Procedure: [Design Procedure Doc Title]

1. SUMMARY
   1. The purpose of this procedure is to define the requirements for designing product which meets all requirements.
   2. The [who?] is responsible for implementation and management of this procedure.
2. REVISION AND APPROVAL

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| --- | --- | --- | --- |
| **Rev.** | **Date** | **Nature of Changes** | **Approved By** |
| [Rev Number] | [Date of Issue] | Original issue. | [Procedure Approver Name] |
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1. DESIGN PLANNING
   1. The [what?] department is responsible for design activities.
   2. Top management will determine when a research and development project is sufficient mature to warrant controlled design. This is typically decided when a project appears to have a high likelihood of being produced, or making it to market. Prior to this decision, any R&D activity is outside the scope of the management system.
   3. The decision to move a R&D project into controlled design is recorded on the [form?].
   4. This is then provided to [who?] who will begin to plan the design activities to be conducted.
   5. The design planning documentation is recorded [where? how?]. This will include the assigned design engineers, support staff, subordinate third party providers, and the responsibility and authority for each. Where third parties are utilized, this shall define the approved points of contact.
   6. The [who?] will develop a design schedule; this will be developed with the input of the customer and third party providers, if necessary. The schedule will be updated as the design work progresses.
2. DESIGN INPUTS
   1. Design “inputs” are the requirements for the final product.
   2. The [who?] will ensure the capture of all requirements related to the product. These include:

* Customer requirements
* Regulatory and statutory requirements
* Internal requirements (capabilities, capacities, etc.)
* Safety requirements, if applicable
* Human factors, if applicable
* Measurement and inspection methods, acceptance criteria and tolerances
* Applicable third party specifications, standards, etc.
* Material requirements
* Functional requirements
* More
* More
* More
  1. The design inputs will be captured in [document or record?].

1. DESIGN OUTPUTS
   1. Once design inputs are captured, the production of design outputs may begin. Typically, these are:

* Drawing
* Specifications
* Models
* Internal standards, work instructions etc.
* More here
  1. The [who?] will oversee the development of the appropriate design outputs, including those produced by third party providers.
  2. All design outputs must be developed so they properly address the applicable design input requirements.

1. DESIGN REVIEWS AND VERIFICATION
   1. The design outputs must undergo two types of review. The first is a simple design review performed by the drafter of the design output, who may review his/her own work. Based on the design planning performed earlier, additional reviews may include having the work reviewed and signed off by an objective third party.
   2. Next, design verification shall be performed. This is a verification that all design inputs have been addressed satisfactorily in the design outputs. This is conducted by [who?] by [how?]. Records of design verification are maintained [how?]
   3. The design process may not proceed until all design outputs are verified as having addressed the design inputs.
2. DESIGN VALIDATION
   1. Design validation is done by comparing the design requirements with a physical product produced from the design data.
   2. This is accomplished by [explain methods here; may include building sample parts and conducting first article inspections, or submitting test batches for testing.]
3. DESIGN CHANGES
   1. Where changes are required of design data, these shall be requested by submitting a [method here; could be a typical Engineering Change Request, or something similar.]
   2. The change request will be reviewed by [who?] and if approved, shall then be implemented [how?]
   3. Applicable design data or documents will be revised with their revision indicator incremented.
   4. Changed designs must go through the same design review, verification and validation as original releases.