Quality Procedure

Design Management

Table of Contents

1 DESIGN MANAGEMENT 3
1.1 INTRODUCTION & PURPOSE 3
1.1.1 Process Activity Map 3
1.1.2 References 3
1.1.3 Terms & Definitions 3
1.2 APPLICATION & SCOPE 4
1.3 RESPONSIBILITIES 4
1.4 DESIGN MANAGEMENT PROCESS 5
1.4.1 Design Management Planning 5
1.4.2 Design Inputs 6
1.4.2.1 General 6
1.4.2.2 Conceptual Design Statement (CDS) 7
1.4.2.3 Design Standards 7
1.4.2.4 Assumptions 7
1.4.2.5 Requirements 8
1.4.2.6 Concept Failure Mode Effects Analysis (CFMEA) 9
1.4.2.7 Interfaces 10
1.4.2.8 Documentation 10
1.4.3 Design Control Activities 11
1.4.3.1 General 11
1.4.3.2 CAD Management 11
1.4.3.3 Value Engineering 11
1.4.3.4 Design Failure Mode Effects Analysis (DFMEA) 12
1.4.3.5 Design Risk Management 12
1.4.3.6 Safety Risk Management 13
1.4.3.7 Tools & Techniques 13
1.4.3.8 Design Checking 14
1.4.3.9 Design Reviews 15
1.4.3.10 Verification & Validation 19
1.4.3.11 Final Design Submission (FDS) 21
1.4.3.12 Design Completion Certification 21
1.4.4 Design Outputs 22
1.4.5 Design Transfer 22
1.4.6 Design Changes 23
1.5 MONITORING & MEASUREMENT 24
1.6 FORMS & RECORDS 25
1.7 DESIGN MANAGEMENT PROCESS MAP 26

Organizational and technical interfaces between different functions and departments that contribute to the design and development process are defined and the necessary information documented, transmitted and regularly reviewed. Products may be subdivided into four generic product categories:

Product Category	Types of Product
Hardware	Products consisting of manufactured pieces and parts, or assemblies thereof.
Software	Products, such as computer software, consisting of written, or otherwise recordable information, concepts, transactions or procedures.
Process materials	Products (final or intermediate) consisting of solids, liquids, gases or combinations thereof, including particulate materials, ingots, filaments or sheet structures. Typically, delivered (packaged) in containers such as drums, bags, tanks, cans, pipelines, or rolls.
Services	Intangible products which may be the entire or principal offering, or incorporated features of the offering, relating to activities such as planning, selling, directing, delivering, improving, evaluating, training, operating or servicing for a tangible product.

1.4.2 Design Inputs

1.4.2.1 General

Design input requirements are unambiguous and are able to be verified by subsequent objective methods of analysis, inspection, or testing. Design inputs are identified and reviewed for adequacy, completeness, and lack of conflict. Design inputs include functional and technical requirements, and the following as applicable:

1. Customer specified requirements;
2. Product description specifications (e.g. configuration, composition, or other design features);
3. Requirements provided from external sources and best practices;
4. Environmental and operational conditions;
5. Methodology, assumptions, and formulae documentation;
6. Historical performance and other information derived from previous similar designs;
7. Regulatory requirements;
8. Market and trend analysis;
9. Results of risk assessment;
10. Resources, including manpower and consumables;
11. Supply chain;
12. Performance objectives including creation of measures of success KPIs;
13. Design constraints that should be respected by the designer(s);
14. Reliability, availability, maintainability and safety;
15. Information gathered from similar projects;
16. Any other internal or external factors affecting design and performance.

All documents constituting design input are recorded in the *Master Design Document List*. All pertinent design inputs (such as performance, functional, descriptive, environmental, safety, quality assurance and regulatory requirements), are defined, reviewed and recorded in various design documents that are described in the following sections.

These design documents quantify all requirements wherever practicable to lay the foundation and provide a unified approach to the design. The design documents also record the resolutions of any incomplete, ambiguous or conflicting requirements which have been uncovered during the development process.

The Design Manager ensures the changes meet the overall project objectives, obligations and that any engineering risks associated are identified, captured and fully integrated, ensuring that any corrective actions are tracked to completion.

- Produce an audit trail to track changes;
- Ensure that the change is supported by an authorised instruction;
- Maintain configuration control so that the interface impacts are fully understood and accounted for;
- The cost of the change is accurately estimated and incorporated into the cost forecast.

Once the change is approved, changes are implemented in such a manner that the original problem is resolved and no new problems are created; or if new problems are created, they are also tracked to resolution and incorporated with new requirements into the design.

The Engineering Manager adjusts the activities and schedules to accommodate the revised design and development input. Design and development changes to released products are submitted via a change request. Other instances of design reviews may be required when the Engineering Manager has identified significant design change that requires a review to revalidate the design.

The Engineering Manager is responsible for managing assured state of design changes that are identified post design transfer for production and for evaluating the risks and impact against Assurance Gates criteria.

1.5 Monitoring & Measurement

The list is not exhaustive and will evolve as needed. Some of the key design programme management performance indicators described in this section are used to directly measure aspects of our performance and are monitored by Top management to manage our design and development process:

Adherence to Gate and Design Review Milestones

- Adherence to gate and design reviews measures the number of programme gates successfully passed on time as planned, expressed as Percent% Passed on time.
- Measures the number of programme milestones successfully passed on time.
- Programme gates are usually passed based on the approval of senior management to pass the gate as the outcome of a successful gate review.

Design Nonconformities

- A measure of missed requirements or requirements that are noncompliant with the defined design or specification, expressed as Percent%.
- An Engineering or Design Nonconformity escape occurs when components, products, or other deliverable products or services do not meet technical specifications or technical requirements and expectations, as identified by the producer or customer and the root-cause determines the event is a result of:
    1. A noncompliance to standard work in place at the time the hardware, software or service was designed, or the service was provided, and/or
    2. A failure to meet reasonable engineering design practices at the time the hardware, software or service was designed, or the service was provided.

Design Changes Requested

- It is a measure of design changes requests received and registered within a certain period of time, expressed as the Number of Design Changes per period of the programme and measures the quantity of requested design or product changes.

On-Time Design Changes Completed

- It is a measure of design changes completed on-time vs. total number of design changes due to have been completed within a certain period of time, expressed as Percent%.
- Measures the quantity of engineering design/product changes.

Design Non-Quality at Design Review

- Measures the number of design issues raised during a gate or design reviews that require design or engineering action, expressed as the Count per designated frequency of the design programme or project.
- Measure of design non-quality at a specific design review by tracking and classifying the design issued raised during a gate or design review.

1.6 Forms & Records

All documentation and records generated by the design and development process, such as design methods, assumptions, formulae and calculations related to the design, design and development reviews, including corrective action plans and those in attendance, are retained and managed in accordance with the *Documented Information Procedure*.

All records are to be retained for 15 years and are to be destroyed or archived as appropriate after this period elapses.

Title & Description
Design Change Request
Design Change Request Log
Requirements Review Checklist
FMEA Template
Design Requirements Register
Design Assumptions Register
Master Design Documents List
Design Issues Log
Design Review Meeting Minutes
Design Document Review