2.2 The QMS integrity.
- 3.2.3 The available resources.
- 3.2.4 Allocation or reallocation of responsibilities and authorities.

4.0 REFERENCES

4.1 1-QA-QMP-25 Quality Planning

4.2 1-QA-QMP-18 Planning for Continual Improvement

4.3 1-QA-QMP-10 Corrective and Preventive Action

1.0 PURPOSE

1.1 To define MO SCI's policy concerning the provision of resources for the establishment, implementation, maintenance, and continual improvement of the QMS.

2.0 SCOPE

2.1 This section applies to the determination of the capabilities and constraints on the existing MO SCI resources, including personnel, suppliers, information, infrastructure, maintenance, work environment, including both the human and physical factors which influence it, and the monitoring and measuring equipment used, including test software, in determining product and process conformance and which can affect product quality.

3.0 POLICY

3.1 General

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

- Implementing, maintaining, and continually improving the QMS.
- Enhancing customer satisfaction by meeting customer requirements.
- Current business opportunities and constraints.
- Mechanisms that will encourage innovative continual improvement.
- Methods to enhance existing competency.
- Future resource requirements.

3.2 People

3.2.1 MO SCI shall determine and provide the persons necessary for the effective implementation of its QMS and for the operation and control of its processes.

3.3 Infrastructure

3.3.1 MO SCI determines, provides, and maintains the infrastructure required for the operation of its processes and to achieve conformity of products and services to provide a foundation for operations and to ensure product conformity to requirements.

3.3.2 Buildings, workspace and associated utilities, and equipment: Process equipment, utilities, office, and production buildings shall be routinely maintained per 1-QA-QMP-21 Preventive Maintenance to ensure continuous quality output and conformity to product requirements.

- Existing infrastructure is maintained to ensure conformity to product requirements. Maintenance requirements are documented in preventive maintenance, sanitation, and/or building maintenance plans as needed.
- New infrastructure requirements will be documented as they arise.
- Initial qualification and determination of maintenance and calibration activities are performed per 1-QA-QMP-27 Validation of Processes, 1-QA-QMP-7 Control of Monitoring & Measuring Devices and 1-MFG-COM-36, IQ, OQ, PQ.

3.3.2.1 Hardware and software: To ensure acceptable monitoring and measuring for hardware and software are used to verify and validate products and processes, such equipment shall be controlled and subject to calibration as defined within 1-QA-QMP-7 Control of Monitoring & Measuring Devices and 1-IT-COM-83 Software Assessment & Validation.

3.3.2.2 Transportation Resources: Required support services, such as transport, shall be provided as identified to ensure the conformity to product requirements, continual system improvement, and customer satisfaction.

3.3.2.3 Information and Communication Technology: Required support services, such as information and communication technology, shall be provided as identified to ensure the conformity to product requirements, continual system improvement, and customer satisfaction.

3.3.3 The infrastructure shall be reviewed for continual compliance to operational needs with required corrective action taken.

3.4 **Environment for the Operation of Processes**

3.4.1 MO SCI is to determine, provide, and maintain the environment necessary for the operation of its processes to achieve requirement conformity of products and services conformity as outlined in 1-MFG-COM-47 Manufacturing Environment. MO SCI manages both the human and physical factors which affect the work environment as defined below:

3.4.1.1 **Human Factors**

- Creative Work Methodologies: MO SCI actively promotes and encourages employee participation, creativity, and new ideas from everyone per 1-QA-SOP-110 Suggestion for Improvement.
- 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 everyone 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 short courses and seminars for professional advancement.
- Safety Rules and Guidance: Safety rules and guidance are provided in the Safety and EHS Procedures, including the use of protective equipment and special facilities which have been allocated for personnel.
- 1-ADM-EPPM-3 Employee Policy and Procedure Manual (EPPM): 1-ADM-EPPM-3 outlines other expectations regarding employee relationships with co-workers, supervisors and customers, language courtesy, disciplinary procedures, and more.

3.4.1.2 **Physical Factors**

- 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 performance.

3.5 **Monitoring and Measuring Resources**

3.5.1 MO SCI shall determine the monitoring and measurements to be undertaken and provide the monitoring and measuring resources needed to obtain evidence of conformity of product to determined requirements.

3.5.2 The organization shall ensure that the resources provided are:

a) Suitable for the specific type of monitoring and measurement activities being undertaken.
b) Maintained to ensure continuing fitness for their purpose.

3.5.3 The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

Measurement Traceability

3.5.4 When measurement traceability is a requirement, or is essential to providing confidence in the validity of measurement 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. When no such standards exist or for some reason a different standard is used, the rationale for what was used for calibration or verification shall be retained as documented information.
b) Identified 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.
c) Safeguarded from adjustments that would invalidate the measurement result.
d) Protected from damage and deterioration during handling, maintenance, and storage.
e) Adjusted or re-adjusted as necessary.

3.5.5 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.

3.5.6 Calibration intervals are defined based on stability, purpose, and usage of the equipment.

3.5.7 The measurements to be made, the accuracy required and the comparator to be used is identified within documented calibration instructions.

3.5.8 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.

3.5.9 1-QA-QMP-7 Control of Monitoring and Measuring Devices describes the methodology to be used and the personnel responsible for conducting, documenting, and controlling calibration of monitoring and measuring equipment.

3.5.10 MO SCI maintains a register of monitoring and measuring equipment, and defines the process employed for their calibration/verification including details of the equipment type, unique identification, location, frequency of check method and acceptance criteria.

3.5.11 Monitoring and measuring devices equipment includes but is not limited to: test hardware, test software, Automated Test Equipment (ATE) and plotters used to produce inspection data.
   - It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.
   - Equipment such as jigs, fixtures or templates used by production shall be subject to accuracy verification prior to usage.

3.5.12 Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.
   - Computer software used for monitoring and measuring of specified requirements shall be validated prior to initial use and reconfirmed as necessary.

3.5.13 Established processes should ensure monitoring and measurement can be and is carried out in a manner consistent with 1-QA-QMP-19 Planning of Product Realization and 1-QA-QMP-7. MO SCI ensures that environmental conditions are

suitable for the calibrations, inspections, measurements, and testing being performed.

3.5.14 MO SCI shall establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification in 1-QA-QMP-8 Control of Nonconforming Product.

3.5.15 MO SCI shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements per 1-QA-QMP-8.

- 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 1-QA-QMP-10 Corrective and Preventive Action.

3.5.16 Calibration certificates received from outside laboratories and internal calibration records shall be maintained in accordance with 1-QA-QMP-9 Control of Quality Records.

- 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.

3.6 **Organizational Knowledge**

3.6.1 Organizational knowledge is knowledge specific to MO SCI and is generally gained by experience. It is information that is used and shared to achieve the MO SCI's objectives.

3.6.2 Organizational knowledge can be based on:

a) Internal sources (e.g., intellectual property; experience; failed and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services).

b) External sources (e.g., standards; academia; conferences; gathering knowledge from customers or external providers).

3.6.3 MO SCI determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

3.6.4 MO SCI maintains and makes this knowledge available to the extent necessary.

3.6.5 When addressing changing needs and trends, MO SCI considers its current knowledge to determine how to acquire the necessary additional knowledge and updates.

4.0 REFERENCES

4.1 1-ADM-EPPM-3 Employee Policy and Procedure Manual (EPPM)
4.2 1-ADM-QMP-5 Competency, Training, and Awareness
4.3 1-IT-COM-83 Software Assessment and Validation
4.4 1-QA-QMP-10 Corrective Action
4.5 1-QA-QMP-19 Planning of Product Realization
4.6 1-QA-QMP-21 Preventive Maintenance
4.7 1-QA-QMP-7 Control of Monitoring and Measuring Devices
4.8 1-QA-QMP-8 Control of Nonconforming Product
4.9 1-QA-QMP-9 Control of Quality Records
4.10 1-QA-QMP-27 Validation of Processes
4.11 1-MFG-COM-36 IQ, OQ, PQ
4.12 1-MFG-COM-47 Manufacturing Environment

4.13 1-QA-SOP-110 Suggestion for Improvement.
4.14 Common Procedures for Calibration
4.15 Equipment manuals
4.16 Safety and EHS Procedures.

1.0 PURPOSE

1.1 To define MO SCI, LLC's policy in determining the competency of persons doing work under its control that affects the QMS performance and effectiveness.

2.0 SCOPE

2.1 This section applies to employees and contractors with assigned responsibilities in the QMS and includes their training to ensure competency when performing activities affecting conformity of product to 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 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 and TRAINING

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 MO SCI's quality indoctrination course explains the QMS and the importance of conformity to product requirements.

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 1-ADM-QMP-5 Competency, Training and Awareness.

3.2.7 Training Records

3.2.7.1 Records related to employee education, training, skills, qualifications, experience, and training assessments shall be retained by MO SCI.

3.2.7.2 Administration maintains employee qualification records.

4.0 REFERENCES

4.1 1-ADM-QMP-5 Competency, Training and Awareness

1.0 PURPOSE

1.1 To define MO SCI LLC's policy to ensure that persons doing work under its control are aware of the importance of their participation in the QMS, Safety, and Ethical Behavior.

2.0 SCOPE

2.1 This section applies to personnel with assigned responsibilities in the QMS to ensure they are aware of their role in the QMS, safety, and ethical behavior when performing activities affecting conformity to product requirements during process development, purchasing, and manufacturing.

3.0 POLICY

3.1 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 developed a Quality Indoctrination.

3.2 MO SCI employees are to be aware of:

- 3.2.1 The quality policy – MIRRCE – which is introduced in 1-ADM-Form-214 New Employee Orientation Checklist, 1-ADM-EPPM-3 Employee Policy and Procedure Manual (EPPM), documented in the Quality Manual, posted throughout the facility, and practiced in our daily job performance.
- 3.2.2 The relevant Quality Objectives.
- 3.2.3 Their contribution to the effectiveness of the QMS, including the benefits of improved performance.
- 3.2.4 The implications of NOT conforming with the QMS requirements.
- 3.2.5 Relevant QMS documented information and changes thereto.
- 3.2.6 Their contribution to product or service conformity.
- 3.2.7 Their contribution to product safety.
- 3.2.8 The importance of ethical behavior as described in the EPPM.

4.0 REFERENCES

4.1 1-ADM-QMP-5 Competency, Training and Awareness
4.2 1-ADM-EPPM-3 Employee Policy and Procedure Manual (EPPM)
4.3 1-ADM-Form-214 New Employee Orientation Checklist

1.0 PURPOSE

1.1 To define MO SCI, LLC's policy concerning communications relevant to the QMS.

2.0 SCOPE

2.1 This section applies to employees providing information relevant to the QMS to the interested parties, as well as the context and format of the information.

3.0 POLICY

3.1 MO SCI has determined the internal and external communications relevant to the QMS, including:

a) What it will communicate.
b) When to communicate.
c) With whom to communicate.
d) How to communicate.
e) Who communicates.

3.2 **INTERNAL COMMUNICATION**

3.2.1 The Quality Manual is maintained in MO SCI's electronic documentation system to ensure that the Quality Policy, QMS requirements, and Quality Objectives are adequately understood, implemented, and maintained.

3.2.2 The Quality Policy and QMS requirements are reviewed during Employee Orientation as defined in 1-ADM-QMP-5 Competency, Training, and Awareness.

3.2.3 Managers are to review QMPs annually.

3.2.4 As part of the feedback loop, the Director of QA shall ensure that the effectiveness of the QMS processes and accomplishment towards Quality Objectives are properly communicated to the various levels and functions within the organization through:

- QMR, Team briefings, and departmental meetings.
- Postings on bulletin boards.
- Electronic communication.
- GEMBA Metrics, Displays, and Walks

3.3 **EXTERNAL COMMUNICATION**

3.3.1 A copy of the QM, as well as certifications, is posted on MO SCI's website www.mo-sci.com.

3.3.2 The Head of Sales will guide external communications, such as

a) Enquiries, contracts, or order handling, including amendments.
b) Product Value and Cost.

3.4 MO SCI shall identify and implement effective arrangements for communication with employees, customers and other interested parties needs and expectations relating to:

a) Internal and external feedback relevant to the QMS.
b) Product information.
c) Customer feedback, including customer complaints.
d) Direct Customers and End Users.
e) Suppliers, Distributers, Partners, and Competitors.
f) Social issues and Regulations such as Conflict Metals, Youth Employment, Pollution.
g) Cultural issues.
h) Innovation, Technological and Intellectual Property Opportunities.
i) Timely Delivery.
j) Specifications.
k) Risk.

l) Financial and Environmental Sustainability – International, National, Regional, and Local.
m) International, National, Regional, and Local Legal, Statutory and Regulatory Environments.
n) Social Media.
o) Events such as Conferences.

4.0 REFERENCES

4.1 1-QA-SOP-76 Inspection Protocol
4.2 1-SLS-QMP-3 Customer Requirements and Communication
4.3 1-ADM-QMP-5 Competency, Training, and Awareness
4.4 1-ADM-EPPM-3 Employee Policy and Procedure Manual (EPPM)
4.5 1-ADM-Form-214 New Employee Orientation Checklist

1.0 PURPOSE

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

2.0 SCOPE

2.1 This section describes the Quality Management System (QMS) documentation used to ensure product compliance to ISO 13485 and AS 9100 quality and contractual requirements and includes the creation, revision, control, review, approval, and storage of documented information.

3.0 POLICY

3.1 **General**

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): A single stand-alone controlled document that defines the quality policy, quality objectives, commitment to customer satisfaction, and continual improvement. It also addresses each of the QMS processes established by the company.

Tier 2 Quality Management Procedures (QMP): Consists of 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 reference 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.

3.1.1 The extent of detail contained within each procedure has been based on MO SCI's size, 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.

3.1.2 Resulting quality records are documented information and shall be controlled 1-QA-QMP-9 Control of Quality Records.

3.2 **CREATION, REVISION AND CONTROL OF DOCUMENTED INFORMATION**

3.2.1 Documents required for the QMS such as this QM, QMPs, instructions, checklists and quality system forms shall be developed per 1-QA-QMP-4 Documentation Development and reviewed, approved, and controlled in accordance with 1-QA-QMP-6 Control of Documents including documents of external origin, such as standards, specifications, records, and customer drawings.

3.2.2 MO SCI uses the electronic document control and management software in conjunction with hard copies to ensure information is available and suitable for use where and when it is needed and to ensure documented information is protected from situations such as loss of confidentiality, loss of integrity, unintended alteration, unauthorized changes or improper use.

3.2.3 Documented information defined as quality records shall be controlled as described 1-QA-QMP-9 Control of Quality Records.

3.3 **CONTROL OF RECORDS**

3.3.1 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.

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

3.3.3 After the completion of a contract, documents and quality records shall be assembled and stored.

3.3.4 Periodic verification of stored documentation shall be conducted per 1-QA-QMP-14 Internal Quality Audits to ensure that environment, access, contract, and QMS requirements are met.

3.3.5 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 1-QA-QMP-9.

4.0 REFERENCES

4.1 AS 9100:2016 - Quality Management Systems – Requirements.

4.2 ISO 13485:2016 – Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes

4.3 ISO Standard 9000 Quality Management Systems – Fundamentals and Vocabulary.

4.4 ISO Standard 9001 Quality Management Systems – Requirements

4.5 Quality Management Procedures (QMPs)

4.6 1-QA-QMP-4 Documentation Development

4.7 1-QA-QMP-6 Control of Documents

4.8 1-QA-QMP-9 Control of Quality Records

4.9 1-QA-QMP-14 Internal Quality Audits

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 describes the methods employed by MO SCI to plan, implement, and control the processes needed to meet the requirements for the provision of products and services and to implement the actions.

3.0 POLICY

Planning of Product Realization

3.1 Quality planning is required before new products or processes are implemented.

3.2 MO SCI shall plan and develop the processes needed for product realization.

3.3 Planning of product realization shall be consistent with the requirements of the other processes of the QMS.

3.4 The methodology to be used and the personnel responsible for the planning of product realization shall be as defined within procedure 1-QA-QMP-19 Planning of Product Realization.

3.5 The following items are to be considered and if s appropriate identified per 1-SLS-COM-73 Project Kickoff Meeting. Identified risks may be evaluated per 1-ADM-COM-86 Risk Analysis

a) The quality objectives and requirements to be achieved for the product, project or contract involved, including the consideration of aspects such as:
   - Product and Personal Safety.
   - Producibility and Inspectability.
   - Reliability, Availability, and Maintainability.
   - Suitability of parts and materials used in the product as determined by customers.
   - No selection and development of embedded software is required for glass raw materials
   - Product obsolescence.
   - Prevention, Detection, and Removal of foreign objects.
   - Handling, Packaging, and Preservation.
   - Recycling or final disposal of the product at the end of its life.

b) Establish the criteria for processes and product and services acceptance, which can include product and/or process:
   - Verification.
   - 1-SLS-Form-317 Failure Mode and Effects Analysis (FMEA) Worksheet
   - Inspection and test activities.
   - Monitoring and Measurement of Critical to Quality characteristics.
   - Process Control and Capability requirements.

c) Determine the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery.

d) Implement control of the processes in accordance with the criteria.

e) Determine, maintain, and retain required documented information. This information will provide evidence the processes have been carried out as planned and demonstrate the conformity of products and services to their requirements.

f) Determine the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified by customers.
g) Engage representatives from affected areas in operational planning and control.
h) Determine the process and resources to support the use and maintenance of the products and services.
i) Determine the products and services to be obtained from external providers.
j) Establish the controls needed to prevent the delivery of nonconforming products and services to the customer.

Project Management

3.6 Kickoff Meetings are used to plan and manage new and unique product realization projects in a structured and controlled manner to meet requirements at acceptable risk identified in FMEA, within resource, and schedule constraints per 1-SLS-COM-73 Project Kickoff Meeting.

Control of Work Transfers

3.7 MO SCI shall establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work (e.g., from one organization facility to another, from the organization to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements and ensure the impact and risk of work transfers is managed.

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.

Operational Risk Management

3.9 MO SCI shall plan, implement, and control a process for managing operational risk to the achievement of applicable requirements that includes the following, as product and service appropriate:
Assignment of responsibilities for operational risk management. Definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance) per 1-ADM-COM-86, 1-PUR-COM-92 Supply Chain Risk Management and/or 1-IT-ISMP-5 Data Risk Management Policy.

3.9.1 Identification, assessment, and communication of risks throughout product realization (e.g. An identified risk could be use of a new technology or a short delivery time).
3.9.2 Identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria.
3.9.3 Acceptance of residual risks after implementation of mitigating actions.

Configuration Management

3.10 MO SCI shall plan, implement, and control a configuration management process to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:

3.10.1 Control product identity and traceability to requirements, including the implementation of identified changes.
3.10.2 Ensure that the documented information (e.g., requirements, verification, validation, and acceptance documentation) is consistent with the actual attributes of the products and services.

Product Safety

3.11 MO SCI shall plan, implement, and control the processes needed to assure product safety during the raw material's life cycle, as appropriate to the organization and the product, such as:

3.11.1 Assessment of hazards and management of associated risks.

3.11.2 Management of safety critical items.
3.11.3 Analysis and reporting of occurred events affecting safety.
3.11.4 Communication of these events and training of persons.

Prevention of Counterfeit Parts

3.12 MO SCI shall plan, implement, and control processes, as appropriate, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product delivered to the customer. The following should be considered:
3.12.1 Train appropriate persons in the awareness and prevention of counterfeit parts.
3.12.2 Application of a parts obsolescence monitoring program.
3.12.3 Control for acquiring externally provided product from original or approved manufacturers, authorized distributors, or other approved sources.
3.12.4 Requirements for assuring traceability of parts and components to their original or approved manufacturers.
3.12.5 Verification and test methodologies to detect counterfeit parts.
3.12.6 Monitoring of counterfeit parts reporting from external sources.
3.12.7 Quarantine and reporting of suspect or detected counterfeit parts.

4.0 REFERENCES

4.1 1-QA-QMP-19 Planning of Product Realization
4.2 ISO 10007 Quality Management – Guidelines for Configuration Management
4.3 1-SLS-COM-73 Project Kickoff Meeting
4.4 1-SLS-Form-317 Failure Mode and Effects Analysis (FMEA) Worksheet
4.5 1-ADM-COM-86 Risk Analysis
4.6 1-PUR-COM-92 Supply Chain Risk Management
4.7 1-IT-ISMP-5 Data Risk Management Policy

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 CUSTOMER COMMUNICATION

3.1.1 Per 1-SLS-QMP-3 Customer Requirements & Communication, MO SCI shall identify and implement effective arrangements for communication with customers relating to:

a) Product and service information.
b) Enquiries, contracts, or order handling, including amendments.
c) Customer feedback, including customer complaints.
d) Handling or controlling customer property.
e) Establishing specific requirements for contingency actions, when relevant.

3.2 DETERMINING THE REQUIREMENTS FOR PRODUCT AND SERVICES

3.2.1 Upon receipt of a customer's request for quotation or query, MO SCI shall determine the customer's requirements including:

a) Customer-specific product requirements.
b) Requirements for delivery activities.
c) Product requirements not specified by the customer but considered essential for intended, specified, or known use, including special requirements.
d) Statutory and regulatory requirements applicable to the product.
e) Post-delivery requirements (e.g. Warranty provisions, contractual obligations such as maintenance services, or supplementary services such as recycling or final disposal).
f) Additional requirements considered necessary by MO SCI.

3.2.2 MO SCI shall ensure:

a) It can meet the claims for the products and services it offers.
b) Special requirements of the products and services are determined.
c) Operational risks (e.g., new technology, ability, and capacity to provide, short delivery time frame) have been identified.
d) MO SCI does not manufacture finished devices therefore regulatory requirements are the responsibility of the legal device manufacturers not MO SCI.

3.3 REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT AND SERVICES

3.3.1 Requests for quotation, customer requirements and requirements perceived by MO SCI to be relevant to the product, project, or contract, shall be reviewed by the prior to bidding to determine:

3.3.2 Upon receipt of a contract or order, and prior to acceptance, the company shall review and evaluate it to determine:

a) If differences exist between the original quote and the contract received.
b) Relevant issue of codes, standards, and specifications applicable
c) What are the schedules of data submissions to the customer or jurisdiction.
d) The quality objectives to be attained.
e) What are the formal lines of contractual communication.

3.3.3 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.

3.3.4 If MO SCI determines that some customer requirements cannot be met or can only partially be met, the organization shall negotiate a mutually acceptable requirement with the customer.

3.3.5 No contract or order shall be accepted until detected differences have been resolved.

3.3.6 If the customer does not provide a documented statement of requirements, the company shall confirm the requirements with the customer before acceptance.

3.3.6.1 In situations such as internet sales a formal review is impractical for each order. Instead, the review can cover relevant product information, such as the website information.

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

3.4 **CHANGES TO REQUIREMENTS FOR PRODUCTS AND SERVICES**

3.4.1 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.

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

3.4.3 Changes to the requirements are to be communicated internally also.

3.5 **DOCUMENTED INFORMATION**

3.5.1 MO SCI shall retain documented information, as applicable on the results of the review and new requirements for the products and services.

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

3.5.3 Records may be returned to Customers requiring recordkeeping greater than 7 years.

3.6 The methodology to be used and the personnel responsible for conducting and documenting the evaluation of Request for Quote (RFQ), contract review, contract amendments and customer communications shall be as defined within procedure, 1-SLS-QMP-3 Customer Requirements and Communication.

4.0 REFERENCES

4.1 1-SLS-QMP-3 Customer Requirements and Communication

1.0 PURPOSE

1.1 MO SCI's AS9100 and ISO 13485 certification are without product design and development for products or medical devices. The purpose of this section is to outline MO SCI's policy concerning working with customers to support their design and development activities for their products and/or process.

2.0 SCOPE

2.1 This section covers the activities employed to establish, implement, and maintain the process design and development phases of products, processes and custom orders that are appropriate to ensure the subsequent provision of products and services.

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 1-QA-QMP-22 Process Design & Development.

3.2 PROCESS DESIGN AND DEVELOPMENT PLANNING

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

3.2.1 Process design and development planning shall include:

- The nature, duration, and complexity of the design and development activities.
- Process design and development stages including organization, task sequence, mandatory steps, significant stages, and reviews.
- Required verification and validation activities.
- Responsibilities and authorities.
- Establishment of internal and external resource needs for the products and services.
- Management of technical and organizational interfaces between groups involved to ensure effective communication and clarity of responsibilities.
- The need for involvement of customers and users in the process.
- The requirements for subsequent provision of products and services.
- The level of control expected for the process by customers and other relevant interested parties.
- The documented information needed to demonstrate that requirements are met.

3.2.2 Where appropriate, due to complexity, MO SCI considers the following activities:

- Structuring the process design effort into significant elements.
- For each element, analyzing the tasks and the necessary resources for its development.
- Consider an identified responsible person, content, input/output data, planning constraints, and performance conditions.
- The input data specific to each element is reviewed to ensure consistency with requirements.

3.2.3 Design and development planning shall consider the ability to provide, verify, test, and maintain products and services.

3.3 PROCESS DESIGN AND DEVELOPMENT INPUTS

3.3.1 Inputs relating to product requirements are determined and documented according to 1-QA-QMP-22 Process Design & Development. Inputs are reviewed for adequacy and completeness, and to resolve ambiguous inputs. Inputs include:

- Functional and performance requirements.

- Where applicable, information derived from previous similar processes.
- Applicable statutory and regulatory requirements.
- MO SCI product and process standards and other requirements essential for the process.
- Potential consequences of failure due to the nature of the products and services.
- When applicable, the potential consequences of obsolescence e.g., materials, processes, components, equipment, products.

3.3.2 Inputs shall be adequate for development purposes, complete, and unambiguous.

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

3.3.4 MO SCI shall retain documented information on design and development inputs.

3.3.4.1 Information such as Kickoff Meeting notes, external provider feedback, internally generated data, and in-service data are useful design and development inputs.

3.4 PROCESS DESIGN AND DEVELOPMENT CONTROLS

3.4.1 MO SCI applies controls to the process design and development to:

a) Define the results to be achieved.
b) Plan, perform, and document reviews to evaluate the ability of the process to meet requirements.
c) Conduct verification activities to ensure that the design and development outputs meet the input requirements.
d) Conduct validation activities to ensure the resulting products and services meet the requirements for the specified application or intended use.
e) Identify problems and take the necessary actions.
f) Retain documented information of these activities.
g) Authorize progression to the next stage.

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

3.4.3 Design and development reviews, verification, and validation have distinct purposes and can be conducted separately or in combination, as is suitable for the products and services.

3.4.4 When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:

a) Test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria.
b) Test procedures describe the test methods to be used, how to perform the test, and how to record the results.
c) The correct configuration of the test item is submitted for the test.
d) The requirements of the test plan and the test procedures are observed.
e) The acceptance criteria are met.

3.4.5 Monitoring and measuring devices used for testing shall be controlled as defined in 1-QA-QMP-7 Control of Monitoring & Measurement Devices

3.4.6 Upon completion, MO SCI shall ensure that reports, calculations, test results, etc., are able to demonstrate that the process design for the product or service meets the specification requirements for the identified operational conditions.

3.5 PROCESS DESIGN AND DEVELOPMENT OUTPUTS

3.5.1 Outputs of process design and development are documented according to 1-QA-QMP-22, Process Design & Development. They are documented in a form suitable for verification against the inputs and are approved prior to release. Outputs shall:
- a) Meet the input requirements.
- b) Be adequate for the subsequent processes for the provision of products and services.
- c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria.
- d) Specify the characteristics of products and services that are essential for their intended purpose and safe and proper provision.
- e) Specify, as applicable, critical items, including any key characteristics and specific actions to be taken for these items.
- f) Be approved by authorized persons prior to release.

3.5.2 MO SCI shall define the data required to allow the product to be identified, manufactured, inspected, verified, used, and maintained. This data can include:
- a) The customer drawings, parts lists, and specifications necessary to define the configuration and the design features of the product.
- b) The material, process, manufacturing, handling, packaging, and preservation data needed to provide and maintain a conforming product or service.
- c) The technical data for operating and maintaining the product.
- d) The relevant statutory and regulatory requirements.
- e) Preservation of production requirements, such as packaging.

3.5.3 MO SCI shall retain documented information on design and development outputs. These are to be reviewed and approved prior to release and updated as needed per 1-QA-QMP-6 Control of Documents

3.6 **PROCESS DESIGN AND DEVELOPMENT CHANGES**

3.6.1 MO SCI shall identify, review, and control changes made during, or after, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

3.6.2 MO SCI shall implement a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements.

3.6.3 MO SCI shall retain documented information on:
- a) Process design and development changes.
- b) The results of reviews including the evaluation of the effect of the changes on delivered product.
- c) The authorization of the changes.
- d) The actions taken to prevent adverse impacts.

3.6.4 Results of these reviews and necessary actions shall be maintained per 1-QA-QMP-9 Control of Quality Records and retained for seven years from the date of completion of the contract.

3.6.4.1 Records may be returned to Customers requiring recordkeeping greater than 7 years.

3.6.5 The process design and development changes shall be controlled in accordance with the configuration management process.

4.0 REFERENCES

4.1 1-QA-QMP-6 Control of Documents
4.2 1-QA-QMP-9 Control of Quality Records
4.3 1-QA-QMP-22 Process Design and Development
4.4 1-QA-QMP-7 Control of Monitoring & Measurement Devices

1.0 PURPOSE

1.1 To define MO SCI's policy concerning externally provided processes, products, and services 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

General

3.1 MO SCI is responsible for the conformity of externally provided processes, products, and services, including from sources defined by the customer.

3.2 MO SCI shall ensure, when required, that customer-designated or approved external providers, including process sources, are used.

3.3 MO SCI shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.

3.4 MO SCI shall require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

3.5 1-PUR-QMP-23 Purchasing procedure is used when externally provided processes, products, and services:

a) Are intended for incorporation into the MO SCI's products and services.
b) Are provided directly to the customers by external providers on behalf of MO SCI.
c) Provide a process, or part of a process because of a MO SCI decision.

3.6 Purchasing processes are conducted and controlled per 1-PUR-QMP-23 to ensure purchased products conform to quality and contractual requirements.

3.6.1 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.

3.6.2 Material and products procured shall be subject to verification and testing by authorized personnel as required per 1-QA-QMP-15 Monitoring & Measurement of Product.

3.7 1-PUR-QMP-26 Supplier Selection & Evaluation and 1-PUR-QMP-11 External Quality Audits define the methodology and the personnel responsible for evaluating and selecting suppliers. This process is based on the supplier's ability to meet the contract/order specifications and quality requirements.

3.7.1 Quality data from objective and reliable external sources, such as information from accredited Quality Management System (QMS) or process certification bodies, external provider approvals from government authorities or customers can be used in the evaluation and selection of an external provider. This data is one element of MO SCI's external provider control process and MO SCI remains responsible for verifying that externally provided processes, products, and services meet specified requirements.

3.7.2 These activities and actions arising from the evaluations are retained as documented information.

3.8 The criteria for supplier selection, evaluation and re-evaluation are based on the criticality and classification of the products or services purchased as defined within 1-PUR-QMP-26.

3.9 Quality records containing the results of supplier evaluations and subsequent necessary

actions shall be maintained per 1-QA-QMP-9 Control of Quality Records.

3.10 MO SCI shall:

a) Define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status.
b) Maintain a register of approved suppliers that includes:
   - The approval status (e.g., approved, conditional, disapproved).
   - The scope of the approval (e.g., product type, process family).
c) Periodically review external provider performance including process, product and service conformity, and on-time delivery performance.
   - The results of these reviews shall be used as a basis for establishing the level of controls to be implemented.
d) Define the necessary actions to take when dealing with external providers that do not meet requirements.
e) Define the requirements for controlling documented information created by and/or retained by external providers.

Type and Extent of Control

3.11 To ensure externally provided processes, products, and services do not adversely affect MO SCIs ability to consistently deliver conforming products and services to customers, MO SCI shall:

a) Ensure that externally provided processes remain within the control of its QMS.
b) Define the controls that it intends to apply to an external provider and those it intends to apply to the resulting output.
c) Take into consideration:
   - The potential impact of the externally provided processes, products, and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements.
   - The effectiveness of the controls applied by the external provider.
   - The results of the periodic review of external provider performance.
d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

3.12 Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by the organization. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.

3.12.1 Customer verification activities performed at any level in the supply chain should not be used by MO SCI or the supplier as evidence of effective quality control and not absolve MO SCI of its responsibility to provide acceptable product and comply with requirements.

3.12.2 Verification activities necessary for ensuring purchased product meets specified purchase requirements and are established and implemented per 1-QA-QMP-15. Verification activities include one or all the following:

a) Review of objective evidence of the conformity of the processes, products, and services from the external provider, such as accompanying documentation, certificate of analysis, test reports, statistical records, process control records.
b) Inspection and audit at the external provider's premises.
c) Review of the required documentation.

d) Review of Production Part Approval Process (PPAP) data.
e) Inspection of products or verification of services upon receipt.
f) Delegation of verification of product to the external provider supplier certification.

3.13 Where purchased product is released for production use pending completion of required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

3.14 When verification activities are delegated to the external provider, the scope and requirements for delegation are defined and a register of delegations shall be maintained.

3.14.1 MO SCI shall periodically monitor the external provider's delegated verification activities.

3.15 When external provider test reports are utilized to verify externally provided products, MO SCI will implement a process to evaluate the data in the test reports to confirm that the product meets requirements.

3.15.1 If MO SCI or the customer has identified raw material as a significant operational risk or critical item, MO SCI shall implement a process to validate the accuracy of test reports.

3.16 Nonconforming product detected while verifying purchased product shall be processed in accordance with 1-QA-QMP-8 Control of Nonconforming Product.

3.16.1 Nonconforming products found at an external provider shall be dispositioned by the external provider.

Information for External Providers

3.17 MO SCI ensures the adequacy of requirements prior to communication with the external provider.

3.18 MO SCI communicate to external providers its requirements in documents containing clear descriptions of the items or services required and include or reference any or all the following:

a) The processes, products, and services to be provided including the identification of relevant technical data, such as the identification and revision status of specifications, drawings, process requirements, work instructions, inspection/verification instructions and other relevant technical data.
b) The approval of:
- Products and services.
- Methods, processes, and equipment.
- The release of products and services.

c) Competence requirements for qualified personnel.
d) The external providers' interactions with the organization.
e) Control and monitoring of the external providers' performance to be applied by the organization.
f) Verification or validation activities that MO SCI or its customer intends to perform at the external providers' premises.
g) Process design and development control requirements.
h) Special requirements, critical items, or key characteristics; test, inspection, and verification including production process verification.
i) The use of statistical techniques for product acceptance and related instructions for acceptance by MO SCI.
j) The need to:
- Follow QMS requirements.

- Use customer-designated or approved external providers, including process sources e.g. special processes.
- Notify MO SCI of nonconforming processes, products, or services and obtain approval for their disposition.
- Prevent the use of counterfeit parts.
- Notify MO SCI of changes in processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval.
- Flow down to external providers applicable requirements including customer requirements.
- Provide test specimens for design approval, inspection/verification, investigation, or auditing.
- Retain documented information, including the seven-year retention period and disposition requirements.

k) Right of Access by MO SCI, our customer, and regulatory authorities to the applicable areas of the facilities and to applicable documented information, at any level of the supply chain, involved in the order and to applicable records.

l) Ensuring that persons are aware of:
- Their contribution to product or service conformity.
- Their contribution to product safety.
- The importance of ethical behavior.

3.19 The purchasing documents are reviewed for adequacy of requirements before orders are placed with the supplier.

4.0 REFERENCES

4.1 1-QA-QMP-9 Control of Quality Records
4.2 1-PUR-QMP-23 Purchasing
4.3 1-PUR-QMP-26 Supplier Selection and Evaluation
4.4 1-QA-QMP-15 Monitoring and Measurement of Product
4.5 1-QA-QMP-8 Control of Nonconforming Product
4.6 1-PUR-QMP-11 External Quality Audits

1.0 PURPOSE

1.1 To define MO SCI's policy concerning production and service 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.

3.0 POLICY

3.1 CONTROL OF PRODUCTION AND SERIVCE PROVISION

3.1.1 MO SCI shall plan and carry out production operations under controlled conditions. Controlled conditions shall include, as appropriate:

a) Documented information that defines:
   1. Product characteristics, the services to be provided, or the activities to be performed. Documented information defining product and service characteristics can include digital definition data, drawings, parts lists, materials, process specifications acceptance criteria and work orders issued.
   2. Results to be achieved. Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents, e.g., Standard Operating Procedure (SOP), work orders, and verification documents.

b) Ensure suitable monitoring and measuring equipment is available to verify production processes and products per 1-QA-QMP-7 Control of Monitoring and Measuring Devices.

c) Implement monitoring and measurement activities at appropriate stages to verify that control criteria of processes or outputs, and acceptance criteria for products and services, have been met ensuring that:
   - Documented information for monitoring and measurement activity for product acceptance includes:
     - Criteria for acceptance and rejection.
     - Where in the sequence verification operations are to be performed.
     - Measurement results to be retained. At a minimum this is an indication of acceptance or rejection.
     - Specific monitoring and measurement equipment required, and instructions associated with their use.
   - When sampling is used as a means of product acceptance, the sampling plan is justified based on recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

d) Use of suitable infrastructure and environment for the operation of processes, which can include product specific tools (e.g., jigs, molds) and software programs.

e) Appointment of competent persons, including required qualification.

f) Validation, and periodic revalidation, of the ability to achieve planned results of the special processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement.
   a. MO SCI is EXEMPT from ISO 13485 clause 7.5.5 as pertaining to Sterile Medical Devices.

g) Implement actions to prevent human error.

h) Implement release, delivery, and post-delivery activities.
i) Criteria for workmanship specified in the clearest practical manner (e.g. written standards, representative samples, illustrations).
j) Accountability for products during production (e.g., part quantities, split orders, nonconforming product.
k) Control and monitor identified critical items, including key characteristics, in accordance with established processes.
l) Determine methods to measure variable data (e.g., inspection equipment) to ensure continuous quality output, suitable process equipment is used and routinely maintained per 1-QA-QMP-21 Preventive Maintenance.
m) Identify in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages.
n) Evidence that production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized.
o) Provision for the prevention, detection, and removal of foreign objects.
p) Monitor and control utilities and supplies (e.g. water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements.
q) Identify and record products released for production use pending completion of required measuring and monitoring activities defined within 1-QA-QMP-15 Monitoring & Measurement of Product, to allow recall and replacement if it is later found that the product does not meet requirements.

3.1.2 Equipment, tools, and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release for production and shall be maintained.

3.1.2.1 Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks per 1-ADM-QMP-20 Preservation of Product.

3.1.3 MO SCI established the following arrangements for Special Processes, or processes where the resulting output cannot be verified by subsequent monitoring or measurement per 1-QA-QMP-27 Validation of Processes, as applicable:

a) Define criteria for the review and approval of the processes.
b) Determine conditions to maintain the approval.
c) Approval of facilities and equipment.
d) Qualification of persons.
e) Specific methods and procedures for implementation and monitoring the processes.
f) Requirements for documented information to be retained.

3.1.4 MO SCI implemented production process verification activities to ensure the production process can produce products that meet requirements in 1-QA-QMP-17 Monitoring & Measurement of Processes

3.1.4.1 These activities can include risk assessments, capacity studies, capability studies, and control plans per 1-QA-QMP-19 Planning of Product Realization.

3.1.4.2 MO SCI uses a representative item from the first production run of a new part or assembly to verify that the production documentation and tooling can produce parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results, e.g. engineering changes, manufacturing process changes, tooling changes.

a) This is often referred to as First Article Inspection (FAI).
b) The organization shall retain documented information on the results of production process verification.

3.2 **IDENTIFICATION AND TRACEABILITY**

3.2.1 MO SCI identifies the product throughout product realization according to 1-QA-QMP-12 Identification & Traceability unless otherwise defined by contract.

3.2.2 MO SCI maintains the identification of the configuration of the product to identify differences between the actual and the required configuration.

3.2.3 MO SCI identifies the product status with respect to monitoring and measurement requirements throughout product realization.

3.2.4 When acceptance authority media such as labels, electronic signatures or passwords are used, MO SCI establishes and documents appropriate controls for the media.

3.2.5 Where traceability is a requirement, MO SCI shall control the unique identification of the product and maintain records per 1-SLS-QMP-3 Customer Requirements & Communication.

3.2.5.1 According to the level of traceability required by contract, regulatory, or other established requirement, MO SCI's system provides for:

- Identification to be maintained throughout the product life.
- The ability to trace products manufactured from the same batch of raw material or from the same manufacturing batch to the destination (e.g. delivery, scrap).
- For an assembly, the ability to trace its components to the assembly and then to the next higher assembly.
- For a product, a sequential record of its production (manufacture, assembly, inspection/verification) is to be retrievable.

3.2.6 In some industry sectors, configuration management is a means by which identification and traceability are maintained.

3.3 **PROPERTY BELONGING TO CUSTOMERS OR EXTERNAL PROVIDERS**

3.3.1 MO SCI exercises care with property belonging to customers or external providers while it is under MO SCI control or use.

3.3.1.1 This property can include materials, components, tools, equipment, intellectual property, or personal data, including customer furnished data used for design, production and/or inspection.

3.3.2 1-ADM-QMP-2 Customer Property outlines the identification, verification, protection and safeguarding of customers or external providers' property provided for use or incorporation into the products and services.

3.3.3 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 1-ADM-QMP-2 and applicable contract requirements.

3.3.4 Unless otherwise defined by contract, upon receipt of customer or external providers' property, MO SCI shall examine items for completeness, proper identification, and possible transit damage.

3.3.4.1 If customer or external providers' property is lost, damaged or otherwise found to be unsuitable for use, MO SCI shall report this to the customer or external providers and maintain records.

3.3.4.2 Items found to be nonconforming shall be identified and recorded as defined within 1-QA-QMP-8 and brought to the immediate attention of the customer or

external providers.

3.4 **PRESERVATION**

3.4.1 MO SCI shall preserve the production and service provision outputs to ensure conformity to requirements per 1-ADM-QMP-20 Preservation of Product.

3.4.2 As applicable, preservation shall include identification, handling, contamination control packaging, storage, transmission or transportation, and protection. Preservation shall also apply to the constituent parts of a product.

3.4.3 Preservation outputs include, where applicable in accordance with specifications and applicable statutory and regulations, provisions for:

a) Cleaning.
b) Prevention, detection, and removal of foreign objects.
c) Special handling and storage for sensitive products.
d) Marking and labeling including safety warnings and cautions.
e) Shelf-life control and stock rotation.
f) Special handling and storage for hazardous materials.

3,4,4 As appropriate, MO SCI shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of work environment, personnel, or product.

3.4.3.1 MO SCI is EXEMPT from clause 6.4.2 parts of ISO 13485 pertaining to sterile medical devices.

3.5 **POST-DELIVERY ACTIVITIES**

3.5.1 Post-delivery support for products and services shall be provided as required.

3.5.2 MO SCI considers the following when determining the extent of post-delivery activities:

a) Statutory and regulatory requirements.
b) Potential undesired consequences associated with its products and services.
c) Nature, use, and intended lifetime of its products and services.
d) Customer requirements.
e) Customer feedback.
f) Collection and analysis of in-service data (e.g., performance, reliability, lessons learned).
g) Control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul.
h) Controls required for work undertaken external to the organization or off-site work.
i) Product/customer support (e.g., queries, maintenance, resources).

3.5.3 MO SCI is EXEMPT from ISO 13485 7.5.3 and 7.5.4 requirements as pertaining to medical device servicing activities, installation, and acceptance criteria for verification of installation.

3.5.4 When problems are detected after delivery, the MO SCI will take appropriate action including investigation and reporting.

3.5.4.1 Post-delivery activities can include actions under contractual obligations such as supplementary services like recycling or final disposal.

3.5.5 Reporting to regulatory authorities- MO SCI is a raw material manufacturer and is not a Manufacturer, Device User Facility, and Importer but is contractually responsible for providing information to customer and regulatory authorities reporting or investigating incidents or adverse events involving MO SCI products.

3.6 **CONTROL OF CHANGES**

3.6.1 MO SCI reviews and controls changes for production or service provision, to the

extent necessary to ensure continuing conformity with requirements.

3.6.2 Personnel authorized to approve changes to production processes or service provision are identified.

3.6.2.1 MO SCI identifies and obtains acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements per 1-SLS-QMP-3 Customer Requirements and Communication and 1-QA-QMP-22 Process Design and Development.

3.6.3 MO SCI retains documented information describing the results of the review of changes, the persons authorizing the change, and necessary actions arising from the review.

4.0 REFERENCES

4.1 1-SLS-QMP-3 Customer Requirements and Communication
4.2 1-QA-QMP-21 Preventive Maintenance
4.3 1-QA-QMP-12 Identification and Traceability
4.4 1-QA-QMP-13 Inspection and Test Status
4.5 1-ADM-QMP-2 Customer Property
4.6 1-ADM-QMP-20 Preservation of Product
4.7 1-QA-QMP-27 Validation of Processes
4.8 1-QA-QMP-7 Control of Monitoring and Measuring Equipment
4.9 1-QA-QMP-17 Monitoring and Measurement of Processes
4.10 1-QA-QMP-15 Monitoring and Measurement of Product
4.11 1-QA-QMP-8 Control of Nonconforming Product
4.12 1-QA-QMP-22 Process Design and Development

1.0 PURPOSE

1.1 To define MO SCI's policy concerning the release of products and services and to reference specific procedures that apply to this subject.

2.0 SCOPE

2.1 This section covers the activities employed to verify that the product and service have met requirements prior to release.

3.0 POLICY

3.1 MO SCI shall monitor and measure the characteristics of the product to verify that product requirements have been met.

3.1.1 This shall be carried out at appropriate stages of the product realization process per 1-QA-QMP-15 Monitoring & Measurement of Product (e.g. tests and product verification activities required by contract and established internally to ensure product conformance).

3.1.1.1 When sampling plans are justified based on recognized statistical principles and appropriate, they can be used as a means of product acceptance. (i.e. matching the sampling plan to the criticality of the product and to the process capability).

3.1.2 When critical items, including key activities shall be as identified, MO SCI shall ensure they are controlled and monitored in accordance with the established processes.

3.1.3 In-Process Product and Service Monitoring and Measurement

a) This includes 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 per 1-QA-QMP-8 Control of Nonconforming Product.

3.1.4 Final Product and Service Monitoring and Measurement

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.
d) If MO SCI or the customer performs verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.
   - Customer verification activities performed at any level in the supply chain should not be used by MO SCI or the supplier as evidence of effective quality control and not absolve MO SCI of its responsibility to provide acceptable product and comply with requirements.

- Nonconforming products shall be dispositioned by the supplier.

3.1.5 The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

3.2 Measurement requirements for product acceptance shall be documented and shall include:

a) Criteria for acceptance and/or rejection.
b) Where in the sequence measurement and testing operations are performed.
c) Required records of the measurement results at a minimum, indication of acceptance or rejection.

3.3 Documented Information

3.3.1 Completed product should not be shipped until records resulting from verification and test points have been reviewed and confirmed as acceptable.

3.3.1.1 Where required to demonstrate product qualification, the MO SCI shall ensure that documented information provide evidence that the product meets the defined requirements.

3.3.1.2 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.

3.3.2 Records are to identify the personnel responsible for authorizing product release of product for delivery to the customer and shall be filed and maintained per 1-QA-QMP-9 Control of Quality Records.

3.3.3 Evidence of conformity with the acceptance criteria shall be maintained.

3.4 MO SCI shall ensure that the document requirements needed to accompany the product are present at delivery.

4.0 REFERENCES

4.1 1-QA-QMP-9 Control of Quality Records
4.2 1-QA-QMP-15 Monitoring and Measurement of Product
4.3 1-QA-QMP-8 Control of Nonconforming Product

1.0 PURPOSE

1.1 To define MO SCI's policy concerning the control of nonconforming outputs 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 Outputs, such as 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 The term “nonconforming outputs” includes nonconforming product or service generated internally, received from an external provider, identified, or returned by a customer.

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.

3.2 The actions taken by MO SCI are based on the nature of the nonconformity and its effect on the conformity of products and services.

3.2.1 This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

3.3 1-QA-QMP-8 Control of Nonconforming Product is maintained as documented information to describe the control process and related responsibilities and authorities for dealing with nonconforming product including:

3.3.1 Defining the responsibility and authority for the review and disposition of nonconforming output and the process for approving personnel making these decisions is defined in the procedure.

3.3.1.1 Personnel have the authority and responsibility to report a nonconformance during any stage of the realization process.

3.3.2 Ensuring nonconformities shall be contained labeled and/or physically segregated from conforming items and documented using QT9’s Nonconforming Products module in QT9.

3.3.2.1 QA shall maintain control of NCP Reports.

3.3.2.2 NCPs shall identify and include:

- The nature and extent of the nonconformance detected.
- The disposition of the nonconformance, including concessions.
- Objective evidence that re-work was successfully carried out.
- Objective evidence that re-verification and re-testing is performed in accordance with applicable requirements and found to be acceptable.
- Date of NC and Name of person issuing the NCP.
- Date of NC and Name of person deciding the action to be taken for the NC.

3.3.3 MO SCI's product control process shall provide for timely reporting of delivered nonconforming product and services to the customer and to relevant interested parties requiring notification such as external providers, internal organizations, customers, distributors, and regulatory authorities.

3.3.3.1 Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or product numbers, quantity, and dates delivered.

3.3.3.2 MO SCI will work with the interested party to finding an agreement for the replacement or correction of the items involved or the approval of a Concession as defined within 1-QA-QMP-8.

3.3.4 Defining the corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts, such as:

- Actions taken to preclude its original intended use or application.
- Actions taken appropriate to the effects, or potential effects, of nonconformity when nonconforming product is detected after delivery or use has started.

3.4 Nonconforming outputs can be dealt with in one or more of the following ways:

a) Actions taken to correct or eliminate the detected nonconformity.
b) Segregation, containment, return, or suspension of provision of products and services.
c) Informing the customer.
d) Obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

3.5 Nonconforming product may be dispositioned per 1-QA-QMP-8 Control of Nonconforming Product.

3.5.1 Dispositions of use-as-is for the acceptance of nonconforming products shall be implemented after:

a) Approval by a representative of the organization responsible design or by persons having delegated authority from the design organization.
b) Authorization by the customer if the nonconformity results in a departure from the contract requirements.

3.5.2 Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

3.5.3 Counterfeit, or suspect counterfeit, parts shall be controlled to prevent re-entry into the supply chain.

3.6 Conformity to the requirements shall be verified when nonconforming outputs are corrected.

3.6.1 No nonconforming material or product shall be released for use or allowed to be further processed until a dispositioned NCP has been received or approval for release is issued by the Director of Quality Assurance.

3.6.2 When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

3.7 Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained. The documented information should include:

a) Nonconformity description.
b) Description of the actions taken.
c) Describe concessions obtained.
d) Identify the authority deciding the action in respect of the nonconformity.

3.8 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 are to be obtained from the customer prior to implementation.

4.0 REFERENCES

4.1 1-QA-QMP-8 Control of Nonconforming Product

1.0 PURPOSE

1.1 To define MO SCI's policy concerning monitoring, measurement, analysis, and evaluation 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 evaluation activities within MO SCI to ensure product and process conformity and continually improve the Quality Management System (QMS) effectiveness.

3.0 POLICY

3.1 MO SCI plans and implements methods for the monitoring, measurement, analysis, and evaluation per 1-QA-QMP-17 Monitoring & Measurement of Processes by determining:

a) What needs to be monitored and measured.
b) The methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results.
c) When the monitoring and measuring shall be performed.
d) When the results from monitoring and measurement shall be analyzed and evaluated.

3.2 MO SCI shall evaluate the performance and the effectiveness of the QMS by

3.2.1 Performing audits to ensure QMS conformity per 1-QA-QMP-14 Internal Quality Audits.

3.2.2 Collecting and analyzing monitoring and measurement data per 1-QA-QMP-1 Analysis of Data to continually improve the effectiveness of the QMS.

3.2.3 Using documented information to support 1-QA-QMP-18 Planning for Continual Improvement.

3.2.4 Determining applicable methods, including statistical techniques, and the extent of their use, and per 1-QA-QMP-24 Quality Management Review routinely evaluate the data to ensure the information collected remains useful, relevant, and supportive of continual improvement.

3.3 MO SCI plans and implements methods for the monitoring, measurement, analysis, and evaluation of processes, as needed, to

3.3.1 Demonstrate conformity to product requirements throughout the realization cycle per 1-QA-QMP-15 Monitoring & Measurement of Product

3.3.2 Ensure process conformity using the monitoring and measurement techniques per 1-QA-QMP-17 and employed during process validation in per 1-QA-QMP-27 Validation of Processes

3.3.2.1 According to the nature of the product and depending on the specified requirements, statistical techniques can 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.
  - Design of Experiment.
- Inspection.
- Failure mode effect and criticality analysis.

3.4 MO SCI retains the appropriate documented information as evidence of the results.

Customer Satisfaction

3.5 One measurement used to evaluate the QMS performance, the company shall monitor the

following factors affecting customer perception as to the degree to which their needs and expectations have been met.

3.5.1 Factors creating customer satisfaction include:
+ Expected product conformity.
+ On-time delivery performance.
+ Attention to queries or complaints.
+ Corrective Action Requests.
+ Successful achievement of both stated and implied needs.

3.5.2 Factors causing customer dissatisfaction include:
- Defective products or service.
- Late delivery.
- Poor response time to queries or complaints.

3.6 Customer satisfaction information to be monitored and used for the evaluation include, but is not limited to, product conformity, on-time delivery performance, customer complaints, and corrective action requests.

3.6.1 MO SCI shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations and assess the effectiveness of the results.

3.6.2 Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer feedback on delivered products and services, customer meetings, market-share analysis, compliments, and business analysis.

3.6.2.1 This data can be collected quantitatively using the interviews or questionnaire survey methods defined within 1-QA-QMP-16 Measuring Customer Satisfaction.

3.6.3 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.
- A comparison to previous results and trends when possible.

3.6.4 Customer satisfaction reports shall be distributed, reviewed, and analyzed during QMRs per 1-QA-QMP-24.

3.6.5 Analysis shall determine opportunities for improvement, such as:
- Correction or prevention of nonconformities.
- Continuous improvement.

3.6.6 Opportunities for improvement shall be documented, approved, planned, and processed per 1-QA-QMP-18.

3.6.7 The results of improvement implementations shall be reviewed by the Management Review Team (MRT) to ensure the effectiveness of the actions taken.

Analysis and Evaluation

3.7 MO SCI shall collect, analyze, and evaluate appropriate data and information arising from monitoring and measurement.

3.7.1 Appropriate data can include:
- Information on product and service problems reported by external sources. including government/industry alerts and advisories.
- Customer surveys results.
- Employee surveys results.

- Customer, supplier, and employee feedback.
- Internal audits results.
- Process monitoring and measurements results.
- Product monitoring and measurements results.
- Nonconformance reports.
- Returned products.

3.8 The purpose of analyzing this data is to evaluate:
a) Products and services conformity.
b) Customer satisfaction.
c) QMS performance and effectiveness.
d) Effectiveness of planning and implementation.
e) Effectiveness of actions taken to address risks and opportunities.
f) External providers performance.
g) Need for improvements to the QMS.
h) Assess organizational performance against established quality plans and stated quality objectives.
i) Determine the cause of problems.

3.9 Upon completion, analyzed data provides information on:
a) Customer satisfaction and dissatisfaction.
b) Employee satisfaction and dissatisfaction.
c) Conformity to product requirements.
d) Process and product characteristics and trends, including opportunities for improvement.
e) Suppliers and their contribution
f) Organizational effectiveness and efficiency.

3.10 The methodology to be used and the personnel responsible for collecting, analyzing reporting, and distributing QMS data is found in 1-QA-QMP-1.
3.10.1 Methods to analyze data can include statistical techniques.
3.10.2 The results of data analysis may be depicted within graphs and charts when possible and distributed to members of the MRT.

4.0 REFERENCES

4.1 1-QA-QMP-6 Control of Documents
4.2 1-QA-QMP-9 Control of Quality Records
4.3 1-QA-QMP-24 Quality Management Review
4.4 1-QA-QMP-27 Validation of Processes
4.5 1-QA-QMP-16 Measuring Customer Satisfaction
4.6 1-QA-QMP-14 Internal Quality Audits
4.7 1-QA-QMP-17 Monitoring and Measurement of Processes
4.8 1-QA-QMP-15 Monitoring and Measurement of Product
4.9 1-QA-QMP-1 Analysis of Data
4.10 1-QA-QMP-18 Planning for Continual Improvement

1.0 PURPOSE

1.1 To define MO SCI policy concerning the use of Internal Audits to monitor and measure 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 in an Internal Quality Audit (IQA) to evaluate the overall effectiveness and efficiency of the QMS and find areas of required improvement.

3.0 POLICY

3.1 MO SCI plans and conducts Internal Quality Audits at intervals to determine whether the QMS:

a) Conforms to planned arrangements to meet MO SCI's, AS 9100, and ISO 13485, customer and applicable statutory and/or regulatory QMS requirements.
b) Is effectively implemented and maintained.

3.2 When planning, establishing, implementing, and maintaining the audit program, MO SCI considers the status and importance of the activities and areas to be audited, changes affecting the organization, as well as previous audit results when scheduling the frequency, methods, responsibilities, planning requirements, and reporting of audits before defining the criteria and scope.

3.2.1 The methodology to be used and personnel responsible for planning, conducting, reporting and follow-up on audits is defined in 1-QA-QMP-14 Internal Quality Audits.

3.3 Auditors are selected in a manner that ensures objectivity and impartiality of the audit process.

3.3.1 IQA shall be performed by personnel who are independent of the activity being evaluated.

3.4 Audit findings shall be documented and brought to the attention of the responsible manager.

3.5 Management responsible for the area being audited shall ensure that the 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.

3.6 A summary of audit findings will be discussed in Quality Management Review for evaluation to determine possible system improvements.

3.7 Documented information is retained as evidence of the implementation of the audit program and the audit results.

4.0 REFERENCES

4.1 1-QA-QMP-14 Internal Quality Audits

1.0 PURPOSE

1.1 To define MO SCI's policy concerning the review of the QMS to ensure its continuing suitability, adequacy, effectiveness, and alignment with the MO SCI's strategic direction and reference specific procedures that apply to this subject.

2.0 SCOPE

2.1 This section covers the review of the QMS by the Management Review Team (MRT) which is made up of Top Management, during the Quality Management Review (QMR) process.

3.0 POLICY

3.1 GENERAL

3.1.1 MRT holds QMRs at planned intervals during the year to review the QMS.

3.1.2 These reviews include assessing opportunities for improvement and the need for change to the current QMS, including the Quality Policy and Quality Objectives.

3.1.3 The methodology used for QMS review is described in 1-QA-QMP-24 Quality Management Review.

3.1.4 QMR minutes shall be maintained in accordance with 1-QA-QMP-9 Control of Quality Records.

3.2 MANAGEMENT REVIEW INPUTS

3.2.1 QMR is planned and carried out taking into consideration the following sources of information regarding the performance of the QMS:

a) Status of action items from previous QMR.
b) Changes in external and internal issues relevant to the QMS.
c) Information on the performance and effectiveness of the QMS, including trends in:
d) Adequacy of resources.
e) Effectiveness of actions taken to address risks and opportunities.
f) Recommendations and opportunities for improvement.

3.3 MANAGEMENT REVIEW OUTPUT

3.3.1 Outputs from QMS reviews shall be documented in the QMR minutes and shall include decisions made and actions taken related to:

a) Opportunities for improvement.
b) Need for changes to the QMS.
c) Resource needs.
d) Newly identified risks.

3.4 MO SCI maintains documented information as evidence of the results of QMR per 1-QA-QMP-9.

4.0 REFERENCES

4.1 1-QA-QMP-9 Control of Quality Records
4.2 1-QA-QMP-24 Quality Management Review

1.0 PURPOSE

1.1 To define MO SCI's policy for deploying actions to meet customer requirements and enhance customer satisfaction and to reference specific procedures that apply to this subject.

2.0 SCOPE

2.1 This section covers the actions MO SCI takes to determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

3.0 POLICY

3.1 **General**

The actions MO SCI takes to determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction shall include:

a) Improving products and services to meet requirements and address future needs and expectations.
b) Correcting, preventing, or reducing undesired effects.
c) Improving Quality Management System (QMS) performance and effectiveness through Correction, Corrective Actions (CA), Continual Improvement, Breakthrough change, Innovation, and Reorganization.
d) Quality Policy, Quality Objectives, Audit Results, Post Market Surveillance, Analysis of Data, and information gained from the Quality Management Review (QMR).

4.0 REFERENCES

4.1 1-QA-QMP-24 Quality Management Review
4.2 1-SLS-QMP-3 Customer Requirements & Communication
4.3 1-QA-QMP-22 Process Design & Development
4.4 1-QA-QMP-18 Planning for Continual Improvement
4.5 1-QA-QMP-10 Corrective Action

1.0 PURPOSE

1.1 To define MO SCI's policy for handling nonconformities and required corrective actions and 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 Nonconformity (NC) and Corrective and Preventive Action (CA, and PA)
Materials or products that do not conform to requirements shall be identified as nonconformities and shall be controlled to prevent unintended use or delivery.

3.1.1 1-QA-QMP-8 Control of Nonconforming Product 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 NC product returned by 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 and authority for the review and disposition of NC product and the process for approving personnel making these decisions is defined in 1-QA-QMP-8.

3.2.1 Personnel have the authority and responsibility to report a NC during any stage of the realization process.

3.2.2 NC product shall be labeled and/or physically segregated from conforming items and documented using QT9 Nonconforming Product (NCP) module.

- Quality Assurance (QA) maintains control of NCP.
- 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 was successfully carried out, re-verified, and re-tested per the applicable requirements and found to be acceptable.
  - Date of NCR and Name of person issuing the NCP.

3.2.3 No NC material or product shall be released for use or allowed to be processed until a dispositioned NCP has been received or approval for release is issued by the Director of QA or Top Management.

3.2.4 Action should be taken to preclude a NC original intended use or application.

3.2.5 Action should be taken appropriate to the effects, or potential effects, of nonconformity when NC product is detected after delivery or use has started.

- MO SCI's product control process shall provide for timely reporting of delivered NC product.
- Notification includes a clear description of the NC, which includes as necessary,

parts affected, customer/product numbers, quantity, and dates delivered.
- Parties requiring notification of NC product can include suppliers, internal organizations, customers, distributors, and regulatory authorities.
- Find an agreement for the replacement or correction of the items involved.

3.2.6 NC product may be dispositioned as: Rework; Reject; Scrap; Return-to-Supplier, or Concession Request.

3.2.6.1 MO SCI shall not use dispositions of Use-as-is or Concession Request unless authorization by the customer, if the NC results in a departure from contract requirements.

3.2.6.2 Dispositions of Concession Request can be used after approval by an authorized representative of the organization responsible for the design.

3.2.6.3 Authorized representative includes personnel having delegated authority from the design organization.

3.2.6.4 Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, unless physically rendered unusable.

3.2.7 When NC product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

3.3 When a NC occurs, including arising from complaints, MO SCI shall:

a) React to the nonconformity and, as applicable:
- Act to Correct (CA) or Prevent (PA) the NC and implement control of the NC.
- Deal with the consequences.

b) Evaluate the need for action to eliminate the causes of the NC, in order that it does not recur or occur elsewhere, by:
- Reviewing and analyzing the NC.
- Determining the NC causes, including, as applicable, those related to human factors.
- Determining if similar NCs exist or could potentially occur.

c) Implement action needed.
d) Review the effectiveness of CAPA taken.
e) Update risks and opportunities determined during planning, if necessary.
f) Make QMS changes, if necessary.
g) Flow down CAPA requirements to an external provider when it is determined that the external provider is responsible for the NC.
h) Take specific actions when timely and effective CAPAs are not achieved.
i) Determine if additional NC product exists and take further action when required.

3.4 CAPA shall be appropriate to the NC effects encountered and magnitude of the problems and risks involved.

3.5 MO SCI maintains documented information as evidence of:

a) The NCs' nature and subsequent actions taken, including concessions obtained.
b) The results of CAPA.

3.6 1-QA-QMP-10 Corrective and Preventive Action outlines the methods used and the personnel responsible for determining the steps required to deal with CAPA problems, initiation of CAPAs, and establishing controls to ensure effective implementation.

4.0 REFERENCES

4.1 1-QA-QMP-8 Control of Nonconforming Product

4.2 1-QA-QMP-10 Corrective and Preventive Action

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 MO SCI shall continually improve the suitability, adequacy, and effectiveness of the QMS through the use 1-QA-QMP-18 Planning for Continual Improvement.

3.2 MO SCI shall consider the results of analysis and evaluation, and the outputs from QMR to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

3.3 MO SCI shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

3.4 Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices.

3.5 To eliminate the causes of potential nonconformities (NC) and to prevent their occurrence MO SCI should:

- 3.5.1 Determine potential NC and their causes.
- 3.5.2 Evaluate the need for action to prevent NC occurrence.
- 3.5.3 Determine and implement action needed.
- 3.5.4 Document information resulting from action taken.
- 3.5.5 Review the effectiveness of preventive action taken.
- 3.5.6 Examples of preventive action opportunities include risk management, error proofing, Failure Mode and Effect Analysis (FMEA), and information on product problems reported by external sources.

4.0 REFERENCES

4.1 1-QA-QMP-18 Planning for Continual Improvement