

[Organization logo]

[Organization name]

**Commented [9100A1]:** All fields in this document marked by square brackets [ ] must be filled in.

## PROCEDURE FOR SOFTWARE DEVELOPMENT

**Commented [9100A2]:** If you want to find out more about production and service provision, see this 9001Academy article: Understanding Product & Service Provision in ISO 9001 <http://advisera.com/9001academy/blog/2014/10/07/understanding-product-service-provision-iso-9001/>

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Created by:	
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**Commented [9100A3]:** Adapt to the existing practice in organization.

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## Change history

Date	Version	Created by	Description of change
	0.1	9100Academy	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 [9100A5]:** Adapt to organization's needs.

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

## 2. Reference documents

- AS9100 Rev D 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

### 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, considering the ability to provide, verify, test and maintain produced software's functionalities, by taking into account:

**Commented [9100A6]:** E.g., Design and development team leader

- Nature and complexity of the software production activities
- The required design, analysis and testing activities
- The required verification and validation activities
- Control and control resources needed for software production
- The need to control interfaces between persons involved in the design and development process
- The requirement for software production of products and services

[Job title] will ensure that when the design and development effort are divided into distinct activities, each activity.

**Commented [AS91007]:** E.g., Design and development team leader

**Commented [AS91008]:** E.g. mechanical engineering, electrical engineering, etc.

#### 3.2.2. Authorities and responsibilities in software production

The design team is responsible for:

- Implementing design control

**Commented [91A9]:** Control that ensures compliance with legal and regulatory regulations or standard.

[organization name]

- Generating project schedule and plan
- [Redacted]
- [Redacted]

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]
- Maintaining the Design History File (DHF)
- [Redacted]
- [Redacted]
- Resolving conflicting software design inputs
- Defining software design phases
- [Redacted]

**Commented [9100A10]:** Design History File is a compilation of [Redacted]

**Commented [9100A11]:** E.g. customers, suppliers, third parties, etc.

### 3.3. Software design inputs

[Redacted] the customer's design. The design leader creates a Design Task, which contains input data that defines the request for product by including the following:

**Commented [91A12]:** These inputs are not a definitive list. The [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 [9100A13]:** 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 [9100A14]:** 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 [9100A15]:** E.g. Design and development team leader.

International Electrotechnical Commission (IEC) standards and practices should be used.

**Commented [9100A16]:** Adapt to organization.

#### 3.3.3. Information gathered from previous similar projects

[organization name]

The design team leader must take into consideration the previous similar projects in order to prevent [redacted] [job title] enters it into the Project Task.

**Commented [9100A17]:** 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 internal and external [redacted]

When appropriate, [Job title] will include consideration of the potential consequences of [redacted]

**Commented [91A18]:** E.g., in response to legal requirements or results of risk assessments.

### 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]
- Project phase status (reviewed, validated, verified and completed)
- [redacted]

**Commented [AS910019]:** Note: Appendix 2 – Project Plan

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]
- Resources needed

**Commented [AS910020]:** E.g. Legal and regulatory

**Commented [9100A21]:** Deliverables can be in different form. E.g. part of the software, code, etc.

**Commented [9100A22]:** 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 in software [redacted] review if the design team leader finds it appropriate.

The design team leader convenes a formal meeting attended by all participants in software design, [redacted]

[organization name]

If the project phase review discovers problems, [job title] suggests actions to resolve them and [job title] ensures that the actions are implemented. The action of the reviewer is the subject of the next review.

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

[Job title] ensures that design and development results to be achieved are defined, and reviews are conducted to ensure the quality of the results of design and development to meet requirements.

#### 3.6.1. Verification of design and development process

The design team leader conducts verification in project phases where necessary and determines when the design process meets the requirements of the software development process. The results of the verification are recorded in the Project Plan and Review.

#### 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 to specified conditions of use.

The design team together with the client conducts validation before release of the software on the market.

[Job title] ensures that the results of verification and validation activities, and record them in the Project Plan and Review.

#### 3.6.3. Testing for Verification and Validation

When testing is necessary for verification and validation [job title] will ensure that the tests are planned, controlled, documented and verified by competent personnel, to ensure the following:

- Test plans or specifications identify the test item being tested and the resources being used, as well as define test objectives and conditions, parameters to be recorded and relevant acceptance criteria.
- The test procedures identify the test methods to be used, as well as how to perform the test and how to record the results.
- The correct configuration of the test item is submitted for the test
- The requirements of the test plan and the test procedures are observed
- The test results are recorded
- Monitoring and measurement devices used for testing are controlled as defined in **Procedure for Equipment Maintenance and Measuring Equipment**

[Job title] will ensure that, when testing for verification and validation is completed, the reports,

[Job title] will ensure that the reports are recorded in the Project Plan and Review.

**Commented [9100A23]:** In some cases, validation can be

**Commented [AS910024]:** E.g. Design and development team leader.

**Commented [AS910025]:** E.g. Design and development team leader.

**Commented [AS910026]:** Operational conditions may include different temperatures, different vacuum levels, etc.

### 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:

- Software code
- [redacted]
- [redacted]
- References to monitoring and measurement requirements
- [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 [9100A27]:** Deliverables can be in different form. E.g. engineering documentation, drawings, calculations, code, etc.

**Commented [91A28]:** e.g., data that allows the software to be identified, verified, used, and maintained.

**Commented [9100A29]:** 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 [redacted] further activities in sales and marketing can be initiated.

**Commented [9100A30]:** E.g. Production manager

### 3.9. Design and development of changes

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

- Changes of software specification on customer request
- [redacted]
- [redacted]
- Problems during production
- [redacted]
- [redacted]
- Verification activities
- [redacted]

The design team leader must document all changes in the Change Review Record, and review, verify, [redacted] parts of product and delivered product.

**Commented [9100A31]:** Organization can add or delete listed reasons in order to adapt it to organization's needs.

[Job title] will ensure that customers are notified of design changes that affect compliance to [redacted] controlled in accordance with the Procedure for Production and Service Provision.

**Commented [AS910032]:** E.g. Design and development team leader.

### 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 [9100A33]:** 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 [9100A34]:** If the records in this column are 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