Text

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**ISO 9001:2015**

**Control of Design & Development**

Approval

The signatures below certify that this management system procedure has been reviewed and accepted, and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensuring their provision.

|  |  |  |  |  |
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Amendment Record

This procedure is reviewed to ensure its continuing relevance to the systems and process that it describes. A record of contextual additions or omissions is given below:

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| Page No. | Context | Revision | Date |
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# Contents

[Contents 2](#_Toc195708183)

[1 Design & Development 4](#_Toc195708184)

[1.1 Introduction & Purpose 4](#_Toc195708185)

[1.1.1 Process Activity Map 4](#_Toc195708186)

[1.1.2 References 4](#_Toc195708187)

[1.1.3 Terms & Definitions 4](#_Toc195708188)

[1.2 Application & Scope 5](#_Toc195708189)

[1.3 Responsibilities 5](#_Toc195708190)

[1.4 Design Management Process 6](#_Toc195708191)

[1.4.1 Design Management Planning 6](#_Toc195708192)

[1.4.2 Design Inputs 6](#_Toc195708193)

[1.4.2.1 General 6](#_Toc195708194)

[1.4.2.2 Conceptual Design Statement (CDS) 7](#_Toc195708195)

[1.4.2.3 Design Standards 7](#_Toc195708196)

[1.4.2.4 Assumptions 7](#_Toc195708197)

[1.4.2.5 Requirements 8](#_Toc195708198)

[1.4.2.6 Concept Failure Mode Effects Analysis (CFMEA) 8](#_Toc195708199)

[1.4.2.7 Interfaces 9](#_Toc195708200)

[1.4.2.8 Documentation 9](#_Toc195708201)

[1.4.3 Design Control Activities 9](#_Toc195708202)

[1.4.3.1 General 9](#_Toc195708203)

[1.4.3.2 CAD Management 9](#_Toc195708204)

[1.4.3.3 Value Engineering 10](#_Toc195708205)

[1.4.3.4 Design Failure Mode Effects Analysis (DFMEA) 10](#_Toc195708206)

[1.4.3.5 Design Risk Management 10](#_Toc195708207)

[1.4.3.6 Safety Risk Management 10](#_Toc195708208)

[1.4.3.7 Tools & Techniques 11](#_Toc195708209)

[1.4.3.8 Design Checking 11](#_Toc195708210)

[1.4.3.9 Design Reviews 11](#_Toc195708211)

[1.4.3.9.1 Design Assurance Reviews 11](#_Toc195708212)

[1.4.3.9.2 Assurance Gate Reviews 12](#_Toc195708213)

[1.4.3.10 Verification & Validation 13](#_Toc195708214)

[1.4.3.10.1 Design Verification 14](#_Toc195708215)

[1.4.3.10.2 Verification of Calculations 14](#_Toc195708216)

[1.4.3.10.3 Design Validation 14](#_Toc195708217)

[1.4.3.10.4 Validation of Calculations 14](#_Toc195708218)

[1.4.3.11 Final Design Submission (FDS) 15](#_Toc195708219)

[1.4.3.12 Design Completion Certification 15](#_Toc195708220)

[1.4.4 Design Outputs 15](#_Toc195708221)

[1.4.5 Design Transfer 15](#_Toc195708222)

[1.4.6 Design Changes 16](#_Toc195708223)

[1.5 Monitoring & Measurement 17](#_Toc195708224)

[1.6 Forms & Records 17](#_Toc195708225)

[1.7 Design Management Process Map 19](#_Toc195708226)

1. Design & Development
   1. Introduction & Purpose

The purpose of this procedure is to ensure that all projects’ design and development activities are coordinated between different organizational functions and that interfaces between stakeholder groups are defined to ensure effective communication and clear assignment of responsibility. This procedure also ensures that good quality assurance practices are used during the design process and that they are consistent with quality system requirements.

* + 1. Process Activity Map

Output

* Approved product design
* CAM programme files
* Design assurance records
* Customer acceptance
* BoMs/Specifications
* Purchasing requirements
* Packaging requirements
* Engineering changes

How

* Standards baseline
* Design FMEA
* Validation and verification
* Customer design reviews
* Internal design reviews
* Design certification

With what measure

* On-time delivery
* Budget versus actual
* Customer satisfaction
* Management review
* Internal auditing
* No. of corrective actions

With what

* Project order management
* Stock and materials
* Competencies and skills
* Facilities, plant and tools
* Equipment and processes
* Risks and opportunities

With who

* Gate Review Panel
* Senior Engineer
* Design Dept Head
* Design Team
* Customers & stakeholders

Activity

Input

* Design statement/concept
* CAD models and drawings
* Technical specifications
* Concept FMEA
* Design changes
* Customer requirements checklist

Transforming requirements into project via design planning, design controls, staged design reviews, internal design checks, design approval, certification, and release.

(Initial concept (20% complete – Gate 1), functional design (60% complete – Gate 2), detailed design ready for manufacture, fabrication or construction ready (100% complete – Gate 3)

* + 1. References

| **Standard** | **Title** | **Description** |
| --- | --- | --- |
| BS EN ISO 9000:2015 | Quality management systems | Fundamentals and vocabulary |
| BS EN ISO 9001:2015 | Quality management systems | Requirements |
| BS EN ISO 9004:2018 | Quality management systems | Guidelines for performance improvements |

* + 1. Terms & Definitions

| **Term** | **Definition** |
| --- | --- |
| Design and development | Transforming requirements (3.6.4) for product/project into detailed requirements |
| Interfacing party | A contractor, consultant, or representative responsible for design or implementation |
| Requirements | A need or expectation that is stated, generally implied or obligatory |
| Verification | Confirmation, through the objective evidence (3.8.3), requirements (3.6.4) were fulfilled |
| Validation | Confirmation that particular requirements for a specific intended use are fulfilled |
| Design Input | The physical and performance requirements of a product used as a basis for design |
| Design Output | Documented information that defines the product |
| Design Review | Comprehensive examination of the design to evaluate adequacy in meeting requirements |
| Design Transfer | Ensures that the design is correctly translated into production specifications |
| Design Changes | Process for initiating, assessing the impact and approving the proposed change |

* 1. Application & Scope

The scope of this procedure is to ensure that quality assurance practices are used for the design of our projects are consistent with quality system requirements. This procedure applies to the development of all products, including design modifications, product changes, and customer specific projects.

All design and development processes are carried out under controlled conditions where all activities are planned and documented. Designs are reviewed at appropriate stages and where applicable; verified and validated. Design outputs are verified before release for prototyping or production.

Where any part of the design and development process is outsourced, the supplier will meet the requirements of this procedure and provide objective evidence that all requirements were met.

* 1. Responsibilities

**Top Management**

* Establish and maintain the design management process
* Identify customer and market needs
* Monitor design performance and lead reviews

**Senior Engineer / Gate Review Panel**

* Review and approve design stages
* Consider feedback from relevant stakeholders
* Document and issue review outcomes

**Design Engineers, Quality Manager, and Senior Engineer**

* Control risks within legal and commercial limits
* Ensure complete and clear specifications
* Apply proper design control methods
* Evaluate risks at each design stage
* Manage changes and maintain design integrity

**Design Team**

* Plan, develop, and coordinate design activities
* Assign tasks and assess design results
* Review and validate design solutions
* Present designs for gate reviews
* Conduct Designer’s Risk Assessments

**Quality Manager**

* Maintain and review customer specifications
* Coordinate internal audits
* Oversee quality assurance and certification in design
* Manage design records and reporting systems
* Verify effectiveness of corrective actions

**Design Team**

* Ensure design outputs meet requirements and standards
* Create and maintain all design-related documents
* Control each stage of new designs or changes
  1. Design Management Process
     1. Design Management Planning

The Design Management Plan (DMP) outlines the quality practices, activities, responsibilities, and resources needed to manage a specific design project. It references relevant standards and defines interfaces between involved departments or stakeholders.

Each design activity is planned in phases, with tasks assigned to competent personnel. The plan is updated as the design progresses.

At a minimum, the DMP includes:

* Standards baseline and how compliance will be shown
* Roles, responsibilities, and a skills matrix for involved staff
* Project scope, key interfaces, and operational requirements
* Deliverables, timelines, and milestones
* Assurance Gate stages at 20%, 60%, and 100%
* Design review may be conducted by external consultants depending upon project complexity
* Evidence of compliance with input and performance requirements

Interfaces across teams are clearly defined, communicated, and reviewed throughout the process.

* + 1. Design Inputs
       1. General

Design inputs must be clear, complete, and verifiable through analysis, inspection, or testing. Inputs are reviewed for accuracy and relevance before use.

Typical inputs include:

* Customer requirements
* Product specifications
* External standards or best practices
* Environmental and operating conditions
* Key assumptions and calculation methods
* Data from similar past projects
* Legal and regulatory requirements
* Market trends and risk assessments
* Resource needs and supply chain factors
* KPIs and performance targets
* Design constraints (e.g. safety, reliability, maintainability)

All inputs are documented in the *Master Design Document List* and used to guide the design. Conflicts or unclear requirements are resolved and documented. Inputs are refined and verified through appropriate reviews, testing, or prototyping as needed.

* + - 1. Conceptual Design Statement (CDS)

The Conceptual Design Statement (CDS) outlines the key design inputs and proposed solution. It helps stakeholders understand the design approach and its rationale.

The CDS includes:

* Applicable standards and requirements
* Design methods and processes
* Level of independent review based on risk (if any)

The Design Team uses the CDS to guide development. Inputs are clearly documented and controlled, and may include drawings, specifications, data sheets, photos, and standards.

* + - 1. Design Standards

All designs follow an approved list of standards known as the Standards Baseline, maintained by the Senior Engineer. This includes national and international standards, engineering specs, and codes of practice.a

The baseline is reviewed every 6 months. For each new design package, the Design Team must declare which standards apply.

Once a design starts, its baseline is fixed. Any updates to standards are managed under strict configuration control and only applied if formally agreed.

The Senior Engineer ensures the correct standards are used and that design outputs comply.

* + - 1. Assumptions

Assumptions are used by the Design Team to manage uncertainty during early design stages. They help progress the design while missing or unclear information is being clarified. Assumptions are temporary and must be resolved with supporting data or documentation.

Since assumptions can introduce risk, they are recorded in the *Assumptions Register* and reviewed by the Senior Engineer. Any related risks are also logged in the *Risk Register*.

Common types of assumptions include:

1. Gaps in scope, system capability, or data
2. Conflicts between standards or interfaces
3. Design decisions made without full information

**Process Summary:**

* Design Team proposes assumptions
* Senior Engineer reviews and approves
* Resolving Body agrees on actions
* Design Team updates and tracks closure
* Unresolved assumptions at the end of the design phase are transferred to the Risk Register

Assumptions are closed only after verification and formal documentation. Final approval rests with the Gate Review Authority (Senior Engineer), and closure details are recorded in the *Assumptions Register*.

* + - 1. Requirements

The design process ensures customer, user, and regulatory requirements are met while maintaining cost-effectiveness.

Requirements are translated into technical specifications and may relate to hardware or software. A cross-functional team reviews them to ensure they are complete, clear, and conflict-free. Any issues are escalated to the Senior Engineer.

The Design Team documents and tracks all requirements in the **Requirements Register** using compliance matrices and verification reports. Requirements must be:

* Traceable to their source and owner
* Approved and validated by relevant personnel
* Reviewed and agreed upon with the customer
* Clearly understood and accepted by all involved

As the design progresses (Gate 1, 2, and 3), compliance statements and supporting documents are updated accordingly.

The **Senior Engineer** also defines market needs through a **requirement statement**, which includes:

* What is needed and why
* Delivery timelines
* Assumptions
* Risk and opportunity considerations
* Performance, safety, and legal criteria
* Pricing and milestones

For customer-specific projects, the Design Team receives an outline design brief from the Senior Engineer and CEO and develops technical specifications accordingly.

* + - 1. Concept Failure Mode Effects Analysis (CFMEA)

**Concept Failure Mode and Effects Analysis (CFMEA)** is used early in the design process to identify potential design risks before hardware is defined. It focuses on system-level failure modes and interactions between components.

The **Senior Engineer** decides when CFMEA is needed to:

* Select or refine concept options
* Identify failure risks within the design concept
* Ensure all failure effects are considered
* Define system-level testing needs
* Assess the need for redundancy in the design
  + - 1. Interfaces

The Design Team forms working groups when needed to manage interfaces with other stakeholders. These groups define key requirements and ensure effective coordination during design.

Key activities include:

* Identifying and managing design interfaces
* Resolving interface-related issues
* Creating and agreeing interface documents
* Supporting interface management throughout the design
* Reviewing and tracking interface development
* The level of documentation matches the complexity of the design.
  + - 1. Documentation

The Design Team uses a defined document numbering system. All design-related documents are listed in the *Master Design Document List*, which tracks plans, procedures, and records supporting safety, quality, and compliance.

All design documents follow a structured approval process:

* **Prepared** – by a qualified individual who creates and checks the document
* **Checked** – by another competent person (same discipline, different individual)
* **Approved** – by a senior reviewer from the same discipline, outside the design team

Only the latest versions of reference materials (e.g. standards, catalogues) are used. These are maintained by the **Senior Engineer**.

* + 1. Design Control Activities
       1. General

Design controls are procedures used to manage uncertainty and ensure the design meets all requirements before approval.

They help identify and correct gaps in inputs or conflicts with requirements during development. Key quality and regulatory needs—such as safety, performance, and reliability—are established in this phase.

Control methods are tailored to the level of risk and integrated into the overall design process.

* + - 1. CAD Management

All drawings are created using SolidWorks and follow best practices.

Each stage of the CAD workflow (prepare, check, approve) is completed by qualified personnel. Roles and sign-offs are tracked to ensure only authorised individuals progress the design.

The Design Team defines the workflow, and all stages are recorded for traceability. Final CAD files are stored in **OneDrive**, with approved PDFs managed in the Document Management System under version control.

* + - 1. Value Engineering

The goal of engineering design is to create safe, compliant, and cost-effective solutions with the Lowest Total Cost (LTC).

Value Engineering (VE) focuses on reducing costs without compromising quality. It is applied throughout the design process, with the greatest benefits often achieved in the early stages.

* + - 1. Design Failure Mode Effects Analysis (DFMEA)

DFMEA is used early in the design process to identify potential design failures and assess their impact. It helps evaluate design options and reduce risk.

The Senior Engineer ensures DFMEA is completed before preliminary drawings or manufacturing plan.

Key purposes of DFMEA:

* Identify potential design failure modes and their effects
* Support manufacturing and assembly planning
* Prioritise risks and improvements
* Guide test planning
* Track and resolve design risks
* Provide input for design reviews and future analysis
  + - 1. Design Risk Management

Design risk management starts with reviewing input requirements and continues as the design evolves. Risks are identified early to allow timely and cost-effective actions.

Typical risk factors include:

* Quality and compliance
* Assumptions and requirements
* Financial and resource constraints
* Customer satisfaction and delivery
* Supplier control and capabilities
* Design and manufacturing complexity

The Design Manager leads regular risk reviews, ensuring risks are assessed, updated with changes, and aligned with the latest design. All risks are documented for action, communication, and learning.

* + - 1. Safety Risk Management

Safety is built into the design process to ensure designs are safe to build, operate, and maintain. The Design Team follows checks and reviews to meet relevant standards.

Key safety measures include:

* Ensuring staff have the right technical skills
* Following processes to eliminate or reduce hazards
* Meeting all project safety requirements

The Design Team must:

* Complete a Designer’s Risk Assessment
* Minimise risks to **ALARP** (As Low As Reasonably Practicable)
* Manage risks within legal and commercial limits
* Stay aware of evolving risk throughout the design process
  + - 1. Tools & Techniques

The Design Team uses appropriate tools and methods suited to each project. Only competent personnel carry out design tasks.

The Senior Engineer ensures designs are producible, testable, and controllable throughout development using project management tools.

Software used for design and calculations must be validated and approved. Commercial CAD and calculation tools with proven use may be exempt from revalidation. If any In-house software is used must be validated before use and documented.

Spreadsheets used for calculations must be:

* Verified by manual checks or alternate methods
* Protected against editing errors (e.g. locked cells, data validation, password protection)
* Clearly labeled with user details, version, and validation history

All validation and verification records are kept as part of the design documentation.

* + - 1. Design Checking

All design outputs are reviewed by qualified staff and approved by the Senior Engineer before release. Every design follows a Prepare–Check–Approve process, with sign-off by competent individuals.

The Design Manager assigns a check level based on project risk:

* **Category I** – Checked by someone other than the designer in the same team
* **Category II** – Checked by a different group or maybe external reviewer
* **Category III** – Checked by an independent engineering body (for complex designs)

For Category II and III, independent calculations and technical assessments are required. The check ensures the design is practical, safe, and aligned with its intended purpose.

* + - 1. Design Reviews

Design reviews are held at key stages—after concept development, detailed design, and before final release—to ensure the design meets input requirements and objectives.

Reviews are scheduled based on project complexity and may also be held as needed. Review participants must be competent in the relevant design discipline to effectively assess the design and raise any concerns or issues.

* + - * 1. Design Assurance Reviews

The Design Manager ensures reviews are conducted at 20%, 60%, and 100% design completion, as defined in the Design Management Plan. A cross-functional team—including someone independent of the current design stage—carries out the review.

Each review checks if the design meets requirements, identifies issues, and confirms readiness to proceed. The process includes:

* Input from all stakeholders
* Tracking and closure of previous actions
* Documentation and timely sharing of outcomes

Reviews assess:

* Compliance with customer needs, technical specs, and regulations
* Safety, reliability, and usability
* Risk assessments (e.g., FMEA), assembly, packaging, and testability
* Previous design issues, standard parts, and maintainability

Reviewers raise comments; the Design Manager records them in the *Design Review Meeting Minutes*. The Senior Engineer decides if concerns require action. Most issues are resolved through design or requirement changes.

All decisions and attendance are documented.

* + - * 1. Assurance Gate Reviews

Assurance Gate Reviews are conducted at key design stages (20%, 60%, and 100%) to confirm the design meets project objectives and risks are properly understood and managed.

* Gate 1 (20%) – Initial concept: defines basic form, scope, and intent.
* Gate 2 (60%) – Functional design: intermediate check to confirm progress and alignment.
* Gate 3 (100%) – Final design: fully complete and ready for manufacture or construction.

Each Gate Review ensures the design is ready to move to the next phase. If it does not meet the criteria, it must be revised before progressing.

The Gate Review Panel (Approval Personnels) includes cross-functional stakeholders selected based on risk, complexity, and compliance needs (e.g. Engineering, Quality, Planning, Procurement, Legal).

Panel responsibilities include:

* Confirming design maturity, cost, and timeline alignment
* Ensuring all risks are managed or mitigated
* Reviewing supporting evidence against approval criteria
* Deciding on a pass, fail, or conditional pass (with actions and deadlines)

The Design engineers prepares the required documentation and submits evidence at least 5 working days before the review. Results and decisions are recorded in the *Design Review Meeting Minutes*.

| **Assurance Gate Review Deliverables** | **Gate 1** (20%) | **Gate 2** (60%) | **Gate 3** (100%) |
| --- | --- | --- | --- |
| Requirements Identified and Allocated | **** | **** | **** |
| Compliance Statements for each Requirement |  | **** | **** |
| Compliance with Requirements Verified |  |  | **** |
| Design Assumptions Raised and Recorded | **** | **** | **** |
| All Design Assumptions Closed (Accepted or Transferred to risk register) |  |  | **** |
| Concept Design Statement | **** | **** |  |
| Maintainability and Usability Report |  | **** | **** |
| Value Engineering Report |  | **** | **** |
| Reliability, Availability, Maintainability and Safety Assessment |  | **** | **** |
| Concept Failure Mode Effects Analysis (CFMEA) | **** | **** |  |
| Design Failure Mode Effects Analysis (DFMEA) |  | **** | **** |
| Interface Documents | **** | **** | **** |
| Material Specifications |  |  | **** |
| Bills of Materials |  | **** | **** |
| Workmanship Specifications |  | **** | **** |
| Packaging Specifications |  |  | **** |
| CAD Models and/or CAM Programmes |  | **** | **** |
| Drawings | **** | **** | **** |
| Master Design Documents List | **** | **** | **** |
| Risk Register | **** | **** | **** |
| Results of Verification and Validation |  | **** | **** |
| HAZID and HAZOP logs |  | **** | **** |
| Final Design Submission (FDS) |  |  | **** |
| Design Completion Certificate |  |  | **** |

It is important that all the evidence is issued to the Gate Review Panel at least 5 working days prior to the gate review so that a decision can be made about the completeness of the evidence and whether the planned Assurance Gate Review should go ahead. Each design submission must include a full list of all the documents, drawings and any other design products (including revision) that form the subject of the Gate Review.

* + - 1. Verification & Validation

Designs are verified and validated before release to ensure they meet all specified requirements. This may include calculations, analysis, or testing of samples.

Verification and validation often overlap with design reviews. Typically, the sequence is:

1. **Verification** – confirms requirements are met
2. **Review** – evaluates the design
3. **Validation** – confirms suitability for intended use

Where appropriate, verification and validation are integrated into the design review process, especially for complex or multidisciplinary projects.

* + - * 1. Design Verification

Design verification confirms that design outputs meet the input requirements using objective evidence—such as calculations, tests, or reviews.

Verification methods depend on the complexity and type of design. Each phase is checked to ensure outputs meet requirements and align with the design concept.

Verification is completed before design reviews and is tracked throughout Assurance Gate Reviews. Results are documented, including the method, date, and responsible person.

* + - * 1. Verification of Calculations

All design calculations must be verified using an independent method or tool. The Senior Engineer sets the frequency of verification based on risk.

Verification is required:

* After any changes to software or hardware
* Using a known dataset to confirm consistent results

Each verification is documented with:

* Date, method, comments, and verifier’s signature
* Records stored in the validation file or system

Spreadsheets should include:

* A description of purpose, inputs, layout, and data rules
* Documented version history and compatibility notes

This ensures spreadsheets remain valid and reliable throughout their use.

* + - * 1. Design Validation

Design validation confirms the final design meets user needs and intended use under real-world conditions. It follows successful verification and uses objective evidence to confirm all requirements are met.

Validation includes:

* Identifying performance criteria and acceptance methods
* Reviewing requirements to ensure completeness and relevance
* Addressing any missing or unclear assumptions

All validation activities are documented, including method, date, and responsible person.

* + - * 1. Validation of Calculations

To ensure only the latest validated version is used, all **validated spreadsheets** are stored in read-only format on a protected network. Only authorised personnel can edit them.

Validation methods include:

* Comparing spreadsheet results with commercial software or manual calculations
* Using reference data to check accuracy

If different versions of Excel are used, functionality must be validated for each one.

Validation steps:

* Lock non-input cells and restrict access
* Use password protection where needed
* Record validation results, access rights, and verification details

Once verified, the spreadsheet is marked as validated and stored securely.

* + - 1. Final Design Submission (FDS)

At the end of the detailed design phase, the Design department head prepares a Final Design Submission (FDS). It shows how the design meets the Conceptual Design Statement, highlights any changes, and includes all final deliverables and approved calculations for record-keeping.

* + - 1. Design Completion Certification

The Design department head issues the Design Completion Certificate (DCC) to confirm the design meets all project requirements and aligns with the Conceptual Design Statement, including approved changes.

At Gate 3, all reviewer comments must be resolved before the certificate is signed. The Approval Authority countersigns the DCC after successful review.

* + 1. Design Outputs

Design outputs include all documents and specifications needed to manufacture or prototyping, install, test, and maintain the product. They define key characteristics such as safety, performance, and reliability.

Typical outputs include:

* Drawings, schematics, and diagrams
* Material and component specs
* Process and production/prototypying instructions
* Bills of materials (BoMs)
* Software specs and source code
* Risk assessments and residual risk notes
* Verification and validation results
* Packaging, labelling, and user instructions
* Quality standards and test criteria

These outputs form the complete technical package used for production/prototyping and support.

* + 1. Design Transfer

Design transfer ensures the final design is accurately translated into production-ready specifications and instructions.

This may include not limited to:

* Drawings, material specs, and manufacturing instructions
* Inspection and test criteria
* CAM files, jigs, templates, and training materials

The Senior Engineer is responsible for:

* Reviewing completeness and accuracy of production/prototyping specs
* Approving all documents before use
* Ensuring only approved specs are used in production/prototyping

Regulatory and contractual requirements are reviewed and communicated to the supply chain before production begins.

* + 1. Design Changes

All design changes must be documented, revision-controlled, and approved by authorised personnel.

Reasons for change may include:

* Errors or omissions in the original design
* Manufacturing or installation issues
* Customer or supplier requests
* Performance improvements
* Compliance with updated safety or regulatory requirements
* Results from verification or corrective actions

Change requests can come from any relevant stakeholder and are submitted using a Design Change Request Form.

The Senior Engineer and Design department head:

* Review and log all requests
* Evaluate risk and impact
* Approve or reject the change
* Involve other stakeholders for major changes

Once approved:

* All related design documentation is updated
* An audit trail is maintained
* Interface impacts and cost implications are reviewed
* Any new risks or corrective actions are tracked
* Design reviews may be repeated if required

Post-transfer changes are managed by the Senior Engineer, who ensures risks are evaluated against Assurance Gate criteria.

* 1. Monitoring & Measurement

The following key indicators are used by Top Management to monitor and improve the design and development process. This list evolves as needed:

**1. Adherence to Milestones**

* Measures how many gate and design reviews are completed **on time**
* Tracked as a percentage of gates passed as scheduled
* Approval is based on successful review outcomes

**2. Design Nonconformities**

* Tracks missed or noncompliant design requirements
* Measured as a percentage of nonconformities
* Causes may include:
* Deviation from standard design practices
* Failure to meet technical expectations

**3. Design Changes Requested**

* Number of change requests received during a set time period
* Indicates how often designs need adjustment

**4. On-Time Design Changes Completed**

* Percentage of design changes completed on schedule
* Helps track responsiveness and efficiency

**5. Design Non-Quality at Review**

* Counts design issues raised during reviews that require correction
* Used to assess design quality at each gate or milestone
  1. 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 (Folder Contract Review) |
| FMEA Document |
| Design Requirements Register |
| Design Assumptions Register |
| Master Design Documents List |
| Design Issues Log |
| Design Review Meeting Minutes |
| Design Document Review |

* 1. Design Management Process Map

Analysis of market trends, new technology and emerging customer needs

**Design Controls**

**Design Validation**

**Design Inputs**

**Design Verification**

Requirement for new design, revision due to design change or improvement identified

**Design Planning**

Customer contracts, order management, scheduling and customer requirement checklists from 8.2

**DESIGN REVIEWS** (Checking the outputs of each stage meet the requirements of the previous stage)

Functional Requirements

Performance Requirements

Interface Requirements

Statutory/Regulatory Requirements

Conceptual Design Statement

Manufacturing Process

Specifications/BoMs

Prototypes

Purchasing requirements

Calculations verified

Requirements traceability

Evaluation reports

Customer acceptance criteria

Calculations validated

Testing requirements

**Design Transfer**

Gate Assurance Criteria

Gate Review Deliverables List

Gate Review Report

Gate Review Conditions

Pass

Fail

Gate 1 - Initial concept (20% complete

Gate 2 - functional design 60% complete

Gate 3 - detailed design ready for manufacture, fabrication or construction 100% complete

**Assurance Gate Review**

**Design Output**

CAD Management

Design Assurance Reviews

DFMEA

Design Risk Management

Standards Baseline

Responsibilities of Designers

Projected Output

Defined Deliverables