



# QUALITY MANUAL

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## Section 1.

### REVISION STATUS

Revision 01	Initial Issue	02/13/95
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## Section 1 cont.

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## **Section 2.**

### **COMPANY PROFILE**

Design Mark, was founded in 1971. It is a manufacturer of custom labels, graphic overlays, nameplates shielding, insulators, and integrated membrane keypads, serving multinational customers and OEM's in the computer, electronics, instrumentation, telecommunications, appliance and industrial products industries.

The facility located in Wareham, MA. includes our customer service, art, engineering, manufacturing, and quality operations. In addition Design Mark works strategically with subcontractors in the United States, Singapore, China, and Taiwan.

Design Mark provides a high level of service through a global network of account managers, sales representatives and a dedicated customer service team, working closely together to satisfy the needs of our customers.

The following document describes our quality management system based on "ISO 9001: Latest Revision of Standard", and is the basis of our commitment to continually improve our systems to satisfy the needs of our customers.

## **Section 2 cont.**

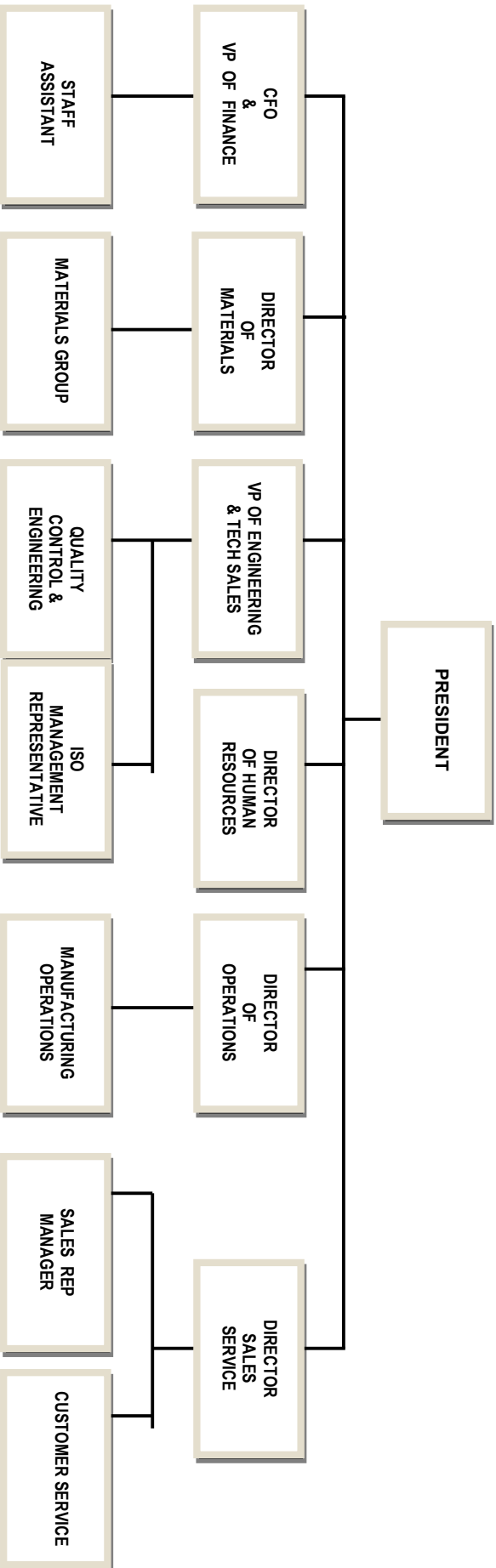
### **QUALITY POLICY**

Design Mark is committed to satisfying our Customers by continually improving the effectiveness of our quality management system.

This policy has been formulated by the President of Design Mark, and approved by its managers. The policy is explained and discussed at the general orientation training given to all existing and new employees. Copies of the policy are posted in prominent locations throughout the company. Employee understanding and participation with regard to this policy is checked during internal quality audits. Measures of company performance are posted in conspicuous locations for the information of all employees.

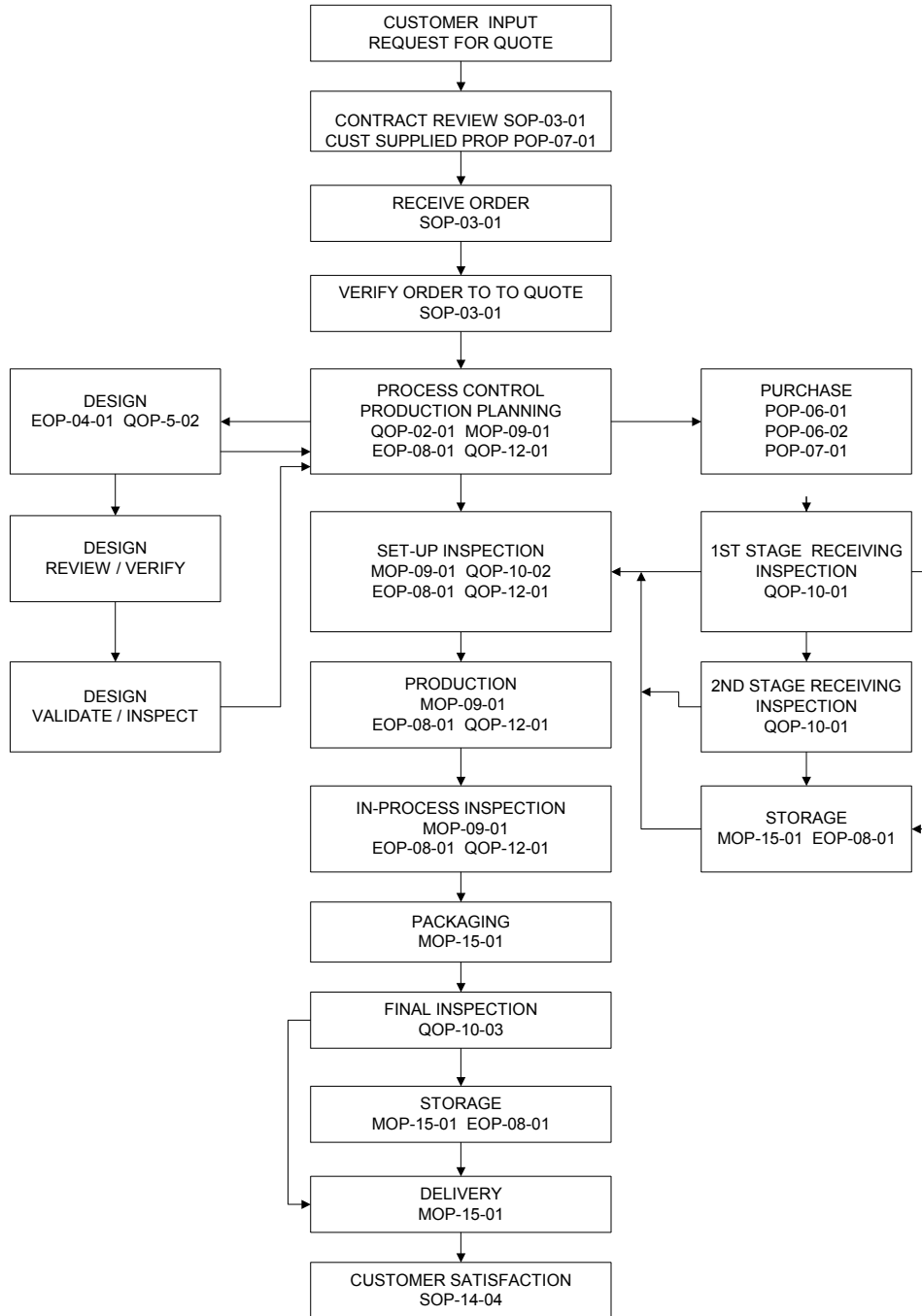
Approved by: John Winzeler 06/10/2009  
President, Design Mark

# Organization Chart



Section 3 cont.

QUALITY PLAN



## Section 3 cont.

### INDEX OF OPERATIONAL PROCEDURES

QOP-01-01	MANAGEMENT REVIEW
QOP-01-02	QUALITY MANAGEMENT RESPONSIBILITY
OQP-01-03	PROCESS MEASUREMENT
QOP-02-01	QUALITY PLANNING
SOP-03-01	CONTRACT REVIEW
EOP-04-01	DESIGN CONTROL
QOP-05-01	QUALITY SYSTEM DOCUMENTATION
QOP-05-02	DOCUMENT CONTROL
POP-06-01	SUPPLIER AND SUBCONTRACTOR ASSESSMENT
POP-06-02	PURCHASING
POP-07-01	CUSTOMER SUPPLIED PRODUCT
EOP-08-01	PRODUCT IDENTIFICATION AND TRACEABILITY
MOP-09-01	PROCESS CONTROL
QOP-10-01	RECEIVING INSPECTION
QOP-10-02	IN-PROCESS INSPECTIONS
QOP-10-03	FINAL INSPECTION
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QOP-12-01	INSPECTION AND TEST STATUS
QOP-13-01	CONTROL OF NON-CONFORMING PRODUCT
QOP-14-01	CORRECTIVE ACTION
QOP-14-03	PREVENTIVE ACTION
SOP-14-02	CUSTOMER COMPLAINTS
SOP-14-04	CUSTOMER SATISFACTION
MOP-15-01	HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY
QOP-16-01	QUALITY RECORDS
QOP-17-01	INTERNAL QUALITY AUDITS
AOP-18-01	TRAINING
QOP-20-01	STATISTICAL TECHNIQUES

## Section 4.

### INTRODUCTION

This Quality Manual contains the overall policies for the quality management system of Design Mark. This quality system complies with the international standard, "ISO 9001: Latest Revision of Standard".

It shows our understanding that Design Mark

- a) Needs to demonstrate its ability to consistently provide products and services that meet customer requirements and applicable statutory and regulatory requirements, and
- b) Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer expectations and applicable statutory and regulatory requirements.

### Application

When any requirement of ISO 9001 cannot be applied due to the nature of our organization and our products and services, it has been excluded from our quality management system.

When exclusions are made, they are limited to requirements contained in clause 7. Such exclusions do not affect the organization's ability or responsibility to provide products and services that fulfill customer requirements and applicable regulatory requirements.

The exclusions which have been made are listed below:

Design Mark does not in its normal course of business provide field service to any of its products. Therefore this element of ISO 9001 does not apply to Design Mark. Therefore, the Service provisions in clause 7.5 do not apply to our Quality Management System. If this were to become applicable, documented procedures would be put in place.

### Scope

This Quality Management System pertains to all operations performed at the facilities located in Wareham, Massachusetts, and is applicable to the design and manufacture of custom labels, graphic overlays and integrated membrane keypads.

## 4 Quality Management System Policies

### 4.1 General Requirements

Design Mark has established, documented, implemented and maintains a quality management system in accordance with the requirements of "ISO 9001: Latest Revision of Standard".

Design Mark:

- a) Determine the processes needed for the quality management system and their application throughout the organization, (see *Index of operational procedures, page 8*)
- b) Determines the sequence and interaction of these processes, (see *quality plan, page 7*) (sec 4.2.2 c)
- c) Determines criteria and methods required to ensure that both the operation and control of these processes are effective,
- d) Ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) Monitors, measures where applicable and analyze these processes,
- f) Implements actions necessary to achieve planned results and continual improvement of these processes,
- g) Manages its processes in accordance with the requirements of "ISO 9001: Latest Revision of Standard", and
- h) Identifies the controls to be applied within the quality management system to outsourced processes, which affect product conformity to requirements. (see sec 7.4.1)

See procedure QOP-01-02, QUALITY MANAGEMENT RESPONSIBILITY  
QOP-01-01, MANAGEMENT REVIEW  
QOP-05-01, QUALITY SYSTEM DOCUMENTATION

### 4.2 Documentation Requirements

#### 4.2.1 General

Quality management system documentation includes:

- a) Documented statements of quality policy and quality objectives, [see page 6 and section 8]
- b) A Quality Manual, [this document]
- c) Documents and records required by the International Standard to implement the policies stated in this manual and referenced here by paragraph, See *Index of Operational Procedures, page 8*
- d) Other documents including records determined by the organization to be necessary to ensure the effective planning, operation and control of its processes and

See procedure QOP-01-02, QUALITY MANAGEMENT RESPONSIBILITY  
QOP-05-01, QUALITY SYSTEM DOCUMENTATION  
QOP-05-02, DOCUMENT CONTROL

#### 4.2.2 Quality Manual

Design Mark has established and maintains this Quality Manual, which includes or references:

- a) The scope of the quality management system, including details of, and justification for, any exclusions [see section 1],
- b) The documented procedures established for the quality management system, and
- c) Description of the interaction between the processes of the quality management system See *QUALITY PLAN, page 7*

### **4.2.3 Control of Documents**

Documents required for the quality management system are controlled. Quality records are a special type of document and are controlled according to the policy described in 4.2.4.

A documented procedure has been established to define the controls needed to:

- a) Approve documents for adequacy prior to issue,
- b) Review and update as necessary and re-approve documents,
- c) Ensure that changes to, and current revision status of, documents are identified,
- d) Ensure that relevant versions of applicable documents are available at points of use,
- e) Ensure that documents remain legible and readily identifiable,
- f) Ensure that documents of external origin determined by Design Mark to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

*See procedure QOP-05-02, DOCUMENT CONTROL*

### **4.2.4 Control of Quality Records**

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

A documented procedure has been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of quality records.

Quality records are maintained so as to remain legible, readily identifiable and retrievable.

*See procedure QOP-16-01, QUALITY RECORDS*

## **5 Management Responsibility**

### **5.1 Management Commitment**

Design Mark top management provides evidence of its commitment to the development and improvement of the quality management system and continually improving its effectiveness by:

- a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements [sec 5.3],
- b) Establishing the quality policy [sec 5.3],
- c) Ensuring that quality objectives are established [sec 5.4.1],
- d) Conducting management reviews [sec 5.6], and
- e) Ensuring the availability of resources [sec 6].

### **5.2 Customer Focus**

Design Mark top management ensures that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction [sec 7.2.1 and 8.2.1]

*See procedure SOP-03-01, CONTRACT REVIEW*

### **5.3 Quality Policy**

Design Mark top management ensures that the quality policy:

- a) Is appropriate to the purpose of the organization,
- b) Includes a commitment to meet requirements and continually improve the effectiveness of the quality management system,
- c) Provides a framework for establishing and reviewing quality objectives,
- d) Is communicated and understood within the organization, and
- e) Is reviewed for continuing suitability.

*See page 5 and section 5.6*

### **5.4 Planning**

#### **5.4.1 Quality Objectives**

Design Mark top management ensures that quality objectives, including those needed to meet product requirements, are established at relevant functions and levels within the organization. Quality objectives are measurable and consistent with our quality policy, customer satisfaction, on-time delivery and to reduce scrap. [sec 5.6 and 7.1]

#### **5.4.2 Quality Management System Planning**

Design Mark top management ensures that:

- a) The planning of the quality management system is carried out in order to meet system requirements [see 4.1], as well as quality objectives, and
- b) The integrity of the quality management system is maintained when changes to the system are planned and implemented and,
- c) The changes are assessed at Management Review .

*See section 4.0*

*See procedure QOP-05-01, QUALITY SYSTEM DOCUMENTATION*

### **5.5 Responsibility, Authority and Communication**

#### **5.5.1 Responsibility and Authority**

Design Mark management ensures that the responsibilities and authorities, and their interrelation are defined and communicated within the organization.

*See procedure QOP-01-02, QUALITY MANAGEMENT RESPONSIBILITY & ORGANIZATION CHART PAGE 6 OF THIS MANUAL..*

### **5.5.2 Management Representative**

Design Mark top management has appointed a member of management who, irrespective of other responsibilities, has responsibilities and authority that include:

- a) Ensuring that processes needed for the **quality management system** are established, implemented and maintained,
- b) Reporting to top management on the performance of the quality management system and any need for improvement, and
- c) Ensuring the promotion of awareness of customer requirements throughout the organization.

See *ORGANIZATION CHART, PAGE 6*.

### **5.5.3 Internal Communication**

Design Mark 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.

## **5.6 Management Review**

### **5.6.1 General**

Design Mark top management reviews the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review includes the assessment of opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

See *procedure QOP-01-01, MANAGEMENT REVIEW*  
*QOP-16-01, QUALITY RECORDS*

### **5.6.2 Review Input**

The input to management review includes information on:

- a) Results of audits [including corrective action],
- b) Customer feedback [both direct (surveys) and indirect (returns/complaints)],
- c) Process performance and product conformity,
- d) Status of preventive and corrective actions [product/service: supplier; in-process; customer],
- e) Follow-up actions from earlier management reviews ["old business"],
- f) Planned changes that could affect the quality management system, and
- g) Recommendations for improvement.

### **5.6.3 Review Output**

The output from the management review includes any decisions and actions related to:

- a) Improvement of the effectiveness of the quality management system and its processes,
- b) Improvement of product related customer requirements,
- c) Resource requirements,
- d) Revisions to quality objectives, and
- e) Revisions to the quality policy.

## **6 Resource Management**

### **6.1 Provision of Resources**

Design Mark identifies and provides the resources needed to:

- a) Implement and maintain the quality management system and continually improve its effectiveness, and
- b) Enhance customer satisfaction by meeting customer requirements.

*See Procedure QOP-01-01, MANAGEMENT REVIEW*

*See Sec 5.4 and 5.6*

### **6.2 Human Resources**

#### **6.2.1 General**

The competence of personnel performing work affecting conformity to product requirements is maintained on the basis of appropriate education, training, skills and experience.

#### **6.2.2 Competence, Training and Awareness**

Design Mark:

- a) Determines the necessary competence for personnel performing work affecting conformity to product requirements,
- b) Where applicable, provides training or takes other actions to achieve the necessary competence,
- c) Evaluates the effectiveness of the actions taken,
- d) Ensures that our personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of their quality objectives, and
- e) Maintains appropriate records of education, training, skills and experience (see 4.2.4).

*See Procedure AOP-18-01, TRAINING*

### **6.3 Infrastructure**

Design Mark determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, for example:

- a) Buildings, workspace and associated utilities,
- b) Process equipment, both hardware and software, and
- c) Supporting services such as transport, communication or information systems.

*See Procedure MOP-09-01, PROCESS CONTROL*

*MOP-MOP-15-01, Handling, Storage, Packaging, Preservation and Delivery.*

## 6.4 Work Environment

Our organization determines and manages the work environment needed to achieve conformity to product requirements.

*See procedure MOP-09-01, PROCESS CONTROL*

## 7 Product Realization

### 7.1 Planning of Product Realization

Design Mark 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.

When planning for product realization, Design Mark determines the following, as appropriate:

- a) Quality objectives and requirements for the product;
- b) The need to establish processes and documents, and to provide resources specific to the product;
- c) Required verification, validation, monitoring, measuring, inspection and test activities specific to the product and the criteria for product acceptance;
- d) Records needed to provide evidence that the realization processes and resulting product fulfill requirements. The requirements of section 7.3 shall be applied to the development of product realization processes

*See procedure QOP-02-01, QUALITY PLANNING  
MOP-09-01 PROCESS CONTROL  
QOP-10-01,-02, -03 INSPECTION*

The output of this planning is in a form suitable for Design Mark's method of operations.

The document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, is referred to as our quality plan.

*See QUALITY PLAN, PAGE 7.*

### 7.2 Customer-related processes

#### 7.2.1 Determination of Requirements Related to the Product

Design Mark determines:

- a) Requirements specified by the customer, including requirements for delivery and post-delivery activities,
- b) Requirements not stated by the customer, but necessary for specified use or known and intended use,
- c) Statutory and regulatory requirements applicable to the product, and
- d) Any additional requirements considered necessary by our organization.

*See procedure SOP-03-01, CONTRACT REVIEW  
EOP-04-01 DESIGN CONTROL*

## **7.2.2 Review of Requirements Related to the Product**

Design Mark 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) and ensures that:

- a) Product requirements are defined,
- b) Contract or order requirements differing from those previously expressed are resolved, and
- c) The organization has the ability to meet defined requirements.

Records of the results of the review and actions arising from the review are maintained.

When the customer does not provide a documented statement of requirement, customer requirements are confirmed by our organization before acceptance.

When product requirements are changed, our organization ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

In some situations, such as internet or telephone sales, a formal review is impractical for each order. Instead the review covers relevant product information such as catalogues or advertising material.

*See procedure SOP-03-01, CONTRACT REVIEW*

## **7.2.3 Customer Communication**

Design Mark determines and implements effective arrangements for communicating with customers relative to:

- a) Product information,
- b) Enquiries, contracts or order handling, including amendments, and
- c) Customer feedback, including customer complaints.

*See procedure SOP-03-01, CONTRACT REVIEW*

## **7.3 Design and Development**

### **7.3.1 Design and Development Planning**

Product design and development projects are planned and controlled.

During design and development planning, our organization determines:

- a) The stages of the design and development project,
- b) The review, verification and validation activities appropriate to each design and development stage, and
- c) The responsibilities and authorities for design and development.

The Interfaces between different groups involved in design and development projects are managed to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and development progresses.

Design Mark may at times verify and or validate design control and review in combination or independently as suited for product or process as needed.

### **7.3.2 Design and Development Inputs**

Inputs relating to product requirements are determined and records maintained. These include:

- a) Functional and performance requirements,
- b) Applicable statutory and regulatory requirements,
- c) Where applicable, information derived from previous similar designs, and
- d) Other requirements essential for design and development.

The inputs are reviewed for adequacy. Requirements are complete, unambiguous and not in conflict with each other.

### **7.3.3 Design and Development Outputs**

The outputs of design and development are in a form suitable for verification against the design and development input and are approved prior to release.

Design and development outputs:

- a) Meet the input requirements for design and development,
- b) Provide appropriate information for purchasing, production and service provision,
- c) Contain or reference product acceptance criteria, and
- d) Specify the characteristics of the product that are essential for its safe and proper use.

Information for production and service provision may include details for preservation of product.

### **7.3.4 Design and Development Review**

At suitable stages, systematic reviews of design and development are conducted to:

- a) Evaluate the ability of the results of design and development to fulfill requirements, and
- b) Identify any problems and propose necessary actions.

Participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of verifications and any necessary actions are maintained.

### **7.3.5 Design and Development Verification**

Verification is performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

### **7.3.6 Design and Development Validation**

Design and development validation are performed to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

### **7.3.7 Control of Design and Development Changes**

Design and development changes are identified and records maintained. Changes are reviewed, verified and validated, as appropriate, and approved before implementation. Review of design and development changes includes evaluation of the changes on constituent parts and delivered product. Records of the results of the review of changes and any necessary actions are maintained.

See procedure *EOP-04-01, DESIGN CONTROL*  
*SOP-03-01, CONTRACT REVIEW*  
*QOP-16-01, QUALITY RECORDS*

## **7.4 Purchasing**

### **7.4.1 Purchasing**

Design Mark 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 realization or the final product.

Design Mark 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. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

See procedure *POP-06-01, SUPPLIER AND SUBCONTRACTOR ASSESSMENT*  
*POP-06-02, PURCHASING*

### **7.4.2 Purchasing Information**

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

- a) Requirements for approval of product, procedures, processes and equipment,
- b) Requirements for qualification of personnel, and
- c) Quality management system requirements.

Design Mark ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

See procedure *POP-06-02, PURCHASING*

### **7.4.3 Verification of Purchased Product**

Design Mark identifies and implements inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

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

See procedure *POP-06-02, PURCHASING*  
*QOP-10-01, RECEIVING INSPECTION*

## **7.5 Production**

### **7.5.1 Control of Production**

Design Mark plans and carries out production under controlled conditions. Controlled conditions include, as applicable

- a) The availability of information that describes the characteristics of the product,
- b) The availability of work instructions,
- c) The use of suitable equipment,
- d) The availability and use of measuring and monitoring equipment,
- e) The implementation of monitoring and measurement, and
- f) The implementation of product release, and delivery.

*See procedure MOP-09-01, PROCESS CONTROL  
MOP-15-01, HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY*

### **7.5.2 Validation of processes for production**

Design Mark validates production processes where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

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

Design Mark makes arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes,
- b) Approval of equipment and qualification of personnel,
- c) Use of specific methods and procedures,
- d) Requirements for records, and
- e) Revalidation.

*See procedure MOP-09-01, PROCESS CONTROL*

### **7.5.3 Identification and Traceability**

Where appropriate, Design Mark identifies the product by suitable means throughout production realization.

Design Mark identifies the product status with respect to monitoring and measurement requirements throughout the product realization.

Where traceability is a requirement, our organization controls and the unique identification of the product and maintains records.

*See procedure EOP-08-01, PRODUCT IDENTIFICATION AND TRACEABILITY  
QOP-12-01, INSPECTION AND TEST STATUS*

#### **7.5.4 Customer Property**

Design Mark exercises care with customer property while it is under the organization's control or being used by the organization. Our 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, Design Mark will report this to the customer and maintain records.

Customer property includes intellectual property and personal data.

*See procedure POP-07-01, CUSTOMER SUPPLIED PRODUCT*

#### **7.5.5 Preservation of Product**

Design Mark preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

*See procedure MOP-15-01, HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY*

### **7.6 Control of Monitoring and Measuring Equipment**

Design Mark determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to specified requirements.

Design Mark 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.

To ensure valid results, measuring equipment is:

- a) Calibrated and 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 are recorded, (see 4.2.4),
- b) Adjusted or re-adjusted as necessary,
- c) Have identification in order to determine its calibration status,
- d) Safeguarded from adjustments that would invalidate the measurement result, and
- e) Protected from damage and deterioration during handling, maintenance and storage.

In addition, Design Mark assesses and records the validity of previous measuring results when the equipment is found not to conform to requirements. Design Mark takes appropriate action on the equipment and any product affected.

Records of the results of calibration and verification are maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

Confirmation of the ability of computer software to satisfy the intended application would typically include verification and configuration management to maintain its suitability for use.

*See procedure QOP-11-01, INSPECTION MEASURING AND TEST EQUIPMENT*

## **8 Measurement, analysis and improvement**

### **8.1 General**

Design Mark plans and implements the monitoring, measurement, analysis and improvement processes needed to:

- a) Demonstrate conformity to product requirements,
- b) Ensure conformity of the quality management system, and
- c) Continually improve the effectiveness of the quality management system.

This includes the determination of applicable methods, including statistical techniques, and the extent of their use.

*See procedure QOP-10-01, 02, 03, INSPECTION  
QOP-17-01, INTERNAL QUALITY AUDITS  
QOP-20-01, STATISTICAL TECHNIQUES*

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction**

As one of the measurements of performance of the quality management system, Design Mark monitors information relating to customer perception as to whether Design Mark has fulfilled customer requirements. Design Mark determines the methods for obtaining and using this information.

*See procedure SOP-14-02, CUSTOMER COMPLAINTS  
SOP-14-04, CUSTOMER SATISFACTION*

#### **8.2.2 Internal Audit**

Design Mark conducts internal audits at planned intervals to determine whether the quality management system:

- a) Conforms to the planned arrangements, to the requirements of "ISO 9001: Latest Revision of Standard and to the quality management system requirements established by our organization, and
- b) Is effectively implemented and maintained.

Our audit program is 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. The selection of auditors and conduct of audits is accomplished so as to ensure objectivity and impartiality of the audit process. Auditors are not assigned to audit their own work.

Design Marks audit procedure defines responsibility and requirements for planning and conducting audits, establishing records and reporting results.

Records of audits and their results are maintained.

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

*See procedure QOP-17-01, INTERNAL QUALITY AUDITS*

### **8.2.3 Monitoring and measurement of processes**

Design Mark applies suitable methods to monitor, and where applicable, measure 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, as appropriate.

When necessary, Design Mark will consider the type and extent of monitoring and measurement for each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of our quality management system.

*See procedure QOP-01-03, PROCESS MEASUREMENT  
MOP-09-01, PROCESS CONTROL  
QOP-17-01, INTERNAL QUALITY AUDITS  
QOP-20-01, STATISTICAL TECHNIQUES*

### **8.2.4 Monitoring and measurement of product**

Design Mark monitors and measures product characteristics to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process in accordance with planned arrangements and maintains evidence of conformity to the acceptance criteria.

Records indicate the person(s) authorizing release of product for delivery to the customer.

The release of product and service delivery to the customer does not proceed until all the planned arrangements have been satisfactorily completed unless otherwise approved by a relevant authority and, where applicable, by the customer.

*See procedure QOP-10-01, 02, 03 INSPECTION  
QOP-20-01 STATISTICAL TECHNIQUES*

### **8.3 Control of nonconforming product**

Design Mark 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 and defines the controls and related responsibilities for dealing with and isolating nonconforming product.

When applicable, Design Mark deals with nonconforming product in one or more of the following ways:

- a) By taking action to eliminate the detected nonconformity,
- b) By authorizing the use, release or acceptance under concession by a relevant authority and, where applicable, by the customer,
- c) By taking action to preclude its original intended use or application.
- d) 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.

*See procedure QOP-13-01, CONTROL OF NONCONFORMING PRODUCT*

## 8.4 Analysis of data

Design Mark 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 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:

- a) Customer satisfaction,(see 8.2.1)
- b) Conformance to product requirements,(see 8.2.4)
- c) Characteristics and trends of processes and products including opportunities for preventive action, and (see 8.2.3 and 8.2.4)
- d) Suppliers (see 7.4)

See procedure QOP-01-01, MANAGEMENT REVIEW  
POP-06-01, SUPPLIER AND SUBCONTRACTOR ASSESSMENT  
QOP-13-01, CONTROL OF NONCONFORMING PRODUCTS  
QOP-14-01, CORRECTIVE ACTION  
QOP-14-03, PREVENTIVE ACTION  
QOP-20-01, STATISTICAL TECHNIQUES

## 8.5 Improvement

### 8.5.1 Continual Improvement

Design Mark continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

See procedure QOP-01-01, MANAGEMENT REVIEW

### 8.5.2 Corrective action

Design Mark takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

Our procedure for corrective action defines requirements for:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the causes of nonconformities,
- c) Evaluating the need for action to ensure that nonconformities do not recur,
- d) Determining and implementing action needed,
- e) Recording the results of action taken (see 4.2.4), and
- f) Reviewing effectiveness of the corrective action taken.

See procedure QOP-14-01, CORRECTIVE ACTION

### **8.5.3 Preventive action**

Design Mark takes action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions taken are appropriate to the effects of the potential problems.

Our procedure for Preventive Action defines requirements for:

- a) Determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities,
- c) Determining and implementing action needed,
- d) Recording results of action taken (see 4.2.4), and
- e) Reviewing effectiveness of preventive action taken.

*See procedure QOP-14-03, PREVENTIVE ACTION*