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AUTHOR: James Beifus  
Quality System Manager

APPROVAL: Ralph E. Barnes  
President

### 1.0 PURPOSE / SCOPE

#### “Manufacture and Assembly of Custom Injection Molded Products”

This Quality Manual documented for Ontario Plastics, Inc., (herein referred to as OPI) provides guidance for conducting our business within a quality management system compliant with ISO 9001:2008. These policies apply to all segments of our operation and to all phases of our product life cycle. While developed to implement and sustain the ISO 9001-2008 standard, these policies are also responsive to established statutory, regulatory, and customer standards for quality management.

A principle objective of these policies is to define standard requirements for managing our business, which lead to achieving our goals, sharing our values, and realizing our vision and mission. These policies provide essential guidance to the successful pursuit of our journey to satisfied customers, business growth, employee excellence, achieving productivity, and creating a great place to work through learning and innovation.

#### Exclusions:

7.3 Design and Development is excluded as Ontario Plastics does not design or develop product for our customers.

7.5.2 Validation of Processes for Production and Service Provision is excluded, as Ontario Plastics does not have any special processes whose output cannot be verified by subsequent monitoring or measurement.

### 2.0 REFERENCES AND LINKAGE

To provide support to the Quality Management System. As appropriate, there are procedure references identified at the end of categories. These provide further linkage and clarification of the OPI Quality Management System and its processes.

### 3.0 CHANGE HISTORY and INTRODUCTION

Date	REV #	Description of Change
12/02/05	A	Initial Release
04/01/06	B	Updated Organization Chart
5/15/08	C	Reviewed. Updated Management Team members and removed Organization Chart
01/06/10	D	Reviewed against ISO 9001:2008. 1.0 (and throughout) Updated reference to ISO 9001:2008 standard. 8.5.2 added provision for effectiveness. 8.5.3 added provision for effectiveness.
07/23/10	E	1.0 Added justification to exclusions, 5.3 Updated to current Quality Policy Appendix A: Blended into single Word Document file.

### 3.1 INTRODUCTION

- **BUSINESS DESCRIPTION**

Founded in 1946, OPI is located in Rochester, New York, USA. OPI is a custom injection molding company that serves an international base of distinguished and loyal customers from such diverse industries as electronic, aerospace, business machines and medical. Year to year our capabilities have consistently provided creative and economical solutions to the most demanding customer requirements. Our manufacturing processes are supported by up to 20 injection molding machines, and are supported by a state of the art tooling and quality control departments, and an experienced, team oriented work force that consistently maintains OPI's pride and tradition of producing the highest quality products and services.

An environment of continual learning and improvement supports and sustains the OPI Quality Management System. The entire process of manufacturing, assembly, packaging, storage and shipping is specified and guided by this system. The Quality Management process is designed and implemented to assure that suppliers and the entire supply chain are adequately controlled to ensure that Customer's standards as well as OPI's standards are satisfied. These processes are documented and implemented to provide early detection of discrepancies and to ensure positive root cause corrective actions and improvements, as necessary. Process Set-Up Sheets, Checkpoint Sheets, Work Instructions and Customer Part Folders information are in place at the manufacturing operation level ensuring critical customer specifications and testing are carried out in a controlled manner using the proper calibrated equipment in conjunction with work environment, infrastructure and facility preventive maintenance programs.

As stated by our Quality Policy and Quality Objectives, it is the goal of OPI and its people to provide product that conform to the requirements of our customers and to deliver them on time, defect free. We are committed to achieving and improving the high standard of personal and corporate excellence required to make this goal a reality. The responsibility for quality is with everyone jointly and individually in the Company from the Management Team to the Operations Team.

To effectively implement our Quality Policy, once the specifications are agreed with the customer, then it is up to each person in the company to ensure that his/her obligations are complete and to verify that the work is completed right the first time. Inspection and testing of products further verify the conformance to requirements. As stated, Quality belongs to everyone in our Company. In order to provide our customers that extra assurance the Quality Control function, through the Quality Manager and staff, is charged with the duty of enabling the organization to provide a standard of excellence to our clients and to produce the evidence that this has occurred.

- **DEFINITIONS**

- **FACTORED ITEMS**

- Any product purchased in its finished form that is inspected, trade dressed and subsequently resold without any value added operation and without control of the Ontario Plastics manufacturing process. OPI does not have Factored Items.

- **MANAGEMENT TEAM**

- A Management Team comprised of our top management: President, Engineering/Sales Mgr., Operations Mgr., Production Mgr., Customer Service Mgr., Quality System Manager, Office Mgr. and Purchasing/Shipping/Receiving Mgr.

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**Q9001-2008**

The term used for the reference document ANSI/ASQC Q9001-2008: American National Standards Institute/American Society for Quality Control. Q9001 references the Quality Standard, and 2008 is the revision date.

**4.0 QUALITY MANAGEMENT SYSTEM****4.1 GENERAL REQUIREMENTS**

The OPI Management Team recognizes that leading a successful business operation requires our organization to be managed in a systematic and visible manner. As a result, we have documented, implemented, and maintain a quality management system in accordance with the requirements of the ISO 9001-2008 International Standard. We have identified our processes so they are clearly understood and can be more easily applied, managed and improved. The sequence and interaction of these processes as well as the criteria and methods required for the effective operation and control of these processes have been described in this quality manual, see Appendix A (Process Chart). The Management Team determines and makes the necessary resources and information available to support the operation and monitoring of these processes. Any outsourced processes are identified and controlled within the Quality Management System.

**4.2 DOCUMENTATION REQUIREMENTS****4.2.1 GENERAL**

OPI has a functional and documented Quality System to ensure that all the products produced conform to specified requirements. Our quality management system includes the procedures required by the Q9001-2008 American National Standard, this Quality Manual, specifications, system procedures, functional job work instructions, the Quality Policy and Quality Objectives. OPI maintains the records required by the Q9001-2008 Standard as well as additional records required to support and improve the Quality System (see 4.2.4) and ensures effective implementation by reviewing these records. The extent and nature of our process documentation is based on the complexity and interaction of the processes, as well as, the competence of our personnel. Reviewing contractual requirements, applicable standards, and relevant regulations ensure that the necessary documentation is in place.

The Quality System documentation is structured in a pyramidal form, with the Quality Manual at the Apex. Supporting documents are divided into three major groups: Quality Procedures, Work Instructions, and Forms/Records.

## QUALITY SYSTEM DOCUMENTATION STRUCTURE

**Level and Document Name**

**Description of Level**

Level I  
Quality Manual (QM)

Business Quality Policies  
And Principles

Level II  
Quality Procedures (QP)

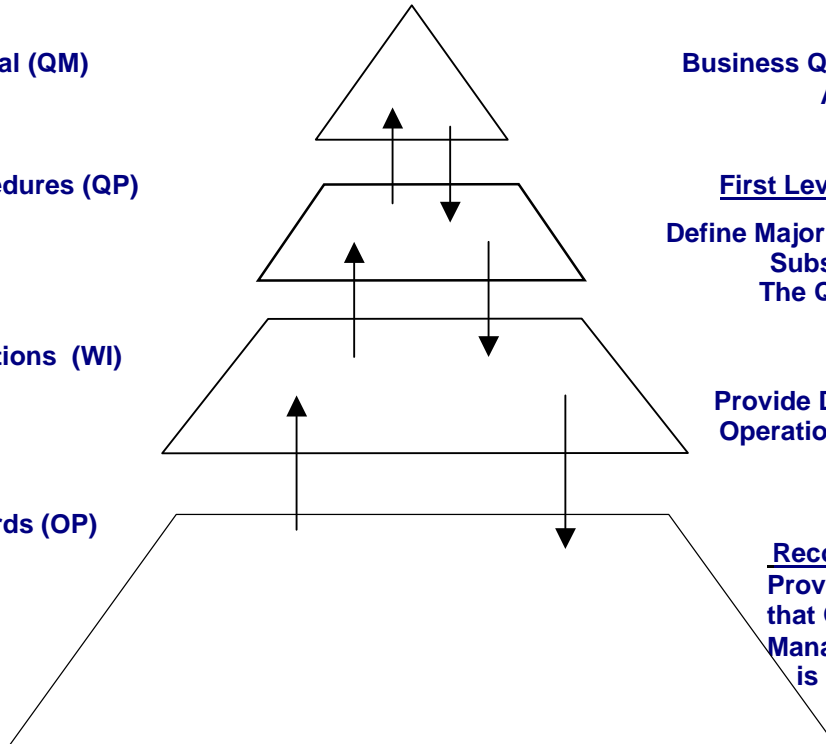
First Level Procedures  
Define Major Elements and  
Subsystems of the  
The Quality System

Level III  
Work Instructions (WI)

Provide Detailed  
Operation Instructions

Level IV  
Forms/Records (OP)

Records  
Provide Evidence  
that Quality  
Management System  
is implemented



### 4.2.2 QUALITY MANUAL

The Quality System Manager has the responsibility and authority for maintaining this document and is responsible for the review, maintenance, and update of the material as well as authorization of changes. All users of this manual are responsible for advising the Quality System Manager when a change to their operation impacts the material described herein. To provide linkage and support for each section of this manual, applicable procedures will be referenced. Changes and control are handled in accordance with procedure QP-QS-001: Control of Documents.

### 4.2.3 CONTROL OF DOCUMENTS

Procedure QP-QS-001: Control of Documents has been implemented to control all documents necessary to support the Quality System. The control extends to documents of external origin such as standards and customer furnished documents, to the extent applicable. Master lists are used to identify the latest revision of controlled documents. Any obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified and stored. Changes made to Quality System documents and data are subjected to a review process by those functions having performed the original review. The designated reviewers have access to pertinent background information upon which to base their review and approval. The nature of the change and the current revision status is identified in the document.

**REFERENCES & LINKAGES:**

QP-QS-001: Control of Documents

#### 4.2.4 CONTROL OF RECORDS

Records are maintained in designated locations appropriate to the nature of the record. Procedures provide for storage and maintenance methods to prevent deterioration and loss, and also allow for ready retrieval when required. These records demonstrate conformance to specified requirements or document authorized concessions. Analysis of these records enables the product and process to be monitored against requirements and demonstrates the effective operation of the Quality System. Guidelines for the retention and handling of records within OPI, comply with and are compatible with customer's requirements and are made available to customers when stipulated in contracts.

##### REFERENCES & LINKAGES:

QP-QS-002: Control of Records

## 5.0 MANAGEMENT RESPONSIBILITY

### 5.1 MANAGEMENT COMMITMENT

The Management Team communicates the importance of meeting customer, as well as, regulatory and legal requirements. We demonstrate our management commitment by maintaining our quality policy, monitoring quality objectives, providing adequate resources, and conducting management reviews.

### 5.2 CUSTOMER FOCUS

Our success as an organization depends on understanding and satisfying the needs and expectations of our customers. We have processes in place to determine expectations, convert them into product requirements, monitor, measure, and meet them with the aim of enhancing customer satisfaction.

### 5.3 QUALITY POLICY

**Ontario Plastics  
Is Committed to:  
'Bending Over Backwards'  
for our Customers  
and each other.**

**Striving to continually improve in the eyes  
of our customers, our employees, and owners.**

**Monitoring and measuring our effectiveness through:  
Employee Excellence  
Customer Satisfaction  
Operations Excellence**

This Quality Policy is communicated and posted throughout our facility. Audits are used to ensure the quality policy is understood within our organization. We review the policy statement at the management review meeting to ensure its continued suitability and use it as the framework for setting our quality objectives.

## 5.4 PLANNING

### 5.4.1 QUALITY OBJECTIVES

Measured quality objectives are established and deployed throughout the organization. They are communicated so employees understand their contributions. These objectives are measurable and defined for consistency with our Quality Policy, meeting product requirements, and used as a means or analysis of data and continual improvement.

There are three primary Quality Objectives that will successfully achieve our Quality Policy and Objectives:

- **Employee Excellence**: To create and maintain a workforce of continuous learning, that will possess the knowledge and skills necessary to meet our business and customer requirements.
- **Customer Satisfaction**: To create a work system that effectively identifies, measures, and optimizes customer requirements and satisfaction.
- **Operational Excellence**: To develop work system excellence in a way that allows proper resourcing, perfection of the material flow, and cost management, thus achieving Quality and financial superiority.

Three Quality Objectives are implemented through “Key Result Areas” and “Key Result Measures”. Key Result Measures provide the catalyst for continuous improvement efforts. These are closely monitored and communicated throughout the organization.

### 5.4.2 QUALITY MANAGEMENT SYSTEM PLANNING

The OPI Quality Management System contains procedures and processes that address Quality Management System Planning. The integrity of the quality management system is maintained through regularly scheduled Management Review meetings, which address the overall performance of the company and its quality system. The contract review process assures customer product requirements and specifications are achievable in the timeframe required and with our technical and personnel capabilities.

#### REFERENCES & LINKAGES:

QP-QS-003

## 5.5 RESPONSIBILITIES, AUTHORITY, AND COMMUNICATION

### 5.5.1 RESPONSIBILITY AND AUTHORITY

Responsibilities and authorities of employees are defined in QP-MR-001: Management Responsibility and more specifically called out in the various work instruction procedures. Management communicates the responsibilities and authority through training and the employee performance reviews.

### 5.5.2 MANAGEMENT REPRESENTATIVE

The Quality System Manager has been appointed as the management representative with Quality responsibility and authority for ensuring organizational conformance with Q9001. This Manager ensures processes are established, implemented, and maintained; and promotes awareness of customer requirements throughout the organization. This Manager is also responsible for reporting the performance of the Quality System to the Management Team at the Management Review

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meeting. The Management Representative serves as the Liaison with external parties on matters relating to the Quality System.

### **5.5.3 INTERNAL COMMUNICATIONS**

The OPI Management Team communicates quality requirements, objectives, audit results and accomplishments that define the effectiveness of the Quality Management System within the various levels and functions of our organization. This communication takes place through such vehicles as team meetings, company meetings, notice boards and electronic medium.

## **5.6 MANAGEMENT REVIEW**

The Quality System Manager is responsible for planning, scheduling, documenting and maintaining records for the Management Review meetings. The purpose is to ensure continuing suitability, adequacy, effectiveness, and compliance of the Quality System with Q9001 and to review the Quality Policy and Objectives. The agenda for the Management Review includes topics required by the ISO 9001-2008 standard and outlined in the Management Responsibility procedure. As a result of these reviews, decisions and action items related to resource needs, improvements to the effectiveness of the Quality Management System, its processes, and customer requirements are documented.

#### **REFERENCES & LINKAGES:**

**QP-MR-001: Management Responsibility**

## **6.0 RESOURCE MANAGEMENT**

### **6.1 PROVISION OF RESOURCES**

The Management Team identifies the resources needed to implement and maintain the quality management system, to continually improve its effectiveness and to enhance customer satisfaction by meeting customer requirements.

### **6.2 HUMAN RESOURCES**

OPI ensures personnel that perform work affecting product quality are competent on the basis of the appropriate education, training, skills, and experience. Employee training addresses specific areas required for current or future job assignments. This analysis considers present and expected needs of the organization and the existing competence levels. Training is arranged to provide the knowledge, which together with skills and experience, will lead to the needed competence. Effectiveness of the training is evaluated and records are maintained for each employee. In addition, employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objective and business impact when requirements are not achieved.

#### **REFERENCES & LINKAGES:**

**QP-RM-001: Training**

### **6.3 INFRASTRUCTURE**

The OPI Infrastructure provides the foundation for effective operations. We identify, provide, and maintain the infrastructure necessary to achieve product conformity, including buildings, workspace, utilities, equipment, software, tools, transport and communication services.

#### **REFERENCES & LINKAGES:**

**QP-RM-002 Equipment Maintenance and Infrastructure**

## 6.4 WORK ENVIRONMENT

The human and physical factors needed to achieve product conformity have been determined and managed. Human factors include such things as work methods and safety guidance. Physical factors may include where appropriate, noise, lighting, cleanliness, and airflow.

OPI devotes attention and has high regard for the safety and general well being of every employee. Procedures exist to ensure that all safety and environmental regulations are in place and monitored. Further, all employees receive ongoing training to ensure safe working habits are developed, safe practices and procedures are implemented and understood.

### REFERENCES & LINKAGES:

QP-RM-003: Work Environment and Safety Management

## 7.0 PRODUCT REALIZATION

### 7.1 PLANNING PRODUCT REALIZATION

OPI plans and develops the processes needed for product realization ensuring these are consistent with the requirements of other processes of the quality management system (see 4.1 and 5.4.2 for details). In planning for product realization, consideration is given, where appropriate, to quality objectives, product/customer requirements, documentation, resources, inspection and test activities and records needed to provide evidence that the realization processes and resulting product meet requirements. The output of this planning is made suitable to OPI methods of operation.

### REFERENCES & LINKAGES:

QP-MR-001: Management Responsibility

QP-PR-005: Process and Product Control

QP-PR-001: Contract Review and Order Entry

### 7.2 CUSTOMER –RELATED PROCESSES

We follow a defined process to communicate with customers regarding products, inquiries, contracts, orders, amendments and customer feedback and complaints. Customer requirements are identified, including requirements for product availability, delivery, and support. We determine any product requirements not specified by the customer, but necessary for the intended product use, where known. Statutory and regulatory requirements are also identified. Appropriate personnel review every contract to ensure that all customer requirements are adequately defined, understood, differences resolved, and that the company has the technical capability and operational capacity to meet the stated requirements. In the case where requirements definition is a portion of the contract, mutually agreed to plans are developed with the customer to define these requirements. It is our policy to accept verbal contracts only when written confirmation of the order is received within the time period agreed upon by the company and the Customer. Amendments to contracts are reviewed and processed in the same manner as the original contract to ensure that changes are communicated in a timely manner to the appropriate functional area.

### REFERENCES & LINKAGES:

QP-PR-001: Contract Review and Order Entry

### 7.3 DESIGN AND DEVELOPMENT “Exclusion and Justification”

OPI does not presently have the in house capabilities or resources necessary to design and develop products. Currently, customers provide a part drawing, FAX and/or CAD file at which time

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OPI determines if it has the technical ability and manufacturing capacity to make the product and meet all requirements specified. If determined that we can manufacture this product to meet specifications, the request for quote is completed and the process and product cycle begins. A mold is then developed and manufactured by an approved mold maker (unless the customer supplies the mold). When the materials and mold are received, the sample order provides a tracking method for initial trial runs. Product prototypes are then inspected to ensure they meet with customer requirements and sent to the customer for approval. If there comes a time when OPI does acquire the capability and resources to design and develop products and molds, procedures and processes will be identified, implemented and controlled to meet all requirements stated in 7.3 Design and Development of the Q9001 standard.

#### **7.4 PURCHASING**

The purchasing process is documented to ensure that suppliers provide products and services that conform to specified requirements. Suppliers are evaluated and selected on the basis of their ability to meet OPI requirements. Supplier evaluation criteria may include Supplier Survey and Evaluation, product performance, delivery, and price. The depth and complexity of the evaluation process varies with the type of material supplied and demonstrated supplier capability and performance. Supplier performance is monitored regularly and supplier ratings are revised accordingly. An Approved Supplier Listing is maintained. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

Purchasing documents contain data that accurately describes the product, material, or service, supplier, and other relevant process and technical requirements which may include requirements for the qualification of personnel or quality system management requirements. The buyer is responsible for ensuring the details of the purchase order are an accurate description of the requirements. Where appropriate, OPI may choose to verify purchased product at the supplier's premises. The methods for verification and product release are specified in purchasing documents. Our system also provides for customer inspection of purchased products at the supplier's premises, and customer visitation, when required by contract. Customer inspection at the supplier's premises does not absolve OPI of the responsibility to provide acceptable product nor does it preclude subsequent rejection by the customer. Customer inspection requirements and the methods for verification and product release are specified in the purchasing documents.

**REFERENCES & LINKAGES:**

**QP-PR-002: Purchasing and Supplier Control**

#### **7.5 PRODUCTION AND SERVICE PROVISION**

##### **7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION**

Procedures and Work Instructions outline the general criteria used in manufacturing, inspecting, testing, handling, and use of suitable equipment. Manufacturing process set up sheets; check point sheets and work instructions are used to provide a description of the tasks involved in manufacturing a particular product and the controlled conditions. Status of product is identified on the inspection reports, as it completes its manufacturing cycle. Special processes are defined and documented by the Management Team.

**REFERENCES & LINKAGES:**

**QP-PR-005: Process and Product Control**

##### **7.5.2 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION**

OPI products are verified during production through weight and dimensions of the product. Therefore special processes do not apply to OPI.

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If OPI were to have any special processes in the future, we shall have processes validated to achieve planned results.

### **7.5.3 IDENTIFICATION AND TRACEABILITY**

Where appropriate, instructions are maintained for identifying product from time of receipt and throughout all stages of production and delivery by suitable means. Part number, lot number, and serial number maintain traceability. Where applicable, unique identification of assemblies, subassemblies, components, materials, and parts is maintained and recorded for ensuring that identification is maintained at all times.

Instructions exist throughout receiving, production, inspection, and test operations for identifying the inspection and tests status of incoming material and process and finished product. These systems ensure that only product which has passed the required inspection or testing, or product released under an authorized concession by the Customer is released for subsequent use or delivery.

#### **REFERENCES & LINKAGES:**

**QP-PR-005: Process and Product Control**

### **7.5.4 CUSTOMER PROPERTY**

As appropriate, customers may provide us with specifications, drawings, components, etc. for our use as we manufacture their order. A process is in place so that we properly identify, verify, store and maintain customer property according to the requirements necessary for proper control. In addition measures are outlined that address the potential for lost, damaged, or product otherwise unsuitable for use. Customer supplied product receives a unique part number and is stored in a location separate from general raw materials to prevent inadvertent use.

#### **REFERENCES & LINKAGES:**

**QP-PR-005: Process and Product Control**

### **7.5.5 PRESERVATION OF PRODUCT**

Handling, storage, packaging, preservation and delivery of product are controlled by manufacturing checkpoint sheets, work instructions, and customer part folders. It is the responsibility of all personnel who handle, store, package, preserve and deliver product from initial material receipt through final product shipping to ensure that product and materials are handled safely and are secure from damage. Environmental conditions such as cleanliness, humidity, temperature control, etc. are maintained where appropriate to ensure the integrity of the materials and product, including constituent parts, throughout the manufacturing process. If material shelf-life sensitivity is required, it will be maintained.

#### **REFERENCES & LINKAGES:**

**QP-PR-003: Preservation Of Product and Materials**

## **7.6 CONTROL OF MONITORING AND MEASURING DEVICES**

OPI uses the equipment Gage Track System to ensure production; monitoring and measuring equipment having a direct effect on product quality is maintained to a properly calibrated condition using traceable standards so that all measurements taken are valid and of known accuracy.

Where test equipment is used for inspection, capability verification will be determined prior to use and rechecked at prescribed intervals. Records of such control will be maintained.

When requested by the customer, measurement data will be made available for verification of functional adequacy.

In addition, we assess and record validity of the previous measuring results when equipment is found not to conform to requirements. We take appropriate action on the equipment and any product affected. Records of results of calibration and verification are maintained.

REFERENCES & LINKAGES: QP-PR-004:  
Control of Monitoring and Measuring Devices

## 8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

### 8.1 GENERAL

OPI monitors, measures, and evaluates its products, processes, and customer satisfaction at appropriate intervals. The resulting data is analyzed to;

- Demonstrate conformity of the product
- Ensure conformity of the quality management system
- Continually improve the effectiveness of the quality management system.

If and when the need for statistical techniques is identified, procedures would be established and maintained to implement and control the application of the techniques. Appropriate education and training would be provided to those applying statistical techniques.

REFERENCES & LINKAGES:  
QP-PR-005: Product and Process Control  
QP-AI-005: Analysis of Data and Continuous Improvement

### 8.2 MONITORING AND MEASUREMENT

#### 8.2.1 CUSTOMER SATISFACTION

The essence of the OPI Quality Policy is to ensure that "Total Customer Satisfaction" is maintained and implemented at all levels of the organization. To ensure that Customer Satisfaction is embedded in our culture, all employees have been trained to recognize how they impact Quality and Customer requirements, and on an on-going basis, a continuous cycle of process and product improvements are identified, implemented and monitored. Customer feedback is obtained through various means and is used to monitor the customer's perception as to whether OPI has met the customer's requirements

REFERENCES & LINKAGES:  
QP-PR-001: Contract Review and Order Entry  
QP-AI-001: Customer Satisfaction Survey  
QP-MR-001: Management Responsibility

#### 8.2.2 INTERNAL AUDIT

Internal audits of the Quality System are systematically performed to ensure compliance with documented Quality System and the ISO Q9001-2008 Standard and to ensure that the quality management system is effectively implemented and maintained. Internal quality audits are the responsibility of the Quality System Manager, and are conducted by qualified personnel who are independent of the function being audited. The audit program is designed so that all aspects of the quality system are audited at least once a year.

Results of audits are documented and promptly reported to the responsible Management Team member.

Each member ensures that timely corrective action is taken against Internal Quality Audit results. Records of all audit activities and corrective actions are maintained. Analysis of these records is completed, and the results are reviewed at the management review meetings. Internal Quality Audits further require verification of the implementation and effectiveness of the corrective action taken.

**REFERENCES & LINKAGES:**

QP-AI-002: Internal Audits

**8.2.3 MONITORING AND MEASUREMENT OF PROCESSES**

Operations personnel apply suitable methods for monitoring and measuring the realization processes necessary to meet customer requirements in their functional area of responsibility. These methods demonstrate the ability of this process to achieve planned results and if not achieved, appropriate correction and corrective action is taken.

**REFERENCES & LINKAGES:**

QP-PR-005: Process and Product Control

**8.2.4 MONITORING AND MEASUREMENT OF PRODUCT**

Product characteristics are monitored and measured to verify product requirements are met. The monitoring and measuring activities are carried out at the appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria is maintained and records indicate the person (s) that authorized release of the product. Product release does not proceed until all the specified activities have been satisfactorily completed, unless otherwise approved by the customer. Records provide evidence of product conformity or nonconformity to specifications and identify the authority for release. The Quality Control Manager or designee has the authority to release final product.

**REFERENCES & LINKAGES:**

QP-PR-005: Process and Product Control

QO-WI-001: Receiving Inspection

**8.3 CONTROL OF NONCONFORMING PRODUCT**

A documented process ensures that nonconforming product is prevented from use. The control process provides for identification, documentation, evaluation, segregation (when practical) and disposition of product as well as notification of affected personnel or operations. The responsibility for review and authority for the disposition of nonconforming product is identified. Corrective Actions are taken to ensure that the product is verified to meet customer requirements. Nonconforming product reports and customer concessions are maintained.

**REFERENCES & LINKAGES:**

QP-AI-003: Control of Nonconforming Product

**8.4 ANALYSIS OF DATA**

OPI determines, collects, and analyzes data from processes, operations, and records to determine the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality system can be made. This includes data generated as a result of monitoring and measurement and other relevant sources. The analysis of data provides OPI with information relating to

- Customer Satisfaction
- Conformity to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action.

**REFERENCES & LINKAGES**

QP-AI-005: Analysis of Data and Continuous Improvement

## 8.5 IMPROVEMENT

### 8.5.1 CONTINUAL IMPROVEMENT

We plan and manage the processes necessary for the continual improvement of the Quality Management System. Continual improvement is facilitated through the use of the quality policy, quality objectives, audit reports, data analysis, corrective and preventive actions, and management reviews.

**REFERENCES & LINKAGES**

QP-AI-005: Analysis of Data and Continuous Improvement

### 8.5.2 CORRECTIVE ACTION

Documented Corrective Action processes are designed to detect and correct deficiencies, or conditions that adversely affect quality as well as review the effectiveness of the action taken. Any corrective action taken to eliminate the cause of nonconformity will be to a degree appropriate for the magnitude of the problem and commensurate with the risks encountered.

**REFERENCES & LINKAGES:**

QP-AI-004: Corrective Action and Preventive Action

### 8.5.3 PREVENTIVE ACTION

Preventive Action processes are designed to detect and correct potential deficiencies, trends, or conditions that may adversely affect quality as well as review the effectiveness of the action taken. Any preventive action taken to eliminate the cause of a potential nonconformity shall be to a degree appropriate for the magnitude of the problem and commensurate with the risks encountered.

**REFERENCES & LINKAGES:**

QP-AI-004: Corrective Action and Preventive Action

## APPENDIX A

