**PROCEDURE FOR DESIGN AND DEVELOPMENT**

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

**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/ISO9001academy/blog/2013/11/05/iso-9001-design-process-explained/)
- [free online course: ISO 9001 Foundations Course](http://training.advisera.com/course/iso-9001-foundations-course/)
- [free online course: ISO 14001 Foundations Course](http://training.advisera.com/course/iso-14001-foundations-course/)

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

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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].

2. Reference documents

- ISO 9001:2015 standard, clause 8.3
- ISO 14001:2015 standard, clause 8.1
- Integrated Management System Manual
- [other legal and contractual requirements]
3. Design and development process

3.1. Process flow

3.2. Forming Preliminary design
According to the customer’s request or determined needs of the market, [job title] defines the

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 organization’s needs
- The requirements for the design and development team leader's approval
- The requirement for subsequent provision of products and services

Documented information needed to demonstrate that design and development requirements have

3.3.2. Authorities and responsibilities in design and development

The design and development team is responsible for:

- Implementing design control
- Preparing design inputs
- Understanding design and development activities
- Ensuring conformance of design and development activities to any relevant 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
- Obtaining top management approval for any additional resources and/or funding

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

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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

[Job title] must list as a reference the documents, database records, and other information and data

3.4.2. Statutory, regulatory, environmental 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

3.4.3. Information gathered from previous similar projects

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

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

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:

- Project phases
- Responsibilities of team members for each phase

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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 in the reviews are [job title], design and development team leader, and any relevant stakeholders. The purpose of the review is to ensure that all the activities and deliverables are completed as required.

The design and development team leader convenes a formal meeting attended by all participants in the review. The meeting agenda includes reviewing the deviations from the project plan and the progress of the deliverables.

If the project phase review discovers problems, [job title] suggests actions to resolve them and any necessary changes to the project plan to ensure the phase is completed successfully.

After phase review, the design and development team leader approves the start of the new phase by signing the project phase completion report.

3.7. Design and development controls

[job title] ensures that design and development results to be achieved are defined, and reviews are conducted to ensure compliance with the design and development controls.

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 the output elements address the input elements of the design and development process. The verification process involves checking the deliverables against the design specifications.

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.

[Note: Adapt to organization’s needs. 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
- Deliverables can be in different forms, e.g., engineering documentation, drawings, calculations, product, product parts, etc.
- Human resources, finance, equipment, raw materials, etc.

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Commented [9A19]: Deliverables can be in different forms, 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 ISO 9001 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.
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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
- 
- 
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- 

[Job title] must approve these output elements of design and development before acceptance of

3.9. Release in production/market

[Job title], together with the design and development team leader, organizes a test production of the product, allowing the product to enter the production market. Any changes in design and development must be documented in the Change Review Record.

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
- 
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The design and development team leader must document all changes in the Change Review Record, ensuring that the changes are implemented correctly and that the process is documented in the Design History File.

3.11. Project review
After completion of all phases of design and development, making a prototype and releasing to
[Commented [9A31]: E.g. CEO]

3.12. Environmental operational controls

[Job title] is responsible for including environmental requirements in design and development inputs
that contain, but are not limited to:

- Selection of environmentally friendly raw materials
- Changes in technology, processes, and activities in order to decrease environmental aspects
- 
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Design and development outputs can include, but are not limited to:

- Instruction on handling replaced parts and product after use
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4. Managing records kept on the basis of this document

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5. Appendices

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