



Section 7

Product Realization



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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, measuring, inspection and test requirements
- Configuration management
- Criteria for product acceptance
- Resources necessary to support use and maintenance of the product
- Resources to support operation and maintenance of the product.

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

7.1.1 Project Management

Management assigns responsibility for project management and ensuring that product realization is planned and managed in a controlled manner, meeting requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

Risks are managed according to the Risk Management procedure (MP-712). The process of risk management includes;

- Assigning responsibility for risk management
- Defining risk criteria
- Identification, assessment and communication of risks
- Identification, implementation and management of actions to mitigate risks
- Acceptance of risks remaining after implementation of mitigating actions

7.1.3 Configuration Management

Configuration management is defined in MP-713, Configuration Management. The procedure defines the process for:

- Configuration management planning
- Configuration identification
- Change control



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- Configuration status accounting
- Configuration audit

7.1.4 Control of Work Transfers

Temporary or permanent transfer of work is planned to control and verify the conformity of the work to requirements. Planning takes place according to the Planning of Realization Processes procedure (MP-710).

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
- Contract or order requirements differing from those previously expressed are resolved
- *Your Company* has the ability to meet the defined requirements
- Records are maintained showing the results of the review and any actions arising from the review
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- Contractual requirements are reviewed and special product requirements are determined



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- When product requirements are changed, *Your Company* communicates changes to relevant personnel and amends relevant documents
- Risks (e.g., new technology, short delivery time scale) have been evaluated (EP-712).

7.2.3 Customer communication

Your Company has implemented an effective procedure (SP-720) for communicating with customers in relation to:

- Product Information
- Enquiries, contracts and order handling, including amendments
- Customer Feedback, including customer complaints

7.3 Design and Development

7.3.1 Design and development planning

The design and development procedure (EP-730) outlines the process for controlling the design and development process. The *R&D Department* plans design and development according to this procedure. The design plan includes:

- Design and development stages
- Required design reviews, verification and validation appropriate to each design stage
- Responsibilities and authorities for design and development.
- The division of the design effort into distinct activities where appropriate
- The tasks, resources, responsibilities, design content, input, output and planning constraints for each activity
- The ability to produce, inspect, test and maintain the product
- Identification of the technical interfaces required for the project
- Updating of the design plan as the project progresses
- The different design and development tasks to be carried out, defined according to specified safety or functional objectives of the product in accordance with customer or regulatory authority requirements.

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:



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- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Where applicable, information derived from previous similar designs
- Other requirements essential for design and development

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.
- Identify critical items such as key characteristics in accordance with design or contract requirements (EP-731) and action to be taken for these items

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained is defined by the organization according to the Design and Development Procedure (EP-730)

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 procedure; results of design review are recorded in minutes of the design review meetings which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfill requirements
- Identify any problems and propose necessary actions
- Include representatives of functions concerned with the design and development stage being reviewed to authorize progression to the next stage.