



Polycraft, Inc.	QM - 11
Title: Polycraft, Inc. Quality Manual	Copy
	Approval: D. Wheeler

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ISO 9001:2015 Standard to Quality Manual Section Matrix

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1.0 Scope and Exclusions

Scope

This Quality Manual contains policies that have been implemented at **Polycraft Incorporated** located at **42075 Avenida Alvarado, Temecula, California.**

This manual pertains to processes relating to: Screen Printing, [Wide Format Digital Printing](#), and Flexographic Printing

The manual and related quality system documentation is written to comply with the requirements of ISO 9001:2015.

Exclusions

The organizations only exclusions are Design and Development and Servicing.

7.3 Design and Development

Justification: Polycraft Incorporated does not design or develop products for our customers.



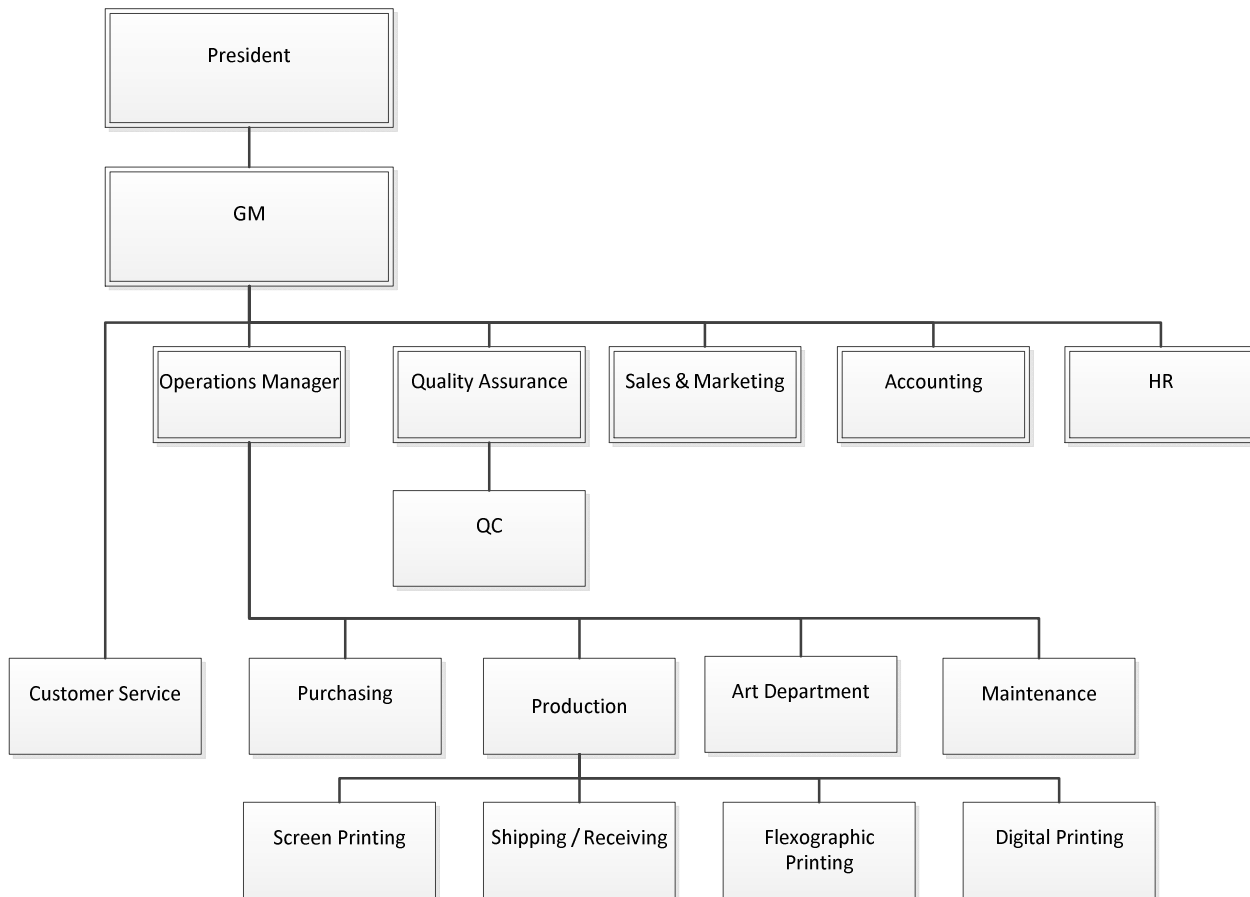
2.0 Company

Polycraft Inc. was formed in 1974 for the purpose of manufacturing labels specifically for the medical device, electronics, and OEM Industries. Success of the organization stems from finding, securing, and maintaining long term business relationships with its loyal external customer base. The organization is committed to providing consistent product meeting external customer and applicable regulatory requirements.

The organization is a custom job shop that produces product from customer requirements. The organization is not involved with product development or product design.

It is the intention of the organization to enhance customer satisfaction, promote continual process improvement, and increase product assurance through effective application of the International Standard 9001:2015 Quality Management System. This QMS Manual and its contents are applicable to every process within the organization.

POLYCRAFT ORGANIZATION CHART:

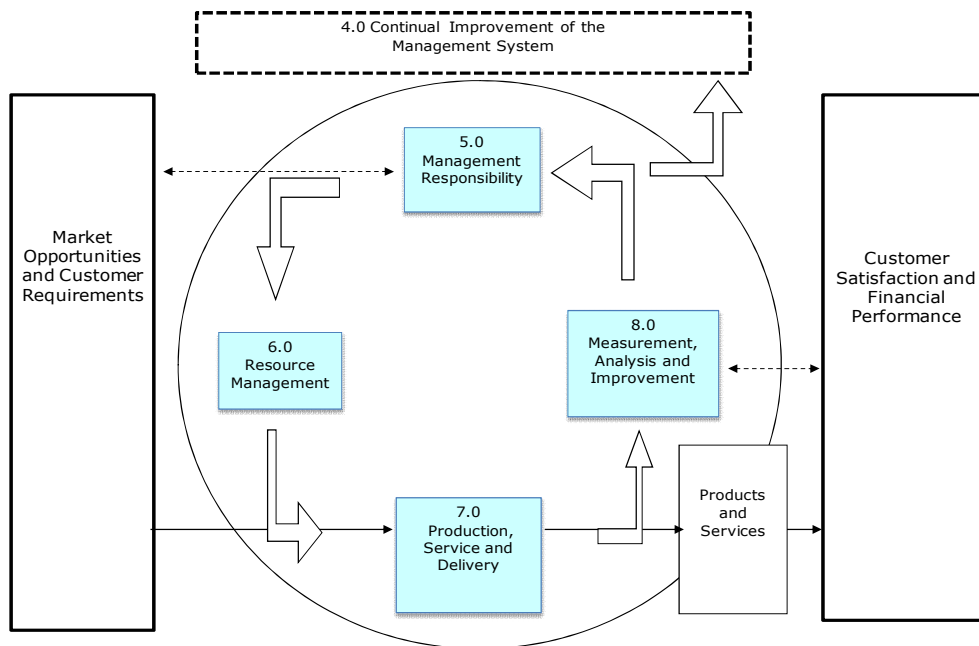


3.0 Terms and Definitions

Throughout this Quality Manual, the term “**organization**” refers to Polycraft Incorporated.

Quality Management System (QMS) refers to a system that considers the three main components: quality control, quality assurance and quality improvement. Quality management is focused not only on product or service quality, but also the means to achieve it. A QMS, therefore, uses quality assurance and control of processes, as well as products/services to achieve more consistent quality.

ISO 9001:2015 Quality Management System Model





4.0 Quality Management System

4.1 General requirements

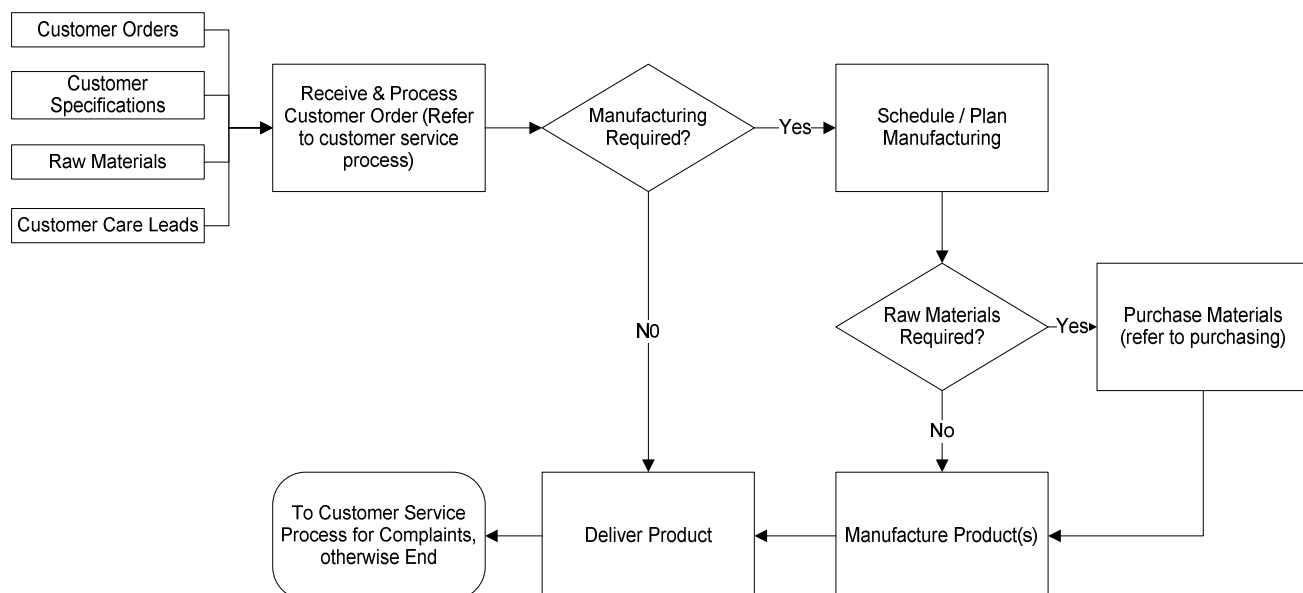
Management Review OP01

The organization Polycraft Incorporated has established, documented, implemented and currently maintains a quality management system. We continually improve its effectiveness in accordance with the requirements of ISO 9001:2015.

The organization:

- has determined the processes needed for the quality management system and their application throughout the organization,
- determined the sequence and interaction of these processes,
- determined criteria and methods needed to ensure that both the operation and control of these processes are effective,
- ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
- monitors, measures where applicable, and analyzes these processes, and
- implements actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed by the organization in accordance with the requirements of ISO 9001:2015.





Where the organization chooses to outsource any process that affect product conformity to requirements, the organization ensures control over and responsibility for such processes. The type and extent of control to be applied to these outsourced processes are defined within the quality management system.

Polycraft Inc. Outsourced Processes

Outsourced Process	Provider	Controls
Embossing	Form X	QC upon receipt
Doming	Hi Dome	QC upon receipt

4.2 Documentation Requirements

4.2.1 General

The quality management system documentation includes:

- documented statements of a quality policy and quality objectives,
- a quality manual,
- documented procedures and records required by ISO 9001, including Document Control, Record Control, Internal Audit, Control of Non-conforming Product, Corrective and Preventive Action,
- documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

4.2.2 Quality Manual

The organization has established and currently maintains a quality manual that includes:

- the scope of the quality management system, including details of and justification for any exclusions,
- the documented procedures established for the quality management system, or reference to them, and
- a description of the interaction between the processes of the quality management system.

The Quality Assurance Manager is responsible for maintaining the quality manual.

4.2.3 Document Control

Document Control OP05

Documents required by the quality management system are controlled. Records are a special type of document and are controlled according to the requirements given in section 4.2.4.

A documented procedure has been established (see Control of Documents Procedure) to define the controls needed:

- to approve documents for adequacy prior to issue,
- to review and update as necessary and re-approve documents,
- to ensure that changes and the current revision status of documents are identified,
- to ensure that relevant versions of applicable documents are available at points of use,
- to ensure that documents remain legible and readily identifiable,



- to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The Quality Assurance Manager is responsible to maintain the Document Control Procedure, to ensure that relevant versions are available at points of use, to remove obsolete documents, and to control external documents. Documents are reviewed and approved, including re-approval as required, by the appropriate functional manager along with the Quality Assurance Manager.

4.2.4 Control of Records

Control of Quality Records OP16

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

A documented procedure has been established (see Control of Records Procedure) to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records are legible, readily identifiable and retrievable.

The Quality Assurance Manager is responsible to maintain the Records Control Procedure.



5.0 Management Responsibility

5.1 Management Commitment

Management Review OP01

Top management provides evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

- communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- establishing the quality policy,
- ensuring that quality objectives are established,
- conducting management reviews, and
- ensuring the availability of resources.

Top management is considered to be the Quality Steering Team, that includes the following members: [QA Manager](#) and General Manager

5.2 Customer Focus

Contract Review and Customer Related Processes OP03

Top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.3 Quality Policy

Top management ensures that the quality policy:

- is appropriate to the purpose of the organization,
- includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- provides a framework for establishing and reviewing quality objectives,
- is communicated and understood within the organization, and
- is reviewed for continuing suitability.

The stated quality policy is as follows:

Our goals are to sustain profitability and growth by meeting the changing needs of our internal and external customers through continual and timely improvement of the quality management system.

The Quality Assurance Manager is responsible for ensuring the quality policy is reviewed during the Management Review process.

5.4 Planning



5.4.1 Quality Objectives

Top management ensures that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

The General Manager is responsible for establishing and maintaining the following quality objectives in order to measure customer satisfaction:

Measure/ Quality Objective	Owner	Reporting Frequency	Target
In Process Batch Rejections	Operations Manager	Monthly	99% or better first time quality
On Time Delivery	Operations Manager	Monthly	99.8% or better on-time delivery
Customer Rejects	Operations Manager	Monthly	99.5% or better first time quality

5.4.2 Quality management system planning

Top management ensures that:

- the planning of the quality management system is carried out in order to meet the requirements given in section 4.1, as well as the quality objectives, and
- the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and authority

Top management ensures that responsibilities and authorities are defined and communicated within the organization. This is achieved via organization chart (Refer to section 2.0), job descriptions, and training.

5.5.2 Management Representative

Top management has appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

- ensuring that processes needed for the quality management system are established, implemented and maintained,
- reporting to Top management on the performance of the quality management system and any need for improvement, and
- ensuring the promotion of awareness of customer requirements throughout the organization.

The appointed management representative is the QA Manager and serves as the liaison to external parties on matters relating to the quality system.



5.5.3 Internal communication

Top management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. This is achieved by

- A central e-mail address and phone directory
- Employee meetings
- E-mails to employees
- Bulletin board postings

5.6 Management Review

OP01 Management Review

Top management reviews the organization's quality management system, at planned intervals (at least annually), to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews are maintained by the Quality Assurance Manager.

The input to management review includes information on:

- results of audits,
- customer feedback,
- process performance and product conformity,
- status of preventive and corrective actions,
- follow-up actions from previous management reviews,
- changes that could affect the quality management system, and
- recommendations for improvement.

The output from the management review includes:

- any decisions and actions related to improvement of the effectiveness of the quality management system and its processes,
- improvement of product related to customer requirements, and
- resource needs.

The following individuals attend Management Reviews:

- Quality Assurance Manager
- General Manager
- Others may be brought in for part or all of the review as required



6.0 Resources Management

6.1 Provision of Resources

Production Planning OP02

The organization determines and provides the resources needed to implement and maintain the quality management system and continually improve its effectiveness and to enhance customer satisfaction by meeting customer requirements. Resource needs are discussed during management review, operations meetings, staff meetings, and other meetings as well as according to customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements are deemed competent on the basis of appropriate education, training, skills and experience. The Operations Manager is responsible for assessing competence in conjunction with the hiring manager. Competency requirements are defined in job descriptions.

6.2.2 Competence, training and awareness

Training OP18

The organization:

- determines the necessary competence for personnel performing work affecting conformity to product requirements,
- where applicable, provides training or takes other actions to achieve the necessary competence,
- evaluates the effectiveness of the actions taken,
- ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- maintains appropriate records of education, training, skills and experience.
- Evaluates performance and competence of employees during annual and probationary employee reviews.

The Operations Manager is responsible to determine competency requirements and to oversee the training process. Training requirements are defined in job descriptions.

Human Resources also maintains appropriate records of education, training, skills, and experience.

As of the initial release of this document, all current employees are considered to be competent.

6.3 Infrastructure

The organization determines, provides and maintains the infrastructure needed to achieve conformity to product requirements.

Infrastructure includes, as applicable:

- buildings, workspace and associated utilities,
- process equipment (both hardware and software), and
- supporting services (such as transport, communication or information systems).



Scheduled maintenance, including data backup, is performed on the following:

Scheduled Maint Items	Responsible
Server and files backed up	Forum Infotech
Vehicle	Shipping/Receiving
Flexographic presses	Operators
Screen presses	Operators

6.4 Work Environment

The organization determines and manages the work environment needed to achieve conformity to product requirements. The Facilities Department is responsible to identify and control work environment requirements. Work environment controls include the following:

Condition	Control
Particulate and dust control	WI032 Environmental Process Control



7.0 Product Realization

7.1 Planning of Product Realization

Contract Review OP03
Production Planning OP02

The organization plans and develops the processes needed for product realization.

Planning of product realization is consistent with the requirements of the other processes of the quality management system.

In planning product realization, the organization determines the following, as appropriate:

- quality objectives and requirements for the product,
- the need to establish processes and documents, and to provide resources specific to the product,
- required verification, validation, monitoring, measurement, inspection and test activities, specific to the product and the criteria for product acceptance,
- records needed to provide evidence that the realization processes and resulting product meet requirements.

The output of this planning is in a form suitable for the organization's method of operations. Planning output includes production schedule and work order (traveler).

Customer Service is responsible for planning production provision and for maintaining associated records.

7.2 Customer-related Processes

7.2.1 Determination of requirements related to the product

The organization determines:

- requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- requirements not stated by the customer but necessary for specified or intended use, where known,
- statutory and regulatory requirements applicable to the product, and
- any additional requirements considered necessary by the organization.

The **Estimator** is responsible for determining all customer requirements, whether specified; not stated, but necessary; or statutory and regulatory. Requirements are determined by customer documentation, and knowledge of available production methods.

7.2.2 Review of requirements related to the product

The organization reviews the requirements related to the product. This review is conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that:

- product requirements are defined,
- contract or order requirements differing from those previously expressed are resolved, and



- the organization has the ability to meet the defined requirements.

Requirements are reviewed via contract review.

Records of the results of the review and actions arising from the review are maintained. The Customer Service Department is responsible for the review and for maintaining the records.

Where the customer provides no documented statement of requirement, the customer requirements are confirmed fax or email before acceptance.

Where product requirements are changed, the Customer Service Department ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer communication

Contract Review OP/03

The organization determines and implements effective arrangements for communicating with customers in relation to:

- product information,
- enquiries, contracts or order handling, including amendments, and
- customer feedback, including customer complaints.
- customer feedback from information received through customer care.

Product information includes construction details such as raw material, PMS colors, dimensions and quantities and are maintained in job specific folder.

Customer enquiries, contracts, orders, etc. are received by email or fax.

Customer feedback is recorded and managed by form and/or email.

7.3 Design and Development

The organization makes no changes to process, procedure, raw materials, suppliers, and equipment without formal notification and approval from the customer.

7.4 Purchasing

7.4.1 Purchasing process

Purchasing OP06

The organization ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.



Criteria	Selection	Evaluation/ Re-evaluation
System performance and reliability data	X	X
Capabilities and experience	X	
Project completion		X
Technical specifications	X	X
Price and availability	X	X
Product quality		X
On time delivery		X

Records of the results of evaluations and any necessary actions arising from the evaluation are maintained in the Management Review.

The Purchasing Department is responsible for controlling the purchasing process and for maintaining appropriate records. Approved suppliers are listed in the Approved Supplier List.

As of the initial release of this document, all current suppliers in good standing are considered to be approved.

7.4.2 Purchasing information

Purchasing information describes the product to be purchased, including where appropriate:

- requirements for approval of product, procedures, processes and equipment,
- requirements for qualification of personnel, and
- quality management system requirements.

Purchasing information includes purchase orders, specifications, and/or contracts.

The organization ensures the adequacy of specified purchase requirements prior to communication to the supplier.

7.4.3 Verification of purchased product

The organization establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Purchased product is verified by receiving inspection including, count verification and review of supplier documentation.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization states the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service provision

7.5.1 Control of production provision and service provision

The organization plans and carries out production provision under controlled conditions. The products that the company manufactures do not require servicing. Controlled conditions include, as applicable:

- the availability of information that describes the characteristics of the product,



- the availability of work instructions, as necessary,
- the use of suitable equipment,
- the availability and use of monitoring and measuring equipment,
- the implementation of monitoring and measurement, and
- the implementation of product release, delivery and post-delivery activities.

The Operations Manager is responsible for controlling all product phases and for maintaining appropriate records. The organization plans and carries out production under controlled conditions to include the availability of information describing characteristics of the product, work instructions, suitable equipment, monitoring and measuring devices, and delivery.

7.5.2 Validation of processes for production

Process Control OP09

Final Inspection and Test Status OP10

The organization validates processes for production by verifying the output of those processes, per OP09 Process Control and OP10 Final Inspection and Test Status.

Validation demonstrates the ability of these processes to achieve planned results.

The organization establishes arrangements for these processes including, as applicable:

- 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, and
- revalidation.

All process outputs are verified by subsequent monitoring or measurement. Any deficiencies are observable during production or before final product release.

7.5.3 Identification and traceability

Product Identification and Traceability OP08

Where appropriate, the organization identifies the product by suitable means throughout product realization. Products are identified per OP08, Product Identification and Traceability.

The organization identifies the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the Production Department controls the unique identification of the product and maintains records. Traceability is documented by use of manufacturing lot number.

7.5.4 Customer property

Customer Supplied Material OP07

The organization exercises care with customer property while it is under the organization's control or being used by the organization. The organization identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be



unsuitable for use, the organization shall report this to the customer and maintain records. Customer property can include intellectual property and personal data.

Customer property includes raw material, drawings. Customer property is controlled by means of segregation.

The Production Department is responsible for controlling and recording customer property. Customer Service is responsible for all communication with the customer regarding their property.

7.5.5 Preservation of product

Handling, Storage, Packing , Preservation and Delivery (HSPPD) OP15

The Production Department is responsible for preserving the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, this preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Appropriate handling techniques are applied to mitigate risk factors in handling products.

7.6 Control of monitoring and measuring equipment

Control of Inspection and Test Equipment OP11

The organization determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization establishes processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. The Quality Department is responsible for all aspects related to the system of controlling monitoring and measurement.

Where necessary to ensure valid results, measuring equipment is:

- calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded,
- adjusted or re-adjusted as necessary,
- identified in order to determine its calibration status,
- safeguarded from adjustments that would invalidate the measurement result,
- protected from damage and deterioration during handling, maintenance and storage.

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

Equipment requiring calibration and/or verification include calipers.



8.0 Measurement, analysis and improvement

8.1 General

The organization plans and implements the monitoring, measurement, analysis and improvement processes needed:

- to demonstrate conformity to product requirements,
- to ensure conformity of the quality management system, and
- to continually improve the effectiveness of the quality management system.
- To ensure continual operational control

This includes determination of applicable methods, including statistical techniques, and the extent of their use. The Quality Department is responsible for systems related to monitoring, measurement, analysis and improvement.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

Customer Complaints OP19

As one of the measurements of the performance of the quality management system, the organization monitors information relating to customer perception as to whether the organization has met customer requirements.

Customer satisfaction is monitored by means of customer interviews, measuring repeat sales, and monitoring returned product.

The methods for obtaining and using this information are determined by the Customer Service Department.

8.2.2 Internal audit

Internal Audit Procedure OP17

The organization conducts internal audits at planned intervals to determine whether the quality management system:

- conforms to the planned arrangements, to the requirements of ISO 9001 and to the quality management system requirements established by the organization, and
- is effectively implemented and maintained.

An audit program has been 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 are defined. This selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

A documented procedure has been established to define the responsibilities and requirements for planning and conducting audits, establishing records and for reporting results. Records of the audits and their results are maintained. The QA Manager is responsible to oversee the internal auditing system and for maintaining appropriate records.



The management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

8.2.3 Monitoring and measurement of processes

Final Inspections and Test Results OP10

The organization 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, correction and corrective action is taken by the appropriate personnel, to ensure conformity of the product.

Methods for monitoring and measuring of processes are outlined in OP10, Final Inspections and Test Results.

8.2.4 Monitoring and measurement of product

The organization monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Refer to OP10, Final Inspections and Test Status for methods of monitoring and measuring of products.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product for delivery to the customer. Product release is indicated by means of QC inspection form.

The release of product and delivery of service to the customer does not proceed until 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

Control of Nonconforming Material OP13

The organization ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure has been established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, the organization deals with nonconforming product by one or more of the following ways:

- by taking action to eliminate the detected nonconformity;
- by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- by taking action to preclude its original intended use or application;
- by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.



When nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

8.4 Analysis of data

Statistical Techniques OP20

The organization determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This 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,
- conformity to product requirements,
- characteristics and trends of processes and products including opportunities for preventive action, and
- suppliers.

Data analysis is conducted by means of team meetings and/or summary reports.

The Quality Department is responsible for determining the data requirements and for coordinating with other departments to collect and subsequently analyze the data in order to make improvements.

8.5 Improvement

8.5.1 Continual improvement

Management Review OP01

The organization continually improves the effectiveness of the quality management system using the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective Action

Corrective / Preventive Action OP14

The organization takes action to eliminate the cause of nonconformities in order to prevent their recurrence.

Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure has been established (see Corrective and Preventive Action Procedure) that defines requirements for:

- reviewing nonconformities (including customer complaints),



- taking action to correct and contain the immediate issue
- determining the causes of nonconformities,
- evaluating the need for action to ensure that nonconformities do not recur,
- determining and implementing action needed,
- recording and maintaining records of the results of action taken, and
- reviewing the effectiveness of the corrective action taken.

The Quality Department is responsible for maintaining the procedure and the associated records.

8.5.3 Preventive Action

The organization 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 has been established (see Corrective and Preventive Action Procedure) to define requirements for:

- determining potential nonconformities and their causes,
- evaluating the need for action to prevent occurrence of nonconformities,
- determining and implementing action needed,
- recording and maintaining the results of action taken, and
- reviewing the effectiveness of the preventive action taken.

The Quality Department is responsible for maintaining the procedure and the associated records.



Reference Documents

REFERENCE	TITLE
OP-01	Management Review
OP-02	Production Planning
OP-03	Contract Review and Customer Related Processes
OP-04	Receiving Inspection
OP-05	Document and Data Control
OP-06	Purchasing
OP-07	Customer Supplied Material
OP-08	Identification and Traceability
OP-09	Process Control
OP-10	Product Inspection and Release
OP-11	Control of Inspection, Measuring, and Test Equipment
OP-12	Preventive Maintenance
OP-13	Control of Nonconforming Material
OP-14	Corrective and Preventive Action
OP-15	Handling, Storage, Packing, Preservation, and Delivery
OP-16	Control of Quality Records
OP-17	Internal Quality Audit
OP-18	Training
OP-19	Customer Complaints and Feedback
OP-20	Statistical Techniques