



7.1 Planning of product realization

Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to the Planning of Product Realization procedure (MP-710). During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product,
- Processes, documentation and resources required
- Verification, validation, monitoring, inspection and test requirements, and
- Criteria for product acceptance

The output of quality planning includes *documented quality plans, processes, procedures and design outputs*.

Risk management requirements are documented in EP-722, Risk Management. Records arising from risk management are maintained.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Your Company determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities
- Not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- Additional requirements determined by *Your Company*

Customer requirements are determined according to the Customer Related Processes Procedure. (SP-720)

7.2.2 Review of requirements related to the product

Your Company has a process in place for the review of requirements related to the product (SP-720). The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined and documented.



- Updating of the design plan as the project progresses

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

7.3.2 Design and development inputs

Inputs relating to product requirements are determined and documented according to the Design and Development procedure (EP-730). All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. 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
- Outputs of risk management

7.3.3 Design and development outputs

Outputs of design and development are documented according to the Design and Development Procedure (EP-730). They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

- Meet the input requirements
- Provide 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.

Records of design and development outputs are maintained.

NOTE Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.

7.3.4 Design and development review

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development



This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Documented procedures and work instructions are used for the control of product with a limited shelf-life or requiring special storage conditions. Special storage conditions are controlled and recorded.

Your Company preserves the conformity of product during internal processing and delivery to the intended destination per procedure (MP-755). This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.6 Control of monitoring and measuring devices

Your Company has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. A documented procedure (MP-760) outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

Your Company shall establish documented procedures 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.

Where 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
- 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, *Quality Control* assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. *Your Company* takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

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

Related Documents

Planning of Product Realization Processes MP-710

Customer Related Processes SP-720

Risk Management EP-722