PROCEDURE FOR DESIGN AND DEVELOPMENT

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</table>

Table of contents

1. PURPOSE, SCOPE AND USERS ................................................. 4
2. REFERENCE DOCUMENTS ................................................................... 4
3. DESIGN AND DEVELOPMENT PROCESS ............................................. 5
   3.1. PROCESS FLOW ................................................................... 5
   3.2. FORMING PRELIMINARY DESIGN ............................................. 5
   3.3. DESIGN AND DEVELOPMENT PLANNING ...................................... 6
   3.3.1. Planning design and development stages and activities .......... 6
   3.3.2. Authorities and responsibilities in design and development .... 6
   3.4. DESIGN AND DEVELOPMENT INPUTS ........................................ 6
   3.4.1. Functional and performance requirements .......................... 6
   3.4.2. Statutory, regulatory and other requirements ....................... 7
   3.4.3. Information gathered from previous similar projects ............. 7
   3.4.4. Other requirements important for design and development ....... 7
   3.5. DEVELOPING THE PROJECT PLAN AND REVIEW ........................ 7
   3.6. DESIGN AND DEVELOPMENT EXECUTION .................................. 8
   3.7. DESIGN AND DEVELOPMENT CONTROLS ................................... 8
   3.7.1. Verification of design and development process .................... 8
   3.7.2. Validation of design and development process .................... 8
   3.8. DESIGN AND DEVELOPMENT OUTPUTS ..................................... 9
   3.9. RELEASE IN PRODUCTION/MARKET ......................................... 9
   3.10. DESIGN AND DEVELOPMENT CHANGES .................................... 9
   3.11. PROJECT REVIEW ............................................................ 9
4. MANAGING RECORDS KEPT ON THE BASIS OF THIS DOCUMENT .......... 10
5. APPENDICES ........................................................................... 10
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
- [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 preliminary design of products, processes or services. The designated design and development team member 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 verification and validation activities
- Internal and external resources needed for design and development of products and services
- The need to control interfaces between persons involved in the design and development process
- The requirement for subsequent provision of products and services

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

Documented information needed to demonstrate that design and development requirements have been met are the procedures and the records maintained in section 3 of this procedure.

3.3.2. Authorities and responsibilities in design and development

The design and development team is responsible for:

- Implementing design control
- Generating project schedule and plan
- Revising changes to project scope or design
- Defining activities of verification and validation for any phase of design and development

Comment [9A7]: Adopt responsibilities to organization’s needs.

Comment [9A8]: Control that ensures standard.

The design and development team leader has the following responsibilities:

- Assuring that all requirements are addressed, documented and approved as necessary
- Preparing and revising design reviews and other project deliverables
- Preparing design performance reports and any additional resource and funding requests
- Maintaining the Design History File (DHF)
- Approving changes to design
- Managing relationships between different groups involved in design and development
- Resolving conflicting design and development inputs
- Defining design and development phases
- Approving review, verification and validation of every phase and start of new phase

Comment [9A9]: Design History File is a document that records all the significant changes in the project.

Comment [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 users in the design and development process and creates the Project Task, which contains input data that defines the request for product by including the following:

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.
- Safety and regulatory requirements constraints.
- The team-related requirements of the design.
- Requirements for calculations, tests and development work, including the construction of prototypes.
- Materials, parts and tools required.

[Job title] must list as a reference the documents, database records, and other information and data used to describe the product or service specifications 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 documenting the project, ensuring the project, defining manufacturing security, testing the developed products and services, and any other project-specific activities. These are typically obtained from international standards. Whenever possible, 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 in order to produce a project plan and design the product on time and within budget. If such 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 external resource needs for design and development of products and services, requirements for training the development team, and the organization of products and services, requirements for packaging and delivery, safety requirements, etc.

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
- Phase realization deadlines
- Milestone phases and control of changes
- Project phase status (reviewed, validated, verified and completed)
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 production or service procedures as well as customers and other interested parties may participate in the project review if the design and development team leader finds it appropriate.

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.

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 the output elements address the input elements of the design and 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 the needs of the customer in stipulated conditions of use.

If testing is a procedure to be executed, the product is sent to the market.

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

After completion of the test phases, 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
- Requirements of subsequent processes for the provision of product and service
- Details about preservation of product
- ... [Job title] must approve these output elements of design and development before acceptance of product.

3.9. Release in production/market

[Job title], together with the design and development team leader, organizes a test production of the designed product. After creating a prototype, the design and development team leader conducts a test production in order to determine whether the product complies with all requests defined in the 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
- Problems during production
- Verification activities
- Validation activities
- ... [Job title] must document all changes in the Change Review Record, and monitor, verify, validate and approve changes before their application, and evaluate influence of changes on other parts of product and delivered product.

3.11. Project review
After completion of all phases of design and development, making a prototype and releasing to production or market, the design and development team leader conducts a review of design and development and delivers Design Review Minutes to [job title].

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

[Comment [9A31]: e.g. CEO]

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

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Procedure for Design and Development ver. [version] from [date] Page 9 of 9

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