

## **6.5 Information**

It is our policy to ensure we continually review our information systems to make sure they remain capable of providing accurate and timely data to foster factual management decisions, and the continuing development of our employee's knowledge that can simulate innovation throughout our organization.

We ensure that we:

- identify system information needs
- identify and access internal and external sources of information
- convert data to knowledge for the organization
- use the data, information and knowledge to set and meet strategies and objectives
- ensure appropriate security and confidentiality
- evaluate benefits from the use of the information to improve managing information and knowledge

The Finance and Administration function is responsible and has the authority for information activities.

Reference: Management System Procedure # MSP-06

## **7.0 Product Realization**

### **7.1 Planning of Product Realization**

It is our policy to plan and develop processes needed for product realization.

We provide a trained production team to monitor and control processes that ensure products are efficiently and effectively manufactured to customer specifications in a safe and clean environment that protects our human and material assets.

We ensure that planning of product realization is consistent with the requirements of other processes within our quality management system.

When planning product realization, we determine the following, as appropriate:

- quality objectives and requirements for the product as defined by customer specifications and other inputs
- the need to establish processes and documents
- provide resources specific to the product
- required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance

- records needed to provide evidence that realized processes and resulting product meet requirements

We ensure that processes are well documented.

We have a formal process for problem identification, corrective action and change.

We develop innovative products. We understand our customer's requirements and needs.

Teamwork and individual excellence are keys to our success.

The Top Management team is responsible and has the authority for planning of product realization activities.

Reference: Management System Procedure # MSP-07

## **7.2 Customer Related Activities**

It is our policy to ensure determination of requirements related to the products by identifying:

- 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 related to the product
- additional requirements determined by the organization

The review of these requirements is conducted prior to our commitment to supply product to our customer. We ensure that:

- product requirements are defined
- contract or order requirements differing from those previously expressed are resolved
- we have the ability to meet defined requirements

When a customer provides no documented statement of requirement, company-defined requirements based on customer defined use are presented to the customer for acceptance.

When product requirements are changed, we ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

We develop and strive for increased levels of customer and consumer cooperation to develop the foundation for our business. We determine and implement effective arrangements for communicating with our customers.

The Top Management team is responsible and has the authority for customer-related process activities.

Reference: Management System Procedure # MSP-07

### **7.3 Design and Development**

It is our policy to plan and control the design and development of product. We ensure that during design and development planning, we determine:

- the design and development stages necessary for each product
- the review, verification and validation that are appropriate to each design and development stage
- the responsibilities and authorities for design and development

We manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planned output is updated, as appropriate, as the design and development evolves.

We ensure that inputs relating to product requirements are determined, and records maintained. Inputs include:

- functional and performance requirements
- applicable statutory and regulatory requirements
- where applicable, information derived from previous similar designs
- other requirements essential for design and development

We ensure that inputs are reviewed for adequacy, and that requirements are reviewed to ensure they are complete, unambiguous and not in conflict with each other.

We ensure that outputs of design and development are provided in a form that enables verification against the design and development input, and approved prior to release.

We ensure design and development outputs:

- meet the input requirements for design and development
- provide the appropriate information for purchasing, production and for service provision
- contain or reference product acceptance criteria
- specify the characteristics of the product that are essential for its safe and proper use

We ensure that at suitable stages in the design, systematic reviews of design and development are formally and independently conducted and documented at appropriate stages.

We ensure that these reviews include design verification and validation performance criteria.

We ensure that design reviews:

- evaluate the ability of the results of design and development to meet requirements
- identify any problems and propose necessary actions

We ensure reviews include representatives of all functions concerned with the design and development stage being reviewed.

We ensure verification is performed to ensure that the design and development outputs meet the design and development input requirements.

We ensure that design and development changes are identified and records maintained.

We ensure that changes are reviewed, verified and validated, as appropriate, and approved before implementation.

We ensure the review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered.

The Sales/Marketing and Product Development functions are responsible and have the authority for design and development activities.

Reference: Management System Procedure # MSP-07

#### **7.4 Purchasing**

It is our policy to ensure 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.

We evaluate and select suppliers based on their ability to supply product in accordance with our requirements.

Criteria for selection are defined, and evaluation and re-evaluation are established and reported to the supplier through regular reports.

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
- quality management system requirements

We ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

We establish and implement inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where our customer or we intend to perform verification at our supplier's premises, we state the intended verification arrangements and method of product release in the purchasing information.

We ensure that each approved supplier is evaluated, assessed and selected on their ability to meet contractual requirements.

The terms vendor and supplier are considered synonymous in our quality management system.

The Purchasing function is responsible and has the authority for purchasing activities.

Reference: Management System Procedure # MSP-07

## **7.5 Production and Service Provision**

It is our policy to plan and carry out production and service under controlled conditions. Controlled conditions include, as applicable:

- the availability of information that describes the characteristics of the product
- the availability of procedures and site-wide processes, as necessary
- the use of suitable equipment
- the availability and use of monitoring and measuring devices
- the implementing of monitoring and measurement
- the implementation of release, delivery and post-delivery activities

We validate processes for production and service provision where the resulting output cannot be verified by subsequent monitoring and measurement.

This includes processes where deficiencies become apparent only after the product is in use or the service has been delivered.

When required, we ensure that validation demonstrates the ability of these processes to be capable.

We establish process controls including, as applicable and when necessary:

- defined criteria for review and approval of the processes
- approval of equipment and qualification of personnel
- use of specific methods and procedures
- requirements for records
- revalidation

Where appropriate, we identify the product by suitable means throughout product realization, including product status with respect to monitoring and measurement requirements. When traceability is a requirement, we ensure control, and record the unique identification of product.

We exercise care with customer property while it is under our control or while being used by us, in order to identify, verify, protect and safeguard customer property provided to us for use or to incorporate into product.

We preserve the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection.

When required, we ensure that personnel who periodically adjust machinery and equipment have available for reference any inherent limitations or allowable tolerances.

We ensure that where process results cannot be verified by inspection and testing, the process is continuously monitored to prevent nonconformity, and when required, is adequately validated and approved. Such processes may be referred to as special processes.

We ensure that changes to special processes are conducted under controlled conditions, evaluated through the remainder of the process and revalidated and approved when required.

We ensure proper control of manufacturing process materials, when appropriate and required.

It is our policy to ensure that nonconforming materials, finished goods, or customer returns are identified by product and source, and segregated to prevent unintentional usage within our processes. We ensure that disposition is timely and properly authorized, and that the customer is contacted prior to granting a product waiver, when necessary.

We ensure that reworked materials are routed through the same inspection and test process as the original product for the affected parameters.

We ensure that protective storage areas and stockrooms are provided to prevent damage or deterioration prior to use or shipment.

We ensure that inventory rotation and shelf life issues are properly documented and controlled.

When required, we ensure provision for the protection of our product from the time of shipment through the delivery to its final destination.

It is our policy to ensure that product labels are properly controlled for each product, when required by contract.

The Operations function is responsible and has the authority for production and service provision activities.

Reference: Management System Procedure # MSP-07

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

It is our policy to determine the monitoring and measurement to be undertaken and the equipment needed to provide evidence of conformity of product to determined requirements.

We establish processes to ensure that monitoring and measurement is carried out in a manner that is consistent with the monitoring and measurement requirements.

When necessary to ensure valid results, measuring equipment is:

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

In addition, we assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements.

We take appropriate action on the equipment and any product affected.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed during initial verification and validation of equipment and/or processes utilizing the software. Additional calibration of the computer software is performed according to programmer specifications. Where additional calibration post-installation qualification is required, the calibration status may or may not be displayed along with mechanical calibration status.

This is undertaken prior to initial use and reconfirmed, when necessary.

We ensure that calibration performed is traceable to the National Institute of Standards and Technology [NIST].

We ensure that a Master Calibration List [MCL] is maintained.

The Quality function is responsible and has the authority for control of monitoring and measuring device activities.

Reference: Management System Procedure # MSP-07