

[Organization logo]

[Organization name]

Commented [9A1]: All fields in this document marked by square brackets [] must be filled in.

PROCEDURE FOR DESIGN AND DEVELOPMENT

Commented [9A2]: If you want to find out more about the design and development process, see:

- article: The ISO 9001 Design Process Explained
<http://advisera.com/9001academy/blog/2013/11/05/iso-9001-design-process-explained/>
- free online course: ISO 9001 Foundations Course
<http://training.advisera.com/course/iso-90012015-foundations-course/>

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Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [9A3]: Adapt to the existing practice in organization.

Distribution list

Commented [9A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy No.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	9001Academy	Basic document outline

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1. Purpose, scope and users

The purpose of this procedure is to define the design control process used by [organization name] during the design and development of its products.

This procedure applies to all product development, product modifications, line extensions, product change projects and customer projects.

Users of this document are members of the design and development team of [organization name].

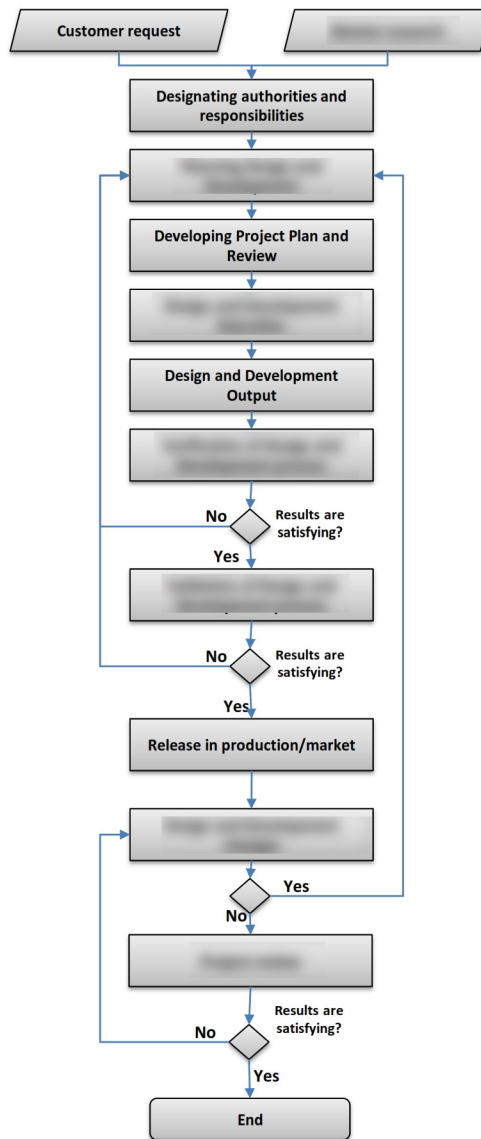
Commented [9A5]: Adapt to organization's needs.

2. Reference documents

- ISO 9001:2015 standard, clause 8.3
- [other legal and contractual requirements]

3. Design and development process

3.1. Process flow



3.2. Forming Preliminary design

[organization name]

According to the customer's request or determined needs of the market, [job title] defines the preliminary design of process, product or service, designates design and development team and team leader and defines their duties and responsibilities.

3.3. Design and development planning

3.3.1. Planning design and development stages and activities

[job title] plans stages and controls for the design and development process, by taking into account:

- Nature, duration, and complexity of the design and development activities
- The required process stages, including applicable design and development reviews
- The required design and development resources
- The required design and development tools
- The required design and development methods
- The required design and development standards

Commented [9A6]: E.g., Design and development team leader

Documented information needed to demonstrate that design and development requirements have been met are this procedure and the records mentioned in section 4 of this procedure.

3.3.2. Authorities and responsibilities in design and development

The design and development team is responsible for:

- Implementing design control
- [Redacted]
- [Redacted]
- [Redacted]

Commented [9A7]: Adapt responsibilities to organization's needs.

Commented [9A8]: Control that ensures compliance with legal and regulatory regulations or standard.

The design and development team leader has the following responsibilities:

- Assuring that all requirements are addressed, documented and approved as necessary including the rationale/justification for not performing certain activities
- Obtaining top management approval for any additional resources and/or funding
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Commented [9A9]: Design History File is a compilation of documentation that describes the design history of a realized product or service. It is specific to a particular design; therefore, it should be provided by the organization itself.

Commented [9A10]: E.g. customers, suppliers, third parties, etc.

3.4. Design and development inputs

According to the preliminary design, the team leader decides whether to involve customers and

3.4.1. Functional and performance requirements

[organization name]

The functional specification described in the Project Task by the design and development team leader according to the customer request for product addresses at least the following points:

- The performance objectives, operating conditions, and the requirements for reliability, availability, and maintainability
- Mechanical, electrical, cryogenic, radiation resistance and other technological constraints to be respected by the design
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Commented [9A11]: Adapt to organization's needs.

[Redacted]

Commented [9A12]: E.g. Design and development team leader or the person who ordered project.

3.4.2. Statutory, regulatory and other requirements

[Job title] identifies statutory and regulatory requirements and other normative documents used for dimensioning the product, selecting materials, defining manufacturing, assembly, testing and

Commented [9A13]: E.g. Design and development team leader.

[Redacted]

Commented [9A14]: Adapt to organization.

3.4.3. Information gathered from previous similar projects

The design and development team leader must take into consideration the previous similar projects in order to prevent recurrent mistakes and to avoid exceeding the budget and timeschedule. If such

Commented [9A15]: E.g. Design and development team leader.

3.4.4. Other requirements important for design and development

[Job title] must define other requirements related to design and development, such as internal and external resource needs for design and development of products and services, requirements for

[Redacted]

Commented [9A16]: Adapt to organization's needs.

3.5. Developing the Project Plan and Review

According to Project Task and input data for design and development, the design and development team leader, together with team members, creates the Project Plan and Review and defines:

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

- [redacted]

The design and development team member responsible for phase execution enters the following into the Project Plan and Review:

- All activities related to phase realization
- [redacted]
- [redacted]
- [redacted]

3.6. Design and development execution

The design and development team member responsible for the project phase ensures that all activities of the phase are conducted and all necessary records about the phase are kept.

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After phase review, the design and development team leader approves the start of the new phase by signing the Project Plan and Review.

3.7. Design and development controls

[job title] ensures that design and development results to be achieved are defined, and reviews are conducted to evaluate the ability of the results of design and development to meet requirements.

3.7.1. Verification of design and development process

The design and development team leader conducts verification in project phases where necessary and determines whether

[redacted]

3.7.2. Validation of design and development process

Validation is a check-up process that determines whether the final product is capable of satisfying the needs of the customer in specified conditions of use.

[redacted]

[redacted]

Commented [9A17]: Adapt to organization's needs.

Note: Appendix 2 – Project Plan and Review is created according to these elements; if organization needs to change these elements, Project Plan and Review must be adapted also.

Commented [9A18]: E.g. Legal and regulatory requirements

Commented [9A19]: Deliverables can be in different form. E.g. engineering documentation, drawings, calculations, product, product parts, etc.

Commented [9A20]: E.g. Human resources, finance, equipment, raw materials, etc.

Commented [9A21]: If you want to find out more about design verification and validation, see: ISO9001 Design Verification vs Design Validation' <http://advisera.com/9001academy/blog/2013/11/12/iso9001-design-verification-vs-design-validation/>

Commented [9A22]: E.g. Software, services, etc.

Commented [9A23]: In some cases validation can be conducted by computer simulations and animation. Validation can be conducted by customers, who must inform Design and development team leader about result. E.g. in design bureau.

[Redacted text]

3.8. Design and development outputs

After completion of the last phase, the design and development team leader, together with team members, enters in Design History File additional information, related to deliverables of design and development, such as:

- Information about purchasing, production and services provision once it's launched
- Criteria for accepting the product before production
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

[Job title] must approve these output elements of design and development before acceptance of product. Output elements must meet input requirements for design and development.

3.9. Release in production/market

[Job title], together with the design and development team leader, organizes a test production of the designed product.

[Redacted text]

3.10. Design and development changes

Changes in design and development can occur in every phase of design and development as a result of:

- Changes of product specification on customer request
- New or updated legal and regulatory requirements
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

The design and development team leader must document all changes in the Change Review Record,

[Redacted text]

3.11. Project review

Commented [9A24]: Deliverables can be in different form. E.g. engineering documentation, drawings, calculations, product, product parts, etc.

Commented [9A25]: E.g. Specification of materials for purchasing, requirements for equipment and management of production process.

Commented [9A26]: E.g. Instruction Manual for Product; or safety regulation for product e.g. type of material used for baby toys, label for inflammable products, etc.

Commented [9A27]: Instruction for handling product in a way that preserves its intended use and condition. For example: "Keep the Product in dry and dark place out of reach of children."

Commented [9A28]: E.g. CEO or Design and development team leader.

Commented [9A29]: E.g. Production manager

Commented [9A30]: Organization can add or delete listed reasons in order to adapt it to organization's needs.

[organization name]

After completion of all phases of design and development, making a prototype and releasing to

Commented [9A31]: E.g. CEO

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Project Task	PR.08.1	2 years	[office of design and development team leader]	[job title]
Project Plan and Review	PR.08.2	2 years	[office of design and development team leader]	[job title]
Change Review Record	PR.08.3	2 years	[office of design and development team leader]	[job title]
Design Review Minutes	PR.08.4	2 years	[office of design and development team leader]	[job title]

Commented [9A32]: If the record is in electronic form, write the name of the folder on Design and development team leader's computer.

Commented [9A33]: If the record is in electronic form, write the name of the folder on Design and development team leader's computer.

Commented [9A34]: If the record is in electronic form, write the name of the folder on Design and development team leader's computer.

Commented [9A35]: If the record is in electronic form, write the name of the folder on Design and development team leader's computer.

5. Appendices

- Appendix 1 – Project Task
- Appendix 2 – Project Plan and Review
- Appendix 3 – Change Review Record
- Appendix 4 – Design Review Minutes