

# **Quality Manual**

\*\*\*\*\*\*\*\*\*

6/18/2017

**Revision 15** 



# Top management approvals

Function/Title:	Approval Signature:	Date:
President	Brian Stevens	6/19/17
Operations Manager	Chris Payne	6/19/17
Quality Assurance	Will Snyder	6/19/17
Engineering Manager	Joe Holt	6/19/17
Business Development Mgr	Mariann Snyder	6/19/17
Controller	Holly Sawyer	6/19/17
HR	Kiersten Kane	6/19/17



#### Introduction

Vision Plastics has developed and implemented a Quality Management System (QMS) in order to document the company's best business practices, better satisfy the requirements and expectations of its customers, and improve the overall management of the company.

The QMS of Vision Plastics meets the requirements of the International Standard ISO 9001. This system addresses new product introduction and production of products for our customers.

The manual is divided into eleven sections. Ten sections correlate to the QMS sections of ISO 9001: and one addresses Social and Environmental Responsibility. Each section describes Vision Plastics' intention to implement the requirements of the section and provides additional information and reference to the methods used to implement the specific requirements.

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

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

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



# Section 1: Purpose

The purpose of this quality manual is to establish and state the general policies governing Vision Plastics' QMS for managing our operations and activities in accordance with the framework established by ISO 9001. These are the top-level policies representing the company's plans or protocols for achieving quality assurance and customer satisfaction. Additional documented information conforms to and parallels these policies. All changes to documented information are reviewed to ensure no conflicts exist with the policies stated in this quality manual.

# Section 2: Scope

The policies stated in this manual apply to all operations and activities at Vision Plastics.

## 2.1 The scope of Vision Plastics' activities under ISO 9001 is:

"Manufacture of Plastic Injection Molded Products and Assemblies."

## 2.2 Applicability:

Vision Plastics has determined the following requirements of ISO 9001 are not applicable since they are not in the scope of our company:

ISO 8.3 Design and development - Vision Plastics does not engage in designing, developing or changing the design of the customer products we manufacture.

ISO 8.5 Control of production and service provision – as related to the service provision, post-delivery servicing is not a specified requirement.

These requirements do not affect Vision Plastics' ability or responsibility to provide product meeting customer and/or applicable regulatory requirements.



# 3 General information Company Description:

Vision Plastics Inc. 26000 SW Parkway Center Drive Wilsonville, OR 97070 www.Visionplastics.com

Vision Plastics was founded in 1988 and is one of the most highly regarded custom injection molding companies in the Pacific Northwest. The combination of state-of-the-art equipment in a modern building and the most highly talented plastics professionals available make this success possible.

Vision Plastics manufactures plastic products with over 40 injection molding presses ranging from 18 to 950 tons with the capability of molding a wide range of parts to extremely tight tolerances. We have expertise with injection molding a broad range of thermoplastic materials including engineering resins, elastomers and filled materials. We employ approximately 175 employees.

Vision Plastics is a full service plastic injection molder providing complete manufacturing solutions from concept to finished product with the following additional value added services:

- Ultrasonic Welding
- Ultrasonic Inserting
- Tapping, Drilling
- Press Fit Inserting
- Heat Staking
- Gluing, annealing
- Machining of plastic and metals (CNC center)
- Coating (paint, dag, metalizing, powder coating)
- Decorating (Heat transfer, Screen Print, and Pad Printing)
- Electro-mechanical assembly

ISO Certificate Identification Number: 74 300 8539 Issued by TUV Rheinland of North America.



#### Quality Policy

We are committed to:

- Providing a safe and healthful workplace
- Continually improving our quality management system
- Complying with customer requirements
- Reducing our environmental impact
- Aiming to enhance customer satisfaction
- Providing products and services on-time

#### **Quality Objectives**

We use the following objectives to monitor and improve processes at relevant functions and levels within the organization. These objectives are measured regularly, reviewed at least annually and actions are taken when results do not meet the targets.

- Track supplier performance and maintain a minimum of 99% On Time Delivery (OTD).
- Maintain less than 1% defects in our Manufacturing processes.
- Maintain a minimum of 99% OTD.
- Maintain less than 200 Defects per Million (DPM) shipped to customers.
- Continually improve safety and permanent employee turnover.
- Reduce the impact on the environment through reduction, reuse and recycling

# 4 Vision Plastics organizational context

## 4.1 Organization and context

Vision Plastics has determined the issues that are relevant to its purpose, strategic direction, and that affects the results of the QMS. Issues, internal and external, are monitored and reviewed.

#### 4.1 General requirements

Vision Plastics has established, documented, and implemented a QMS in accordance with the requirements of ISO 9001. The system is maintained and continually improved through the use of the documented information, quality objectives; internal & external audit results, analysis of data, corrective action and regular management reviews.

To design, implement and manage the QMS in accordance with the requirements of ISO 9001, Vision Plastics has:

- Identified the processes needed for the QMS and their application throughout the organization.
- Determined the inputs, outputs, sequence and interaction of these processes.
- Determined criteria and methods needed to address risks and opportunities; ensuring the operation and control of the processes are effective.
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes.

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



- Established systems to monitor measure and analyze these processes.
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes, including outsourced processes.
- Determined the criteria and information necessary to ensure required regulations and standards are met.

# 5 Leadership

# 5.1 Management commitment

Top management is actively involved in implementing and maintaining the QMS by providing the vision and strategic direction for the growth of the QMS and establishing quality objectives and the quality policy.

To continue to provide leadership and show commitment to improving the effectiveness of the QMS, Management does the following:

- Takes accountability for the effectiveness of the QMS.
- Ensures the quality policy and quality objectives are compatible with the context and strategic direction
- Ensures that the QMS requirements are integrated into the business processes.
- Fosters risk-based thinking and a process approach.
- Ensures the availability of resources.
- Communicates the importance of effective quality management and of conforming to the QMS requirements.
- Conducts regular management reviews to ensure the QMS achieves it intended results.
- Supports and leads people to contribute to the effectiveness of the QMS.
- Promotes continual improvement.
- Supports managerial roles to demonstrate their leadership in their areas of responsibility.

#### 5.1.2 Customer focus

Management commits to customer focus through:

- Determining, understanding and meeting applicable requirements
- Identifying the risks and opportunities of product conformance
- Determining and addressing the ability to enhance customer satisfaction
- Maintaining the focus on enhancing customer satisfaction

## 5.2 Quality Policy

Top management ensures the quality policy is appropriate to the purpose of the organization, supports its strategic direction and communicated to all employees. It is included in new employee training and posted throughout the plant to maintain high standards within our organization. It is made available to other interested parties as it is part of this quality manual, and the quality manual is available on our website.

Management reviews the quality policy periodically to determine the policy's continuing suitability for our organization, confirms the company's commitment to comply with ISO 9001 requirements and **Printed copies of this document are not controlled**. It is the responsibility of the user to verify the correct revision prior to use.



provides a framework for establishing, reviewing and continually improving the company's quality objectives.

# 5.3 Organizational roles, responsibilities and authorities

Top management ensures the responsibilities and authorities for relevant roles are identified, communicated and understood within the organization. Responsibility and authority is assigned to:

- Ensure the QMS conforms to ISO 9001
- Ensures the processes are delivering their intended outputs
- Reports on the performance of the QMS to top management
- Promotes customer focus throughout the organization
- Ensure the integrity of the QMS is maintained when changes to the QMS are planned and implemented

An organizational structure has been established to show the interrelation of personnel in the organization. (See Figure 1, Organizational Chart). Job descriptions define the responsibilities and authorities of each position. Job descriptions and the organizational structure are reviewed and approved by top management for adequacy.



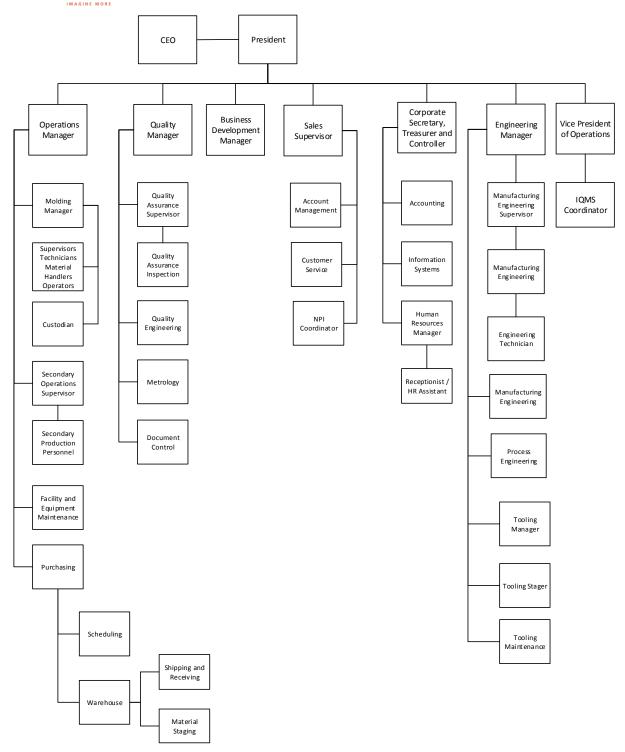


Figure 1 Organizational Chart

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



# 6 Planning

## 6.1 Actions to address risks and opportunities

Our organization considers the risks and opportunities that need to be address to ensure the QMS can achieve its intended results, enhance desirable outcomes, reduce undesirable effects and achieve improvement. To ensure these results, our organization plans actions to address risks and opportunities, integrates and implements the actions into its QMS processes; and evaluates the effectiveness of these actions.

## 6.2 Quality objectives and planning

#### 6.2.1 Quality objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed periodically for suitability. Quality objectives are measurable and are reviewed during management meetings for adherence to applicable requirements, including conformance and enhancement of customer satisfaction. When these quality objectives are not met, actions are taken to improve the results.

## 6.2.2 Quality Management System planning

The QMS has been planned and implemented to meet our quality objectives and the requirements of the ISO 9001: standard. Quality planning takes place as changes affecting the quality system are planned and implemented to ensure the integrity of the system is maintained. Planning includes identifying tasks, resources, responsibilities, task completion and review.

## 6.3 Planning of changes

When changes are required to the QMS, changes are carried out in a planned manner. Considerations include:

- Purpose for the change
- Potential consequences of the change
- Integration to the QMS
- Resource availability
- Allocation or reallocation of responsibilities and authorities

# 7 Support

#### 7.1 Resources

During planning and budgeting processes and as needed throughout the year, top management will determine and ensure the appropriate resources are available to implement and maintain the quality management system, continually improve its effectiveness and enhance customer satisfaction by meeting customer requirements.

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



#### 7.1.1 General

Vision Plastics as determined and provides resources needed for the establishment, implementation, maintenance and continual improvement of the QMS. Capabilities and constraints on internal resources and availability of external resources is considered.

#### 7.1.2 People

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position have changed. Human Resources maintain records of employee qualifications, education, training, skills and experiences. Training and evaluation are conducted according to the P009 Training Procedure.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

#### 7.1.3 Infrastructure

Vision Plastics provides the infrastructure necessary to achieve conformity to product requirements. During the budgeting and strategic planning processes; buildings, equipment, workspace, and associated utilities are evaluated and provided. When new personnel are added, hiring managers coordinate activities to ensure appropriate process equipment including hardware and software if required and supporting services such as information and communication technology etc. are available based on information provided on the Personnel Requisition and Job Description.

### 7.1.4 Environment for process operation

A safe environment for process operation suitable for achieving product conformance is maintained. Requirements are determined during quality planning. The process operation environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the process operation environment is sufficient for achieving product conformance, providing a safe and healthful workplace, or if corrective action related to the environment for process operation is required.

#### 7.1.5 Monitoring and measuring resources

#### 7.1.5.1 Control of monitoring and measuring resources

Vision Plastics has determined the monitoring and measurement to be undertaken and the monitoring and measuring resources needed to provide evidence of conformity of product to determined requirements. A documented procedure outlines the processes used to control monitoring and measurement; the processes are carried out in a manner consistent with the monitoring and measurement requirements. Output of monitoring and measuring resources is retained.

## 7.1.5.2 Measurement traceability

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



Where necessary to ensure valid results, measuring resource equipment is calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. It is:

- Adjusted or re-adjusted as necessary.
- Identified to enable the calibration status to be determined.
- Safeguarded from adjustments which would invalidate the measurement result.
- Protected from damage and deterioration during handling, maintenance and storage.

In addition, Quality Assurance assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Quality Assurance takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained.

#### 7.1.6 Organizational knowledge

Vision plastics as determined the knowledge necessary for the operations of its processes and to achieve product conformance. This includes, but not limited to: operating procedures, inspection procedures, customer standards, and work instructions. The knowledge is retained as documented information and is made available to the appropriate people within Vision Plastics.

# 7.2 Competence

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position affecting conformity to product requirements. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position. Documentation of competence is retained as documented information.

#### 7.3 Awareness

Vision Plastics' personnel policies have been established to ensure open communication throughout the organization. Personnel are made aware of relevant information to ensure conformance to the QMS. This includes posting the quality policy, identifying quality objectives, reporting on their contribution to the effectiveness the QMS on company meetings, reporting on benefits of improved performance and of non-compliance.

#### 7.4 Communication

The effectiveness of our QMS is evident through internal audit results, corrective actions, customer satisfaction results, and departmental performance measures. Such documented information identifies what will be communicated, when communicated, with whom the communications will be shared; how communicated and who communicates in their respective procedures.

#### 7.5 Documented information

#### 7.5.1 General

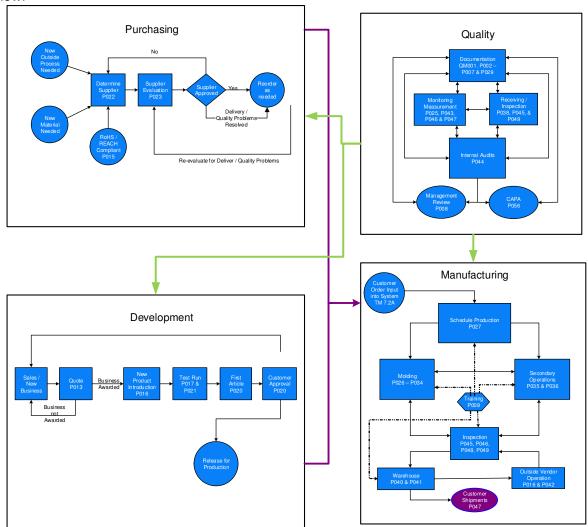
**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



The QMS documented information includes:

- Documented procedures to meet the requirements of ISO 9001 and as needed for the effective planning, operation and control of our processes.
- This quality manual, with its quality policy and objectives.
- Documented work instructions as needed.
- Quality records as needed for the effective planning, operation and control of our processes.

This quality manual describes Vision Plastics' QMS. The purpose, scope and applicability of the QMS are described in sections one and two. The interactions between the processes of the QMS are shown below.



## 7.5.2 Creating and updating

Vision Plastics has set standards for documented information, allowable format types and media types. Documented information has standardized titles, allows the use of electronic formats including but not limited to Microsoft Office Suite products and Adobe products; allowing media in paper and electronic

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



formats. Changes are approved for suitability and adequacy through review processes as referenced in Document Control Procedure P001.

#### 7.5.3 Control of documented information

All QMS documents are controlled according to the following procedures. Documented information is controlled to ensure availability, suitability and protection of the documents. Further, these procedures address the distribution, access, retrieval and use; storage and preservation; control of changes; retention and disposal.

- P001 Document Control Procedure
- P002 Control and Distribution of External Documents
- P003 Change to Master

Documented information is maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records are maintained according to the P006 Control of Records Procedure.

## 8 Operation

### 8.1 Operational planning and control

Quality planning is required before new products or processes are implemented. During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product are developed during the New Product Introduction Process.
- Establishing and documenting criteria for:
  - o processes
  - product acceptance
- Documented information and resources required are established to achieve conformance
- Verification, validation, monitoring, inspection and test requirements are reviewed and established.
- Determining, maintaining and retaining documented information to have confidence that the process is carried out as planned and that products conform requirements.

The output of quality planning includes documented inspection plans, operating instructions, resource requirements, processes, equipment requirements, procedures, test data, and quality outputs. Outsourced processed are checked to be in control through documented inspection plans.

### 8.2 Product requirements

#### 8.2.1 Customer communication

In keeping with our commitment to customer satisfaction, Vision Plastics views effective customer communication as an essential element of customer satisfaction.

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



The Quality department is responsible for assuring customer inquiries in regard to the quality of our products and services are addressed. The Quality department is the key contact in regard to questions pertaining to the company's QMS.

The Sales/Account Managers are responsible for establishing communication methods to ensure inquiries, contracts or order handling, including amendments; customer feedback, controlling customer property and customer complaints are handled expeditiously and professionally. The Account Managers are responsible for initiating the appropriate Return Material Authorization (RMA) documentation per P050 for approved product returns.

#### 8.2.2 Determination of product requirements

Vision Plastics determines customer requirements before acceptance of an order. Customer requirements include the following:

- Customer requirements which pertain to current part numbers being ordered
- Delivery requirements
- Requirements not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- Additional requirements determined by Vision Plastics

Customer requirements are determined according to the Contract Review (CR) procedure. At the CR phase, Vision can ensure that it can meet the claims for the products offered.

#### 8.2.3 Review of product requirements

Prior to committing to the customer, Vision Plastics has a process in place for the review of requirements related to the product. The review is conducted before the order is accepted. The process ensures:

- Product and delivery requirements are defined and documented
- Contract or order requirements differing from those previously expressed are resolved
- Vision Plastics and interested parties have the ability to meet the defined requirements, including statutory and regulatory requirements
- Records are maintained showing the results of the review and any actions arising from the review
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance

Documented information is retained on the results of the review or of any new requirements.

#### 8.2.4 Changes to requirements for products and services

When product requirements are changed, the organization communicates changes to relevant personnel and amends relevant documents.

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



# 8.3 Design and development

Since Vision Plastics does not engage in designing, developing or changing the design of the customer products we manufacture, this section is not applicable.

# 8.4 Control of externally provided processes, products and services

#### 8.4.1 General

The purchasing process is essential to Vision Plastics' ability to provide our customers with products and services meeting their requirements. Vision Plastics has documented procedures to ensure purchased product conforms to specified purchase requirements. Vision Plastics accomplishes this by working with our supplier base and inspecting purchased product as required. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

It is the responsibility of Quality and Purchasing to evaluate suppliers based on their ability to supply product in accordance with specified requirements. Additionally, other internal resources may be called on to assist as required. Criteria for selection, evaluation and re-evaluation are defined in P022 Purchasing Guidelines and P023 Supplier Evaluation procedures. Records of the results of evaluations and any necessary actions arising from the evaluation are retained as documented infromation.

## 8.4.2 Type and extent of control

Vision Plastics uses purchase orders (POs) to describe the externally provided processes to be purchased. POs are created in the company MRP system, by designated individuals within the company. POs include where appropriate:

- Identification of externally provided process to be delivered, quantity, delivery date, and cost.
- Materials used in the manufacture of finished product have identification which is maintained and controlled in the company MRP system and is included on the purchase order.
- QMS requirements.
- Applicable regulatory requirements.

The POs originator is responsible for ensuring the adequacy of specified purchase requirements prior to their communication to the supplier. POs are maintained as documented information.

Receiving Personnel, Material Handlers, QA department, and/or the Purchaser verify purchased items and materials for the effectiveness of the controls applied by the external provider. Verification records are maintained and retained as documented information.

## 8.4.3 Information for external providers

Vision Plastics uses purchase orders (POs) to describe the externally provided processes to be purchased. POs are created in the company MRP system, by designated individuals within the company

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



to ensure adequacy of requirements prior to communication to the external provider. POs include where appropriate:

- Identification of externally provided process to be delivered, quantity, delivery date, and cost.
- Requirements for approval of:
  - Products and services
  - o Methods, processes and equipment
  - o Release of products and services
- Requirements for qualification of personnel
- The external providers' interactions with the organization

Vision controls and monitors the external provider's performance and is reviewed during quarterly manager review meetings. Should Vision Plastics or any of our customers decide to perform verification at the supplier's premises, the verification arrangements and method of product release shall be stated in the purchasing information.

### 8.5 Production provision

#### 8.5.1 Control of product provision

Vision Plastics plans and carries out production provisions under controlled conditions. Controlled conditions include, as applicable:

- The availability of information describing the characteristics of the product and intended results.
- The availability and use of monitoring and measuring resources.
- The implementation of monitoring and measurement processes and acceptance criteria.
- The use of suitable infrastructure and process environment.
- The validation / periodic reevaluation of the intended results where the resulting output cannot be verified by subsequent monitoring or measuring.
- The availability of Operating Procedures, documented requirements, reference materials and reference measurement procedures as necessary to prevent human error.
- The implementation of release, delivery and post-delivery activities.
- The implementation of defined operations for labeling and packaging.

Manufacturing Operating Procedures, Work Orders, and Inspection Control Procedures define our company's plan for manufacturing. These quality control plans provide detailed planning for all phases including the methods and equipment to be used and workmanship criteria. This detailed planning is documented for each product and/or process in the form of Operating Procedures, drawings or specifications. Vision Plastics maintains a record for each batch of product, providing traceability and identifying the amount manufactured and released for distribution. This documented information is verified, approved.

The organization validates any processes for production 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 has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Vision Plastics has documented the process for validation including:

• Defined criteria for review and approval of the processes.

**Printed copies of this document are** not **controlled**. It is the responsibility of the user to verify the correct revision prior to use.



- Approval of equipment and qualification of personnel.
- Use of specific methods and procedures.
- Requirements for records.
- Revalidation as necessary.

Vision Plastics has documented procedures for the validation of processes, including software and computer applications which affect the ability of the product to conform to specified requirements. Where such software is identified in a work instruction or procedure, the validation of the procedure or work instruction includes the software.

#### 8.5.2 Identification and traceability

Product identification will be provided by using the company's part numbering system to assign unique identification for all components and internally manufactured parts. Where not otherwise obvious due to part shape, color, etc., tags, work orders forms, and labels are used as appropriate to clearly identify products and materials throughout the manufacturing process and in storage.

To ensure only items, assemblies or final products having passed required tests and/or inspections proceed to the next operation or process, all products or assemblies will be appropriately labeled, tagged, or stamped, to properly indicate their inspection status. The inspection status shall clearly indicate pass or fail as appropriate. Inspection output is retained as documented information.

In products where component traceability is a requirement, a unique identification will be used to identify the product. Product traceability will be provided by this unique identifier for all completed products. Product traceability is retained as documented information.

#### 8.5.3 Customer and external provider property

Vision Plastics exercises care with customer and external provider property while it is under our control or being used. Receiving Personnel identify customer/provider-supplied product upon receipt and verify it is correct and not damaged. Warehouse and Manufacturing personnel protect and safeguard customer/provider property provided for use or incorporation into the product while it is in Vision Plastics' possession. When customer or external provider property is damaged, lost, or otherwise unusable, Vision reports the issue to the customer or external prover and retains documentation on the occurrence.

#### 8.5.4 Preservation

Vision Plastics has documented procedures for preserving the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection.

#### 8.5.5 Post-delivery activities

Vision Plastics does not engage in post-delivery activities, therefore this section is not applicable.

### 8.5.6 Control of changes

Vision Plastics applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



planned results are not achieved, corrective action is taken, as appropriate, to ensure conformity of the product. Documented information from these actions is retained.

## 8.6 Release of product

The organization monitors and measures the characteristics of the product verifying product requirements are fulfilled. This is carried out at appropriate stages of the product realization process in accordance with documented procedures.

Evidence of conformity with the acceptance criteria is maintained as documented information. Records indicate the person authorizing release of product. Product release and delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

## 8.7 Control of nonconforming product

Vision Plastics ensures product not conforming to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in P048, Non-conformance Report Tracking and Disposition. Further controls and related responsibilities and authorities for dealing with nonconforming product found externally are defined in P050, Return Material Authorization. Documented information is retained that describes the nonconformity and actions taken; any concession obtained and identifies the authority deciding the action with respect to the nonconformance.

#### 9 Performance evaluation

## 9.1 Monitoring, measurement, analysis and evaluation

#### 9.1.1 General

As part of our quality system and our commitment to continuous improvement, Vision Plastics has planned and implemented the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product, to ensure conformity of the quality management system, and to maintain and continually improve the effectiveness of the quality management system. This includes determination of applicable methods, including statistical techniques, and the extent of their use including what and when to measure, with the intention of converting data to information and presenting it in a suitable format for decision-making. Documented information is retained as evidence of results.

#### 9.1.2 Customer satisfaction

As one of the measurements of the performance of the quality management system, we monitor information relating to customer perception and satisfaction as part of a feedback system as to whether the organization has fulfilled customer requirements, to provide early warning of possible quality problems and to provide input for corrective actions. The methods of obtaining and using this information have been determined and documented.

#### 9.1.3 Analysis and evaluation

Vision Plastics has documented procedures to identify, collect and analyze appropriate data to demonstrate the performance and effectiveness of the QMS and to evaluate where continual

**Printed copies of this document are** not **controlled**. It is the responsibility of the user to verify the correct revision prior to use.

OM001 – Rev 15 -Date- Page 19



improvement of the QMS can be made. Appropriate data includes data generated as a result of monitoring and measurement; and from other relevant sources.

The analysis of data provides information relating to evaluating:

- Conformance to product and/or process requirements.
- Customer satisfaction.
- Characteristics and trends of processes and products to confirm if effective planning has been implemented.
- Performance of external providers.
- Effectiveness of actions taken to address risks and opportunities.

Results from the analysis of data are recorded and maintained.

#### 9.2 Internal audit

Vision Plastics conducts internal audits at planned intervals to determine whether the QMS conforms to the planned arrangements for product realization, to the requirements of the ISO 9001standard, to the management system requirements and to determine if the QMS is effectively implemented and maintained. Audits may be performed by Vision Plastics' personnel, or may be contracted to qualified ISO 9001auditors.

The Internal Audit Procedure details the requirements for the audit program, including requirements for the audit program planning and reporting, taking into consideration the status and importance of the processes and areas to be audited, changes affecting the organization and the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are further detailed in the P044 Internal Audit Procedure. Correction and corrective actions resulting from audits are made without undue delay. Documented information of audit results and evidence of implementation are retained.

## 9.3 Management review

#### 9.3.1 General

Top management reviews the QMS at quarterly Management Review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, risks and opportunities; ensuring the alignment with our strategic direction. Records are maintained for each management review meeting.

#### 9.3.2 Review Input

Assessment of the QMS is based on a review of the information provided for review, including the following issues:

- Follow-up actions from previous management reviews.
- Changes which could affect the QMS.

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



- Customer feedback, including relevant interested parties.
- Extent to which quality objectives have been met.
- Process performance and product conformity.
- Corrective actions / nonconformities.
- Monitoring and measurement results
- Audit results.
- Performance of external providers
- Resource adequacy
- Effectiveness of actions taken to address risks and opportunities
- Recommendations for improvement.

#### 9.3.3 Management review output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the QMS and its processes
- Improvement opportunities
- Resource needs

Responsibilities for required actions are assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the management review records. Results of the management review are retained as documented information.

# 10 Improvement

## 10.2 Nonconformity and corrective action

Vision Plastics takes action to eliminate the cause of nonconformities in order to prevent reoccurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. The controls and related responsibilities and authorities for dealing with corrective actions are defined in P056, Corrective Action.

## 10.3 Continual improvement

Vision Plastics continually improves the effectiveness of the QMS through the use of the quality policy, quality objectives, employee training, audit results, analysis of data, corrective actions and management review. Vision Plastics identifies and implements any changes required to maintain the suitability and effectiveness of the quality management system.

Records of all customer complaint investigations are maintained; all corrective actions or lack thereof will be authorized and recorded. Records are retained as documented information.

# 11 Social and environmental responsibility

## 11.1 General

**Printed copies of this document are** not controlled. It is the responsibility of the user to verify the correct revision prior to use.



Vision Plastics has developed and maintains a Social and Environmental Responsibility plan in order to ensure a safe and healthful workplace.

# 11.2 Social Responsibility

VPI operates in compliance with all relevant labor legislation and we strive to use best hiring and employee management practices in all we do in accordance with our objectives.

## 11.3 Environmental Responsibility

VPI operates in compliance with all relevant environmental legislation and we strive to use pollution prevention and environmental best practices in all we do in accordance with our objectives.