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Vancouver, WA 98682


# *Quality System Manual*

*Revision 22*

**ISO 9001:2015**

*ISO registered since 1999*

Approved: \_\_\_\_\_

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end, positioned over a horizontal line.

President

Date: June 19, 2018

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## **1 Scope**

This manual was created to describe the principles and processes used for the quality management system at KASO Plastics, Inc. The system is designed to assure that the quality of our products, services, and business processes meet or exceed our customer's expectations and contract requirements taking into consideration our external and internal issues. This manual and the Quality Management System (QMS) it defines are also designed to meet the intent of ISO 9001:2015 Quality Management Systems (The Standard), as well as other industry-related and relevant interested parties' requirements.

The QMS manual addresses all business functions that may have an impact on the quality of the products we produce. The QMS is incorporated into all levels, areas and functions of the company as they apply to our quality system. We have implemented appropriate procedures and work instructions to ensure the communication of the requirements of not only The Standard and this QMS Manual, but those of customers' and other interested parties' as well, to all employees.

## **2 Company overview**

Established in 1962, KASO is an engineering-focused company specializing in high quality molded products and assemblies for a variety of automotive, electronic, medical and dental, sports equipment, military, and contract manufacturing customers. Within the 50,000 square foot facility located in Vancouver, WA, KASO offers a wide range of production, engineering, and project management capabilities. Equipment includes injection molding presses, vertical clamp molding presses, work cells for optimized manufacturing, robotic part handling, 3-D printing, central material drying system, and gas assist equipment. Secondary services include decorative finishing services, EMI/RFI shielding, pad printing, and ultrasonic welding.

## **3 Company commitment**

KASO has served the greater Northwest with high quality plastic injection molding and engineering services for nearly 60 years. Better service, the most modern technology and processes, and close attention to the small details lead to customer satisfaction.

## **4 Context of the organization**

### **4.1 Understanding the organization and its context**

Utilizing the Strengths, Weaknesses, Opportunities & Threats (SWOT) analysis process, Top Management of KASO determines the external and internal issues that are relevant to our purpose and strategic direction as well as those that affect our ability to achieve the intended results of our Quality Management System. These issues are monitored by appropriate personnel and are reported upon and reviewed at Management Review meetings.

### **4.2 Understanding the needs and expectations of interested parties**

The Top Management of KASO has determined the interested parties that are relevant to the business management system and their relevant requirements. The relevant interested parties include customers, suppliers, employees, owners, regulating bodies, and our ISO registrar.

Appropriate personnel monitor the requirements and review information about these interested parties. Their findings are reported to Top Management during Management Review meetings.

### 4.3 Scope of application of ISO 9001:2015

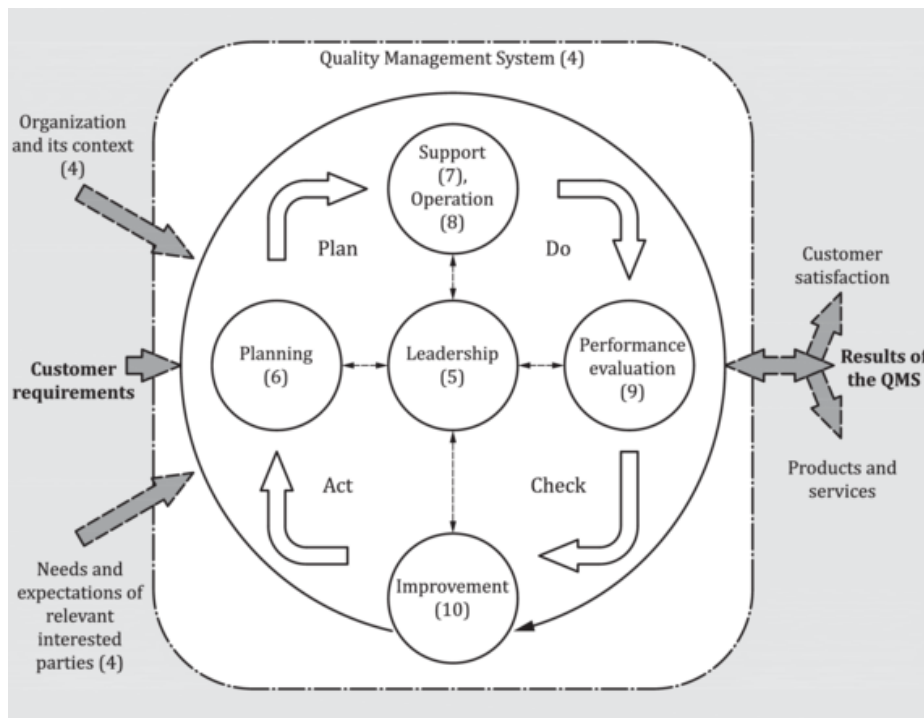
KASO utilizes The Standard for the creation, implementation and evaluation of our Quality Management System. Application and use of this model ensures all appropriate processes are documented, well understood and implemented. All clauses and subsections are addressed within this document, with the exception of those considered not applicable (see below). In addition to the use of The Standard for the creation of our QMS, KASO Plastics has also taken into consider the external and internal issues referred to in clause 4.1, the requirements of the relevant interested parties referred to in clause 4.2, and all the applicable services and production capabilities that we offer. KASO’s scope covers the precision injection molding of thermoplastics and associated services to customer specifications (see company overview).

All elements of The Standard are addressed within this manual with the following exception of clause 8.3 “Design and Development of Products and Services.” KASO does not perform design activities. All products produced at KASO are of its customers’ design and the ultimate responsibility for said product design is that of its customers. Exclusion of clause 8.3 does not affect the organization’s ability or responsibility to ensure the conformity of its processes and the enhancement of customer satisfaction.

### 4.4 Quality Management System and its processes

KASO believes in and practices a philosophy of continual improvement. The model shown below describes how elements of The Standard are used to understand, monitor, and develop solutions to meet our customer’s requirements. Furthermore, the company uses this model to show how it identifies opportunities for improvement as they arise.

(After ASQ/ANSI/ISO 9001:2015, figure 2, page viii)



The Standard requires the establishment of a quality management system, its documentation, implementation, maintenance, review, and continual improvement. The management team of KASO has allocated for, and put in place, the appropriate resources, systems, and processes for the establishment, documentation, implementation, maintenance, and continual evaluation and improvement of its QMS in accordance with The Standard. To this end, we have:

- a) Identified the processes we know to be needed for the Quality Management System;
- b) Determined the inputs required and the outputs expected from these processes;
- c) Determined the sequence and interaction of the processes we have defined;
- d) Determined the appropriate criteria and methods in order to ensure the effective operation and control of the processes, including those provided by outside services. Outsourced services that have a direct impact on product quality are controlled by appropriate means. These controls are identified and documented within the corresponding procedures for these activities.
- e) Continually ensure that proper resources and information are available as needed to support the operation and monitoring of the processes employed;
- f) Assigned the responsibilities and authorities for these processes. Our documented procedures define the responsible departments and personnel and their required duties and actions;
- g) Using risk-based thinking, continually address the risks and opportunities identified in planning;
- h) Continually evaluate our processes and implement any changes needed to ensure that the processes achieve their intended results;
- i) Continually work to improve the company's processes and its business management system

To the degree necessary, KASO maintains documented information to support the operation of its processes and retains documented information to have confidence that its quality management system processes are being carried out as planned. This manual provides an overview of our system and is approved by our president.

KASO's overall process sequences and interaction diagram is located in Appendix A. The diagram provides a visual overview of the sequences and interaction of the processes that make up our QMS. Further details of the interaction can be found within the company's documented procedures. A representative list of processes is attached as Appendix B.

## **5 Leadership**

### **5.1.1 Leadership and commitment**

Top Management of KASO demonstrates its leadership and ensures its commitment to the development and improvement of the QMS by:

- a) Taking accountability for the effectiveness of the QMS;

- b) Establishing our quality policy and supporting quality objectives and ensuring that they are compatible with the context and strategic direction of the company;
- c) Ensuring the integration of the quality management system requirements into the organization's business processes;
- d) Promoting the use of the process approach and risk-based thinking;
- e) Ensuring the availability of resources for both production needs and the needs of the QMS.
- f) Communicating to the company as a whole the importance of effective quality management and of conforming to the QMS requirements including meeting customer as well as statutory and regulatory requirements;
- g) Ensuring that the QMS achieves its intended results;
- h) Engaging, directing and supporting persons to contribute to the effectiveness of the QMS;
- i) Promoting improvement;
- j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

### 5.1.2 Customer focus

The management of KASO maintains a customer-oriented focus in order to increase the overall level of customer satisfaction. Moreover, Top Management demonstrates leadership and commitment with respect to customer focus by ensuring that customer and applicable statutory and regulatory requirements are determined, understood and consistently met. In addition, they ensure that the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed.

### 5.2 Quality policy

The Top Management of KASO has established and documented its quality policy. All employees conduct their work per the company quality policy.

***We at KASO Plastics are dedicated to meeting customer requirements. Our goals are to continually improve quality, on-time delivery, and to reduce costs.***

Top Management of KASO has determined that our quality policy clearly and effectively describes our commitment to our customers (including satisfying applicable requirements), as well as our own internal desire for continual improvement. Our policy is appropriate to the purpose and context of the organization and supports our strategic direction. It also provides a framework for setting our quality objectives.

The quality policy is documented, communicated and applied at all levels of the company. The quality policy, as part of our QMS, is controlled and subject to periodic review for suitability and relevance. Our policy is available to relevant interested parties, as appropriate.

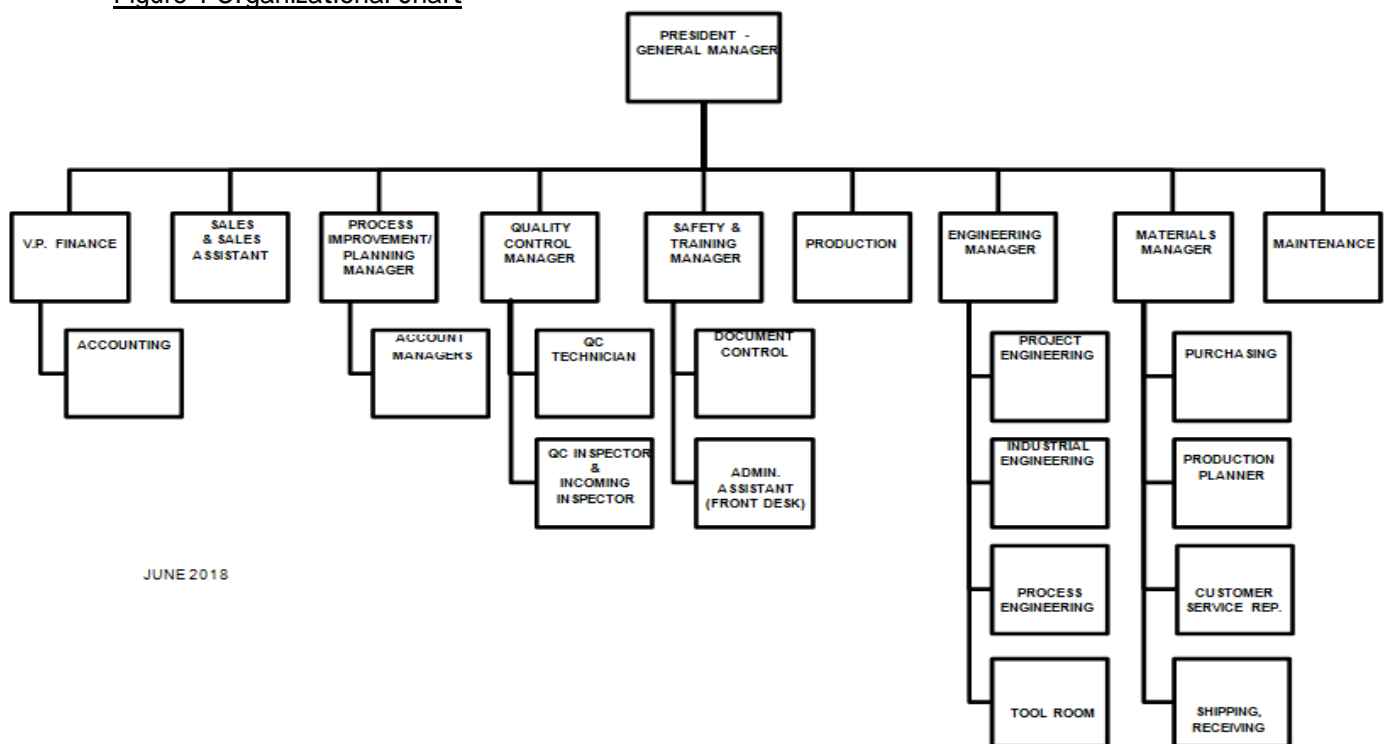
### 5.3 Organizational roles, responsibilities and authorities

Top Management has ensured that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the company. The roles pertaining to the operation of the QMS are defined within the organization in the form of job responsibilities and requirements and their interrelationships can be seen on the organizational chart below (see Figure 1). The documented job responsibilities and requirements outline the responsibilities, required skill sets, and subsequent authority of each position (process owner). Process owners are responsible for ensuring that their assigned processes are delivering their intended outputs. Job descriptions and the organizational structure are reviewed and approved by Top Management for adequacy.

The Management Representative has been assigned the responsibility and authority for:

- a) Ensuring that the QMS conforms to the requirements of The Standard;
- b) Coordinating the reporting of the performance of the QMS and on opportunities for improvement to Top Management;
- c) Coordinating the promotion of awareness of the customers’ requirements (i.e. customer focus) throughout the company;
- d) Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented;
- e) Acting as a liaison with external parties on matters relating to the QMS.

Figure 1 Organizational Chart



JUNE 2018



## **6 Planning**

### **6.1 Actions to address risks and opportunities**

During the planning for the QMS, KASO considers its external and internal issues as well as the requirements of relevant interested parties and determines the risks and opportunities that need to be addressed in order to give assurance that the QMS can achieve its intended results, enhance desirable effects, prevent or reduce undesired effects, and achieve improvement.

Using risk-based thinking, Top Management plans actions to appropriately address identified risks and opportunities and how to integrate and implement the actions into its QMS and evaluate the effectiveness of these actions. The actions taken are proportionate to the potential impact on the conformity of products. The action plans are reviewed during Management Review.

### **6.2 Quality objectives and planning to achieve them**

Top Management of KASO has established business objectives at relevant functions, levels and processes that are utilized for the determination of the effectiveness of our QMS. The objectives are consistent with KASO's quality policy, measurable, take into account applicable requirements, and are relevant to conformity of products and to the enhancement of customer satisfaction. They are monitored, communicated, and updated as appropriate at Management Review meetings.

#### **OBJECTIVES**

- Continually improve quality
- Continually improve on-time delivery
- Reduce all costs to the lowest possible level without sacrificing quality

KASO has planned how to achieve its business objectives by determining what will be done, what resources are needed, who is responsible, when they will be completed, and how the results will be evaluated.

### **6.3 Planning of changes**

Top Management of KASO has ensured that each aspect of the QMS has been carefully designed and implemented to meet the requirements of The Standard and those of the company and our customers as well.

The functional integrity of the QMS is of utmost concern to the management of KASO and we have taken appropriate measures to ensure that during times of change to the QMS there is little to no disruption to the system itself. All changes are thoroughly planned and thought out prior to implementation giving consideration to the purpose of the changes and their potential consequences, the integrity of the QMS, the availability of resources, and the allocation or reallocation of responsibilities and authorities.

## **7 Support**

### **7.1 Resources**

KASO is responsive to changes and the requirements of its QMS. As a result, we have defined, within our QMS procedures, and provided for the resources needed to establish, implement, maintain, and continually improve the processes of the QMS as well as the resources for adequately addressing customer satisfaction. During planning and budgeting processes and as needed throughout the year, KASO considers the capabilities of, and constraints on, existing internal resources and what needs to be obtained from external providers.

#### **7.1.2 People**

KASO has determined and provided the human resources necessary for the effective implementation of its QMS and for the operation and control of our processes.

#### **7.1.3 Infrastructure**

KASO believes the infrastructure of our company is one of the main contributing factors in the ongoing success of our business and our QMS. We continually evaluate and maintain our current and future infrastructure needs. Infrastructure includes:

- a) Buildings, workspace and associated utilities. Our current work centers are specifically designed for the type of product that is produced within the area and systematically undergo preventive maintenance;
- b) Process equipment and software, either in the shop or office area, has been specifically selected to perform the required tasks within the work center and are maintained at regular intervals;
- c) Supportive services such as transportation of product both internally and externally as well as internal and external communication;
- d) Information and communication technology (including alarms and a public address system). Computers and software are backed up to ensure records are not lost.

#### **7.1.4 Work environment**

The company provides and maintains the environment necessary for the operation of its processes and to achieve conformity of our products. The management of KASO believes a safe and clean work environment is critical to our employee's continued success as well as the growth of the company. To facilitate this KASO has adopted and implemented safety programs that are compliant with various regulatory and non-regulatory standards. Management has also instructed departmental supervisors to maintain their areas of the manufacturing facility in such a manner as to promote shop cleanliness and efficiency.

KASO values its employees. We offer competitive benefits (including an Educational Assistance Program) and have implemented HR policies (e.g. non-discriminatory and harassment-free work environment polices) in order to provide a suitable social and psychological work environment.

### 7.1.5 Monitoring and measuring resources

KASO continually defines, utilizes, and acquires the appropriate monitoring and measuring resources needed to ensure valid and reliable results when monitoring or measuring is used for evaluation and determination of product conformity to specified requirements. KASO ensures that our resources are suitable for the specific type of monitoring and measurement activities being undertaken and that they are maintained to ensure their continuing fitness for their purpose.

The procedure *Control of Inspection, Measuring, and Test Equipment Overview* defines the controls we place on monitoring & measuring devices to ensure product conformity to specified requirements. In order to ensure our monitoring and measurement device capabilities are consistent with measurement requirements, we:

- a) Calibrate or verify the devices at defined intervals against devices that are traceable to the National Institute of Standards & Technology, NIST. All measuring devices used are traceable to NIST standards. If no standards existed, we would document the basis used for calibration or verification. Calibration/verifications are performed in-house and/or by approved vendors;
- b) Perform adjustments or re-adjustments as necessary by qualified personnel;
- c) Uniquely identify each device for traceability and determination of calibration status;
- d) Ensure that all calibrated devices are safeguarded from adjustments that would invalidate the measurement results by protecting such pieces as required;
- e) Work to maintain equipment in a safe manner while protecting it from damage and deterioration during handling, maintenance and storage;

Should a device be found to be non-conforming to factory specifications for accuracy and repeatability, we employ the controls to ensure product previously measured with such equipment is re-assessed for compliance to specified product requirements. Records are maintained in accordance with our documented procedures.

The use of specialized software for monitoring and measurement is closely evaluated for its ability to satisfy the needs of the intended application prior to purchase. Once in use, the software is continually evaluated for its suitability to our applications.

### 7.1.6 Organizational knowledge

KASO has determined the knowledge necessary for the operation of our processes and to achieve conformity of our products. This includes, but not limited to: operating procedures, inspection procedures, customer standards and work instructions.

We hire employees and contractors/suppliers with the needed knowledge whenever possible. In addition, needed knowledge is made available to employees and suppliers as applicable through formal training (internal and external), documented information, and on-the-job training. When considering changing needs and trends, KASO assesses its current knowledge base and determines how to acquire or access any additional knowledge or updates needed.

## 7.2 Competence

KASO has determined the necessary competence of people doing work under its control that affects the performance and effectiveness of the QMS. We seek to place employees in positions that match their current level of competency, including the appropriate skill set, education and experience that meet the requirements of the job. Because of this, KASO evaluates the entire skill set that a potential employee brings to the company prior to employment and reviews the qualifications of suppliers as needed. Employees hired by KASO prior to the our original certification to The Standard are considered competent and have been placed accordingly; however, on-going training and skill set improvement activities still apply.

KASO utilizes training processes that work to enhance employee skills and knowledge as well as identify gaps in potential new employee skills sets. The system defined by the procedure allows us to:

- a) Determine the current competency level of personnel performing specific activities affecting quality;
- b) Provide adequate training or other actions to raise the competency level to satisfy our needs. Training may be onsite or offsite and includes both formal and on-the-job training;
- c) Evaluate the effectiveness the training activities provided
- d) Ensure through training that each employee is aware of the importance of their activities and how they assist in contributing to meeting our quality management objectives;
- e) Identify and maintain records of education, experience, training, and skills.

## 7.3 Awareness

KASO ensures that persons doing work under our control are aware of the quality policy, relevant quality objectives, their contribution to the effectiveness of the QMS, including the benefits of improved performance, and the implications of not conforming to the QMS requirements.

## 7.4 Communication

The Management Team has determined the internal and external communications relevant to the QMS. Communication plans include what is communicated, when to communicate, with whom to communicate, how to communicate, and who communicates. The type of communication and associated information are outlined in our QMS manual and procedures.

Top Management is responsible for ensuring that the expectations for, and the status of, the QMS are clear, concise and fully communicated to the entire company. This communication takes many forms including verbal briefs, plant-wide meetings, memos, documents posted in appropriate areas, and e-mails. In addition, the management team has implemented appropriate methods of communicating customer and relevant interest party requirements to the necessary functions within the company. For example, Top Management understands the need for communicating the requirements of each customer to all levels of the company; therefore, customer requirements and specifications are issued to the production floor each time a job is being processed.

KASO has a website. Feedback from the website is monitored and communicated to management as appropriate.

## **7.5 Control of documents and records**

The controlled documents included in the QMS included those required by the ISO 9001:2015 standard and those determined by KASO as being necessary for the effectiveness of the QMS. The document control process is outlined in *Document and Data Control Overview* procedure (covering documented information that is maintained). The controls defined in this procedure include:

- a) The approval and review of documents for suitability and adequacy prior to release for use;
- b) The review, update as needed, and re-approval of changed documents;
- c) The ability to identify changes made to documents and the current revision of documents (i.e. version control);
- d) Ensuring the appropriate documents are available and suitable where and when needed;
- e) Ensuring the documents are legible, readily identifiable and retrievable (i.e. with identification, description, format and media information);
- f) Identifying, obtaining and controlling the distribution of externally originated documents;
- g) Ensuring obsolete documents are not used and that they are suitably marked;
- h) Ensuring that documents are adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

KASO's quality records are retained to provide evidence of conformance and effective operation of our Quality Management System. The procedure *Control of Quality Records Overview*, describes the identification, storage, retrieval and protection of records as well as required retention and disposition periods. We protect documents and records from unintended alterations.

## **8 Operation**

### **8.1 Operational planning and control**

In order to ensure the product is produced per the customer's requirements and to implement the actions plans determined through the company's strategic planning process, KASO employs a production planning process that includes determining product requirements, establishing process criteria (i.e. quality check points) including establishing criteria for the acceptance of products, and determining resource requirements. Given the determined criteria, KASO implements control of its processes and determines what documentation is required (i.e. procedures, work instructions, and records) needed to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products to their requirements. Management review ensures that the outputs of these processes are suitable and that outsourced processes are controlled. Moreover, management controls planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

This process is initiated at the quote stage and finalized during the first production run. The process plan (the document that contains the production steps needed to produce the product) that is developed during this time becomes the production plan for the product. The process plan becomes a part of the work order packet that also contains the following:

- a) The production routing sequence (process planners and control plans);
- b) The product requirements, specifications, drawings, quantity required and other attributes that match the requirements of the customer;
- c) The details of the production steps necessary to produce the product ordered. Any steps that require outside services are also detailed;
- d) All verification activities, including in-process inspection and other more formal documented inspections, are included in the routing steps listed in the work order packet and are monitored.
- e) Individual workmanship is continually monitored, evaluated and approved through operator self-assessment and maintenance of attribute control charts.
- f) Molds, tooling and fixtures are maintained to the specified requirements.

## 8.2 Requirements for products

### 8.2.1. Customer communication

As a part of the initial and ongoing relationship with the customer, KASO ensures avenues of communication are open and known by the customer. Customers have the ability to communicate with many responsible persons at KASO by e-mail, phone, fax, the company website, or in person.

#### Customer Communication

What	Who	How	When
Product information relating to products and services	Sales/Materials/NPI Team	Website, phone, fax, e-mail, in person,	As requested
Production capabilities and order status	Sales/Materials/NPI Team	Phone, fax, e-mail, in person	As requested
Handling and making changes to enquiries, contracts or orders	Sales/Materials/NPI Team	Phone, fax, e-mail, in person	As requested
Customer Feedback	Sales/Materials/NPI Team	Website, phone, fax, e-mail, in person	As requested
Handling or controlling customer property	Sales/Materials/NPI Team	Phone, fax, e-mail, in person	As requested
Establishing specific requirements for contingency actions as needed	Sales/Materials/NPI Team	Phone, fax, e-mail, in person	As needed



Nonconforming product (returns)	Sales/Materials/NPI Team	Phone, fax, e-mail, in person	When applicable
Requests for corrective action	Sales/Materials/NPI Team	Phone, fax, e-mail, in person	When applicable

### 8.2.2 Determining/Reviewing the requirements for products

When determining the requirements for the products to be offered to customers, KASO employs a review process, which assists in identification of the customer and organizational requirements as in, but not limited to, the following:

- a) Requirements known to KASO that support the process and ensure customer requirements are met;
- b) Understanding any other requirements related to our products including any statutory and regulatory requirements;
- c) Understanding any additional requirements KASO feels is important to the success of the product.

KASO can meet the claims (e.g. marketing information on its website) for the products and services we offer.

### 8.2.3 Review of requirements related to the product

KASO has a documented procedure that defines the process for review of customer and/or product requirements. Documents include a quote requirement checklist, acknowledgement forms, and Quote letters. When contractually required, KASO also performs a Production Part Approval Process (PPAP). The process is outlined in *Contract Review Overview*. The review is conducted and documented prior to acceptance of the order and ensures that:

- a) Product requirements as specified by the customer, including our capability and capacity to perform the work desired, the date of delivery to the customer and any other special requirements, which meet the needs of the customer. If the customer does not give KASO a documented statement of their requirements, we will contact the customer to confirm their requirements/order;
- b) Requirements not stated by the customer, but necessary for the specified or intended use are known and understood;
- c) Applicable statutory and regulatory requirements can be met;
- d) Differences between any previously expressed requirements and the received documents are resolved and documented prior to acceptance;
- e) KASO has the capability to meet the requirements set forth by the customer and the company (e.g. reviews customer's designs to verify moldability and KASO's ability to provide a quality product at a competitive price).

Any changes to the order or new requirements, agreed upon by the customer and KASO, are documented and communicated to the appropriate levels of the organization. This includes the updating of any related documentation in order to ensure changes are understood and communicated.

### **8.3 Design and development**

Design and Development are not services provided by KASO (see section 4.3). However, KASO does plan and control the design and development of molds, fixtures, processes and packaging. KASO's *Quality Planning Overview* includes an Overview of Design and Development.

### **8.4 Purchasing**

#### **8.4.1 Purchasing process**

KASO ensures that externally provided processes, products and services conform to requirements. The company determines controls to be applied to processes, products and services when the purchase is incorporated into our own products and services; products and services are provided directly to the customer by suppliers on behalf of KASO; and when we decide that a process or part of a process is to be provided by a supplier.

As a part of our purchasing program, KASO has a system for the selection and evaluation of suppliers. This process monitors the selection and ongoing performance of our suppliers. Further, performance records of our suppliers are reviewed periodically. Records of the evaluations and any follow-up activities are maintained. Refer to *Approval of New Suppliers*, *Periodic Review of Approved Suppliers*, and *Tracking Supplier Performance (Data Collection)*.

The level of control and verification activities placed on purchased processes, products, and services is dependent upon the supplier's ability to consistently provide processes and services in accordance with customer and other requirements (including the effectiveness of their controls), the level of impact the item has upon the final quality outcome for the product delivered to the customer, and to ensure that supplied processes remain within the control of our QMS.

#### **8.4.2 Purchasing information**

The company has implemented documented procedures to ensure purchased product and services are conforming to the specified needs or requirements for the end use of the purchased product. Purchasing documents contain all pertinent information needed to define the purchase including any requirements for product. These requirements are conveyed to our suppliers on the purchase order or PO Terms and Conditions. All purchase orders are reviewed prior to issue in accordance with *Purchase Requisition/Purchase Order Information*.

Our requirements are adequate and communicated to suppliers. These requirements may include, but are not limited to, the following:

- a) The processes, products and services to be provided;
- b) The approval of products and services;



- c) Specific procedures (methods), processes (including quality assurance), equipment and approvals (including the release of products and services);
- d) Competency or qualification requirements (e.g. certifications for qualified personnel who worked on the product purchased);
- e) Supplier interactions with the company;
- f) The control and monitoring of the supplier's performance to be applied by the company;
- g) Certifications of conformance or other such documents as defined by our customer or ourselves

KASO has implemented and documented procedures and processes for the verification of the conformance of purchased products to specific requirements. Should it be necessary to verify product at our suppliers' premises, KASO is responsible to specify the intended verification arrangements and method of product release within the purchasing information. *Receiving in Product* defines the process we use.

## **8.5 Production provision**

### **8.5.1 Control of production provision**

KASO carries out our production processes under controlled conditions. These controls include, but are not limited to, the following:

- a) Clear and concise information regarding product characteristics and other specifications, services to be provided, or the activities to be performed and their intended results;
- b) Appropriate work instructions where needed;
- c) Manufacturing equipment designed for the specific processes required for the product;
- d) The availability and use of appropriate measuring and monitoring devices;
- e) Monitoring and measurement of appropriate process and product characteristics at appropriate stages of the production process in order to verify that control and acceptance criteria have been met;
- f) Implementing actions to prevent human error;
- g) Defined and implemented processes for release, delivery, and post-delivery activities.

KASO utilizes production equipment whereby the resulting output is difficult to monitor via normal means. Such processes include sonic welding. Validation methods include, but are not limited to, the following:

- a) Defined criteria for review and approval of the sonic welding process (e.g. an authorized person's written approval of setup prior to proceeding with work instructions);
- b) The management team and department supervisors are jointly responsible for the selection and approval of appropriate equipment and the qualification of personnel for special processes;

- c) Documented setup instructions, tests, industry standards, and controls;
- d) The recording and tracking of appropriate records as required by our QMS;
- e) The ability to perform additional/subsequent validations at prescribed intervals to ensure continued capability and control.

### **8.5.2 Identification and traceability**

KASO identifies product and materials by appropriate and varied means throughout the production and RMA processes. The status of the product with respect to monitoring and measurement requirements is also known in accordance with our documented procedures.

Raw materials, components, molds, fixtures, and tooling purchased and/or customer supplied are identified and traced by labels and identifying numbers. Procedures and records for their control are included in the quality planning documents. Inspection and/or test results are communicated by attaching or marking the product or the product's shipping box, bag and/or pallet, with an inspection/test records and/or a status stamp or tag. Only products and work processes that have passed inspection and/or testing or have been released as-is by the customer will be incorporated into a product.

Controls for identification and traceability are defined in *Product Identification and Traceability Overview* and *Inspection and Test Status Overview*.

### **8.5.3 Customer and supplier property**

KASO handles customer and supplier property in the same manner as we handle our own property and materials. As a result, the controls defined by our QMS apply to that of customer and supplier property. All customer and supplier property is identified, verified, protected, and safeguarded. Provisions, controls and paths of communication have been implemented for any customer and supplier property that is lost, damaged or found to be unsuitable for use and records are maintained. Refer to *Control of Customer and Supplier Owned Product/Property Overview*.

Customer property includes customer electronic and intellectual property, measurement gages, molds, or fixtures. Procedures document required processes for returning items to the customer, as well as reporting lost or damaged items. The customer is notified, through Material Discrepancy Reports, if supplied product does not conform to requirements.

### **8.5.4 Preservation**

All products are processed, handled, stored and transported in a manner that ensures the safety of the product and the integrity of the customer's requirements for the product. Refer to *Handling, Storage, Packaging, Preservation, and Delivery Overview*.

When appropriate, a product quality plan document provides specific handling instructions to prevent product damage. Product is maintained in designated indoor heated warehouse areas. These areas are regularly monitored and maintained to ensure product does not deteriorate. FIFO (First in, first out) inventory methods control product movement in and out of the warehouse.

### 8.5.5 Post-Delivery activities

KASO post-delivery activities include actions under warranty and/or contractual obligations. In determining the extent of post-delivery activities associated with products, the company considers statutory and regulatory requirements, the potential undesired consequences associated with its products; the nature, use and intended lifetime of its products as applicable, customer requirements and customer feedback. The Return Material Authorization (RMA) process is outlined in *Returned Material Authorization (RMA)*.

### 8.5.6 Control of changes

KASO reviews and controls production changes as needed to ensure continuing conformity with requirements. The company retains records of the review, which authorized the change, and any resulting action items.

## 8.6 Release of products and services

Throughout the entire production process, KASO conducts work center appropriate inspections on all products as required by the customer, specific quality plans and the QMS (see section 8.1). These inspections begin at the receiving process and conclude upon shipment of the product. Refer to *Raw Material Receiving, Secondary In-Process Inspection, Molding In-Process Inspection, Final Inspection*.

Documentation providing evidence of product conformity to the provided acceptance criteria and personnel responsible for authorizing product release are maintained as a requirement of our QMS. These documents are part of the process plan that accompanies the product during processing.

Prior to product release, a final inspection takes place that ensures all processes and paperwork has been completed per the plan prior to final packaging and shipment. Product release does not take place until the final inspection process has confirmed the acceptable completion of the production plan for the product unless otherwise approved by the customer or their authorized agent.

## 8.7 Control of nonconforming product

The QMS procedure *Control of Nonconforming Product Overview*, documents the means by which we control product that does not conform to its requirements in order to prevent the unintended use or shipment of such product. The procedure outlines the approved methods for identification and segregation, specific control issues, responsibilities, authorities and disposition guidelines for nonconforming product.

The disposition of nonconforming product is controlled and authorized by appropriate personnel. (i.e. The Material Review Board). Products which fail to pass an inspection and/or test results in a Material Discrepancy Report. The disposition may include, but not be limited to, the following:

- a) Elimination of the detected nonconformity (i.e. correction);
- b) Segregation, containment, return or suspension of production of the product;
- c) Communication with the customer;
- d) Authorization of its use, release or acceptance by concession by an agent of the customer or the customer;

e) Initiating action(s) to prevent it from being used as originally intended.

Records of the nonconformities are maintained along with the resulting disposition of the nonconforming product. The records describe the nonconformity, actions taken; concessions obtained (if applicable), and identify who dispositioned the product. When nonconforming product is corrected and thought to be conforming, it is re-inspected to the same criteria as before to ensure compliance and to validate the corrective process.

In the event that a nonconformance is detected after product has shipped, KASO takes appropriate action based on the severity of the potential effects of the nonconformance, including contacting our customer(s).

## **9 Performance evaluation**

### **9.1.1 Monitoring, measurement, analysis and evaluation**

KASO has planned and implemented appropriate monitoring, measurement, analysis and improvement processes. Management has determined what needs to be monitored and measured, the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results, when the monitoring and measuring will be performed, and when the results from monitoring and measurement will be analyzed and evaluated.

The company utilizes appropriate metrics to monitor and evaluate key business aspects and processes to demonstrate the continuing suitability, effectiveness, improvement and overall health of our QMS. These metrics are found at multiple levels of the company and are used for continual improvement and business making decisions. Data for each of these key business aspects is collected and analyzed for trends that demonstrate the potential for improvement for the specific area. Our Quality Objectives are one source for this activity. Other metrics concern customer satisfaction and comments, rework and scrap dollars, trends in nonconformities.

### **9.1.2 Customer satisfaction**

The company monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. Customer satisfaction is of great importance to the management of KASO and is taken very seriously. It is for this reason that trends in customer satisfaction are monitored at multiple levels of the company and are included at Management Review. The means by which we monitor and measure customer satisfaction is defined in *Handling Customer Comments/Feedback from Relevant External Interested Parties*.

### **9.1.3 Analysis and evaluation**

KASO has implemented monitoring and measurement methods for our QMS processes (see section 9.1.1) and analyzes and evaluates the resulting information. The results of the analyses are used to evaluate conformity of products and services; the degree of customer satisfaction; the performance and effectiveness of the QMS; whether planning has been implemented effectively; the effectiveness of actions taken to address risks and opportunities; supplier performance; and the need for improvements to the QMS. These methods provide a clear and concise view of the effectiveness of our QMS.

To assist in the achievement of these goals, KASO utilizes a variety of data analysis tools, including statistical methods. These tools help to provide clear information on the performance and effectiveness of

our QMS, information used for making business decisions, and evidence of product conformance. In the event that any one of these methods reflects a less than desirable result, corrective measures are determined by the appropriate personnel and put in place so that we achieve the desired result. The summarized information and evaluation of the effectiveness of the system are found in Management Review minutes.

## **9.2 Internal audits**

Internal audits are conducted at specified intervals for the purpose of determining whether our QMS conforms to the requirements of our quality plans, The Standard, and to our QMS as it is written, and that our QMS is effectively implemented and maintained.

The audit program at KASO is planned, implemented, and maintained. The audit program takes into consideration the importance of the processes and areas to be audited, changes affecting the organization, and past audit performance. Audit criteria and scope are defined for each scheduled audit. Audit frequency, methods, responsibilities, planning requirements, conducting, recording and reporting are defined within our procedure *Auditing Overview*.

Trained Internal auditors are used to conduct audits. The Management Representative develops the audit schedule and schedules auditors to ensure that audits are conducted in a manner to ensure objectivity and the impartiality of the audit process (e.g. auditors are not allowed to audit their own work).

The Management Representative ensures that the results of the audits are reported to relevant management and the results are documented. Management of the areas audited are responsible to ensure that appropriate actions are taken without undue delay to rectify any nonconformity identified and mitigate the identified root cause(s). Follow-up activities to verify the effectiveness of the action(s) taken are documented.

## **9.3 Management review**

### **9.3.1 General**

The Top Management of KASO believes that the process of management review is critical to our continued growth and improvement efforts. Our procedure, *Management Review Meetings*, defines the process, methods and requirements for our management review system. During management review, the suitability, effectiveness and adequacy of our QMS as a whole is evaluated. During the scheduled review meetings, Top Management uses many sources of information to assist in the evaluation of improvement opportunities, changes, and the components of the QMS.

Records of these review meetings are maintained in accordance with the Management Review procedure.

### **9.3.2 Review input**

A variety of mechanisms are in place to provide Top Management with the needed information to make solid decisions regarding our QMS. These mechanisms provide information and input from multiple areas of the company and represent the key factors for determining the overall health of our QMS. Agenda items include, but are not limited to, reviewing the following:

- a) Action items from previous Management Review meetings for status and effectiveness as appropriate;
- b) Changes in external and internal issues that are relevant to our QMS (e.g. changes to the business environment and or the structure of the company that may have an effect on our QMS are reviewed and addressed as needed).
- c) Customer and relevant interested party feedback and customer satisfaction overviews and trends. Metrics are in place that allow Management to determine overall customer satisfaction and where improvements in this area may be needed;
- d) The extent to which quality objectives have been met;
- e) Multiple measures are in place to monitor process performance and product conformance. The results of monitoring and measurements are reviewed as appropriate.
- f) Trends in nonconformities and in the Corrective and Preventive Action (CAPA) system to identify improvement needs;
- g) Summations and trends of internal and external audits reveal the company's strengths and weaknesses. This knowledge allows management to know where improvement efforts are most needed and where we have been successful;
- h) Supplier performance and trends;
- i) Adequacy of resources;
- j) The effectiveness of actions taken to address risks and opportunities;
- k) Recommendations for improvement to our QMS and addressing them as appropriate.

Specific details of the Management Review process and the reports reviewed may be found in the QMS Procedure *Management Review Meetings*.

### **9.3.3 Review output**

The Management Review process, by nature and design, produces outputs of a varying type. These outputs (action Items) that are included in the Management Review minutes include, but are not limited to, the following:

- a) Opportunities for improvement;
- b) Any need for changes to our QMS;
- c) Evaluation and determination of resources needs.
- d) SWOT review and update as necessary



## **10 Improvement**

### **10.1 General**

KASO determines and selects continual improvement projects (CIP) and implements any necessary actions to meet customer requirements and enhance customer satisfaction. Furthermore, the management of KASO fully supports the utilization of a proactive means to eliminate nonconformities before they occur. Types of opportunities include improving products to meet requirements as well as address future needs and expectations; correcting, preventing or reducing undesired or potential undesired effects, and improving the performance and effectiveness of our QMS. See *Continual Improvement Projects (CIP)*.

### **10.2 Nonconformity and corrective action**

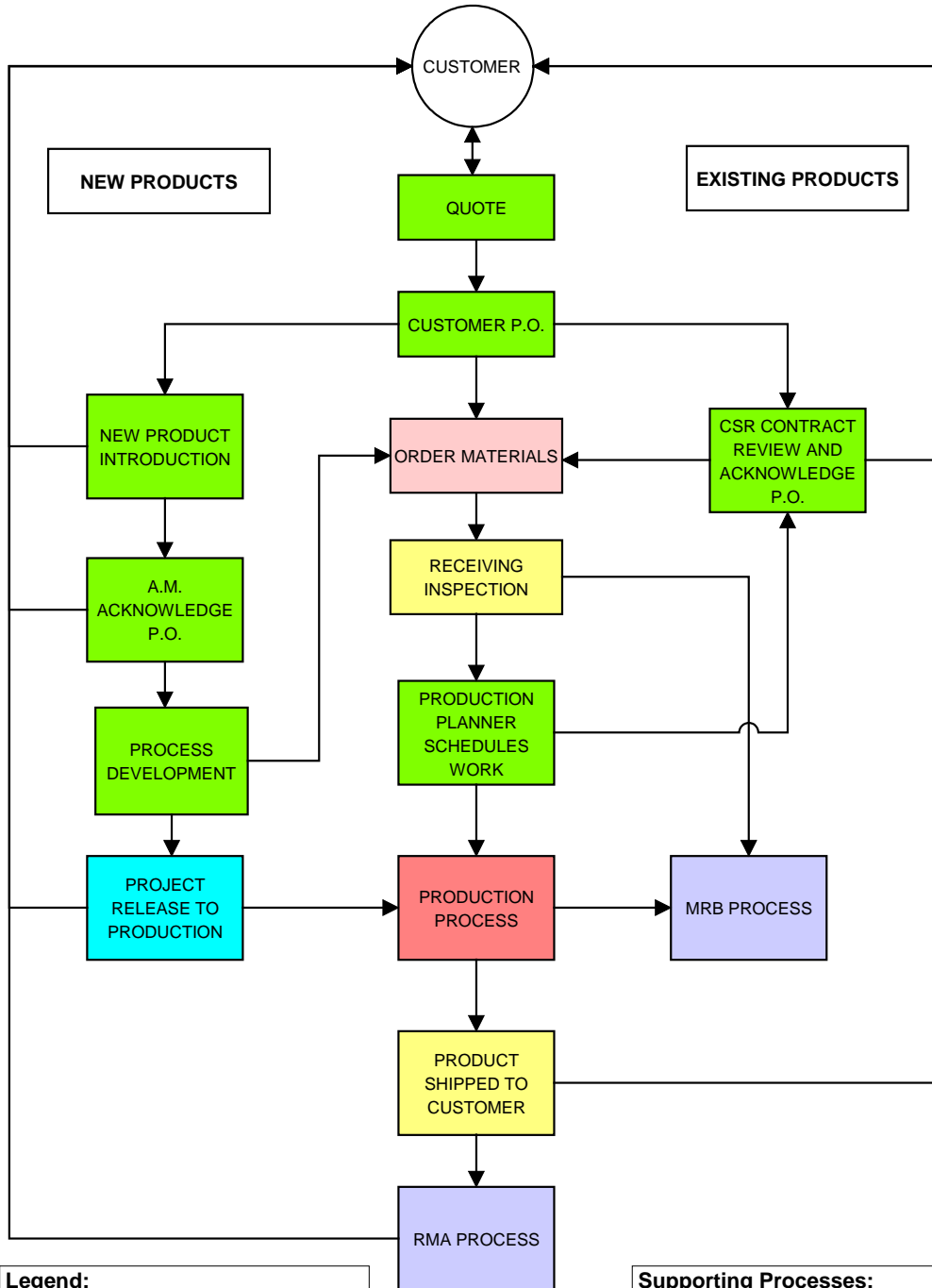
KASO reacts to nonconformities and, as applicable, takes action to control and correct them and deals with the consequences. The company reviews internal and customer complaint nonconformities as they arise, using the risk criteria defined in the corrective and preventive action procedure to determine whether or not individual problems merit formal corrective action. The corrective and preventive action process reviews and analyzes the nonconformity, determines the cause(s), and determines if similar nonconformities exist or could potentially occur. The company also uses risk-based thinking to identify and address potential nonconformities and issues. The procedure Corrective and Preventive Action Overview defines the responsibility and authority structure for the corrective and preventive action system. The procedure also defines the requirements for:

- a) The criteria for reviewing and analyzing nonconformities and potential nonconformities that may warrant formal corrective action. The criteria include evaluating the need for action to eliminate the cause(s) of the nonconformity in order to prevent it from recurring or occurring elsewhere.
- b) The methods used for root cause determination;
- c) Evaluating the need for, and severity of, actions to be taken in order to ensure the nonconformities are prevented or do not occur again;
- d) Determining and implementing the needed actions;
- e) Recording the nature of the nonconformity, the actions taken, and the results of the action(s);
- f) Reviewing the effectiveness of the action(s) taken;
- g) Updating risks and opportunities determined during planning if necessary;
- h) Changing our QMS if necessary.

### **10.3 Continual improvement**

The Management of KASO endeavors to continually improve the suitability adequacy, and effectiveness of its QMS through the review of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, continual improvement projects, and the management review process.

## Appendix A: Overall Process Sequence & Interaction



**Legend:**  
 Green - MRC Departmental Metrics  
 Pink - MRC Departmental Metrics  
 Blue - MRC Departmental Metrics  
 Red - MRC Departmental Metrics  
 Violet - Monthly MDR Report  
 Yellow - KASO Indices

**Supporting Processes:**  
 Corrective and Preventive Actions (14.100)  
 Internal Auditing (17.000)  
 Equipment Calibration (11.000)  
 Training (18.000)



## Appendix B: ISO 9001:2015 Cross Reference

ISO No.	PROCEDURE AND FORM NAMES	KASO NO.
4.1	QSM Quality Systems Manual	QSM
4.2	QSM Quality Systems Manual	QSM
4.3	QSM Quality Systems Manual	QSM
4.4	How KASO Supports the Quality Statement	Introduction
4.4	Management Review Meetings	1.001
4.4	Continual Improvement Project (CIP)	1.400
4.4	Quality System Documents Overview	2.1.000
4.4	Quality Planning Including Design and Development Overview	2.3.000
4.4	Distribution of Project Files	2.3.020
4.4	Production Control Overview	9.000
4.4	Inspection & Testing Overview	10.000
4.4	Corrective and Preventive Action Overview	14.000
4.4	Hand., Stor., Pack., & Del Overview	15.000
4.4	Auditing Overview	17.000
5.1.1	How KASO Supports the Quality Statement	Introduction
5.1.1	Management Review Meetings	1.001
5.1.2	Contract Review Phase	2.3.001
5.1.2	Development Phase - Part 1	2.3.002
5.1.2	Customer Approval	2.3.015
5.1.2	Sales Quote	3.001
5.1.2	General Customer Requirements	5.320
5.2.1	QSM Quality Systems Manual	QSM
5.2.2	How KASO Supports the Quality Statement	Introduction
5.3	Management Responsibility Overview	1.000
5.3	Management Review Meetings	1.001
5.3	Agenda & Meeting Notice	1.100
5.3	Authorization & Distribution of System Documents	5.002
6.1	Corrective and Preventive Action Overview	14.000
6.1	CAPA Authorization	14.001
6.1	CAPA Team Action	14.002
6.1	CAPA Implementation & Verification	14.003
6.1	Preventive Action	14.007
6.1	Corrective and Preventive Action Form	14.100
6.2	Response to Late-Short Supplier Deliveries	6.010
6.2	Discrepant Material Identification & Immediate Action	13.001
6.2	Work Instructions for MDR Reports & Distribution	13.008
6.2	Customer On-Time Delivery Report	15.015
6.2	KASO On-Time Delivery Report	15.240
6.2	PC Exception Report Follow-Up	20.005
6.2	Low P.C. Investigation Worksheet	20.300
6.2	PC Exception Report	20.400
6.3	Agenda & Meeting Notice	1.100
7.1.1	Management Review Meetings	1.001
7.1.2	Management Review Meetings	1.001
7.1.3	System Back-up	5.006
7.1.3	Equipment Maintenance	9.008
7.1.3	Tool Room Request	9.011

<b>ISO No.</b>	<b>PROCEDURE AND FORM NAMES</b>	<b>KASO NO.</b>
7.1.3	Preventive Maintenance	9.015
7.1.3	Maintenance of Molds & Fixtures	9.016
7.1.3	Storm Drain Filters	9.024
7.1.3	Mold & Fixture Maintenance / Repair Request	9.150
7.1.3	Preventative Maintenance Work Order	9.210
7.1.3	Security Practices	20.008
7.1.3	Disaster Plan	N/A
7.1.4	Pellet, Regrind and Small Part Disposal	9.025
7.1.4	Disaster Plan	N/A
7.1.4	Employee Handbook	N/A
7.1.4	Health and Safety Manual	N/A
7.1.4	Temporary Workers Orientation Handbook	N/A
7.1.5.1	Control and Authorization of Method of Measurement Instructions	10.019
7.1.5.1	MOM INSTRUCTIONS	10.700
7.1.5.1	Control of Ins., Mea., & Test Equip Overview	11.000
7.1.5.1	Calibration of Measuring and Test Equipment	11.001
7.1.5.1	Storage and Handling of Measuring and Test Equipment	11.002
7.1.5.1	Control Out-of-Calibration or Suspect Measuring & Test Equipment	11.003
7.1.5.1	Employee-Owned Measuring & Test Equipment	11.004
7.1.5.1	Calibration Record	11.100
7.1.5.1	KASO Internal Calibration Record	11.500
7.1.5.1	Torque Driver Setting Calibration Log	11.600
7.1.5.2	Control of Ins., Mea., & Test Equip Overview	11.000
7.1.5.2	Calibration of Measuring and Test Equipment	11.001
7.1.5.2	Storage and Handling of Measuring and Test Equipment	11.002
7.1.5.2	Control Out-of-Calibration or Suspect Measuring & Test Equipment	11.003
7.1.5.2	Employee-Owned Measuring & Test Equipment	11.004
7.1.5.2	Calibration Record	11.100
7.1.5.2	KASO Internal Calibration Record	11.500
7.1.5.2	Torque Driver Setting Calibration Log	11.600
7.1.6	Training Overview	18.000
7.1.6	Training	18.001
7.1.6	Documenting Training	18.002
7.1.6	Payroll Status Changes	18.003
7.1.6	Mold Technician Training	18.005
7.1.6	Assembly Technician Training	18.006
7.1.6	Attendance Record	18.300
7.2	Training Overview	18.000
7.2	Training	18.001
7.2	Payroll Status Changes	18.003
7.2	Temp Workers Orientation	18.004
7.2	Mold Technician Training	18.005
7.2	Assembly Technician Training	18.006
7.2	Attendance Record	18.300
7.2	Documenting Training	18.002
7.3	Temp Workers Orientation	18.004
7.4	Management Review Meetings	1.001
7.4	Employee Handbook	N/A

<b>ISO No.</b>	<b>PROCEDURE AND FORM NAMES</b>	<b>KASO NO.</b>
7.5.1	Creating a Flowchart and Procedure	2.2.001
7.5.1	Changing Procedures and Forms - Part A	2.2.002A
7.5.1	Changing Procedures and Forms - Part B	2.2.002B
7.5.1	Controlling Temporary Procedures and Forms	2.2.003
7.5.1	Work Instructions	2.2.004
7.5.1	Flowchart Symbols	2.2.100
7.5.1	Distribution of Project Files	2.3.020
7.5.1	Maintenance Request	9.800
7.5.2	Process Plan / Work Order Change Authorization	2.3.014
7.5.2	Distribution of Project Files	2.3.020
7.5.2	Document & Data Control Overview	5.000
7.5.2	Filing System Documents	5.001
7.5.2	Authorization & Distribution of System Documents	5.002
7.5.2	Drawing Control	5.003
7.5.2	Drawing Revision Change - Part 1	5.004
7.5.2	Drawing Revision Change Part 2	5.005
7.5.2	System Back-up	5.006
7.5.2	Database Control	5.007
7.5.2	Maintaining Standards Library	5.008
7.5.2	Artwork Film Control	5.009
7.5.2	Work Instructions for Identifying Drawing Revision Changes	5.010
7.5.2	General Customer Requirements	5.011
7.5.2	General Customer Requirements Form	5.012
7.5.2	Customer Standards - Review, Implement	5.014
7.5.2	Document Master List & Status Log	5.100
7.5.2	Electronic Files' Location	5.110
7.5.2	IQMS Template Change Log	5.120
7.5.2	Customer Drawing Log Receipt	5.200
7.5.2	Customer Drawing Log (DCS) (electronic sample)	5.210
7.5.2	Standards Log	5.300
7.5.2	Other Requirements Log	5.310
7.5.2	Other Requirements Log (Shipping Only)	5.310a
7.5.2	Document Revision Sign-Off sheet	5.400
7.5.2	Engineering Change Notice (ECN)	5.500
7.5.2	Artwork Film Log	5.700
7.5.2	Engineering Change Notice (ECN) Log	5.900
7.5.2	Quality Records Maintenance	16.002
7.5.3	Document Master List & Status Log	5.100
7.5.3	Electronic Files' Location	5.110
7.5.3	File Transfer Log	5.600
7.5.3	Control of Quality Records Overview	16.000
7.5.3	Control of Quality Records	16.001
7.5.3	Storage & Disposal of Archived Records in Storeroom	16.003
7.5.3	Quality Records List (File Sample)	16.100
8.1	Quality Planning Including Design and Development Overview	2.3.000
8.1	Contract Review Phase	2.3.001
8.1	Development Phase - Part 1	2.3.002
8.1	Preparation of Quality Plan	2.3.004

ISO No.	PROCEDURE AND FORM NAMES	KASO NO.
8.1	Development Phase - Part 2	2.3.005A
8.1	Development Phase - Part 2	2.3.005B
8.1	Approval Phase - Part 1	2.3.007A
8.1	Trial Run Request	2.3.008
8.1	Process Compatibility	2.3.009
8.1	Process Plan / Work Order Change Authorization	2.3.014
8.1	Customer Approval	2.3.015
8.1	Revision of PPAP	2.3.016
8.1	Design Review	2.3.017
8.1	Mold Modification	2.3.018
8.1	Approval to Proceed to Next Phase	2.3.019
8.1	Authorization to Design Order & Fabricate	2.3.200
8.1	Approval to Proceed to Next Phase	2.3.390
8.1	Customer Submittal	2.3.400
8.1	Customer Approval	2.3.420
8.1	NPI Team Composition	2.3.430
8.1	Design Review Worksheet	2.3.440
8.1	Trial Run Request	2.3.500
8.1	General Customer Requirements	5.320
8.1	Process Parameters	9.029
8.1	Supplier Dock to Stock Program	10.020
8.1	Bi Hourly Inspection Log	10.300
8.2.1	When is Customer Approval Required	2.3.022
8.2.1	Types of Customer Approval	2.3.023
8.2.1	PFMEA & Control Plan Creation	2.3.024
8.2.1	Customer Approval	2.3.015
8.2.1	Sales Quote	3.001
8.2.1	Prompt Acknowledgement of the Receipt of Customer P.O.'s	3.017
8.2.1	Quoting Piece Part Pricing	3.020
8.2.1	Acknowledgement	3.500
8.2.1	Acknowledgement of Receipt	3.520
8.2.1	Open Order Backlog	3.530
8.2.1	Prior to Production Request for Customer Waiver-Deviation	13.010
8.2.1	Handling Customer Comments	14.005
8.2.1	Distribution of Customer Supplied Performance Reviews	20.007
8.2.2	Design Review	2.3.017
8.2.2	Shelf Life	2.3.021
8.2.2	Contract Review Overview	3.000
8.2.2	Sales Quote	3.001
8.2.2	Customer Shipping Criteria	3.006
8.2.2	Internal Request for Quote	3.014
8.2.2	Auto-MRP Management	3.022
8.2.2	Budgetary Sales Quotes	3.023
8.2.2	Budgetary Quote Form	3.110
8.2.2	KASO Tooling Quote Submittal Worksheet	3.120
8.2.2	Quote Requirement Checklist	3.300
8.2.2	Auto-MRP Management Report (electronic sample)	3.950
8.2.2	Certificates for Restricted Substances	10.018

ISO No.	PROCEDURE AND FORM NAMES	KASO NO.
8.2.2	Shipping Criteria	15.600a
8.2.3	NPI General Meeting Attendance Form	2.3.410
8.2.3	Sales Quote	3.001
8.2.3	Contract Review - Sales	3.002
8.2.3	Contract Review - CSR - Part 1	3.003
8.2.3	Contract Review - CSR - Part 2	3.004
8.2.3	CSR's Authorization for Contract Review	3.005
8.2.3	Acknowledgement of Customer Order	3.007
8.2.3	Review of Part History	3.010
8.2.3	Processing a Customer P.O. for Engineering Goods & Services	3.011
8.2.3	Sales Requote - Sell Price Change Only	3.016
8.2.3	Prompt Acknowledgement of the Receipt of Customer P.O.'s	3.017
8.2.3	Quoting Piece Part Pricing	3.020
8.2.3	General Guidelines (for quoting)	3.600
8.2.3	Departmental Guidelines Approval	3.700
8.2.3	General Customer Requirements	5.320
8.2.4	Acknowledgement	3.500
8.2.4	Authorization & Distribution of System Documents	5.002
8.3.2	Quality Planning Including Design and Development Overview	2.3.000
8.3.2	NPI General Meeting Attendance Form	2.3.410
8.3.2	NPI Team Composition	2.3.430
8.3.2	Design Review Worksheet	2.3.440
8.3.3	Contract Review Phase	2.3.001
8.3.3	Development Phase - Part 1	2.3.002
8.3.3	Preparation of Quality Plan	2.3.004
8.3.3	Design Review	2.3.017
8.3.3	Shelf Life	2.3.021
8.3.3	PFMEA & Control Plan Creation	2.3.024
8.3.3	KASO Tooling Quote Submittal Worksheet	3.120
8.3.3	Quote Requirement Checklist	3.300
8.3.4	Development Phase - Part 2	2.3.005A
8.3.4	Development Phase - Part 2	2.3.005B
8.3.4	Approval Phase - Part 1	2.3.007A
8.3.4	Process Compatibility	2.3.009
8.3.4	Approval to Proceed to Next Phase	2.3.019
8.3.4	Authorization to Design Order & Fabricate	2.3.200
8.3.4	Authorization to Design Order & Fabricate	2.3.200
8.3.4	Design Review Worksheet	2.3.440
8.3.4	NPI Production Process Audit Checklist	2.3.450
8.3.4	Trial Run Request	2.3.500
8.3.4	Mold Specification Sheet	3.800
8.3.4	Incoming Fixture Checklist	7.700
8.3.4	First Shot Approval	10.004
8.3.4	Last Shot Approval	10.005
8.3.4	Dimensional Report	10.900
8.3.5	Development Phase - Part 2	2.3.005A
8.3.5	Development Phase - Part 2	2.3.005B
8.3.6	Quality System Documents Overview	2.1.000

ISO No.	PROCEDURE AND FORM NAMES	KASO NO.
8.3.6	Development Phase - Part 2	2.3.005B
8.3.6	Revision of PPAP	2.3.016
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## Revision History and Approval

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