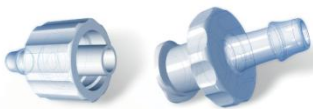




VALUE PLASTICS®, INC.
SPECIALISTS IN FLUID CONNECTIONS™



QUALITY SYSTEMMANUAL



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www.valueplastics.com



Quality Manual

Document Class: QLTY-100

Document #:QM4.2.2

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Introduction

Value Plastics, Inc. developed and implemented a Quality Management System 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 Quality Management System (QMS) of Value Plastics, Inc. meets the requirements of the International Standard ISO 9001:2008. This system addresses the design, development, production, installation, and servicing of the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of ISO 9001:2008. Each section begins with a policy statement expressing Value Plastics, Inc. obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter-relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System 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 ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented, and to assure them that the integrity of the Quality Management System 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 Value Plastics' Quality Management System. These policies define management's intentional provision for managing our operations and activities in accordance with the framework established by ISO 9001:2008. These are the top-level policies representing the company's plans or protocol for achieving quality assurance and customer satisfaction. All departmental or functional policies and written procedures must conform and parallel these policies. All changes to policies and procedures are required to be reviewed to ensure that there are no conflicts with these policies stated in this Quality Manual.

Section 2: Scope

The policies stated in this manual apply to all operations and activities at Value Plastics, Inc..

The scope of Value Plastics activities under ISO 9001 is:

The Design, Manufacture, and Sale of proprietary and distinct plastic tubing connectors and components, quick disconnects assembly devices and services.

It is the responsibility of all department managers to help define, implement and maintain the procedures required by this manual and to ensure all processes conform to these requirements. It is the responsibility of all employees to follow procedures that implement these policies and to help strive for continuous improvement in all activities and processes of Value Plastics Inc.

2.1 Exclusions

None



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Section 3: General Information

**Value Plastics, Inc.
3325 South Timberline Road
Fort Collins, CO. 80525
Phone: (970) 267-5200 Fax: (970) 223-0953
www.valueplastics.com**

Value Plastics, Inc., is a corporation registered in Colorado. The organization is not debarred, suspended, or otherwise ineligible for Federal Programs as may be confirmed in General Services Administration's list of Parties Excluded from Federal Procurement or Non-procurement programs. Value Plastics, Inc. complies with all applicable Colorado State and Federal laws, regulations regarding equal employment opportunities, non-segregated facilities as required by The Civil Rights Act of 1964, including its amendments. Value Plastics, Inc. also complies as applicable with the Rehabilitation Act of 1973, Vietnam Era Veterans' Readjustment Act of 1974 and the Americans with Disabilities Act of 1990.

Colorado State Sales Tax License Number:	11-78110
Federal Employer Identification Number:	84-0700506
ISO Certificate Identification Number:	A0000268-7

QUALITY POLICY

Value Plastics, Inc. is committed to providing superior quality products and services by adhering to a quality management system that benefits our customers, employees and shareholders.

To meet our commitment, we must;

Value our Customers through open communication, timely responses and continual improvement.

Appreciate and foster an environment of trust, integrity, challenge and reward that attracts and retains the best employees in all positions throughout the company.

Leverage efficient technology applied to all business processes in order to maintain a competitive advantage.

Understand that our ultimate purpose is customer satisfaction.

Ensure that our Quality Management System serves our customers' needs.



Type of Manufacture

Value Plastics, Inc. designs and manufactures over 3,400 plastic tubing components. Major product areas include luer fittings and connectors, quick connect fittings (quick disconnect couplings), sanitary fittings or couplers and alternatives to luer fittings.

Products are listed in current catalog, and on website: www.valueplastics.com

Annual Sales - Major Customers

Annual sales are confidential. Value Plastics' customer base is worldwide, and covers a broad spectrum of industries. No single Value Plastics customer currently accounts for more than 5% of its total annual sales.

Facility

State-of-the-art building in excess of 40,000 square feet, constructed in 1995.

- Sales/Marketing
- New Product Development
- Engineering
- Tool Shop
- Manufacturing
- Quality
- Warehouse
- Offices, common area, kitchen, mechanical, rest rooms

Engineering & New Product Development

The Value Plastics Engineering and New Product Development departments support external and internal customers with timely sustaining engineering response and innovative approaches to product line extensions and new product development. Product Line Extensions and New Product Development activities follow a well defined Phased Gate Development approach to ensure that all new products meet and/or exceed external or internal customer requirements. The Phased Gate Development approach is supported by highly trained engineers, who use state-of-the-art software (e.g. SolidWorks – Solid Modeling, FEA Analysis, solid surfacing, etc.), and an R&D lab that has mechanical, thermal and fluid flow analysis capability. Moreover, all projects are tracked via Microsoft Project, and financial progress of all projects is reported to the Finance Department each month. All phases of Product Development are tracked within the Company ERP System (i.e. IFS). Supporting



procedures, work instructions, and data are also maintained within the ERP system. A highly skilled team of Design Engineers, Project Engineers, Tooling Engineers, Engineering Technicians, and Mold Makers make up the these two groups.

Equipment and Capacity

Value Plastics is equipped with all electric injection molding machines, supported by a central material handling and central monitoring system. Moreover, support equipment is utilized during the manufacturing processes. This automated equipment includes: robotic sprue pickers, automated bagging systems, and conveyor systems. The manufacturing process has the capacity to operate 24 hours a day, 7 days a week.

The Tool Room employs the latest technology in CAM software, CNC equipment including mills, grinders, lathes, and EDM equipment.

The Quality function is equipped with several types of inspection equipment to ensure product conformance to documented specifications. Equipment utilized during our inspection processes included the following: calipers, gage pins, thread gages, luer gages, optical scopes, and force gages.

Environmental and Chemical issues

No Class I ozone-depleting chemicals (ODC) or any polybrominated biphenyl and polybrominated biphenyl oxide chemicals (PBB, PBBO, PBBE) of any type or class are intentionally introduced into our processes.

No mold release agents, CFC, or fluorocarbon-based chemicals, additives or agents are used in our processes unless prior approval is obtained from customers.

The injection molding processes and secondary operations at Value Plastics operate in an environment designed to meet ISO 14644 Class 8 (e.g. formerly known as Class 100,000) Clean Room Environment.

None of our stock products are made with a resin, which, in its own manufacture, uses ODC's, PBB's, PBBO's, and PBBE's. We audit our suppliers to this effect, and records are kept on file.

Careful measures are taken so that lubricants, cleaning solvents, water, etc. do not intentionally contact or otherwise contaminate the finished product. However, the production environment precludes our warranting that the finished products are totally free of contamination and thus cannot be certified to be non-pyrogenic.

Regarding latex content of products manufactured by Value Plastics, Inc. Letters from our vendors, who produce the resin used for our products, indicate that latex is not used or intentionally introduced in any formulation of or processing of the final resin material. Likewise, Value Plastics, Inc. does not intentionally introduce any form of latex into our own manufacturing processes.

Section 4: Value Plastics, Inc. Quality Management System

4.1 General requirements

Value Plastics, Inc. has established, documented, and implemented a Quality Management System in accordance with the requirements of ISO 9001:2008. The system is maintained and continually improved through the use of the quality policy, quality objectives, internal & external audit results, analysis of data, corrective and preventive action and periodic management reviews.

To design and implement the QMS Value Plastics, Inc. has:

- Identified the processes needed for the QMS and their application throughout the organization.
- Determined the sequence and interaction of these processes.
- Determined criteria and methods needed to ensure that 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.
- 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.
- Established control processes to identify and implement actions necessary to achieve planned results of outsourced processes.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- Documented Quality Policy.



- Quality Manual.
- Documented Procedures.
- Documents identified as needed for the effective planning, operation and control of our processes.
- Quality Records.

4.2.2 Quality Manual

This Quality Manual has been prepared to describe Value Plastics, Inc. QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures, work instructions, and process diagrams relating to the requirements outlined in that section.

4.2.3 Control of Documents

All of the QMS documents are controlled according to the Document Control Procedure (QP4.2.3). This procedure defines the process for:

- Approving documents for adequacy prior to issue.
- Reviewing and revising as necessary and re-approving documents.
- Ensuring that changes and current revision status of documents are identified.
- Ensuring that relevant versions of applicable documents are available at points of use.
- Ensuring that documents remain legible and readily identifiable.
- Ensuring proper access control.
- Ensuring that documents of external origin are identified and their distribution controlled.
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of Quality Records

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records are maintained according to the Control of Quality Records Procedure (QP4.2.4). This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

Related Documents

Document Control	QP4.2.3
Control of Quality Records	QP4.2.4
Quality Records Table	1005361
Basic Document Control in IFS	1005865

Section 5: Management Responsibility

5.1 Management Commitment

Top management has been actively involved in implementing the Quality Management System. It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, management has done the following.

- Communicated the importance of meeting customer, statutory, and regulatory requirements.
- Established quality objectives.
- Ensured that the quality policy is communicated throughout the organization.
- Conducted periodic management reviews.
- Ensured the availability of resources.

5.2 Customer Focus

Value Plastics, Inc. strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

Top management ensures the focus on improving customer satisfaction is maintained by setting and reviewing objectives related to customer satisfaction at Management Review Meetings.

Top management ensures that customer requirements are understood and met. Customer requirements are understood converted into internal requirements, and communicated to the appropriate personnel in our organization (SP7.2).

5.3 Quality Policy

Top management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted on the organization intranet to maintain high standards within our organization.

Management reviews the quality policy during management review meetings to determine the policy's continuing suitability for our organization.

5.4 Planning

5.4.1 Quality Objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Quality objectives are measurable, and reviewed against performance goals during management reviews, and monthly Management Meetings.

5.4.2 Quality Management System Planning

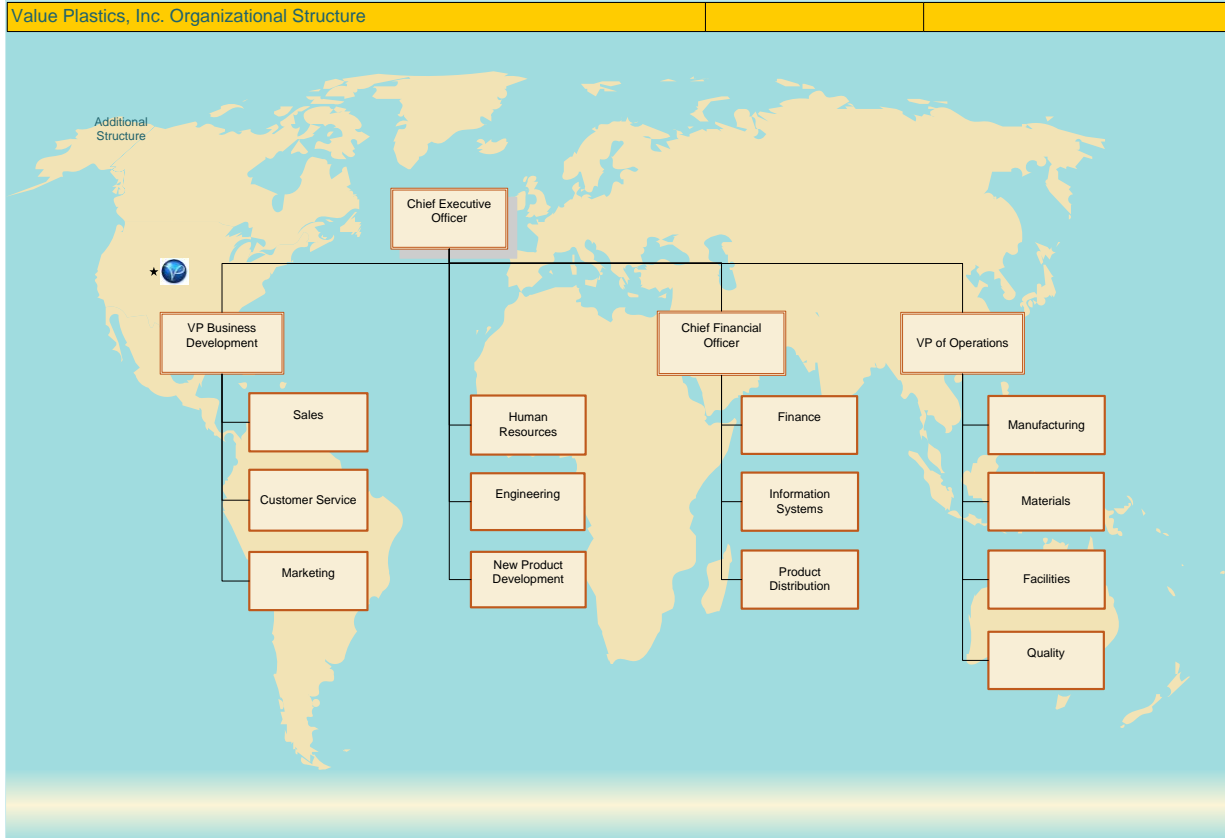
The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 9001 standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

5.5 Responsibility, Authority and Communication

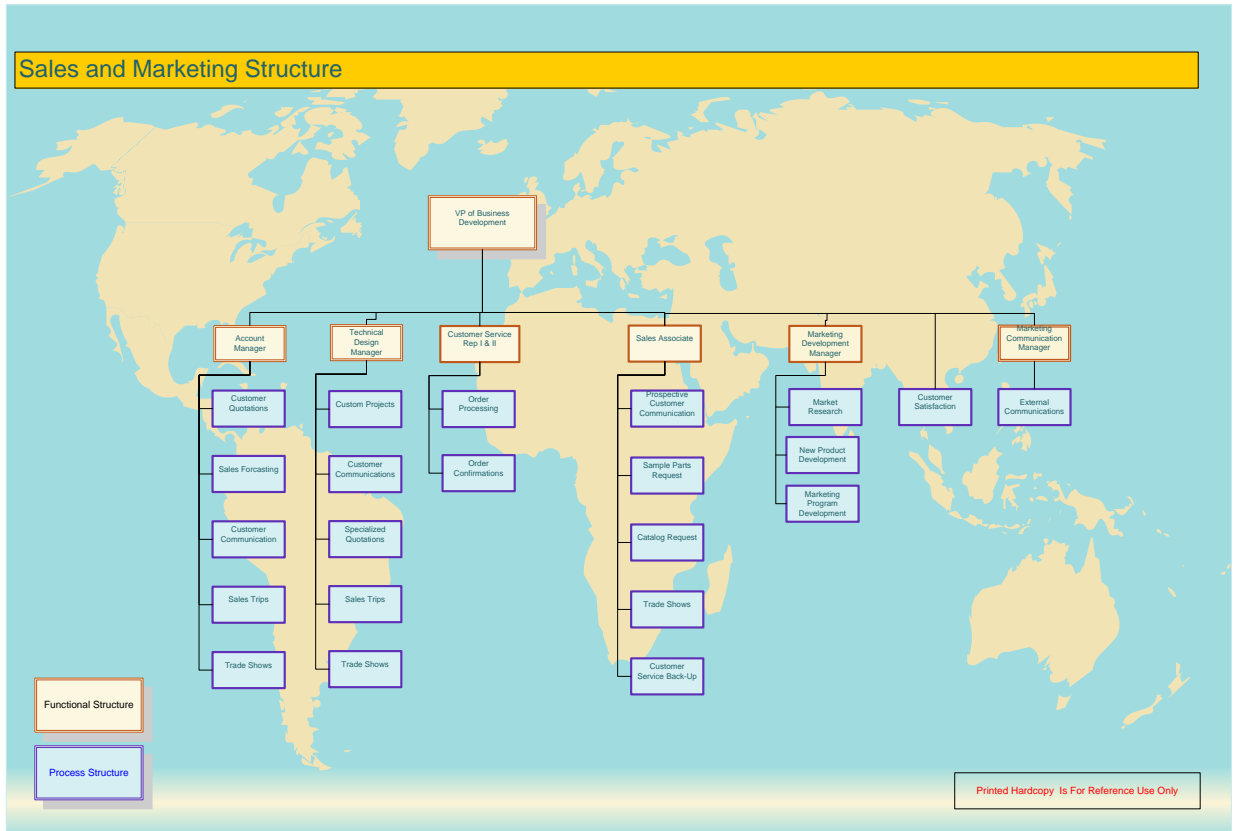
5.5.1 Responsibility and Authority

An organizational structure has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions. Job descriptions and the organizational structure are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities.

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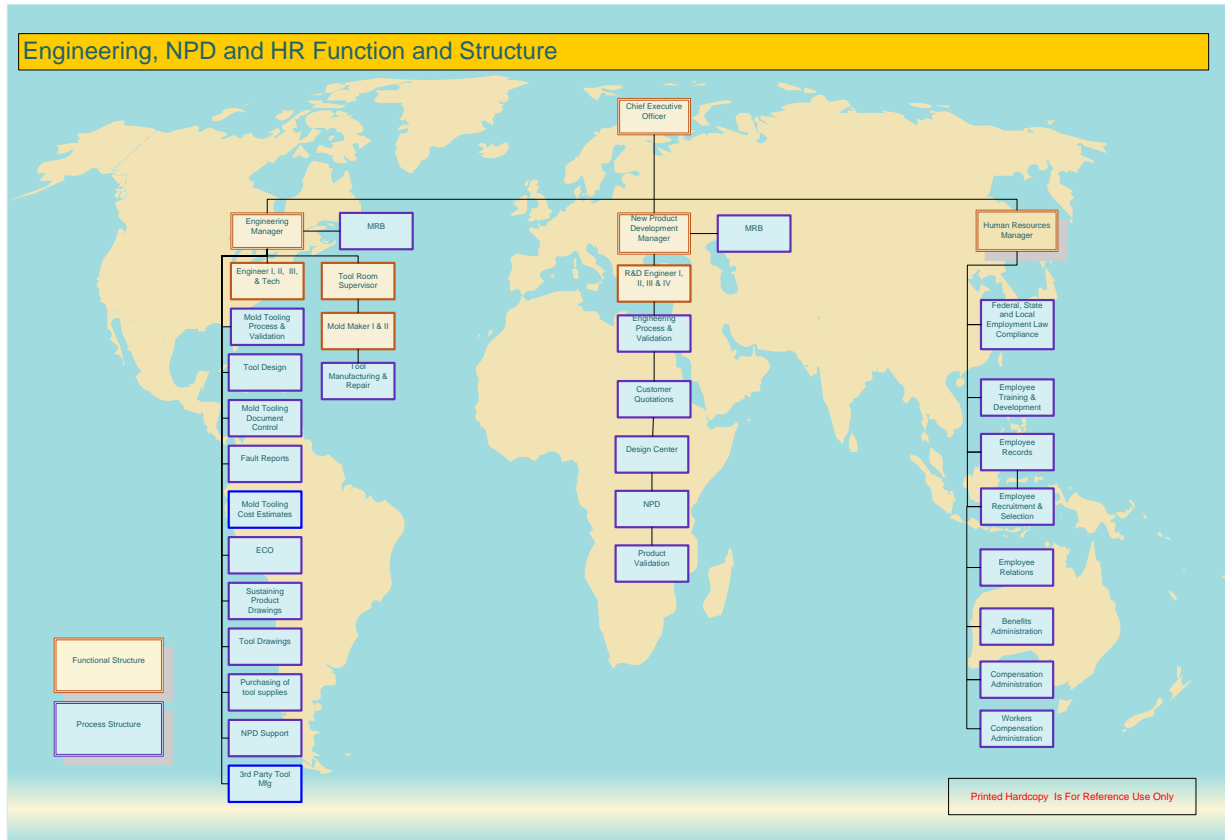
Top Level Organizational Structure



Sales and Marketing structure consist of the following functions:

- Account Manager
- Technical & Design Service Manager
- Customer Service
- Inside & Outside Sales
- Market Development Manager
- Marketing Communications Manager

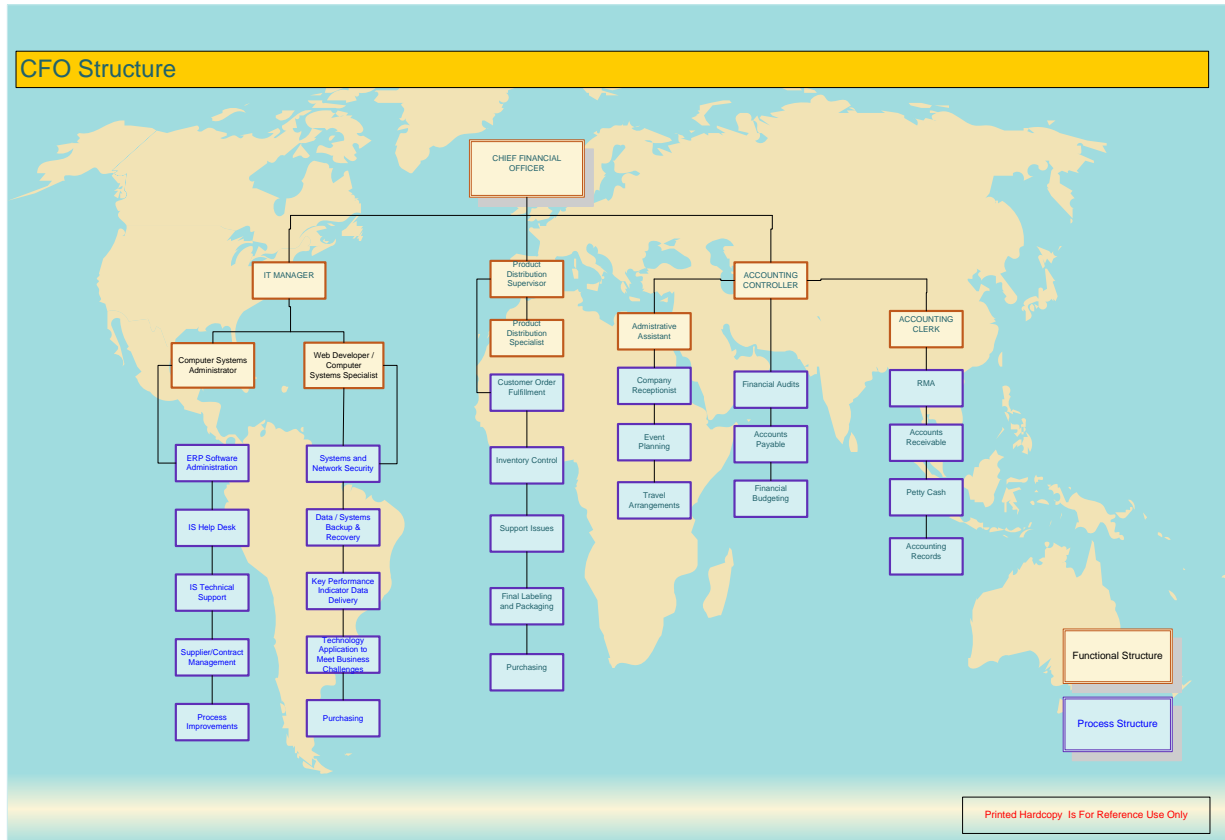
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Engineering, NPD and HR Function Structure:

- Engineering
 - Engineering Manager
 - Engineers I, II, & III
 - Engineering Technicians I, II, & III
 - Tool Room / Mold Makers I, & II
- New Product Development
 - NPD Manager
 - R&D Engineers I, II, III & IV
- HR Manager

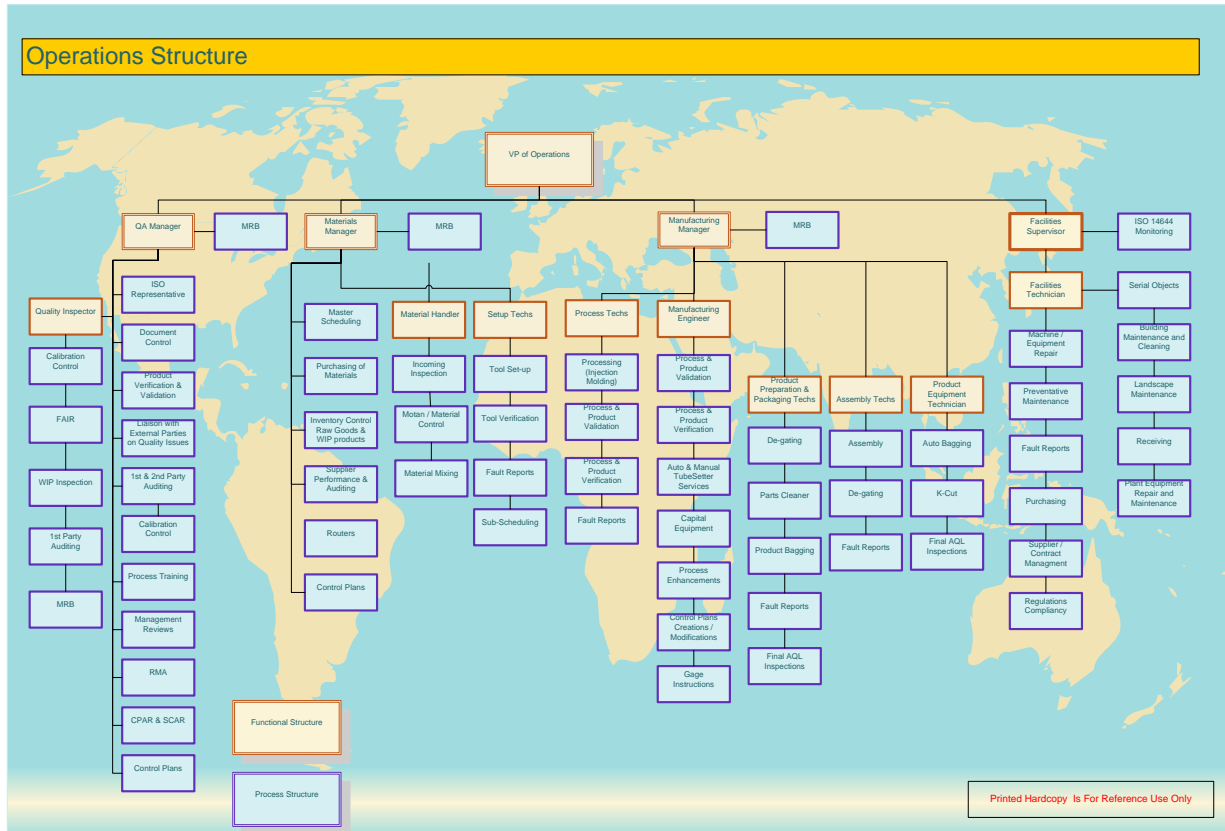
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CFO structure consist of the following functions:

- IT Manager
- Technical Developer Data Analyst
- Computer Systems Administrator
- Inventory & Product Distribution
- Accounting Controller
- Accounting Clerk
- Administrative Assistant

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Operation's structure consist of the following functions:

- Manufacturing & Material Management
 - Manufacturing Manager
 - Materials Manager
 - Manufacturing Engineer
 - Mold Setup Technicians
 - Process Technicians
 - Product Preparation and Packaging
 - Product Equipment Technicians
 - Assembly Technicians & Degating Specialist
 - Material Handler



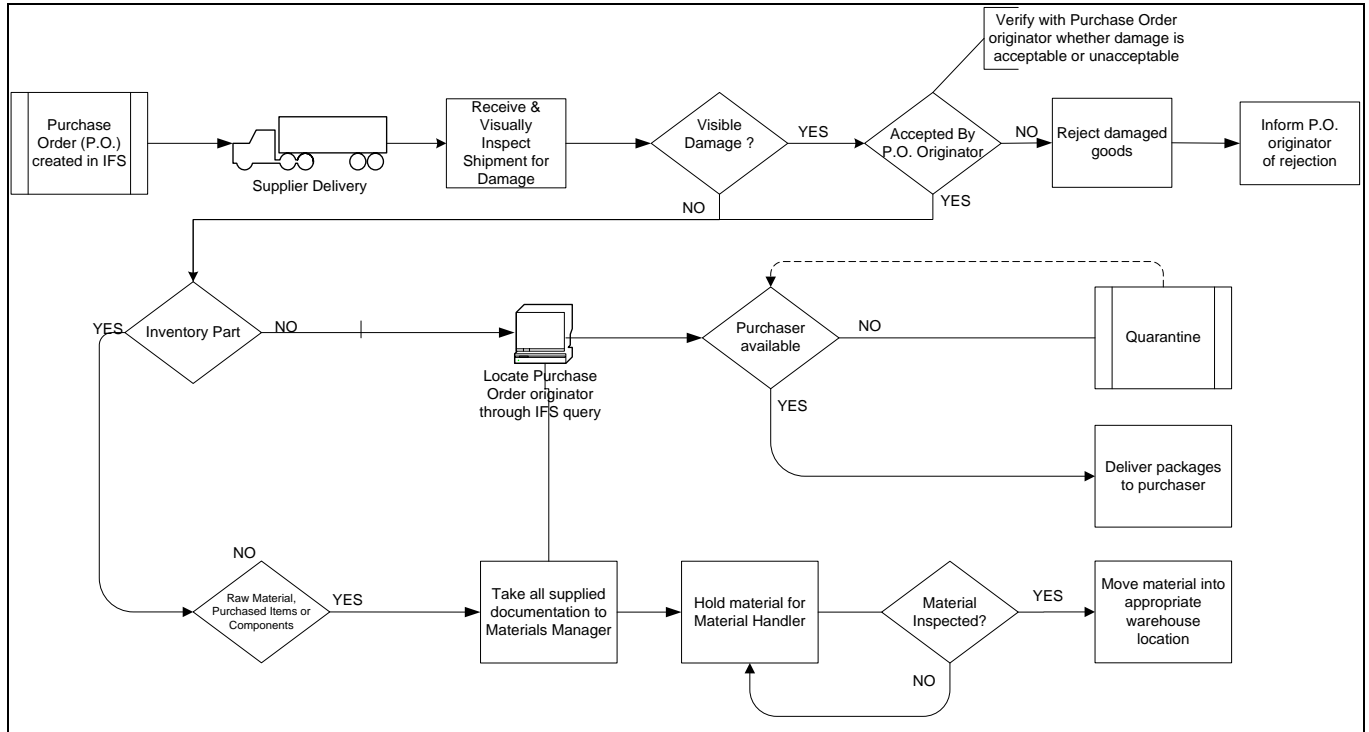
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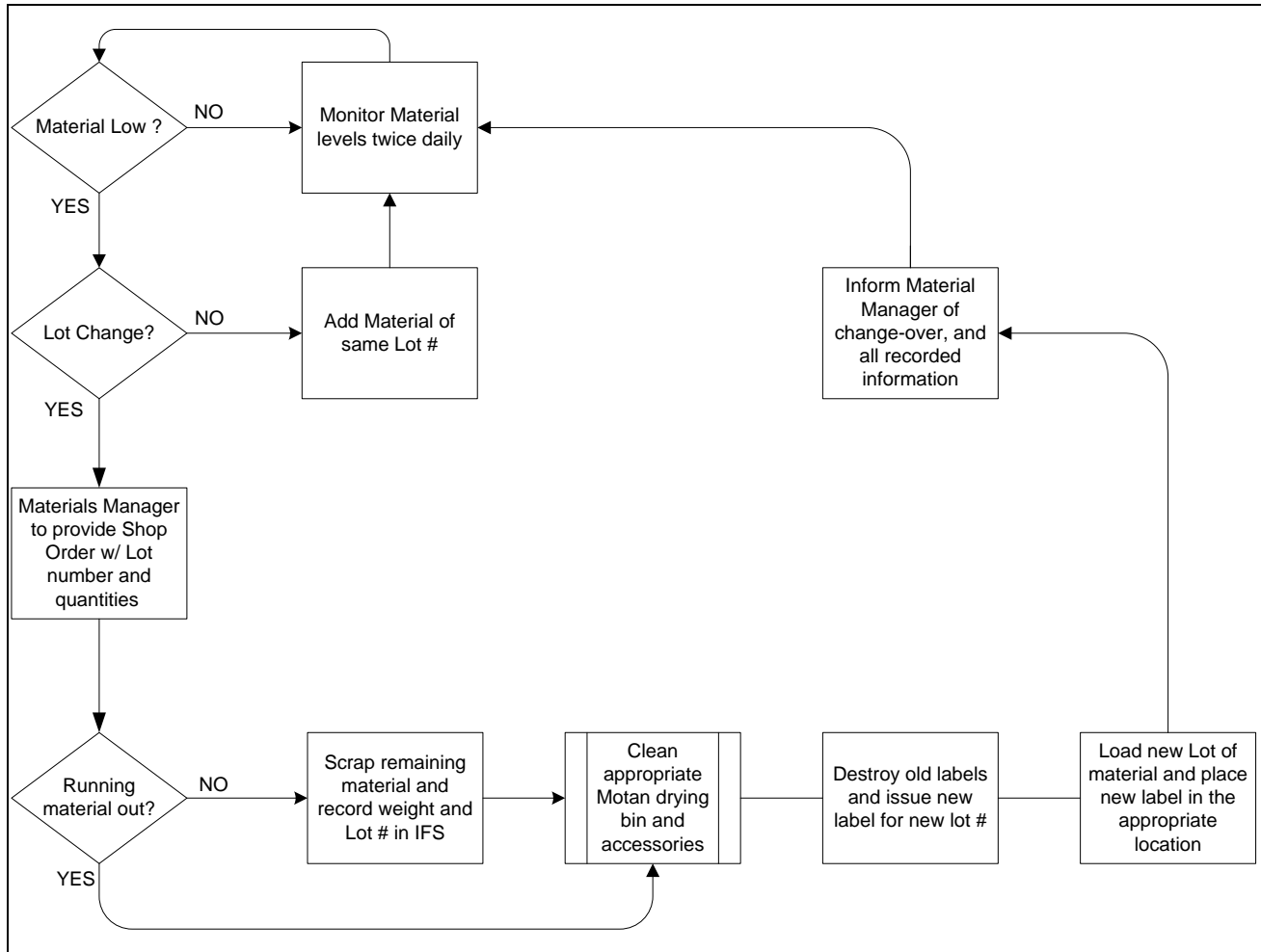
- Quality
 - Quality Assurance Engineer / Manager
 - Quality Control Technicians
 - Quality Control Inspectors
- Facilities
 - Facilities Supervisor
 - Facilities Technician

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Daily Departmental Processes:

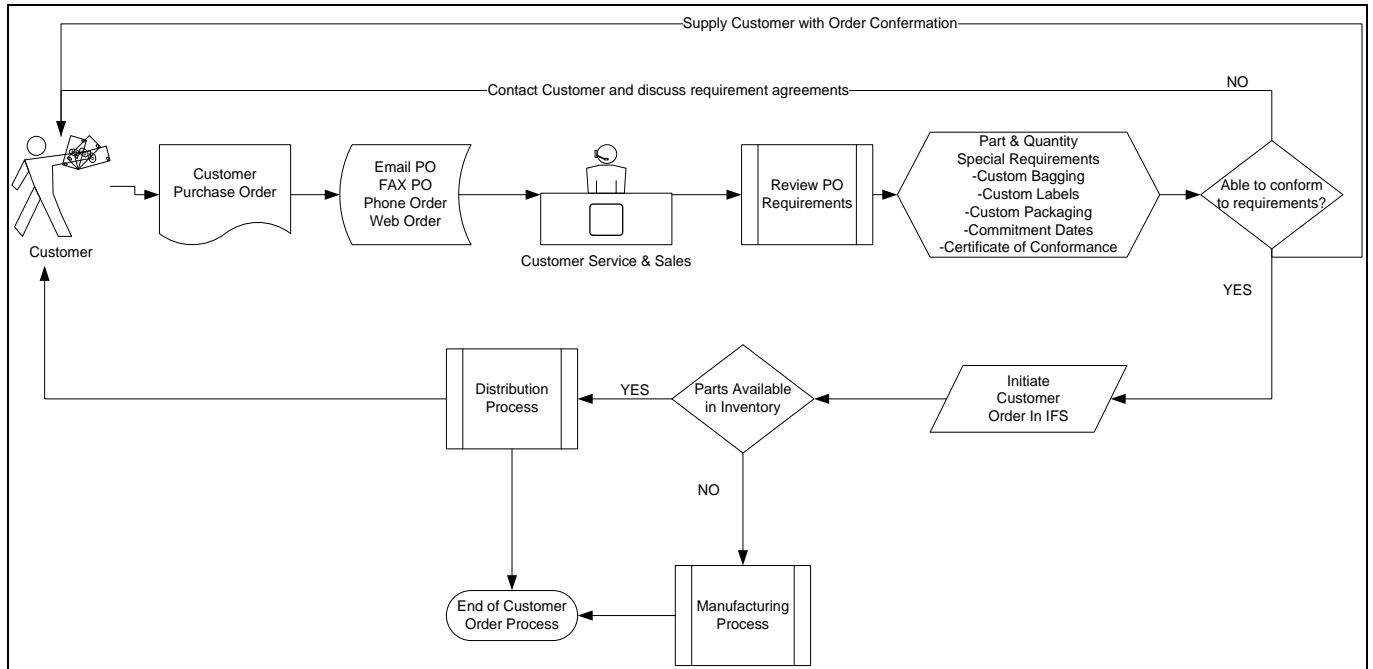


Materials: Receiving Process



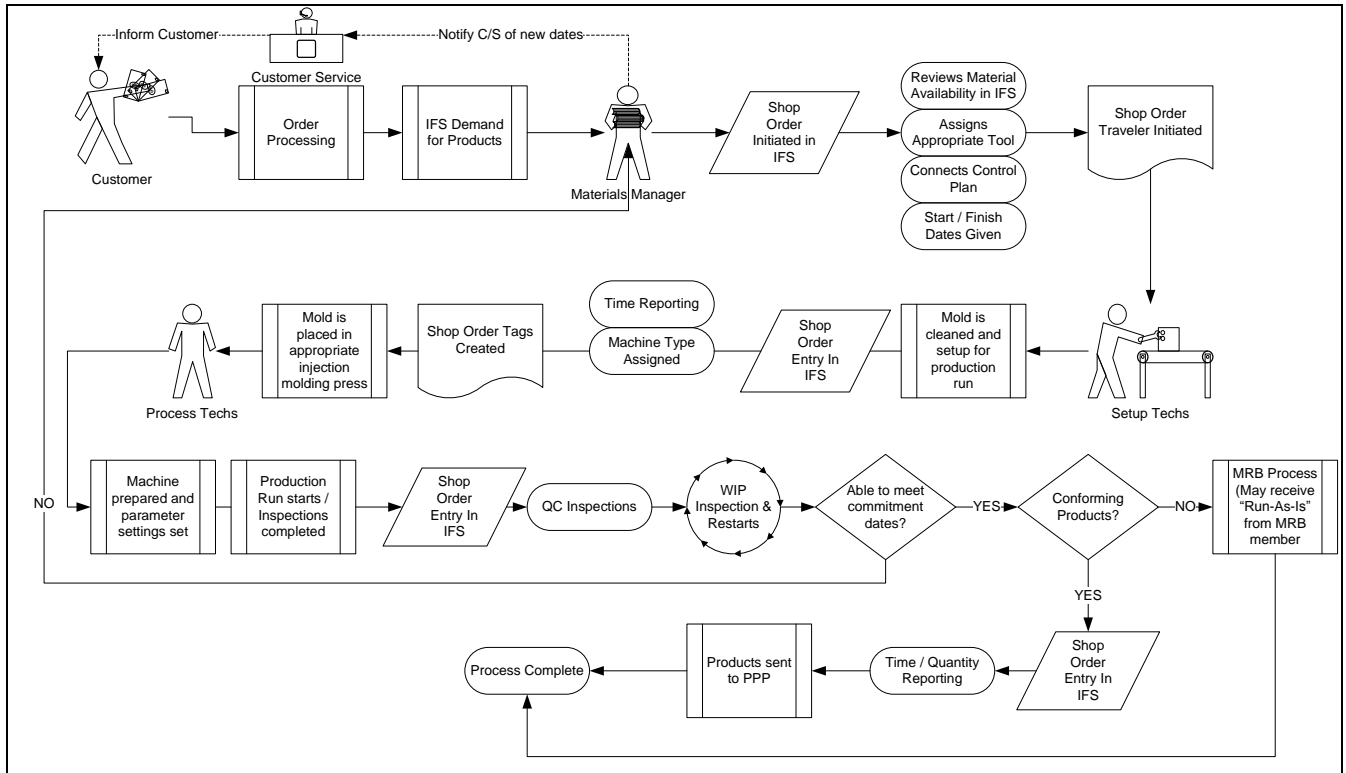
Materials: Raw Material Handling Process

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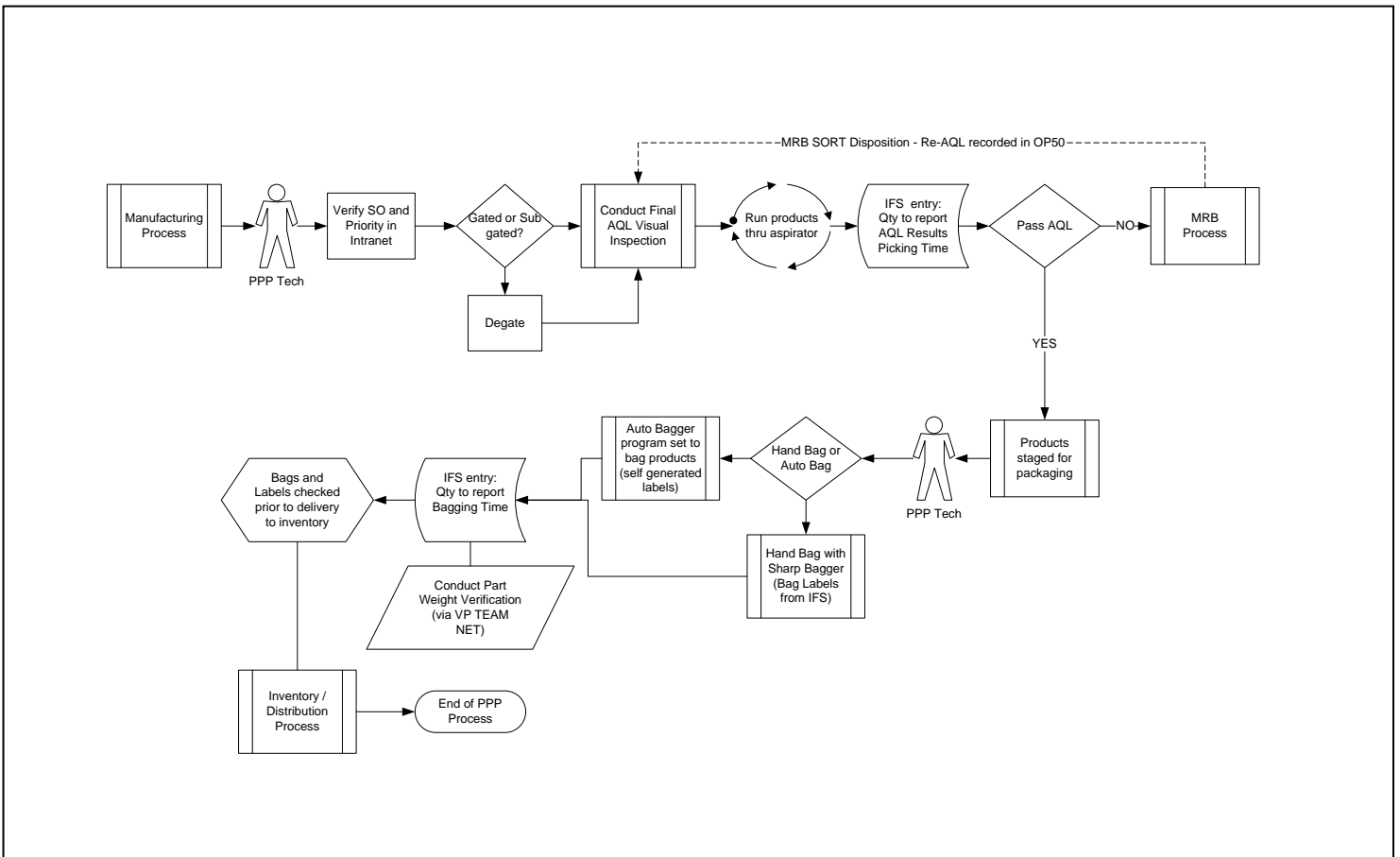
Customer Service: Order Entry Process

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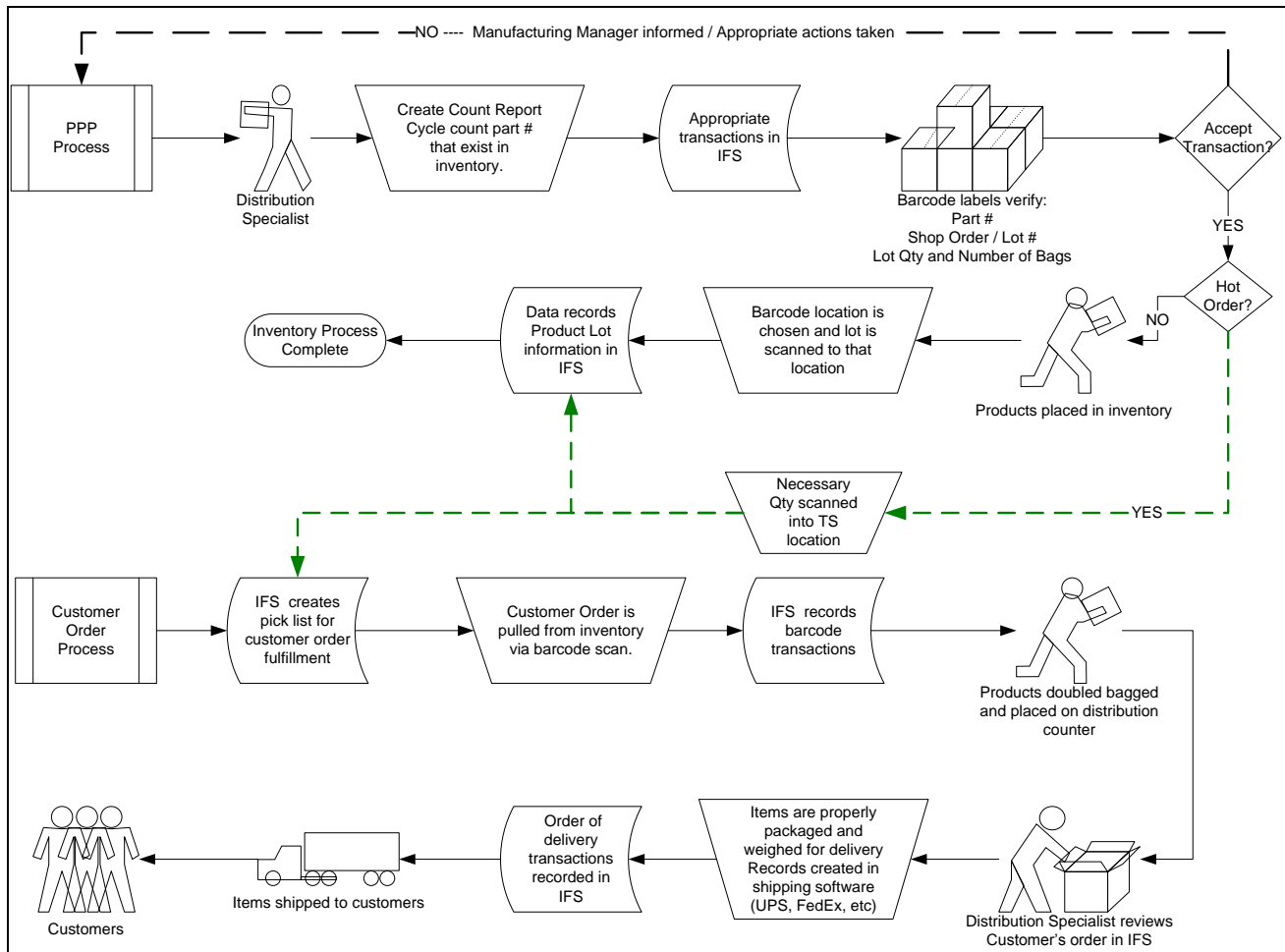
Manufacturing: Injection Molding Process

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Manufacturing: Product Preparations & Packaging Process

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Distribution Process: Product Delivery to Customer



5.5.2 Management representative

The Quality Assurance Engineer/Manager has been appointed as the ISO Management Representative. As Management Representative, he has the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

5.5.3 Internal Communication

In line with Value Plastics' policy of leadership through employee involvement, Value Plastics' personnel policies have established open communication throughout the organization.

The effectiveness of our quality management system is evident through Internal Audit results, Corrective and Preventive Actions, Customer satisfaction results, and the departmental performance measures. Internal Audit results, Customer Satisfaction Survey results, Corrective Actions and Preventive Actions are shared at departmental meetings as appropriate.

5.6 Management Review

5.6.1 General

Top management reviews the QMS periodically at management reviews to be executed three to four times a year. Schedule of Management Reviews will be published at the beginning of each year. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

5.6.2 Review Input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of audits.

- Customer feedback.
- Process performance and product conformity.
- Company level quality data.
- Status of preventive and corrective actions.
- Follow-up actions from previous management reviews.
- Planned changes that could affect the quality management system.
- Recommendations for improvement.

5.6.3 Review Output

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

- Improvement of the effectiveness of the quality management system and its processes.
- Improvement of product related to customer requirements.
- 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 on the management review presentation.

Related Documents:

Customer Related Processes	SP7.2
Management Responsibility	AP5.0
Management Review Process Flow	1009669
Organization Structure & Function	1006106

Section 6: Resource Management

6.1 Provision of Resources

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

6.2 Human Resources

6.2.1 General

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects conformity to product requirements. Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the QMS. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

6.2.2 Competence, Awareness and Training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human Resources maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the Training procedure. (AP6.2.2)

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

6.3 Infrastructure

Value 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 telephones etc. are available based on information provided on the Personnel Requisition.

6.4 Work Environment

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



Related Documents

Competence, Awareness and Training	AP6.2.2
Infrastructure	MP6.3

Section 7: Product Realization

7.1 Planning of Product Realization

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 Development Process.
- Processes, documentation and resources required and stored in IFS.
- Verification, validation, monitoring, inspection and test requirements.
- Criteria for product acceptance.

The output of quality planning includes documented quality plans, resource requirements, processes, equipment requirements, procedures and design outputs.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Value Plastics, Inc. determines customer requirements before acceptance of an order. Customer requirements include the following:

- Previous customer requirements which pertain to current part numbers being ordered.
- Required for delivery and post-delivery activities.
- 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 Value Plastics, Inc.

Customer requirements are determined according to the Customer Related Processes Procedure. (SP7.2)

7.2.2 Review of Requirements Related to the Product

Prior to committing to the customer, Value Plastics, Inc. has a process in place for the review of requirements related to the product (SP7.2). The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined.
- Contract or order requirements differing from those previously expressed are resolved.
- Value Plastics, Inc. has the ability to meet the defined requirements.
- Records are maintained showing the results of the review and any actions arising from the review.
- Where a customer does provide a documented statement of requirement, the customer requirements are confirmed before acceptance.
- When product requirements are changed, The organization communicates changes to relevant personnel and amends relevant documents.

7.2.3 Customer Communication

Value Plastics, Inc. has implemented procedure (SP7.2) for communicating with customers in relation to:

In keeping with our commitment to customer satisfaction, Value Plastics views effective customer communication as an essential element of customer satisfaction. Appropriate handling of communications can reduce customer dissatisfaction in situations and in many cases turn a dissatisfying scenario into a satisfying experience. The Customer Service and Sales department are responsible for establishing communication methods to ensure inquiries, contracts or order handling, including amendments, and customer feedback, including customer complaints which are handled expeditiously and professionally. All customer complaints are classified as Support Issues, which are maintained in IFS.

The Sales and Marketing departments' primary responsibility is directing the business acquisition, retention and product development efforts of the Company, including external communications. Marketing, Sales and Customer Service are the primary customer contacts for product information.

The QA department is committed to addressing all documented customer inquiries that reside within the organization's ERP system. The QA Engineer/Manager has the primary responsibility to address all customer related issues in regard to the quality of



our products and services. The QA Engineer/Manager is the key contact in regard to questions pertaining to the company's QMS. Lastly, the QA Engineer/Manager is responsible for initiating the appropriate Return Material Authorization (RMA) documentation for approved product returns.

7.3 Design and Development

The "Research and Development" (R&D) phase is the most important phase in the life cycle of a product. In Value Plastics' phased product development process, the associated phases are the "Discovery," "Definition," "Development I – Concept" and "Development II – Detailed Design", "Deployment and Dinero" phases. The inherent quality, effectiveness, safety and customer satisfaction of a product are established during these phases. To ensure that specified requirements are met, the following activities as applicable for the design project will be performed:

7.3.1 Design and Development Planning

The design and development process flow (NPD 0-5) outlines the process for controlling the design and development process. The NPD Department ensure that the product specification requirements are clear, creates the necessary planning tools, identifies all necessary resources, oversees designs and testing activities, and coordinates all internal activities according to this procedure. The design plan includes:

- Overall Project Management.
- Design and development stages.
- Required design reviews.
- Customer reviews.
- Verification and validation methods appropriate to each design and development stage.
- Responsibilities and authorities for design and development.
- Identification of the technical interfaces required for the project.
- Updating of the design plan as the project progresses

7.3.2 Design and Development Inputs

Inputs relating to product requirements are determined and documented according to the Design and Development process (NPD Phase 1). All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. Inputs include:

- Functional and performance requirements.

- Applicable statutory and regulatory requirements.
- Where applicable, information derived from previous similar designs.
- Other requirements essential for design and development.

7.3.3 Design and Development Outputs

Outputs of concepts and/or detailed designs and development activities are documented according to the Design and Development process diagram. They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

- Meet the input requirements.
- Provide appropriate information for engineering, materials management, manufacturing and for service provision.
- Contain or reference product acceptance criteria.
- Specify the characteristics of the product that are essential for its safe and proper use.
- Review of initial development and manufacturing costs.

7.3.4 Design and Development Review

The design plan specifies suitable stages of the project to conduct design and development reviews. Reviews take place according to the design and development process diagrams; results of design reviews are recorded within the necessary design meeting records which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfill requirements.
- Identify any problems and propose necessary actions.
- Include representatives of functions concerned with the design and development stage being reviewed.

7.3.5 Design and Development Verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Initial tooling and manufacturing costs may also be reviewed at this time as well. Records of the results of the verification and any necessary actions are maintained according to the Design and Development process flow diagram.



7.3.6 Design and Development Validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. All pertinent tooling and manufacturing costs are reviewed and approved at this point as well. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the design and development procedure.

7.3.7 Control of Design and Development Changes

The design and development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product (i.e. schedule cost, etc.). Records are maintained to show the results of the review and any necessary actions identified during the review.

7.4 Purchasing

7.4.1 Purchasing Process

The purchasing process is essential to Value Plastics' ability to provide our customers with products that meet their requirements. Value Plastics ensures that purchased product conforms to specified purchase requirements. Value Plastics accomplishes this by closely working with our supplier base (i.e. annual audits) and inspecting purchased product as required. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

It is the responsibility of NPD and the Materials Manager to evaluate and select 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 the Supplier Evaluation procedure. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained within the company ERP system.

7.4.2 Purchasing Information

Value Plastics uses purchase orders (PO's) to describe the product or services to be purchased. Purchase Orders are created in the company IFS system, by designated individuals within the company. These purchase orders include where appropriate:

- a) Identification of product or service to be delivered, quantity, delivery date, and cost.



- b) Materials used in the manufacture of finished product have identification which is maintained and controlled in the company IFS system and is included on the purchase order.
- c) Requirements for approval of product, services, or equipment.
- d) Quality management system requirements.

The Purchase Order originator is responsible for ensuring the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The Receiving Personnel, Material Handler and/or Purchaser verify purchased items and materials for correctness.

Should Value 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.

Related Documents

Customer Related Process	SP7.2
NPD/CF Project System Overview	1008395
Purchasing Process	1006139
Customer Order Entry Process	1006112
ENG-100 Work Instructions	1004388
Operations NPD Guidelines	1010365
Injection Molded FAIR Process	1010544
Custom Fitting Process Flow	1010865

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

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

- The availability of information that describes the characteristics of the product.

- The availability of work instructions.
- The use of suitable equipment.
- The availability and use of monitoring and measuring devices.
- The implementation of monitoring and measurement processes.
- The implementation of release, delivery and post-delivery activities.

Manufacturing Procedures, Routers, Inspection Control Plans, and Service Procedures define Our Company's plan for manufacturing and service. These quality control plans provide detailed planning for all phases including the methods and equipment to be used and workmanship criteria. This detailed planning will be documented for each product and/or process in the form of work instructions, drawings or specifications.

7.5.2 Validation of Processes for Production and Service Provision

The organization validates any processes 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. Validation demonstrates the ability of these processes to achieve planned results.

Value Plastics, Inc. has documented the process for validation including:

- Tooling validation.
- Defined criteria for review and approval of the processes.
- Approval of equipment and qualification of personnel.
- Use of specific methods and procedures.
- Requirements for records.
- Revalidation as necessary.

7.5.3 Identification and Traceability

Select personnel are responsible for identifying the product by suitable means throughout the process from receipt of material through shipment of the final product. 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, labels, and routers are used as appropriate to clearly identify products and materials throughout the manufacturing process and in storage.



Personnel performing monitoring and measuring activities are responsible for clearly identifying the product status with respect to monitoring and measurement requirements. To ensure that only items, assemblies or final products that have passed required tests and/or inspections proceed to the next operation or process, all products or assemblies will be appropriately labeled, tagged, stamped, or accompanied by routers or check-out sheets to properly indicate their inspection status. The inspection status shall clearly indicate pass or fail as appropriate.

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.

7.5.4 Customer Property

Value Plastics rarely deals with customer-supplied materials or intellectual property; however should the situation arise, Value Plastics shall exercise care with customer property while it is under our control or being used. The Receiving Personnel shall identify customer-supplied product upon receipt and verify it is correct and not damaged. Warehouse and Manufacturing personnel shall protect and safeguard customer property provided for use or incorporation into the product while it is in Value Plastics' possession. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be recorded on a Nonconformance Report and reported to Inside Sales for notification to the customer.

If the customer property is intellectual property, it may be received and delivered to Quality Assurance, Sales, Marketing, or Engineering. Appropriate safeguards to protect the confidentiality of intellectual property shall be taken. Department Managers may contact the customer directly if the intellectual property is lost, damaged, or found to be unsuitable. Records of these situations may be a letter to the customer or a memo to the customer file.

7.5.5 Preservation of Product

Value Plastics, Inc. preserves the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.6 Control of Monitoring and Measuring Equipments

The organization has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipments needed to provide evidence of conformity of product to determined requirements. A documented procedure (QP7.6) outlines the process used to ensure that monitoring and measurement to be carried out



are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.
- Adjusted or re-adjusted as necessary.
- Identified to enable the calibration status to be determined.
- Safeguarded from adjustments that would invalidate the measurement result.
- Protected from damage and deterioration during handling, maintenance and storage.

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

Related Documents

Customer Related Processes	SP7.2
Purchasing	AP7.4
Control of Monitoring and Measuring Equipment	QP7.6
Master Calibration List	1005866
Preservation of Product	1004886

Section 8: Measurement, Analysis and Improvement

8.1 General

As part of our quality system and our commitment to continuous improvement, Value Plastics Inc. 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 continually improve the effectiveness of the quality management system. This includes determination of applicable methods, including statistical techniques, and the extent of their use, with the intention of converting data to information and presenting it in a suitable format for decision-making.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, the Marketing Department monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the Customer Related Processes (SP7.2), Customer Satisfaction (AP8.2.1), and the Management Responsibility procedures (AP-5.0).

8.2.2 Internal Audit

Value Plastics conducts internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements for product realization, to the requirements of the ISO 9001:2008 standard, and to the quality management system requirements; and to determine if the quality management system is effectively implemented and maintained.

The Internal Audit Procedure (QP8.2.2) details the requirements for the audit program including requirements that the audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The Quality Assurance Engineer/Manager is responsible for the Internal Audit Program. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are further detailed in the Internal Audit Procedure. The VP of Operations is responsible for the internal audit of the QA Department.

Management is responsible for the area being audited to ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken, and the reporting of verification results as indicated in the Corrective Action Procedure.

8.2.3 Monitoring and Measurement of Processes

Value Plastics, Inc. applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and Measurement of Product

The organization monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release and service 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.

8.3 Control of Nonconforming Product

Value Plastics, Inc. ensures that product which does not conform 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 the Control of Nonconforming Product procedure (QP8.3).

8.4 Analysis of Data

Value Plastics, Inc. identifies, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for determining, collecting and analyzing this data is defined in the Management Responsibility procedure (AP5.0). 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

- Customer satisfaction.
- Conformance to product and/or process requirements.
- Characteristics and trends of processes and products including opportunities for preventive action.
- Suppliers.

8.5 Improvement

8.5.1 Continual Improvement

Value Plastics, Inc. shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, employee

training, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective Action

Value Plastics, Inc. takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure (QP8.5.2) defines requirements for:

- Reviewing nonconformities (including customer complaints).
- Determining the causes of nonconformities.
- Evaluating the need for action to ensure that nonconformities do not recur.
- Determining and implementing action needed.
- Records of the results of action taken (see 4.2.4).
- Reviewing corrective action taken.

8.5.3 Preventive Action

Value Plastics, Inc. determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure (QP8.5.3) defines requirements for:

- Determining potential nonconformities and their causes.
- Evaluating the need for action to prevent occurrence of nonconformities.
- Determining and implementing action needed.
- Records of results of action taken.
- Reviewing preventive action taken.

Related Documents

Management Responsibility	AP5.0
Customer Related Processes	SP7.2
Monitoring, Measuring and Analysis of Customer Satisfaction	AP8.2.1
Internal Audits	QP8.2.2
Control of Nonconforming Product	QP8.3
Class 1,2 & 3 Product Conformance Criteria	1005531



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WIP Inspection Process	1005047
MRB Process	1004887
Customer Inquiry - IFS Support Center	1010690
Corrective Action	QP8.5.2
Preventive Action	QP8.5.3