Procedure: Design Control

1. PURPOSE AND SCOPE

1.1. The purpose of this procedure is to define the requirements for designing product which meets design input requirements.

1.2. The Engineering Manager is responsible for implementation and management of this procedure.

2. REVISION AND APPROVAL

Rev.	Date	Nature of Changes	Approved By
N	06/05/2018	Original issue.	Eicher
001	05/31/2024	Clarified Design Change inputs, corrected spelling, updated descriptions of M1 fields	Wagner

3. DESIGN PLANNING

3.1. The Engineering department is responsible for design activities.

3.2. Management will determine when a research and development project is applicable for development to warrant a 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.

3.3. The decision to move a R&D project into controlled design is recorded in M1 by entering a project number for the project.

3.4. This is provided to the Engineering Scheduler who will begin to plan the design activities to be conducted.

3.5. The design input documentation is recorded and attached (if applicable) in M1. This will include the assigned design engineers, support staff, third party providers, and the responsibility and authority for each. Where third parties are utilized, this shall define the approved points of contact. Engineering Calculations for a design project shall be kept on the Engineering server under the appropriate order folder.

3.6. The Engineering Scheduler will develop a design schedule; this will be developed with input of the customer and third-party providers, if necessary. The schedule will be updated as the design work progresses.

4. DESIGN INPUTS

4.1. Design "inputs" are the requirements for the final product.

4.2. The CSR or Application person 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

- Special Design Criteria, if applicable

- Electrical Requirements, If applicable

- Testing Requirements, If applicable

4.3. The design inputs will be captured in order entry module of M1.

5. DESIGN OUTPUTS

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

- Design calculations

- Specifications

- Models

- Drawing/s

- Manuals

- Internal standards, work instructions etc. (In conjunction with ME's input)

5.2. The assigned Engineering Designer will oversee the development of the appropriate design outputs, including those produced by third party providers.

5.3. All design outputs must be developed so they properly address the applicable design input requirements.

6. DESIGN REVIEWS AND VERIFICATION

6.1. The design outputs must undergo two types of review. The first is a simple design review performed by the Engineering Designer of the design input, who may review his/her own work and verify information supplied is sufficient to proceed with the design. Based on the design planning performed earlier or updates/input from the customer, additional reviews may include having the design reviewed and signed off by the customer.

6.2. 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 another qualified

Engineering Designer by reviewing calculations and ensuring the design outputs meet the design input requirements. Records of design verification are maintained in M1, checkboxes.

6.3. The design process may not proceed until all design outputs are verified as having addressed the design inputs.

7. DESIGN VALIDATION

7.1. Design validation is done by comparing the design requirements with a physical product produced from the design data.

7.2. This is accomplished by QA verification prior to shipping. May include building prototypes, conducting first article inspections, and/or proof testing or destructive testing.

8. DESIGN CHANGES

8.1. After release from Engineering, where changes are required (input from Manufacturing or SME preference) of design data, these shall be requested by submitting an Engineering Change Request (ECR).

8.2. The change request will be reviewed by Engineering Manager and if approved, shall then be implemented through the Revision Process.

8.3. Applicable design data or documents will be revised with their revision indicator incremented.

8.4. Changed designs may need to go through the same design review, verification and validation as original releases based on the complexity of the change. This is determined by the Engineering Manager.