

[Organization logo]

[Organization name]

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

PROCEDURE FOR SOFTWARE DEVELOPMENT

Commented [9A2]: If you want to find out more about the product realization process, see:

- article: ISO 9001:2015 clause 8.5 Product realization – Practical examples for compliance
<http://advisera.com/9001academy/blog/2015/11/03/iso-90012015-clause-8-5-product-realization-practical-examples-for-compliance/>
- free online course: ISO 9001 Foundations Course
<http://training.advisera.com/course/iso-90012015-foundations-course/>

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

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

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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 of software development process used by [organization name] during the design and development of its products.

This procedure applies to all software development, modifications, and maintenance.

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

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

2. Reference documents

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

3. Software production process

3.1. Forming Preliminary design

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

3.2. Software production planning

3.2.1. Planning software production stages and activities

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

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

- Nature and complexity of the software production activities
- The required stages, including applicable reviews
- [blurred text]
- [blurred text]
- [blurred text]
- [blurred text]

3.2.2. Authorities and responsibilities in software production

The design team is responsible for:

- Implementing design control
- [blurred text]
- [blurred text]
- [blurred text]

The design 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
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Commented [9A7]: Design History File is a compilation of [Redacted]

Commented [9A8]: E.g. customers, suppliers, third parties, etc.

3.3. Software design inputs

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

3.3.1. Functional and performance requirements

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

Commented [9A9]: Adapt to organization's needs.

[Job title] must list as a reference the documents, database records, and other information and data used to establish the product or service specification in the Design History File.

Commented [9A10]: E.g. Design and development team leader or the person who ordered project.

3.3.2. Statutory, regulatory and other requirements

[Job title] identifies statutory and regulatory requirements and other normative documents used for [Redacted]

Commented [9A11]: E.g. Design and development team leader.

Commented [9A12]: Adapt to organization.

3.3.3. Information gathered from previous similar projects

The design team leader must take into consideration the previous similar projects in order to prevent recurrent mistakes and to avoid exceeding the budget and time schedule. If such information exists, [job title] enters it into the Project Task.

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

3.3.4. Other requirements important for design and development

[Job title] must define other requirements related to software design, such as [Redacted]

3.4. Developing the Project Plan and Review

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

- Project phases
- Responsibilities of team members for each phase
- [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]

Commented [9A14]: Deliverables can be in different form. E.g. part of the software, code, etc.

Commented [9A15]: E.g. Human resources, finance, equipment, etc.

3.5. Software production execution

The design 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.

The design team conducts a review in appropriate project phases. People included [Redacted]

The design team leader convenes a formal meeting attended by all participants in software design, and minutes for the meeting in free form represent a record of the review.

If the project phase review discovers problems, [job title] suggests [Redacted]

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

3.6. Design and development controls

[Redacted]

3.6.1. Verification of design and development process

[Redacted] If the

results of the verification are satisfactory, [redacted]

3.6.2. 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]

[job title] will take any necessary action on [redacted]

Commented [9A16]: 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.

3.7. Design and development outputs

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

Commented [9A17]: Deliverables can be in different form. E.g. engineering documentation, drawings, calculations, code, etc.

- Software code
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[Job title] must approve these output elements of software production before acceptance of the software. Output elements must meet input requirements for software design.

Commented [9A18]: E.g. CEO or Design and development team leader.

3.8. Release in production/market

[Job title], together with the design team leader, organizes software testing. After satisfying testing

Commented [9A19]: E.g. Production manager

[redacted]

3.9. Design and development of changes

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

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

Commented [9A20]: Organization can add or delete listed reasons in order to adapt it to organization's needs.

[organization name]

The design team leader must document all changes in the Change Review Record, and review, verify, validate and approve

3.10. Project review

After completion of all phases of software design, the design team leader conducts a review of software design and delivers Design Review Minutes to [job title].

Commented [9A21]: 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 [9A22]: If the record is in electronic form, write the name of the folder on Design and development team leader's computer.

Commented [9A23]: If the record is in electronic form, write the name of the folder on Design and development team leader's computer.

Commented [9A24]: If the record is in electronic form, write the name of the folder on Design and development team leader's computer.

Commented [9A25]: 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