

[Organization logo]

[Organization name]

Commented [AS91001]: All fields in this document marked by square brackets [] must be filled in.

PROCEDURE FOR DESIGN AND DEVELOPMENT

Commented [AS91002]: If you want to find out more about the design and development process, see this 9001Academy article: The ISO 9001 Design Process Explained
<http://advisera.com/9001academy/blog/2013/11/05/iso-9001-design-process-explained/>

Code:	
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Approved by:	
Date of version:	
Signature:	

Commented [AS91003]: Adapt to the existing practice in organization.

Distribution list

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Change history

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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].

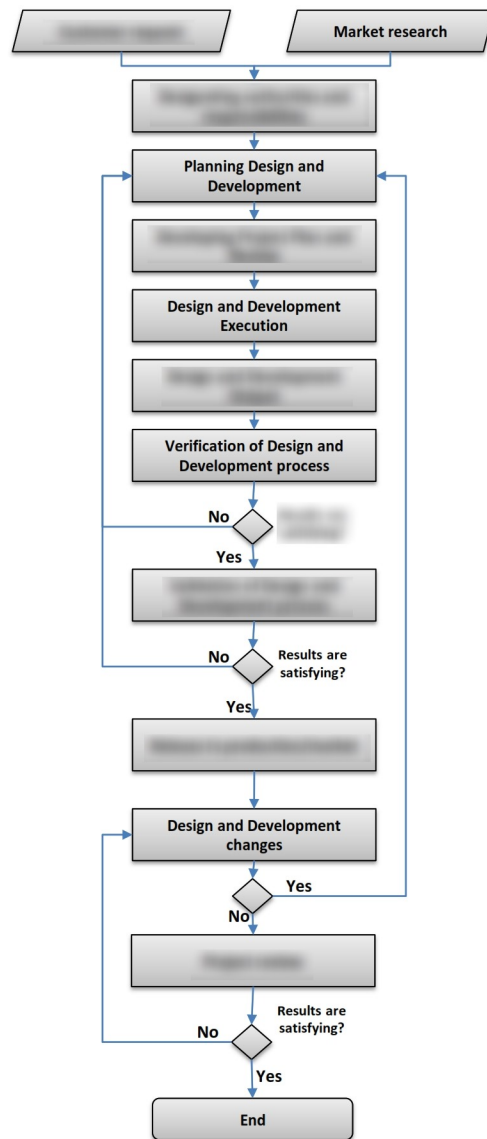
Commented [AS91005]: Adapt to organization's needs.

2. Reference documents

- AS9100 Rev D 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 [redacted] 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, considering the ability to provide, verify, test and maintain products and services, by taking into account:

- Nature, duration, and complexity of the design and development activities
- [redacted]
- Internal and external resources needed for design and development of products and services
- [redacted]
- The requirement for subsequent provision of products and services

Documented information needed to demonstrate that design and development requirements have

[job title] will ensure that when the design and development effort are divided into distinct activities, the tasks, necessary resources, responsibilities, design content, inputs and outputs are defined for each activity.

3.3.2. Authorities and responsibilities in design and development

The design and development team is responsible for:

- Implementing design control
- [redacted]
- [redacted]
- Defining activities of verification and validation for any phase of design and development

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
- [redacted]
- [redacted]
- Approving changes in design
- Managing relationships between different groups involved in design and development
- Resolving conflicting design and development inputs
- [redacted]
- [redacted]

3.4. Design and development inputs

Commented [AS91006]: E.g., Design and development team leader

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

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

Commented [AS91009]: Adapt responsibilities to organization's needs.

Commented [AS910010]: Control that ensures compliance with legal and regulatory regulations or standard.

Commented [AS910011]: Design History File is a compilation

Commented [AS910012]: E.g. customers, suppliers, third parties, etc.

[organization name]

According to the preliminary design, the team leader decides whether to involve customers and users in the design and development process and creates the Project Task, which contains input data

3.4.1. Functional and performance requirements

The functional specification described in the Project Task by the design and development team

- The performance objectives, operating conditions, and the requirements for reliability, availability, and maintainability
- [REDACTED]
- [REDACTED]
- [REDACTED]
- The basic technical interface requirements of the design
- Requirements for calculations, tests and development work, including the construction of prototypes
- [REDACTED]

[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.

3.4.2. Statutory, regulatory and other requirements

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

International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standards and practices should be used.

3.4.3. Information gathered from previous similar projects

The design and development team leader must take into consideration the previous similar projects

information exists, [Job title] enters it into the Project Task.

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

of products and services, requirements for packaging and delivery, safety requirements, etc.

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

3.5. Developing the Project Plan and Review

Commented [AS910013]: Adapt to organization's needs.

Commented [AS910014]: E.g. Design and development team leader or the person who ordered project.

Commented [AS910015]: E.g. Design and development team leader.

Commented [AS910016]: Adapt to organization.

Commented [AS910017]: E.g. Design and development team leader.

Commented [AS910018]: Adapt to organization's needs.

Commented [91A19]: E.g., in response to legal requirements or results of risk assessments.

[organization name]

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:

- Project phases
- [REDACTED]
- [REDACTED]
- [REDACTED]
- Project phase status (reviewed, validated, verified and completed)
- Start of new phase

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.

The design and development team conducts a review in appropriate project phases. People included [REDACTED] participate in the project review if the design and development team leader finds it appropriate.

The design and development team leader convenes a formal meeting attended by all participants in [REDACTED] the review.

If the project phase review discovers problems, [job title] suggests actions to resolve them and enters them into the minutes for the meeting. The effect of the executed action is the subject of the next review.

[REDACTED] 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 [REDACTED]

Commented [AS910020]: 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 [AS910021]: E.g. Legal and regulatory

Commented [AS910022]: Deliverables can be in different form. E.g. engineering documentation, drawings, calculations, product, product parts, etc.

Commented [AS910023]: E.g. Human resources, finance, equipment, raw materials, etc.

Commented [AS910024]: If you want to find out more about design verification and validation, see this 9001Academy article: ISO9001 Design Verification vs Design Validation <http://advisera.com/9001academy/blog/2013/11/12/iso9001-design-verification-vs-design-validation/>

[organization name]

development process. If the results of the verification are satisfactory, the design and development team leader signs the appropriate box in the Project Plan and Review.

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

If making a prototype is not needed, the product is sent to market.

The design and development team conducts validation before release of product in production or market.

validation activities, and record them in the Project Plan and Review.

3.7.3. Testing for Verification and Validation

When testing is necessary for verification and validation [job title] will ensure that the tests are documented and verified by competent personnel, regarding planning, controlling and reviewing activities, to ensure the following:

- Test plans or specifications identify the test item being tested and the resources being used, acceptance criteria.
- The correct configuration of the test item is submitted for the test
- The acceptance criteria are met
- 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,

3.8. Design and development outputs

After completion of the last phase, the design and development team leader, together with team development, such as:

- Information about purchasing, production and services provision once it's launched
- Criteria for accepting the product before production
- References to monitoring and measurement requirements

Commented [AS910025]: E.g. Software, services, etc.

Commented [AS910026]: In some cases, validation can be

Commented [AS910027]: E.g. Design and development team leader.

Commented [AS910028]: E.g. Design and development team leader.

Commented [AS910029]: Operational conditions may include different temperatures, different vacuum levels, etc.

Commented [AS910030]: Deliverables can be in different form. E.g. engineering documentation, drawings, calculations, product, product parts, etc.

Commented [AS910031]: E.g. Specification of materials for purchasing, requirements for equipment and management of production process.

Commented [AS910032]: 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 [AS910033]: Instruction for handling product in a way that preserves its intended use and condition. For example: "Store under environmentally controlled conditions."

[organization name]

- Requirements of subsequent processes for the provision of product and service
- Critical items, including key characteristics, and specific actions to be taken for these items
- [redacted]

[Job title] must approve and authorize 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 [redacted] Project Task.

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
- [redacted]
- [redacted]
- [redacted]
- Demand of market for improved product
- [redacted]
- [redacted]
- Validation activities

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

[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.

3.11. Project review

After completion of all phases of design and development, making a prototype and releasing to [redacted] development and delivers Design Review Minutes to [job title].

4. Managing records kept on the basis of this document

Commented [AS910034]: Items having significant effect on the product (e.g. safety, performance, form, fit, function, etc.)

Commented [AS910035]: Attribute or feature whose variation has a significant effect on form, fit, function, performance, service life, or producibility.

Commented [AS910036]: E.g. CEO or Design and development team leader.

Commented [AS910037]: E.g. Production manager

Commented [AS910038]: Organization can add or delete listed reasons in order to adapt it to organization's needs.

Commented [AS910039]: E.g. Design and development team leader.

Commented [AS910040]: E.g. CEO

[organization name]

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 [AS910041]: 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