Quality Manual

Manasota Optics, Inc.

1743 Northgate Boulevard
Sarasota, FL 34234

Issue # 13 dated 06/20/2025

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Copy Holder: **Master Procedures Binder**
1743 Northgate Blvd

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 9001:2015

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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 must 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 9001:2015 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 nonconformities”	B. MULLINS
QM01 QM08	1 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 QM07	8 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
QM07	8 & 10	5	4/1/14	Revise Page 8 Quality Policy reflects date of 12-4-17; Revise Page 10 QMR & Auditors Authorization reflects signature of Jonah Lowery as Quality Management Representative and Jill Lowery as Quality Auditor	J. LOWERY
All	All	6	1/2/18	Revised Manual to include the requirements of ISO 9001:2015	JILL LOWERY
All	All	7	5/10/18	Removed SOP 819 Process Validation	JILL LOWERY
All	All	8	12/15/18	Removed references to 1749 building and copy #2	JILL LOWERY
QM04 QM05 QM06 QM07 QM08	1, 3-8, 12-13, 17-23, 25, 27, 29-30	9	7/8/2021	QM04: clarified wording. QM05: revised % of military business, removed reference to 2nd building. QM06: clarified wording. QM07: removed extra punctuation. QM08: Updated Internal & External Issues, Quality Objectives revised to reflect new wording outcome only & excluding means of measurement, clarified various wording and punctuation, added Business Standards / Supplier Code of Conduct to 8.4.1	Jill Lowery
QM07	16	10	3/30/2022	Updated Organizational Chart	Jill Lowery
QM08	10, 33, 34	11	12/7/2022	Revised Name of SOP 811	Jill Lowery
QM08	10, 33, 34	12	10/4/2023	Removed SOP 807 Independent Materials Testing	Jill Lowery

Table of Amendment – Quality Manual

Schedule Number	Page Number	Issue	Date	Description of Change	Authorization
QM05 QM06 QM07 QM08	7 14 18 9-10, 13, 19, 23, 26, 29-31	13	6/20/2025	QM05: clarified wording & revised business composition. QM06: updated Quality Policy wording. QM07: updated duties and responsibilities. QM08: added Emergency Action Plan, 4.1 & 4.2 statements regarding climate change ISO 9001:2015/Amd 1:2024, clarified wording, 5.1.1 adjusted Quality Objective wording, 6.1.1 added reference to risk register review.7.5.3.2 included reference to electronic copies. 8.4.1 specified which suppliers receive Supplier Quality Survey.9.1.1 added Variance Log Request Form 785 and form number to external and internal issues review form, 9.2.2 included reference to cyber security internal audits.	Jill Lowery

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.

The Company fabricates metal optical components for a wide range of military and commercial applications. 89% of the business is defense related and includes sighting systems in military vehicles, laser rangefinders, targeting systems, infrared counter measures, and biological/chemical detection systems. The remainder of the business consists of commercial applications including medical applications, satellite imaging, and research development.

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 stress. 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 features a number of prestigious academic institutions.

An essential requirement for 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.

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 9001:2015 for Quality Management Systems for the activities conducted 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 Context of the Organization

4.1 - Understanding the Organization and Its Context

Manasota Optics, Inc. has identified the external and internal issues that are relevant to its purpose and strategic direction and that affect their ability to achieve the intended results of the Quality Management System as:

External Issues

Legal = SAM, ITAR, JCP, IdenTrust, Insurance, NDA's, NADCAP, DFARS, NIST self-assessments, NIST 800-171 – Verify current versions / applicability to MOI
Technological = 3D Printing, monitoring new technology that may affect MOI
Cultural = International Clients – Shipping Restrictions – Any changes to export laws or change to required shipping method – Government leader relationships between countries
Economic = Military Budgets - Diversification - commercial applications – Review any need to identify or pursue more commercial work
Environment = NPDES Storm Water Permitting – File with state, Environmental profiles filed with waste material management companies
Outsourced Processes = External Coating – External Machining Suppliers - Vendors – Lead Times – Review whether to pursue new vendors
Vendor Certifications = Verify that required certifications are up to date.

Internal Issues

Knowledge = Standard Operating Procedures, Work Instructions, System Security Plan, Emergency Action Plan, Hazard Communication Plan, Business Continuity Plan, Business Standards / Supplier Code of Conduct - Employee Training – Verify Annual training review completed for all employees to most recent revisions of procedures / Any new training requirements necessary
Performance = OTD – Causes of late deliveries / any actions necessary to prevent
Equipment = Older equipment, updating / New or Improved equipment needs, Verify Preventive Maintenance has been completed , verify system back-ups are done
Inventory = Forecasting – Review availability of required raw materials – Actions required to ensure availability when needed
Certifications = ISO 9001:2015 – Verify surveillance / re-certification audit dates have been set. OSHA & DOT Hazmat certifications maintained.

External and Internal issues are monitored throughout the year using Form 776 "Internal and External Issues Review" which details the type of issue being reviewed, the due date, responsible party and identifies whether any actions or resources are required.
This form is reviewed annually at management review to determine whether there have been any changes to the external or internal issues throughout the year.

The organization shall determine whether climate change is an issue.

4.2 - Understanding the needs and Expectations of Interested Parties

Interested parties relevant to Manasota Optics, Inc. have been determined to be:

Customers – Review of orders – Form 100 & Form 101, Forecasting – Management Review if necessary
Vendors – Performance review – Management Review
Employees – Training – Annual training review, Internal Audit and Management Review
County – Recycling – Required but no formal documentation necessary
State – NPDES Storm Water Permitting - Documented internally annually – Reported to the state every 5 years

Monitoring of Interested parties' needs and expectations are reviewed by Top Management at management review. The needs and expectations of customers are reviewed as orders are received using Form 100 & Form 101 (if necessary).

Relevant interested parties can have requirements related to climate change.

Section 4.3 - Determining the Scope of the Quality Management System

Manasota Optics, Inc.'s scope is:

"The Manufacture of Metal Optics"

The quality management system encompasses the requirements of ISO 9001:2015. Clause 8.3 "Design and development of products and services"
This is taken as a justified exclusion as the company conducts no design or development activities.

4.4 Quality Management System and It's Processes

4.4.1

Manasota Optics, Inc. Processes have been defined as:

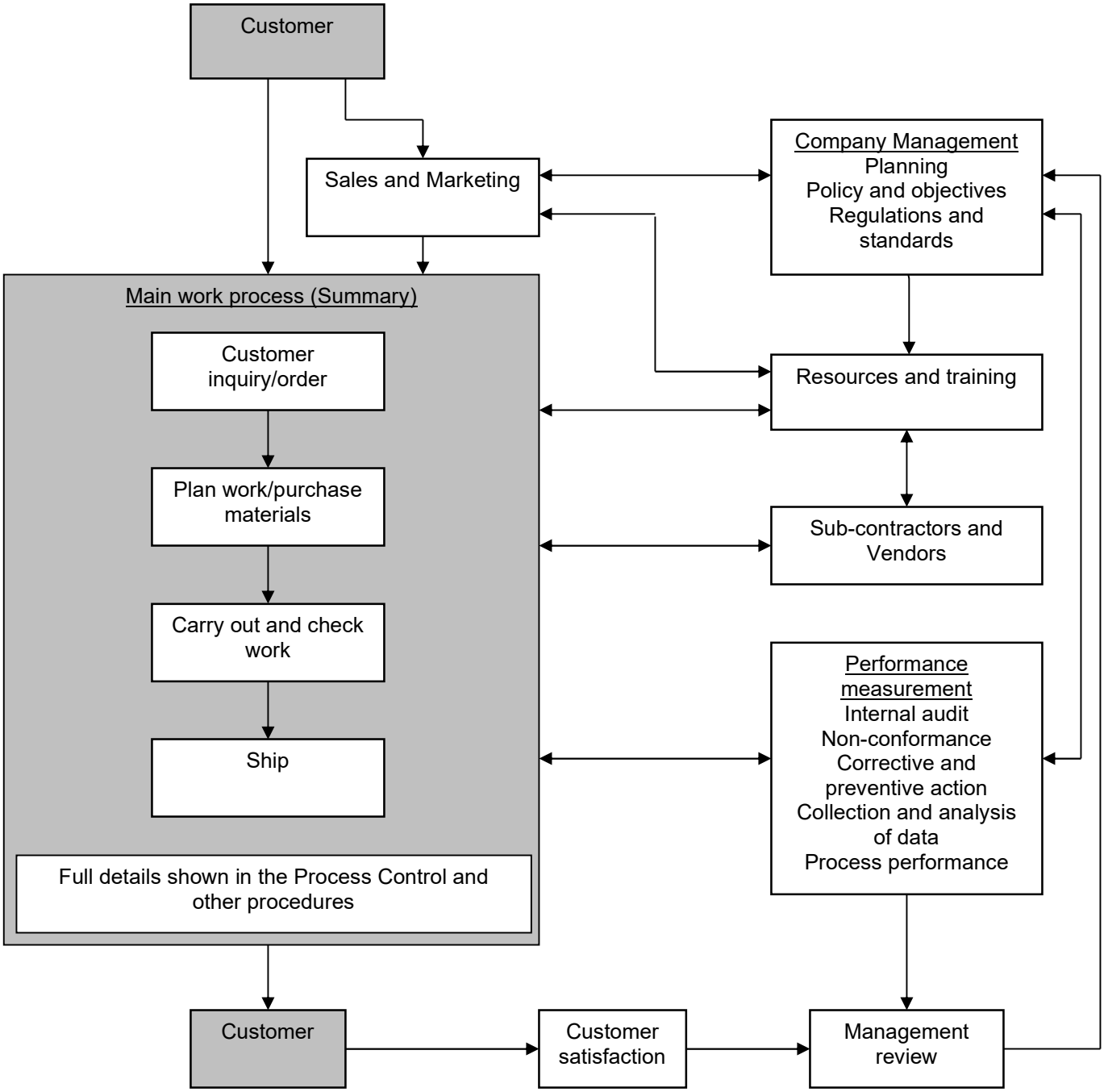
Procedure	ISO 9001:2015 Clause
SOP 800 Receiving	8.4
SOP 801 Control of Non-Conforming Product	8.7
SOP 802 Corrective / Preventive Action	10.2
SOP 803 Final Test and Release Criteria	8.6

SOP 804 Calibration	7.1.5
SOP 805 In Process Inspection	8.6
SOP 806 Document Control	7.5
SOP 808 Customer RFQ & PO Review	8.2
SOP 809 Supplier Purchase Order Procedure	8.4
SOP 810 Care and Control of Critical Tooling & Fixtures	7.1.3
SOP 811 Control of Customer / External Supplied Product	8.5.3
SOP 812 Handling, Care & Packaging of Product	8.5.4
SOP 813 Internal Audits	9.2
SOP 814 Incoming Inspection	8.4
SOP 815 Control of Records	7.5
SOP 816 Management Review	9.3
SOP 817 Resources	7
SOP 818 Measurement & Improvement	9.1

The Interaction of these processes is as defined in the Process Diagram Below, Table 1 and Table 2.

Each SOP defines the required inputs and outputs.
The effective operation and control of these processes is monitored throughout the year by analyzing data regarding customer satisfaction, supplier performance, non-conformances, complaints, scrap, rework, returns, training reviews and annual internal audits.
The results of the analysis are presented to Top Management at Management Review and any required resources are determined and made available.
Risks and Opportunities in relation to the identified External and Internal Issues are recorded on the Manasota Optics, Inc. Risk Register and are reviewed at management review for effectiveness of any actions taken.

Process Diagram



4.4.2

Manasota Optics, Inc. maintains documented information in support of the operation of its process. Work Instructions are maintained for product specific procedures and manufacturing procedures for Diamond Turning, Polishing, Coating, Inspection, Calibration and Statutory Regulations.
Documentation is retained as evidence of processes being conducted as planned. The documented information is retained as defined in SOP 815 Control of Records.

5 Leadership

5.1 Leadership and commitment

5.1.1
Manasota Optics, Inc. takes accountability for the effectiveness of the quality management system through monitoring and measurement of its processes during annual internal audits and Management Reviews.

Manasota Optics, Inc. has established a Quality Policy and Quality Objectives.

Quality Objectives

1 - Customer Satisfaction:
Achieve a customer satisfaction rating of five on a scale of 1 through 5. This will be monitored via interactions with the customer from the initial quote through final shipment and will include communication with engineering, purchasing, quality, etc.

2 - On Time Delivery:
Achieve and maintain an on-time delivery rate of 95% or better.

3 - Defect Free Product:
Attain a scrap rate of <1.0% of the cost of goods sold

4 - Supplier Satisfaction:
Approved suppliers will have a performance measured and less than 10% of all suppliers will recerive a “below expectations” rating.

MANASOTA OPTICS, INC.

QUALITY POLICY

Our mission is to provide our customers with a product that 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 customers' quality standards, but to be the standard for others.

We will achieve our goal by:

- Open communication with our customers. We will clarify customer product specifications and quality requirements to ensure we have a clear understanding during the quotation process. This course of action will continue with our employees during the production stage. The final product compliance will be verified to ensure our product meets or exceeds 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: 6/16/2025

The quality management system requirements have been incorporated into the business processes as noted in SOP's 800-818. The QMS is based on the process approach and risk-based thinking.
Resource needs are evaluated and made available at management review or as necessary throughout the year.
Top management of the Company ensures that all employees are aware of the importance of effective quality management and of conforming to the quality system requirements through training and actions taken based on analysis of process performance while ensuring that the QMS achieves its intended results.
Trained people are authorized and responsible for implementation of the SOP's contributing to the effectiveness of the QMS.
Improvements are promoted and actioned at management review with assigned responsibility and due dates.
Roles are defined with immediate support shown on the Organizational Chart.

5.1.2 Customer Focus

Customer needs and expectations are determined and fulfilled to meet Customer satisfaction. Due consideration is given to product, statutory and regulatory requirements along with any risks and opportunities that can affect the conformity of the product or service through the completion of Form 100 and 101 if applicable prior to the acceptance of customer orders.

5.2 Policy

5.2.1

The Quality Policy is appropriate to the organization, setting a framework for the Quality objectives and commits to satisfying applicable requirements and continual improvement.

5.2.3

The Quality Policy is maintained as documented information in the Quality Manual under schedule QM-06. The Quality Policy is communicated, understood, and applied within the organization and is available to interested parties on the company website.

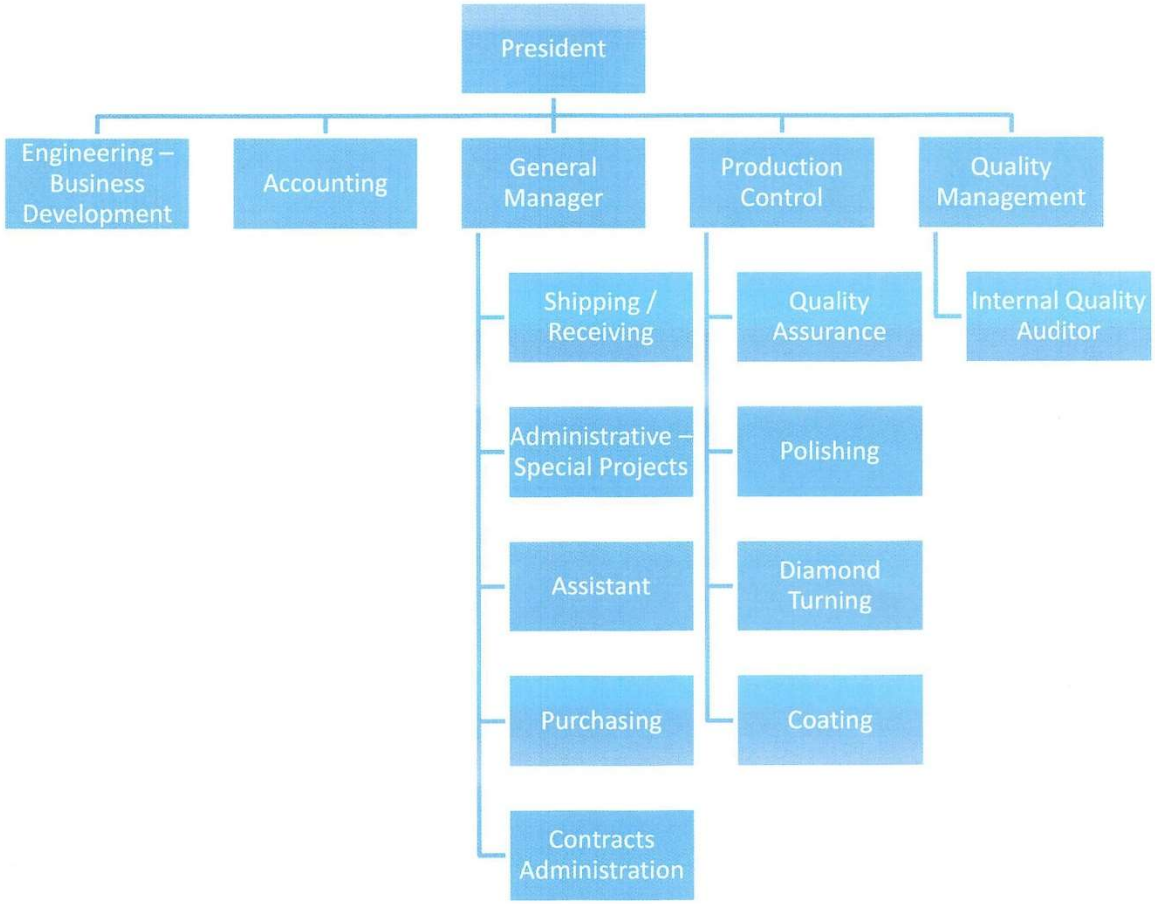
5.3 Organizational roles, responsibilities, and authorities

Top Management has assigned responsibility and authority for relevant roles throughout the organization as described in the Organizational chart in Schedule QM-07. The roles, responsibility and authority are communicated and understood throughout the organization.

Responsibility for ensuring that the QMS conforms to requirements of ISO 9001:2015 has been assigned to the Quality Management Representative.

Ensuring processes are delivering intended outputs is the responsibility of the auditors and top management.
The Management Representative is responsible for communicating the performance of the QMS and opportunities for improvement to Top Management at Management Review.
Customer focus and the integrity of the QMS when changes are planned and implemented is the responsibility of contracts, administration, and document control.

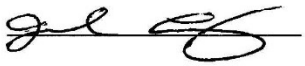
Organization



Duties and Responsibilities (continued)

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

Jonah Lowery  (signature)

Quality Auditor

Jonah Lowery  (signature)

Jill Lowery  (signature)

Signature of Approval


President

Date

June 16, 2025

6 Planning

6.1 Actions to address risks and opportunities

6.1.1

Manasota Optics, Inc. maintains a Risk Register that identifies potential risks and opportunities based on the identified external and internal issues and the needs and expectations of interested parties. The register describes the risk, response, level, owner, and identifies any required action by referencing the CAR number. The risk register is reviewed by top management annually at the management review meeting.
Risks regarding production are identified during the contract review process using Form 100.

6.1.2

Should actions be necessary to address risks and opportunities SOP 802 defines the process used to identify the root cause, action to be taken and how to integrate and implement the actions into the quality management system. Verification that the action taken was effective is recorded. The results of actions taken are further reviewed in Management Review.

6.2 Quality Objectives

6.2.1

Manasota Optics, Inc. has established quality objectives which are consistent with the quality policy, are measurable, consider applicable requirements, are relevant to the conformity of products and services and enhance customer satisfaction. The objectives are monitored and communicated in management review where they are updated, as necessary. The quality objectives are documented in the quality manual.

Documented information regarding the quality objectives is maintained in the management review minutes which include the plans to achieve the objectives.

6.2.2

Planning to achieve the quality objectives is performed at management review and recorded on Form 742 which includes:

- What will be done
- What resources will be required
- Who will be responsible
- When it will be completed
- How the results will be evaluated

6.3 Planning of Changes

Changes to the quality management system are planned at management review or throughout the year, as necessary.
Any changes are documented within the QMS using SOP 806 Document Control. The purpose of the change and potential consequences are considered upon review prior to release. The change made is recorded while the integrity of the system is maintained by acknowledging all applicable documents. Responsibility is assigned and noted on the document. Any required resources are made available.

7 Support

7.1 Resources

7.1.1 General

Manasota Optics, Inc. determines and provides the necessary resources for the establishment, implementation, maintenance, and continual improvement of the quality management system.
The capabilities of and constraints on internal resources are considered and training, work instructions and equipment are provided, as necessary. When the need arises, consultants or outside vendors for equipment needs are used to ensure the effectiveness of the quality management system.

7.1.2 People

Manasota Optics, Inc. provides the necessary personnel to ensure the effectiveness of the quality management system and its processes by retaining trained and experienced employees whose capabilities are reviewed annually.

7.1.3 Infrastructure

Manasota Optics, Inc. provides and maintains the necessary infrastructure for the operation of its processes and to achieve conformity of products and services including:
All required equipment to provide products and services to customers with ongoing equipment maintenance.

Manasota Optics, Inc. provides a calm, non-discriminatory multicultural workplace.
The infrastructure is maintained, well-lit with temperature and humidity controls in place. There are no required temperature or humidity controls for production.

7.1.5 Monitoring and measuring of resources

7.1.5.1 General

Manasota Optics, Inc. provides suitable equipment to verify the conformity of products and services to requirements. SOP 804 describes the controls for the maintenance of monitoring and measuring resources. The documented information verifying the fitness for purpose of the equipment is maintained on Form 705.

7.1.5.2 Measurement traceability

Equipment is calibrated at scheduled intervals to national measurement standards either in-house or by an approved outside service provider. All equipment has an asset ID number which is logged on the IMTE master list. Equipment is suitably safeguarded from adjustments, damage or deterioration in cabinets, bins, or cases as appropriate. Stickers on each asset identify the status.
A calibration discrepancy log is maintained. Any equipment found to be or has been unfit for purpose is segregated, calibrated and an investigation of prior measurement results is completed where necessary if the equipment was used in the verification of product.

7.1.6 Organizational Knowledge

Manasota Optics, Inc. has determined the necessary knowledge for the core processes. This information is maintained and available as manufacturing procedures within the quality management system.
Product specific knowledge is determined at the time the order is placed whereupon employees are made aware of the requirements and trained accordingly. Product specific knowledge gained is similarly recorded and maintained as product specific procedures within the quality management system.
Knowledge from outside sources necessary to the operations is maintained and regularly monitored for updates using Form 776.

7.2 Competence

Where personnel are assigned, responsibilities affecting product conformity, the Company has ensured that they are competent based on applicable education, training, and experience. 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 annually, and appropriate training records are maintained

7.3 Awareness

All the people at Manasota Optics, Inc. are made aware of the quality policy and relevant quality objectives. The quality policy is posted throughout the facility and a copy of the quality manual which includes the quality objectives is available to all employees at point of use.

7.4 Communication

Manasota Optics, Inc. communications relevant to the quality management system have been determined according to the ISO 9001:2015 certification and the quality policy. These are available internally through postings in the buildings and in the quality manual. External interested parties can access these on the company website.

7.5 Documented Information

7.5.1 General

The Company's management system documentation includes:

- Documented statements of quality policy and quality objectives
- The scope of the quality management system
- The documented procedures required by the Standard
- The documents needed to ensure effective planning, operation, and control of its processes
- The retained documented information required by the Standard

7.5.2 Creating and Updating

SOP 806 describes the process for creating and updating documented information.

7.5.3 Control of documented information

7.5.3.1

Documented information is available in the administration office at point of use in hard copy format in the controlled quality manual and procedures binders.

Additionally, controlled versions of all documented information are retained electronically on the company network.

7.5.3.2

Distribution, access, retrieval, use, storage and preservation, control of changes, retention and disposition are defined in SOP 806. The procedure defines:

- 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

Documented information of external origin i.e.: standards, regulatory requirements are identified and controlled through regular monitoring on Form 766.

Product specific procedures are controlled through revision control following SOP 806.

Documented information retained as evidence of conformity is controlled using the process laid out in SOP 815. This includes printed and electronic documents.

The procedure defines:

- The retention period
- Preservation and storage
- Protection
- Disposition

8 Operation

8.1 Operational Planning and Control

Manasota Optics, Inc. determines the processes for the products and services to be provided during initial contract review using Form 100 (and Form 101 as appropriate).
Production procedures and Customer Specific Procedures are created and controlled through the quality management system which include acceptance criteria and required resources to achieve conformity to product and service requirements.

The Process Traveler Form 700 is retained as evidence that the processes have been conducted as planned and that products conform to requirements.

8.2 Requirements for products and services

8.2.1 Customer Communication

Communication with customers includes:

Providing information relating to products and services through the company website and verbal response to inquiries, as necessary.
Inquiries, contracts, or orders, including changes, are communicated through quotes submitted to the customer following SOP 808.

Customer Feedback is obtained through customer satisfaction reports, customer supplied scorecards if applicable and emails. Complaints are addressed through the corrective and preventive action procedure SOP 802.

Handling and/or controlling of customer property is addressed through the process described in SOP 811.

Should contingency actions be required these will be discussed with the customer when relevant.

8.2.2 Determining the requirements for products and services

Manasota Optics, Inc. determines the requirements for products and services including any statutory and regulatory requirements through the quoting process as outlined in SOP 808. During this process, any requirements considered necessary by the organization are determined and Manasota Optics, Inc. ensures that they can meet the claims for the products and services they offer.

8.2.3 Review of the requirements for products and services

8.2.3.1

SOP 808 defines the procedure for reviewing a PO prior to acceptance. The review includes:

- Technical requirements
- Quality assurance requirements
- Statutory and regulatory requirements if applicable
- Customer approved special process suppliers
- Exceptions are specified
- Capacity/Delivery
- General terms and conditions
- Price
- FOB point
- Payment terms

8.2.3.2

Documented information on the results of the review and any changes or new requirements is maintained on Form 100, PO review sheet.

8.2.4 Changes to requirements for products and services

SOP 808 includes the process to be followed. When changes to requirements for products and services are made the relevant documentation – change order and job traveler - are amended and retained.

8.3 Design and Development

Manasota Optics, Inc. takes design and development as a justified exclusion as the company conducts no design or development activities.

8.4 Control of externally provided processes, products, and services

8.4.1 General

SOP 809 supplier purchase order procedure defines the controls to be applied to the purchase of outside processes, products, and services.

Manasota Optics, Inc.'s criteria for the selection of suppliers include:

- The supplier's inclusion on the approved supplier list
- Supplier capabilities
- Quality history
- Price
- Delivery

Initial evaluation is performed through the purchase of a limited quantity of goods and services which are subject to enhanced verification when necessary.

Form 740 Supplier Quality Survey and Form 741 Supplier Quality Survey – Minimum Quality Requirements are used for re-evaluation of machining, metal finishing, or coating suppliers that are not customer-approved or do not have ISO or NADCAP certifications. The Business Standards / Supplier Code of Conduct Acknowledgement is used for any suppliers handling customer product. A supplier performance report is created and presented at management review.

8.4.2 Type and extent of control

Manasota Optics, Inc. ensures that externally provided processes, products and services do not adversely affect the ability to consistently deliver conforming products and services to customers by:

- Ensuring that externally provided processes remain within the control of its quality management system by implementing the actions required in SOP 809.

- Defining the controls that it intends to apply to an external provider in the purchase order and those it intends to apply to the resulting output

Manasota Optics, Inc. takes 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 during the selection process (where applicable, suppliers may be customer mandated)

- The effectiveness of the controls applied by the external provider through SOP 800 Receiving and SOP 814 Incoming Inspection

The verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements are determined and included in the purchase order using Form 601 “PO attachment 2” as applicable.

8.4.3 Information for external providers

Manasota Optics, Inc. communicates to the supplier:

- Government contract number and priority rating
- Item description and part number (when different from drawing number)
- Drawing number and revision level
- Any special instructions imposed by MOI and/or their customer
- Quantity to be purchased
- MOI and/or customer required quality assurance /inspection requirements
- Applicable conditions for orders under US Government contracts
- Price
- Delivery

8.5 Production and service provision

8.5.1 Control of production and service provision

Production is controlled through product specifications, process travelers, and work instructions.

Suitable monitoring and measuring resources are used and properly maintained.

SOP 805 defines the procedure for In-process inspection and SOP 803 defines the Final Test & Release Criteria to verify that requirements have been met.

Production is conducted in a clean, well-lit, temperature and humidity-controlled facility with the appropriately maintained equipment.

People performing work are competent with required qualifications that are reviewed annually.

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.

Actions to prevent human error include providing detailed production procedures, training, in-process and final inspection and the review of the retained documented information to verify processes that have been completed as planned.
Product release, delivery, and post-delivery processes, if any, are defined.

8.5.2 Identification and traceability

Where traceability is a requirement, the Company controls and records the unique identification of the product.

8.5.3 Property belonging to customers or external providers

Handling and/or controlling of customer property is addressed through the process described in SOP 811.

8.5.4 Preservation

The Company identifies the product throughout the production activities and identifies its status with respect to measuring and monitoring activity throughout product realization process using the job travelers.

8.5.5 Post Delivery Activities

Post-delivery activities are limited to contractual obligations. Form 724 RMA is used to process the return. SOP 801 and/or SOP 802 would be followed to determine the nature of the nonconformity and determine the disposition.

8.5.6 Control of changes

SOP 808 includes the process to be followed when changes to requirements for products and services are made, the relevant documentation – change order and job traveler are amended and retained.

8.6 Release of products and services

SOP 805 defines the procedure for In-Process Inspection and SOP 803 defines the Final Test & Release Criteria to verify that requirements have been met. Travelers are reviewed and initialed to verify that all operations have been performed prior to release for shipping and retained as evidence of product conformity and evidence of the person authorizing the release.

8.7 Control of nonconforming output

8.7.1

Manasota Optics, Inc. controls nonconforming product through the implementation of SOP 801.The procedure defines the actions to be taken to correct, segregate, contain or return discrepant product, as necessary.

The customer is informed if required and a customer request for variance Form 732 is issued to obtain authorization for acceptance under concession where appropriate.
When products are corrected documented information of the correction is maintained on the rework portion of the traveler or a new traveler clearly showing the rework steps.
The product is then re-inspected to verify correction of outputs.

8.7.2

The documented information is retained which describes the nonconformity and the actions taken on DR Form 723 and in the DR Log Form 730. Concessions obtained are documented on the customer request for variance Form 732. The President or their designee deciding the action taken in respect of the nonconformity is identified on Form 723.

9 Performance Evaluation

9.1.1 General

Manasota Optics, Inc. monitors:

Supplier performance
Internal process performance
Product conformity
Calibration
Complaints
Customer Feedback
Competence
External and Internal Issues

The following forms and reports are used to perform the monitoring and measuring activities, as necessary.
The data contained within is analyzed and evaluated at management review.

Supplier Discrepancy Report Form 701
Internal Audit Report Form 710
Discrepancy Report Form 723
Return Material Authorization Form 724
Corrective/Preventive Action Request Form 726
Return Material Authorization Log Form 728

Corrective/Preventive Action Request Log Form 729
Discrepancy Report Log Form 730
Supplier Discrepancy Report Log Form 731
Supplier Quality Survey Form 740
Supplier Quality Survey – Minimum Quality Requirements Form 741
Management Review Meeting Form 742
Calibration Discrepancy Log Form 762
"Training Matrix" Form 767
Individual Training Record Form HR-001
Supplier Performance Report
On Time Delivery Report
Customer Satisfaction Report
External and Internal Issues Review Form 776
Risk Register
Variance Log Request Form 785

9.1.2 Customer satisfaction

Manasota Optics, Inc. monitors customers' perception of the degree to which needs and expectations have been fulfilled through customer satisfaction reports with the aim of achieving a 5 on a scale of 1-5 and by monitoring customer emails and customer scorecards (when applicable)

9.1.3 Analysis and evaluation

Manasota Optics, Inc. analyses and evaluates the data from monitoring and measurement activities. The results evaluate:

Conformity of products and services

The degree of customer satisfaction

The performance and effectiveness of the quality management system

If planning has been implemented effectively

The effectiveness of actions taken to address risks and opportunities

The performance of external providers

The need for improvements to the quality management system.

9.2 Internal Audit

9.2.1

Manasota Optics, Inc. conducts, at a minimum, annual internal audits. The internal audit records information regarding the conformance, effective implementation, and maintenance

of the quality management system to internal requirements and that of ISO 9001:2015.

9.2.2

Internal audits are planned; an internal audit program is maintained which records the frequency on the internal audit schedule. SOP 813 details the methods, responsibilities, planning requirements and reporting activities undertaken which include the audit criteria and scope for each audit on the audit check list.

Auditors are selected based on competence and impartiality to the area being audited. Results are reported to the responsible party and the President or designee.
Correction and corrective action when necessary are taken without undue delay.
Documentation is retained on Form 710 as evidence of the implementation of the audit program and the audit results.

Internal Audits of the Cyber Security System Plan are conducted annually including conducting a GAP analysis to identify hidden weaknesses with respect to DFARS regulations.

9.3 Management Review

Management review is performed, at a minimum, annually as described in SOP 816 and includes:

- The status of the actions from previous management reviews
- Changes in external and internal issues that are relevant to the quality management system
- Information on the performance and effectiveness of the quality management system, including trends in:
- Customer satisfaction and feedback from relevant interested parties
- The extent to which quality objectives have been met
- Process performance and conformity of products and services
- Nonconformities and corrective actions
- Monitoring and measurement results
- Audit results
- The performance of external providers

- The adequacy of resources
- The effectiveness of actions taken to address risks and opportunities
- Opportunities for improvement.

9.3.3 Management Review outputs

The management review minutes include decisions and actions related to:

- Opportunities for improvement
- Any need for changes to the quality management system
- Resource needs

The documented information is retained on Form 742 and associated attachments as evidence of the results of management review with copies provided to all attendees and those who have actions placed upon them.

10 Improvement

10.1 General

Manasota Optics, Inc. determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

Including:

- Improving products and services to meet requirements as well as to address future needs and expectations
- Correcting, preventing, or reducing undesired effects
- Improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and corrective action

10.2.1

Manasota Optics, Inc. reacts to nonconformities by:

Acting to control and correct it and deal with the consequences.

Evaluation is performed to assess the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

- Reviewing and analyzing the nonconformity
- Determining the causes of the nonconformity
- Determining if similar nonconformities exist, or could potentially occur
- Implementing any action needed
- Reviewing the effectiveness of any corrective action taken
- Updating risks and opportunities determined during planning, if necessary
- Making changes to the quality management system, if necessary.

Corrective actions are appropriate to the effects of the nonconformities encountered. SOP 802 defines the methods in which these activities are undertaken.

10.2.2

Documented information is retained on Form 726 CAR and Form 729 CAR Log as evidence of:

- The nature of the nonconformities and any subsequent actions taken
- The results of any corrective action

Where a supplier corrective action is determined to be necessary Form 701 SDR and Form 731 SDR Log are utilized and retained.

10.3 Continual improvement

The suitability, adequacy and effectiveness of the quality management system is continually improved considering the results of the evaluation of the data analyzed and the outputs of management review.

Table 1.

Sequence and Interaction of the Quality Management System

#	Process	*Related Procedures*	ISO 9001:2015 Clause
1.	Customer requirements are identified and confirmed	SOP 808 Customer RFQ and PO Review	8.2
2.	Quotations are sent and orders are received	SOP 808 Customer RFQ and PO Review	8.2
3.	Production Planning	SOP 808 Customer RFQ and PO Review	8.2
4.	Materials and services are purchased	SOP 800 – Receiving Procedure SOP 809 – Supplier Purchase Order Procedure SOP 811 – Control of Customer / External Supplied Product SOP 814 – Incoming Inspection	8.4, 8.5.3
5.	Production, verification, shipment	SOP 803 – Final Test and Release SOP 805 – In-process Inspection SOP 812 – Handling, Care and Packaging of Product SOP 815 – Control of Records	7.5, 8.5, 8.5.4, 8.6

Table 2.

Sequence and Interaction of the Quality Management System

PDCA	*Related Procedures*	ISO 9001:2015 Clause
Plan	SOP 806 – Document Control SOP 808 – Customer RFQ and PO Review SOP 809 – Supplier Purchase Order Procedure SOP 810 - Care and Control of Critical Tooling and Fixtures SOP 811 – Control of Customer / External Supplier Product SOP 817 – Resources Form 700 – Process Traveler Form HR-001 – Training Records	7, 7.1.3, 7.5, 8.2, 8.3.3, 8.4, 8.5.3, 8.5
Do	SOP 812 – Handling, Care and Packaging of Product Work Instructions Form 700 – Process Traveler	8.5.4
Check	SOP 800 – Receiving Procedure SOP 801 – Control of Nonconforming Product SOP 803 – Final Test and Release SOP 804 – Calibration SOP 805 – In-process Inspection SOP 813 – Internal Audits SOP 814 – Incoming Inspection SOP 815 – Control of Records Form 742 – Management Review Meeting Form 700 – Process Traveler	7.1.5, 7.5, 8.1, 8.4, 8.5, 8.6, 8.7, 9.2
Act	SOP 802 – Corrective and Preventive Action SOP 816 – Management Review SOP 818 – Measurement & Improvement Form 742 – Management Review Meeting	9.1, 9.3, 10.2