

#### 4. Quality management system

##### 4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard.

##### 4.2 Documentation requirements

###### 4.2.1 General

The quality management system documentation shall include:

- a) documented statements of a quality policy and quality objectives;
- b) a quality manual;
- c) documented procedures and records required by this International Standard;
- d) 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 shall establish and maintain a quality manual that includes:

- a) the scope of the quality management system;
- b) the documented procedures established for the quality management system;
- c) a description of the interaction between the processes of the quality management system.

#### 7. Product realization

##### 7.3 Design and development

###### 7.3.1 Design and development planning

The organization shall plan and control the design and development of the product.

###### 7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained.

#### 8. Measurement, analysis and improvement

##### 8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed.

##### 8.2 Monitoring and measurement

###### 8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception.