# Quality Manual

**Manasota Optics, Inc.**

**1743 & 1749 Northgate Boulevard**
**Sarasota, FL 34234**

Issue # 4 dated 1/2/12

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This Quality Manual covers the activities and functions performed by the operating areas included in the service scope definition :

**The Manufacture of Metal Optics**

The Quality Management System is designed to meet the requirements of

ISO 9001 : 2008

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# Distribution

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# Manual Contents

# Amendments

All controlled copies of this Quality Manual must be kept under strict control to prevent the System from becoming unreliable. The following Procedures will ensure that the system remains current and valid.

1) All controlled copies of the manual are to be clearly numbered and the Holder recorded.

2) Each page in the manual is to carry a unique number.

3) The Quality Management Representative (QMR) is to be responsible for all revisions and additions being recorded.

4) Changes can be suggested by any Employee but must receive signed approval from top management before being entered into the Manual.

5) All changes are to be recorded on the Table of Amendment and appropriate pages in each Manual changed.

6) Uncontrolled copies must be clearly marked as such.

# Table of Amendment – Quality Manual

| Schedule Number | Page Number | Issue | Date | Description of Change | Authorization |
|---|---|---|---|---|---|
| All | All | 1 | 8/17/09 | Manual re-issued as Issue 1 against ISO 9001:2008 to remove all references to ISO 9001:2000 | B. MULLINS |
| QM08 | 20 | 2 | 9/8/10 | Revise Para 8.5.3 – Replace “recurrence of nonconformities” with “the first occurrence of potential non conformities” | B. MULLINS |
| QM01<br>QM08 | 1<br>21 & 22 | 3 | 7/8/11 | Revise Page 1 to remove previous ISO Certificate Number; Revise page 21, Table 1 and Page 22, Table 2 to include SOP 819 for Process Validation | B. MULLINS |
| QM06<br>QM07 | 8<br>9 & 10 | 4 | 1/2/12 | Revise Page 8 Quality Policy reflects signature of Jonah Lowery as President; Revise Page 9 for new Organization Chart; Revise Page 10 QMR & Auditors Authorization reflects signature of Jonah Lowery as President; | B. MULLINS |
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# Company Profile

Manasota Optics, Inc. (The Company) began operations at 1743 Northgate Boulevard, Sarasota, FL in 1994. The Company was founded by David Lowery after acquiring the assets of Applied Optics Center which was closed by IMO Industries (parent company) in 1993. In 2004, the Company expanded into a second building in the same industrial park.

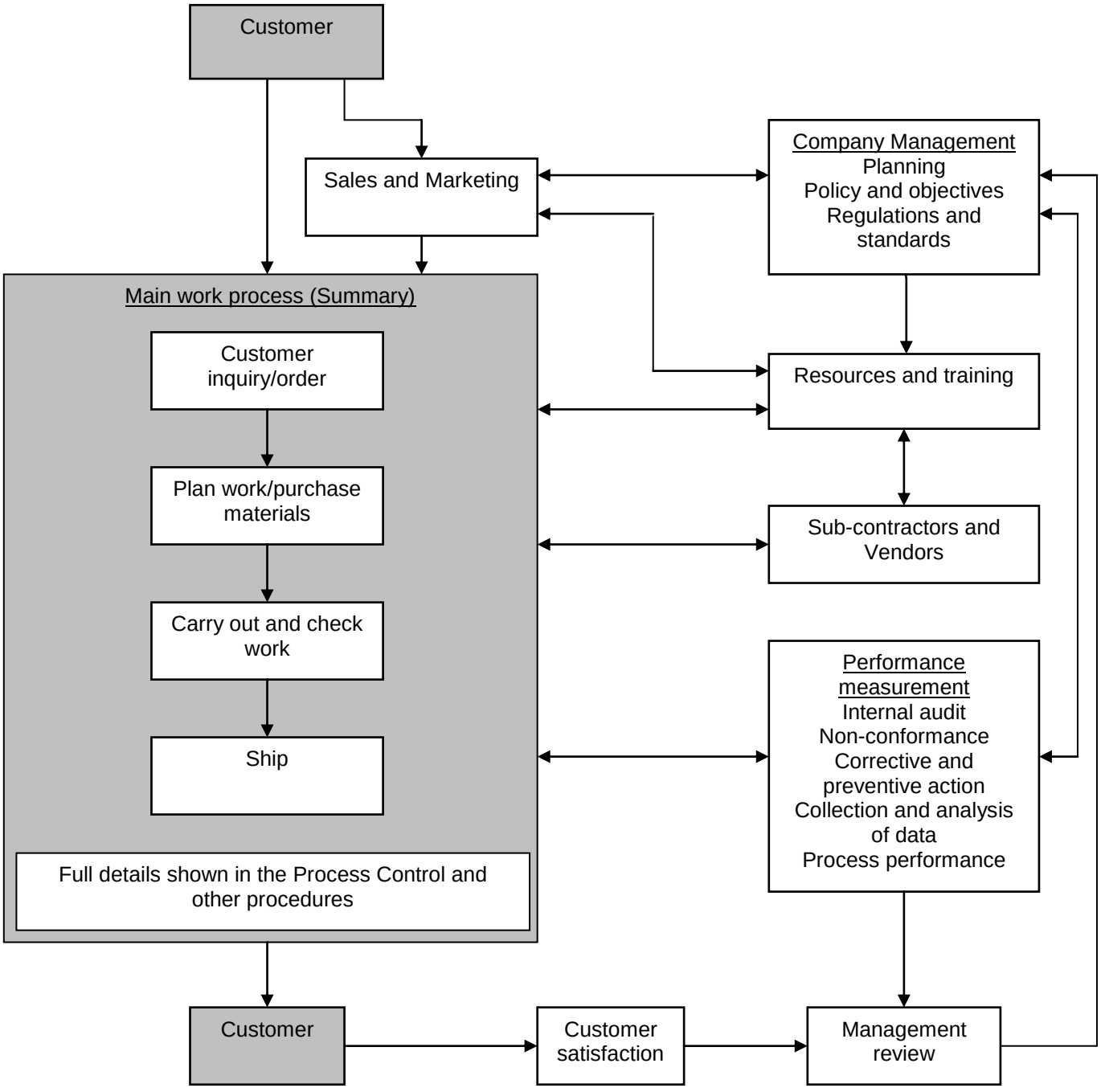
The Company fabricates metal optical components for a wide range of military and commercial applications. 95% of the business is defense related and includes sighting systems in military vehicles, laser rangefinders, targeting systems and biological/chemical detection systems. The remainder of the business consists of commercial applications such as medical applications and barcode scanners.

The techniques used in manufacture (diamond flycutting and polishing) can achieve a flatness of 1/8 wave Peak-to-Valley (.000003 – 3 millionths on an inch) or better with corresponding surface quality and finish accuracies. The manufacturing procedures also include a thermal stabilization process, as necessary to relieve any residual stresses. Standards used include: MIL-PRF-13830, MIL-M-13508, MIL-F-48616 and MIL-C-48497.

The Company's client base includes many well-known national and multi-national corporations in the defense and aerospace industries and also features a number of prestigious academic bodies.

An essential requirement of the continuing maintenance and development of the Company's quality objectives is the installation of a Quality Management System registered to ISO 9001 status as well as compliant to MIL-I-45208 and AS 9003.

# Process Diagram



# MANASOTA OPTICS, INC.

# QUALITY POLICY

Our mission is to provide our customer a product which is second to none in the metal optics industry. It is our personal commitment to deliver a defect free, on time product at the most competitive price within our business sector. Our objective is not only to meet our customer's quality standards, but to be the standard for others.

We will achieve our mission by:

- Open communication with our customer. We will clarify customer product specifications and quality requirements to ensure we have a clear understanding before the production process begins. This process will continue with our employees during the production stage. The final product compliance will be verified to ensure our product meets our customer's expectations.

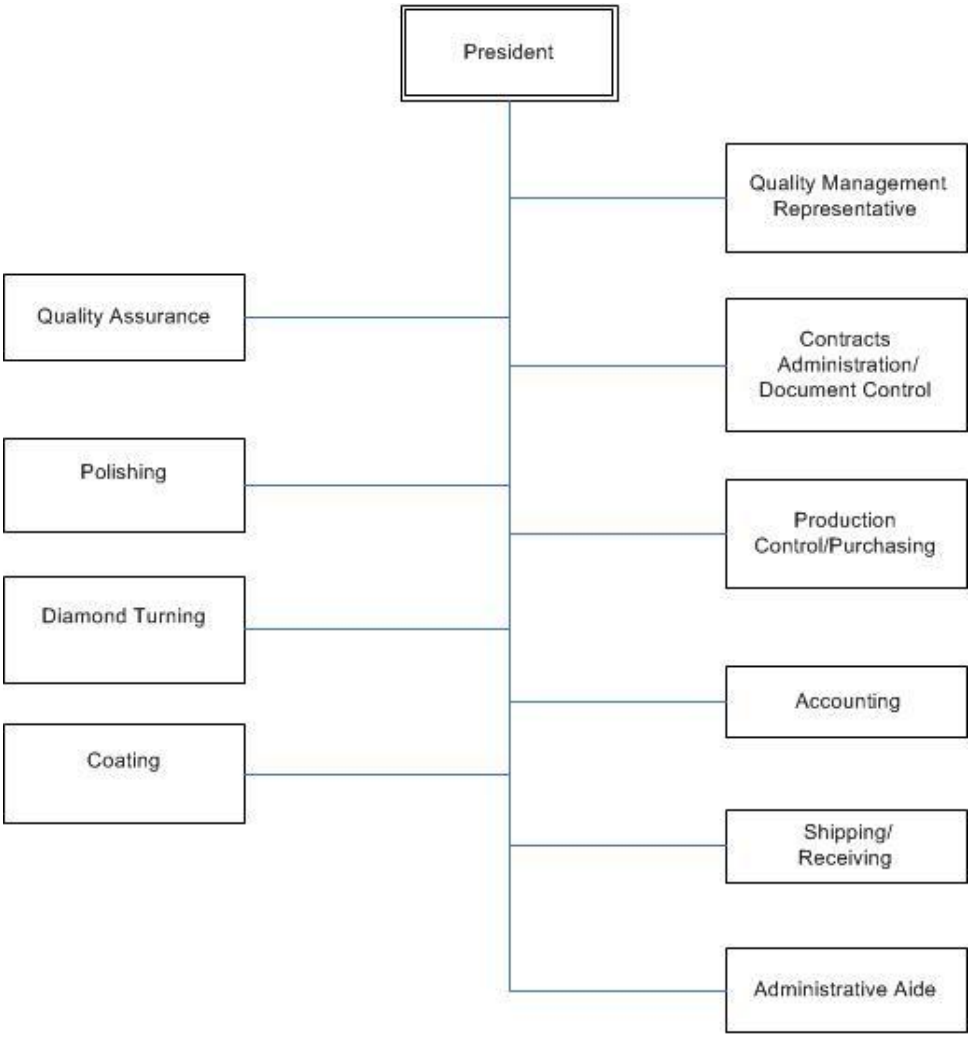
- Understanding that our reputation IS our business. Quality is our basic strategy for survival and a requirement for future growth.

- By adopting a policy of continual improvement and by paying attention to "lessons learned". If we fail by producing a defective product, we will determine what went wrong and how to avoid future occurrences.

Jonah Lowery
President

Date: 1/2/11

# Organization



## Duties and Responsibilities (cont.)

In accordance with the procedures laid down in the authorized Quality Manual and the authorized Procedures Manual, the following are appointed as Quality Representative and Quality Auditors:-

**QUALITY MANAGEMENT REPRESENTATIVE**

**Barbara Mullins** (signature)

QUALITY AUDITOR

**Jonah Lowery** (signature)

QUALITY AUDITOR

**Barbara Mullins** (signature)

QUALITY AUDITOR

**David Lowery** (signature)

QUALITY AUDITOR

**Richard Mullins** (signature)

Signed
**Jonah Lowery**
**President**

Date 1/2/12

# QMS Requirements

## 4 Quality Management System

### Introduction

Manasota Optics, Inc., through the offices of the President, is committed to maintaining an effective Quality Management System.

This Manual has been prepared to satisfy the requirements of ISO 9001:2008 for Quality Management Systems for the activities carried out at the site.

The Quality Management System has been developed using a process approach and the key processes are shown in the Process Diagram. Further details are shown in the appropriate procedure in the Procedures Manual.

Wherever possible, Quality controls have been integrated into existing systems (environment, health and safety) and cross-referenced for ease of interpretation.

The effective implementation of the Quality Management System will be verified by regular inspections, reviews and audits which will compare management practice against the requirements of the written procedures on Quality Management System standards. Corrective action will be taken where necessary and will be subsequently reviewed for effectiveness.

### 4.1 General

The Company has established, documented, implemented, will maintain and continually improve a Quality Management System in accordance with the international standard ISO 9001:2008.

The Company will:

a. Identify the processes needed for quality management throughout the Company.
b. Determine the sequence and interaction of these processes.
c. Determine the criteria and methods needed to ensure that both the operation and control of these processes is effective
d. Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
e. Monitor measure and analyze these processes.

# QMS Requirements

## 4.1 General (cont.)

f. Implement the actions necessary to achieve the planned results and continually improve these processes.

These processes will be managed in accordance with the international standard ISO 9001:2008.

Control of any sub-contracted processes will be exercised in accordance with the Standard.

## 4.2 Documentation

4.2.1 The Company's management system documentation includes:

- Documented statements of quality policy and quality objectives
- A quality Manual
- The documented procedures required by the Standard
- The documents needed to ensure the effective planning, operation and control of its processes
- The records required by the Standard

4.2.2 The Company has established and will maintain a Quality Manual that includes:

- The scope of the Quality Management System and justification for the exclusions
- The documented procedures
- A description of the interaction between the processes of the Quality Management System

# QMS Requirements

**4.2 Documentation (cont.)**

4.2.3 A documented procedure has been established to define:

- How documents are approved for adequacy prior to issue
- How documents are reviewed, updated and re-approved
- How changes to and the current revision status of documents are identified
- How only the relevant versions of documents are available for use
- How documents remain legible and readily identified
- How relevant documents of external origin are identified and controlled
- How the use of obsolete documents is prevented

4.2.4 The appropriate records are established and maintained to provide evidence of conformance to requirements. Records are kept in such conditions as to ensure they remain legible, identifiable and retrievable. A documented procedure has been established and will be maintained which defines the controls in place to identify, store, protect, retrieve and dispose of records whose retention time has expired.

## 5) Management Responsibility

**5.1 Commitment**

Top management of the Company ensures that all employees are aware of the need to meet Customer requirements, statutory regulations and that the necessary resources are available. A Quality Policy and quality objectives have been established. Management reviews are conducted on a regular basis.

**5.2 Customer Focus**

Customer needs and expectations are determined and fulfilled to meet Customer satisfaction. Due consideration is given to product, statutory regulations and statutory legal requirements.

# QMS Requirements

## 5.3 Policy

The Company has established, through its Quality Policy, the need to meet requirements and continually improve its products and services. The Quality Policy and objectives are reviewed for continuing suitability and communicated as appropriate throughout the organization.

## 5.4 Planning

5.4.1 The Company has established that all relevant functions and levels within the organization have clear, measurable quality objectives that are consistent with the Company Quality Policy and product requirements.

5.4.2 Adequate resources are available and output is planned in a controlled manner as is required by its Quality Management System. The integrity of the Quality Management Systems is maintained when changes to the System are planned and implemented.

## 5.5 Administration

5.5.1 Authorities and responsibilities relevant to the Quality Management System are communicated throughout the Company.

5.5.2 A Management Representative from within the organization has been appointed who, irrespective of other duties has the following responsibilities:

- Ensuring that the processes needed for the Quality Management System are established, implemented and maintained
- Reporting to top management on the performance of the Quality Management System and the need for any improvements
- Ensuring the promotion of the awareness of Customer requirements throughout the Company

# QMS Requirements

**5.5 Administration (cont'd)**

5.5.3 Communications between all levels and functions are established so as to ensure the effectiveness of the processes of the Quality Management Systems.

**5.6 Management Review**

5.6.1 The complete Quality Management System is reviewed at planned intervals to ensure its continuing suitability, adequacy and effectiveness to evaluate the need for change. Records of the Review are maintained.

5.6.2 The Review includes the evaluation of current performance and improvement opportunities from internal and external audits, Customer feedback, process performance and product conformity, corrective and preventive actions, follow up from previous meetings and any changes that could affect product quality.

5.6.3 Output from the Review includes improvements to the effectiveness of the Quality Management System and its processes, improvements to the product related to Customer requirements and resource needs to meet these requirements.

**6 Resource Management**

**6.1 Provision of Resources**

The Company has ensured that the necessary resources needed to implement and improve the effectiveness of the Quality Management System and to address Customer satisfaction are available.

**6.2 Human Resources**

6.2.1 Where personnel are assigned responsibilities affecting product conformity, the Company has ensured that they are competent on the basis of applicable education, training, skills and experience.

6.2.2 The Company has identified the training needs for quality related activities and provides training to satisfy these needs. All personnel are made aware of the importance of their activities in achieving the quality objectives. Performance is evaluated and appropriate training records are maintained

# QMS Requirements

### 6.3 Facilities

Suitable equipped premises with appropriate hardware and software with supporting services are provided and maintained as necessary.

### 6.4 Work environment

All aspects of the human and physical factors of the working environment that affect conformity of product have been identified and are managed.

## 7 Product Realization

### 7.1 Planning of realization process

The realization process for the Company's product is planned and documented as defined in the Quality Management System. Quality objectives, resources, processes and documentation needs are defined as are acceptance criteria for verification and validation. Records appropriate to the level of confidence required for the process and product are maintained

### 7.2 Customer related processes

7.2.1 The requirements of the Customer in respect of product, availability, delivery and support are considered as well as any statutory regulations and statutory legal requirements. Additional requirements determined by the Company are also taken into consideration.

7.2.2 Customers requirements are reviewed and any additional requirements for each contract or order are determined. Where no Customer requirements are documented or the details are unclear, details are confirmed before acceptance. Any changes to contracts or quotations are resolved before proceeding and the company's ability to meet the defined requirements is confirmed. Results of these reviews are maintained.

7.2.3 Communications are maintained with the Customer in relation to inquiries, order changes or amendments, product and progress on Customer complaints.

# QMS Requirements

## 7.3 Design and/or development

The Company carries out no design or development activity therefore this clause is not applicable.

## 7.4 Purchasing

7.4.1 The Company controls its purchasing function to ensure that purchased product conforms to requirements. Suppliers are selected against defined criteria and are subject to planned review and evaluation. The results of evaluations and follow up actions are recorded.

7.4.2 Purchasing information includes a description of the product to be purchased and orders are reviewed before release to the supplier.

7.4.3 The Company verifies its purchased product and takes appropriate action in the event of product non-conformance.

## 7.5 Production and service provision

7.5.1 Production is controlled through product specifications process travelers and work instructions. Suitable equipment is used and properly maintained. Product release, delivery and post delivery processes, if any, are defined.

7.5.2 The Company validates any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. The validation demonstrates the ability of these processes to achieve planned results.

7.5.3 The Company identifies the product throughout the production activities and identifies its status with respect to measuring and monitoring activity throughout product realization process. Where traceability is a requirement, the Company controls and records the unique identification of the product.

# QMS Requirements

## 7.5 Production and Service Provision (cont.)

7.5.4 The Company exercises care of Customers' property while it is under their control. Procedures are in place for the protection and preservation of Customers' property, including intellectual property, and loss, damage or unsuitability of such property is reported to the Customer.

7.5.5 The Company preserves conformity of the product during internal processing and delivery to the intended destination. The preservation includes identification, handling, packaging, storage and preservation.

## 7.6 Control of measuring and monitoring equipment

Measuring and monitoring requirements are determined and appropriate equipment selected to provide evidence of conformity to requirements. Measurements and monitoring are carried out in a manner that is consistent with the measuring and monitoring requirements.

Where necessary, measuring and monitoring equipment and software is calibrated or verified at specified intervals using defined standards, adjusted as necessary, identified to show calibration status, safeguarded from unauthorized adjustments and protected from damage and deterioration.

The Company assesses and records the validity of previous measurements when the measuring and monitoring equipment is found not to conform to requirements. Appropriate action is taken on any equipment and product affected.

Records of calibration are maintained.

## 8 Measurement, analysis and improvement

## 8.1 Planning

The requirements for measuring, monitoring and improving product conformity and the effectiveness of the Quality Management System have been determined.

# QMS Requirements

## 8.2 Measurement and monitoring

8.2.1 Methods have been established to measure Customer satisfaction and any failures to meet Company standards.

8.2.2 Suitably trained and impartial personnel conduct periodic independent internal audits on a planned basis. All aspects of internal audits are recorded and reviewed and timely corrective action taken where necessary.

8.2.3 Processes affecting Customer requirements are periodically reviewed to ensure that the intended purpose is being met.

8.2.4 Measuring and monitoring of the product throughout the delivery process is designed to ensure the product meets specification and that authorized personnel control its delivery.

## 8.3 Control of nonconformity

Documented procedures are in place to identify non-conforming product and take appropriate corrective action. Records of non-conformance are maintained.

## 8.4 Analysis of data

Data referring to product quality problems are collected and analyzed and, where changes to the Quality Management System offer improvements, these changes are introduced. Areas for attention are Customer complaints, product conformance, service delivery and Sub-contractor performance.

## 8.5 Improvements

8.5.1 The Quality Management System is managed in a manner to offer continual improvement having regard to statements in its Quality Policy, objectives, audit results, data analysis, corrective and preventive action and management review.

# QMS Requirements

**8.5 Improvements (cont.)**

8.5.2 Appropriate action is taken to rectify faults and prevent their recurrence and the procedure is documented. Requirements for identifying faults and determining their cause with appropriate corrective action is covered and recorded and the results reviewed for effectiveness.

8.5.3 The Company identifies preventive actions to prevent the first occurrence of potential non-conformities and the results of such actions are recorded and reviewed for effectiveness.

# QMS Requirements

**Table 1.**

**Sequence and Interaction of the Quality Management System**

| # | **Process** | *Related Procedures* | **ISO 9001 Clause** |
|---|---|---|---|
| 1. | Customer requirements are identified and confirmed | SOP 808 Customer RFQ and PO Review | 7.1, 7.2 |
| 2. | Quotations are sent and orders are received | SOP 808 Customer RFQ and PO Review | 7.2 |
| 3. | Production Planning | SOP 808 Customer RFQ and PO Review | 7.1 |
| 4. | Materials and services are purchased | SOP 800 – Receiving Procedure<br>SOP 807 – Independent Materials Testing<br>SOP 809 – Supplier Purchase Order Procedure<br>SOP 811 – Control of Customer Supplied Product<br>SOP 814 – Incoming Inspection | 7.4 |
| 5. | Production, verification, shipment | SOP 803 – Final Test and Release<br>SOP 805 – In-process Inspection<br>SOP 812 – Handling, Care and Packaging of Product<br>SOP 815 – Control of Records<br>SOP 819 – Process Validation | 7.5, 8.2.4 |

# QMS Requirements

**Table 2.**

**Sequence and Interaction of the Quality Management System**

| PDCA | *Related Procedures* | ISO 9001 Clause |
|---|---|---|
| Plan | SOP 806 – Document Control<br>SOP 808 – Customer RFQ and PO Review<br>SOP 809 – Supplier Purchase Order Procedure<br>SOP 810 - Care and Control of Critical Tooling and Fixtures<br>SOP 811 – Control of Customer Supplier Product<br>SOP 817 – Resources<br>SOP 819 – Process Validation<br>Form 700 – Process Traveler<br>Form HR-001 – Training Records | 6.1,6.2,<br>6.3, 6.4,<br>7.1, 7.2,<br>7.4, 7.5,<br>8.1 |
| Do | SOP 812 – Handling, Care and Packaging of Product<br>Work Instructions<br>Form 700 – Process Traveler | 7.5 |
| Check | SOP 800 – Receiving Procedure<br>SOP 801 – Control of Nonconforming Product<br>SOP 803 – Final Test and Release<br>SOP 804 – Calibration<br>SOP 805 – In-process Inspection<br>SOP 807 – Independent Materials Testing<br>SOP 813 – Internal Audits<br>SOP 814 – Incoming Inspection<br>SOP 815 – Control of Records<br>SOP 819 – Process Validation<br>Form 742 – Management Review Meeting<br>Form 700 – Process Traveler | 7.5, 7.6,<br>8.1, 8.2,<br>8.3, 8.4 |
| Act | SOP 802 – Corrective and Preventive Action<br>SOP 816 – Management Review<br>SOP 818 – Measurement & Improvement<br>Form 742 – Management Review Meeting | 8.2, 8.5 |

These processes will be managed in accordance with the International Standard ISO 9001:2008.
Control of any sub-contracted processes will be exercised in accordance with the Standards.