

DESIGN AND DEVELOPMENT

Requirements - ISO 9001:2008 (7.3)
Supplemental Guidance - ISO 9004:2000

Design Planning (7.3.1)

- The organization shall plan and control the design and development of product.
- During the design and development planning the organization shall determine
 - the design and development stages,
 - the review, verification and validation that are appropriate to each design and development stage, and
 - the responsibilities and authorities for design and development.
- The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
- Planning output shall be updated, as appropriate, as the design and development progresses.

Design Inputs (7.3.2)

- Inputs relating to product requirements shall be determined and records maintained. These shall include:
 - functional and performance requirements,
 - applicable statutory and regulatory requirements,
 - where applicable, information derived from previous similar designs, and
 - other requirements essential for design and development.
- These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

Design Inputs - External

- customer or marketplace needs and expectations,
- needs and expectation of other interested parties,
- supplier's contributions,
- user input to achieve robust design and development,
- changes in relevant statutory and regulatory requirements,
- international or national standards, and
- industry codes of practice;

Design Inputs - Internal

- policies and objectives,
- needs and expectations of people in the organization, including those receiving the output of the process,
- technological developments,
- competence requirements for people performing design and development,
- feedback information from past experience,
- records and data on existing processes and products, and
- outputs from other processes;

Design Inputs - Other

- inputs that identify those characteristics of processes or products that are crucial to safe and proper functioning and maintenance, such as:
 - operation, installation and application,
 - storage, handling and delivery,
 - physical parameters and the environment, and
 - requirements for disposal of the products.

Design Outputs (7.3.3)

- The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.
- Design and development outputs shall
 - meet the input requirements for design and development,
 - provide appropriate information for purchasing, production and for service provision,
 - contain or reference product acceptance criteria, and
 - specify the characteristics of the product that are essential for its safe and proper use.

Examples - Design Outputs

- data demonstrating the comparison of process inputs to process outputs,
- product specifications, including acceptance criteria,
- process specifications,
- material specifications,
- testing specifications,
- training requirements,
- user and consumer information,
- purchase requirements, and
- reports of qualification tests.

Design Reviews (7.3.4)

- At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements
 - to evaluate the ability of the results of design and development to meet requirements, and
 - to identify any problems and propose necessary actions.
- Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

Examples - Design Reviews

- adequacy of input to perform the design and development tasks,
- progress of the planned design and development process,
- meeting verification and validation goals,
- evaluation of potential hazards or fault modes in product use,
- life-cycle data on performance of the product,
- control of changes and their effect during the design and development process,
- identification and correction of problems,
- opportunities for design and development process improvement, and
- potential impact of the product on the environment.

Design Verification (7.3.5)

- Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.
- Records of the results of the verification and any necessary actions shall be maintained.

Examples - Design Verification

- comparisons of input requirements with the output of the process,
- comparative methods, such as alternative design and development calculations,
- evaluation against similar products,
- testing, simulations or trials to check compliance with specific input requirements, and
- evaluation against lessons learned from past process experience, such as nonconformities and deficiencies.

Design Validation (7.3.6)

- Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, when known.
- Wherever practicable, validation shall be completed prior to the delivery or implementation of the product.
- Records of the results of validation and any necessary actions shall be maintained.

Supplemental - Design Validation

- Validation of the output of the design and development processes is important for the successful reception and use by customers, suppliers, people in the organization and other interested parties.
- Participation by the affected parties permits the actual users to evaluate the output by such means as
 - validation of engineering designs prior to construction, installation or application,
 - validation of software outputs prior to installation or use, and
 - validation of services prior to widespread introduction.
- Partial validation of the design and development outputs may be necessary to provide confidence in their future application.

Change Control (7.3.7)

- Design and development changes shall be identified and records maintained.
- The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.
- The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.
- Records of the results of the review of changes and any necessary actions shall be maintained.

Design Records

Design records specified by ISO 9001:2008:

- Design Input reviews
- Design Output approvals
- Design Reviews (including input)
- Design Verification results
- Design Validation results and actions
- Design Change records

Contact Us

MAS Solutions LLC.

17117 Westheimer Rd #1

Houston TX 77082

Email: information@masquality.com

Website: <http://www.masquality.com>